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S.C. SUPREME COURT

EXHIBIT 1

STATE OF NORTH CAROLINA

FILED

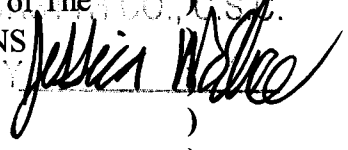
IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT DIVISION

FORSYTH COUNTY

FILE NO. 20 CVS 352

2020 JAN 17 P 2:58

SUSAN K. STEVENS, Administratrix of The Estate of TORIA CAPRI STEVENS

BY 

Plaintiff,

v.

AMERISOURCEBERGEN DRUG

CORPORATION;

ABBOTT LABORATORIES, INC.;

ACTAVIS LLC;

ACTAVIS PHARMA, INC.;

ALLERGAN PLC;

AMNEAL PHARMACEUTICALS, LLC;

CARDINAL HEALTH, INC.;

CEPHALON, INC.;

CVS HEALTH CORPORATION;

CVS HEALTH SOLUTIONS, LLC;

CVS PHARMACY, INC.;

ECKERD CORPORATION d/b/a RITE AID

PHARMACY;

ENDO HEALTH SOLUTIONS INC.;

ENDO PHARMACEUTICALS INC.;

JANSSEN PHARMACEUTICA INC.;

JANSSEN PHARMACEUTICALS, INC.;

J.M. SMITH CORPORATION;

JOHNSON & JOHNSON;

KVK-TECH, INC.;

MALLINCKRODT, LLC;

MALLINCKRODT, PLC;

McKESSON CORPORATION;

NORAMCO, INC.;

ORTHO-MCNEIL-JANSSEN

PHARMACEUTICALS, INC.;

PAR PHARMACEUTICAL, INC.;

PAR PHARMACEUTICAL COMPANIES, INC.;

RITE AID OF NORTH CAROLINA, INC.;

RITE AID CORPORATION;

COMPLAINTPlaintiff's First Set of Interrogatories,
Request for Production of Documents,
and Request for Admissions included

SPECGX, LLC;)
 TEVA PHARMACEUTICAL INDUSTRIES LTD;)
 TEVA PHARMACEUTICALS USA, INC.;)
 THE NORTH CAROLINA MUTUAL)
 WHOLESALE DRUG COMPANY;)
 WALGREENS BOOTS ALLIANCE, INC.;)
 WALMART INC., f/k/a WAL-MART STORES,)
 INC.;)
 WATSON LABORATORIES, INC.;)
 WATSON PHARMACEUTICALS, INC.;)
 BEVERLY SACKLER;)
 DAVID SACKLER;)
 ILENE SACKLER LEFCOURT;)
 JONATHAN SACKLER;)
 KATHE SACKLER;)
 MORTIMER D.A. SACKLER;)
 RICHARD SACKLER;)
 THERESA SACKLER,)
)
 Defendants.)

COMES NOW Plaintiff, by and through undersigned counsel, complaining of Defendants, and alleges and says as follows:

SUMMARY

This suit alleges, in part, two primary causes of the opioid crisis: (a) a marketing scheme involving the false and deceptive marketing of prescription opioids, which was designed to dramatically increase the demand for and sale of opioids and opioid prescriptions; and (b) a supply chain scheme, pursuant to which the various entities in the supply chain failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market. Additionally, some or all of the defendants committed wrongful acts in the chain of supply, manufacture, sale, marketing or distribution of opioids in North Carolina.

ALLEGATIONS

1. Plaintiff, Susan K. Stevens, is the duly appointed Administratrix of the Estate of Toria Capri Stevens, in Forsyth County, North Carolina, having been duly appointed on January 13, 2020.

2. Toria Capri Stevens (hereafter referred to as "Toria") was born on November 24, 1995 and died on January 22, 2018.

3. A copy of the certificate of death of Toria is attached hereto as Exhibit "A." The injury resulting in her death and the immediate cause of her death was Fentanyl and Clonazepam toxicity.

4. Prior to her death, Toria had been a very active student in high school and technical school. At age 16 Toria was prescribed opioids for wisdom teeth extraction from which she developed dependency and addiction to opioids. As a result of her opioid addiction, Toria suffered with anxiety and used opioids in response to stressors in her life. She was unable to simply will herself to successfully discontinue opioid medication due to the unabated addiction to opioids.

5. Upon information and belief, one or more of the Defendants manufactured, and or distributed opioids in Forsyth County, North Carolina prescribed to Toria. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs.

6. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an

Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, TEVA LTD acquired CEPHALON, INC. TEVA PHARMACEUTICALS USA, INC. (“Teva USA”) is a Delaware corporation registered to do business in North Carolina and is a wholly-owned subsidiary of TEVA LTD in Pennsylvania. TEVA USA acquired CEPHALON in October 2011.

7. CEPHALON, INC. manufactures, promotes, sells and distributes opioids, such as Actiq and Fentora, in the United States. Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients sixteen years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.” Fentora has been approved by the FDA only for the “management of breakthrough pain in cancer patients eighteen years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”

8. TEVA LTD, TEVA USA and CEPHALON, INC. work together closely to market and sell CEPHALON products in the United States. TEVA LTD conducts all sales and marketing activities for CEPHALON in the United States through TEVA USA and has done so since its October 2011 acquisition of CEPHALON. TEVA LTD and TEVA USA hold out Actiq and Fentora as TEVA products to the public. TEVA USA sells all former CEPHALON branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with CEPHALON opioids, discloses that TEVA USA submitted the guide, and directs physicians to contact TEVA USA to report adverse events.

9. All of CEPHALON’s promotional websites, including those for Actiq and Fentora, display Teva Ltd’s logo. Teva Ltd’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012 – the year immediately following the

CEPHALON acquisition – attributed a twenty-two percent increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including, inter alia, sales of Fentora®. Through interrelated operations like these, TEVA LTD operates in the United States through its subsidiaries CEPHALON and TEVA USA. The United States is the largest of TEVA LTD’s global markets, representing fifty-three percent of its global revenue in 2015, and, were it not for the existence of TEVA USA and CEPHALON, INC., TEVA LTD would conduct those companies’ business in the United States itself. Upon information and belief, TEVA LTD directs the business practices of CEPHALON and TEVA USA, and their profits inure to the benefit of TEVA LTD as controlling shareholder. TEVA PHARMACEUTICAL INDUSTRIES, LTD, TEVA PHARMACEUTICAL USA, INC. and CEPHALON, INC. are referred to as “Cephalon.”

10. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation registered to do business in North Carolina with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than ten percent of Janssen Pharmaceuticals’ stock, and J&J corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals’ drugs and Janssen’s profits inure

to J&J's benefit. JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC.; Noramco and J&J are referred to as "Janssen."

11. Janssen manufactures, promotes, sells and distributes drugs in the United States, including the opioid Duragesic (fentanyl).

12. Defendant, KVK-TECH, INC. is a privately held Pennsylvania corporation with its principal place of business in Pennsylvania. KVK-TECH, INC. is a manufacturer of generic prescription opioids, including many Schedule II controlled substances such as Oxycodone and Hydrocodone. KVK-TECH, INC. manufactures, markets, sells and/or distributes pharmaceutical drugs nationally and in Plaintiff's Community. KVK-TECH, INC. is registered to conduct business and/or conducts business in Plaintiff's community as a licensed wholesale pharmaceutical distributor. KVK-TECH, INC. distributed opioids, in violation of the duties owed to Plaintiff as set forth herein, in sufficient quantities to be a proximate cause of Plaintiff's injuries KVK-TECH, INC.

13. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation registered to do business in North Carolina with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo."

14. Endo develops, markets and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet and Zydene, in the United States. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

15. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to ACTAVIS, INC. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is registered to do business with the North Carolina Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. ALLERGAN PLC; ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC.; WATSON PHARMACEUTICALS, INC.; WATSON PHARMA, INC. and WATSON LABORATORIES, INC. are referred to as “Actavis.”

16. Actavis manufactures, promotes, sells and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

17. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware and licensed to do business in North Carolina. MALLINCKRODT, LLC is a wholly owned subsidiary of MALLINCKRODT, PLC. MALLINCKRODT, PLC and MALLINCKRODT, LLC are referred to as “Mallinckrodt.”

18. Mallinckrodt manufactures, markets and sells drugs in the United States, including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

19. Upon information and belief, ABBOTT LABORATORIES, INC. is an Illinois corporation authorized to do business and doing business throughout North Carolina. ABBOTT LABORATORIES, INC. engages in the manufacture, sale, and distribution of opioids.

20. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in “wholesale distribution,” as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Toria’s Community.

21. Upon information and belief, Defendant ECKERD CORPORATION d/b/a RITE AID PHARMACY is a foreign corporation authorized to do business and doing business

throughout North Carolina. ECKERD CORPORATION engages in the sale and distribution of opioids.

22. Defendant, J.M. SMITH CORPORATION (“J.M. Smith”) is a South Carolina corporation with its principal place of business in Spartanburg, South Carolina. At all times relevant to this Complaint, J.M. SMITH distributed prescription opioids throughout the eastern United States in at least thirty-two states, including in Plaintiff’s Community. J.M. SMITH conducts business as a licensed wholesale distributor under the name Smith Drug Company which is a division of J.M. SMITH.

23. J.M. SMITH is registered to conduct business and/or conducts business in Plaintiff’s community as a licensed wholesale pharmaceutical distributor. J.M. SMITH distributed opioids, in violation of the duties owed to Plaintiff as set forth herein, in sufficient quantities to be a proximate cause of Plaintiff’s injuries. J.M. SMITH is sued as a Distributor Defendant.

24. Defendant, RITE AID CORPORATION (“Rite Aid”) is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. RITE AID CORPORATION, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor.

25. Defendant RITE AID is registered to conduct business and/or conducts business in Plaintiff’s community as a licensed wholesale pharmaceutical distributor under the following named business entities: Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., Rite Aid of Massachusetts, Rite Aid of Michigan, and Rite Aid of West Virginia, Inc. Rite Aid distributed opioids, in violation of the duties owed to Plaintiff as set

herein, in sufficient quantities to be a proximate cause of Plaintiff's injuries. Rite Aid is sued as a Distributor Defendant.

26. Upon information and belief, Defendant RITE AID OF NORTH CAROLINA, INC. is a North Carolina corporation with its principal place of business in Pennsylvania, doing business throughout North Carolina. RITE AID OF NORTH CAROLINA, INC. engages in the sale and distribution of opioids. Hereinafter, this defendant and ECKERD CORPORATION are collectively referred to as "Rite Aid."

27. Defendant, McKESSON CORPORATION, is registered with the North Carolina Secretary of State as a Delaware corporation. McKesson has its principal place of business located in San Francisco, California.

28. Defendant, CARDINAL HEALTH, INC., is an Ohio corporation with its principal office located in Dublin. CARDINAL HEALTH, INC. operates a distribution center in Greensboro, North Carolina.

29. Defendant, AMERISOURCEBERGEN DRUG CORPORATION, is registered with the North Carolina Secretary of State as a Delaware corporation. Amerisourcebergen Drug Corporation's principal place of business is located in Chesterbrook, Pennsylvania.

30. Plaintiff has named the three (3) wholesale distributors (i.e., AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC. and McKESSON CORPORATION) that dominate eighty-five percent of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. Plaintiff believes and alleges that each of these companies has engaged in conduct that resulted in the diversion of prescription opioids into our community and that

discovery will likely reveal others who likewise engaged in conduct, contrary to statutory regulations and common law duties.

31. Upon information and belief, Defendant THE NORTH CAROLINA MUTUAL WHOLESALE DRUG COMPANY is a North Carolina corporation, also formed as North Carolina Mutual Association, doing business throughout North Carolina, including Forsyth County, and is engaged in the distribution of opioids.

32. Upon information and belief, Defendant SPECGX, LLC is a Delaware limited liability company doing business throughout North Carolina, including Forsyth County, and is engaged in the distribution of opioids. Upon information and belief, Defendant SPECGX, LLC is a wholly owned subsidiary of Defendant MALLINCKRODT, PLC.

33. Upon information and belief, Defendant PAR PHARMACEUTICAL, INC. is a New York corporation doing business throughout North Carolina, including Forsyth County, and is engaged in the distribution of opioids. Upon information and belief, this Defendant is a wholly owned subsidiary of Defendant ENDO.

34. Upon information and belief, Defendant PAR PHARMACEUTICAL COMPANIES, INC. is a New York corporation doing business throughout North Carolina, including Forsyth County, and is engaged in the distribution of opioids. Upon information and belief, this Defendant is a wholly owned subsidiary of Defendant ENDO. Hereinafter, these all PAR defendants are collectively referred to as “Par Pharma.”

35. Upon information and belief, Defendant AMNEAL PHARMACEUTICALS, LLC is a Delaware limited liability company doing business throughout North Carolina, including Forsyth County, and is engaged in the distribution of opioids.

36. Upon information and belief, Defendant CVS PHARMACY, INC. is a Rhode Island corporation doing business throughout North Carolina, including Forsyth County, and is engaged in the distribution of opioids.

37. Upon information and belief, Defendant CVS HEALTH SOLUTIONS LLC is a Delaware limited liability company doing business throughout North Carolina, including Forsyth County, and is engaged in the distribution of opioids. Upon information and belief, Defendant CVS PHARMACY, INC. is the manager of Defendant CVS HEALTH SOLUTIONS LLC.

38. Upon information and belief, Defendant CVS HEALTH CORPORATION is a Delaware corporation doing business throughout North Carolina, including Forsyth County, and is engaged in the distribution of opioids. Hereinafter, all CVS defendants are collectively referred to as "CVS."

39. Upon information and belief, Defendant WALMART INC. f/k/a WAL-MART STORES, INC. is a Delaware corporation doing business throughout North Carolina, including Forsyth County, and is engaged in the distribution of opioids.

40. Upon information and belief, Defendant WALGREENS BOOTS ALLIANCE, INC. is an Illinois corporation doing business throughout North Carolina, including Forsyth County, and is engaged in the distribution of opioids.

41. Upon information and belief, several of the named Defendants are partially- or wholly-owned subsidiaries of other named Defendants. These intertwined Defendants have used these complex relationships to violate statutory regulations, common-law duties, and other like standards of care with impunity. To the extent Plaintiff has not alleged such relationships, and to the extent they exist, Plaintiff alleges such, upon information and belief.

42. Upon information and belief, the following Defendants, all members of the Sackler family which owns PURDUE PHARMA L.P. and other Purdue entities, and hereinafter collectively referred to as “Sackler Defendants,” served on the board of Purdue and greatly benefitted financially from the manufacture, sale, and distribution of opioids throughout North Carolina, including Forsyth County:

- a. Richard Sackler, a competent adult citizen and resident of Florida;
- b. Beverly Sackler, a competent adult citizen and resident of Connecticut;
- c. David Sackler, a competent adult citizen and resident of New York;
- d. Ilene Sackler Lefcourt, a competent adult citizen and resident of New York;
- e. Jonathan Sackler, a competent adult citizen and resident of Connecticut;
- f. Kathe Sackler, a competent adult citizen and resident of Connecticut;
- g. Mortimer D.A. Sackler, a competent adult citizen and resident of New York; and
- h. Theresa Sackler, a competent adult citizen and resident of the United Kingdom.

43. This Court has personal jurisdiction over Defendants because they conduct business in North Carolina, purposefully direct or directed their actions toward North Carolina, consented to be sued in North Carolina by registering an agent for service of process, and/or consensually submitted to the jurisdiction of North Carolina when obtaining a manufacturer or distributor license and have the requisite minimum contacts with North Carolina necessary to constitutionally permit the Court to exercise jurisdiction.

44. This Court has jurisdiction over the parties to this action and the subject matter of this action, and venue is proper in this Court.

45. Toria developed an addiction to opioids for treatment of pain, and for which her family helped her seek rehabilitation; however, Toria's efforts at rehabilitation failed.

46. At age 21 Toria was prescribed opioids again for a leg injury and her sobriety from rehabilitation ended as she relapsed into addiction.

47. After Toria turned twenty-one years of age and took the prescribed opioids again, she could not manage orthopedic and chronic pain without taking opioids.

48. Toria continued to use opioids which resulted in her death.

49. The Defendants' conduct in misrepresenting the non-addictive nature of the prescription opioids, in selling the opioids for chronic pain treatment, and the distributors conduct in supplying opioids yet failing to abide by federal regulations to report suspicious orders and stop shipments of suspicious orders, allowed a flood of opioids into Forsyth County, and the surrounding areas. Furthermore, the extended use of opioids for pain as marketed and described in the advertising and distribution of the Defendants was improper.

FIRST CAUSE OF ACTION

**Negligence, Negligent Misrepresentation, and Wrongful Death
(Against All Defendants)**

50. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

51. Plaintiff seeks economic damages which were the foreseeable result of Defendants' negligent, grossly negligent, intentional and/or willful or wanton actions and omissions.

52. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, selling, distributing and supplying highly dangerous opioid drugs to the State and Toria's Community.

53. Each Defendant had an obligation to exercise due care in manufacturing, marketing, selling, distributing and supplying highly dangerous opioid drugs in the State and Toria's Community.

54. Each Defendant owed a duty to the Toria and to Toria's Community because the injuries alleged herein were foreseeable, and in fact foreseen, by the Defendants.

55. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

56. Defendants were repeatedly warned by law enforcement of the consequences of their actions and omissions and that their misconduct was contrary to statutory regulations and common law duties.

57. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

58. Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution and supply of dangerous opioids, which are highly regulated substances under Federal and State laws, by failing to monitor for, failing to report, and filling highly

suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non- medical purposes – the causal connection between Defendants’ breach of duties and the ensuing harm was entirely foreseeable.

59. Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Toria’s community and destinations from which they knew opioids were likely to be diverted into Toria’s community, in addition to other misrepresentations alleged and incorporated herein.

60. Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids and by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drugs were not safe or suitable.

61. Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and its lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

62. Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

63. Defendants’ breaches were intentional and/or willful, and Defendants’ conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent, and contrary to statutory regulations and common law duties.

64. The causal connection between Defendants’ breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

65. Defendants knew or should have known:

a. Their wrongful misconduct would and did lead people like Toria to become addicted to opioids;

b. Opioid addiction would lead opioid addicts to misuse other substances; and

c. This pattern would lead some of those people, including Toria, to die of overdoses of street drugs.

66. Defendants' breaches of duty and misrepresentations bear a causal connection with, and/or proximately resulted in the damages sought herein.

67. Defendants intended for Toria to rely on information regarding their products; the information was false; the Defendants failed to use reasonable care or competence in obtaining or communicating the information; Toria relied on such information and had no other or actual means to determine its falsity, was denied the opportunity to investigate, could not have learned of the true facts by the exercise of reasonable diligence; and such reliance caused financial damage to Toria and her heirs at law and will continue to do so in the future.

68. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants knowingly traded in drugs and supplied drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Defendants breached their duties to monitor for, report, and halt suspicious orders, breached their duties to stop the wrongful supply and prevent diversion, and, further, misrepresented what their duties were and their compliance with their legal duties.

69. Defendants' willful, wanton, and/or intentional actions constitute negligence and gross, willful, or wanton negligence and were entirely contrary to statutory regulations and common-law duties.

70. As a direct and proximate result of Defendants' conduct, as described herein, Toria sustained injuries that directly and proximately caused her significant, severe, and painful personal injury and caused Toria to incur medical expenses.

71. Defendant's negligence directly and proximately caused damages to Toria, and Plaintiff is entitled to recover an amount in excess of \$25,000.00.

72. As a direct and proximate result of Defendants' conduct, as described herein, Toria sustained injuries that directly and proximately caused her death. Accordingly, Plaintiff, as the Administratrix of the Estate of Toria, Susan K. Stevens, is entitled to recover damages of Defendants, pursuant to North Carolina General Statute § 28A-18-2, including, but not limited to, the following:

- a. Medical expenses related to the injuries and the care and treatment incident to those injuries prior to Toria's death and resulting in the wrongful death of Toria;
- b. Compensation for the pain and suffering of Toria from the moment of her addiction to the time of her death;
- c. The reasonable expenses for the funeral of Toria;
- d. The present monetary value of Toria to the persons entitled to receive the damages recovered, including lost net income as well as damages for the services, protection, care, assistance, society, companionship, comfort, guidance, kindly offices, and advice of Toria; and

e. All other damages permitted by law.

73. Plaintiff, in her capacity as the Administratrix of Decedent's Estate, hereby brings this action for wrongful death against Defendant, to recover all damages permitted by law, in an amount in excess of \$25,000.00.

SECOND CAUSE OF ACTION
Negligence
(Against All Defendants)

74. Plaintiff repeats and restates the previous paragraphs of the Complaint as if set forth again herein.

75. In the alternative to the Wrongful Death claim, Plaintiff, in her capacity as the Administratrix of Decedent's Estate, is entitled to pursue a personal injury claim on behalf of the Estate against Defendants for the above-described negligence, pursuant to North Carolina General Statute § 28A-13-3(a)(15).

76. As a direct and proximate result of Defendants' above-described negligence, Toria sustained injuries that directly and proximately caused her significant, severe, and painful personal injury, and those injuries resulted in Toria's addiction to opioids and her suffering of all the negative effects associated therewith.

77. As a direct and proximate result of Defendants' above-described negligence, Toria incurred medical expenses, became addicted to opioids, and experienced pain and suffering.

78. Plaintiff, in her capacity as the Administratrix of Decedent's Estate, hereby brings this survival action for negligence against Defendants, to recover all damages for Toria's personal injuries suffered as a result of Defendants' conduct, both pre-death and in causing her death, in an amount in excess of \$25,000.00.

THIRD CAUSE OF ACTION**Negligence per se
(Against All Defendants)**

79. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

80. The North Carolina controlled substances laws and regulations are public safety laws. Each Defendant had a duty under, inter alia, these laws maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Toria and Toria's Community are within the class of persons intended to be protected by these laws.

81. Defendants' actions and omissions in violation of law and regulation constitute negligence per se.

82. Defendants' actions and omissions were intentional, and Defendants acted with actual malice and constituted gross, willful, or wanton conduct and contrary to statutory regulations and common law duties.

83. It was foreseeable that the breach of duty described herein would result in the damages for which Plaintiff seeks recovery, including damages for Toria's wrongful death and for Toria's bodily injury, and associated damages, pre-death. To the extent necessary, the claim for pre-death damages may be considered a survival action or survival claim.

84. Defendants breached their duties to maintain effective controls against diversion and wrongful supply of dangerously addictive opioids, including violating public safety statutes requiring such controls as wholesale drug distributors.

85. Defendants' breach of statutory and regulatory duties caused, bear a causal connection with, and proximately resulted in, harm and damages sought by the Plaintiff.

86. Defendant's negligence directly and proximately caused damages to Toria, and Plaintiff is entitled to recover an amount in excess of \$25,000.00.

FOURTH CAUSE OF ACTION
Violations of North Carolina's Unfair and Deceptive Trade Practices Act
(Against All Defendants)

87. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

88. Defendants violated N.C. Gen. Stat. 75-1 et seq., because they engaged in deceptive trade practices in this State.

89. Defendants committed and are committing repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in the conduct of, and in or affecting, commerce.

90. Each Defendant failed to report suspicious orders of and/or prevent the diversion and wrongful supply of highly addictive prescription drugs to illegal sources.

91. Because of the dangerously addictive nature of these drugs, the Defendants' manufacturing, marketing, sales, supply chain and/or distribution practices caused an opioid epidemic in the State and Toria's community. Each Defendant had a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

92. Defendants also omitted material facts, causing confusion or misunderstanding as to approval or certification of goods or services.

93. Defendants failed to disclose the material facts that, inter alia, they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and

refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to supply and sell opioids, and the Distributor Defendants would not have been able to receive and renew licenses to supply and sell opioids. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

94. Manufacturer Defendants wrongfully marketed and misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

95. Manufacturer Defendants engaged in wrongful, misleading marketing and an improper rebate scheme to unfairly target specific markets and increase sales volume.

96. Manufacturer Defendants used exaggeration and/or ambiguity as to material facts and omitted material facts, which tended to deceive and/or did in fact deceive in the course of wrongful and misleading marketing.

97. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted a violation of State law.

98. Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids in the course of misleading and wrongful marketing. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

99. Defendants' unfair, deceptive, and unconscionable representations, concealments, and omissions were reasonably calculated to deceive the State, the public, Toria's community, and Toria.

100. As described more specifically above, Defendants' representations, concealments, and omissions constitute a willful course of conduct which continues to this day.

101. The damages which Plaintiff seeks to recover were sustained as a direct and proximate cause of the Manufacturer and Distributor Defendants' intentional and/or willful or wanton actions and omissions, which were contrary to statutory regulations and common law duties.

102. Defendants' actions and omissions in the course of marketing, selling, supplying and distributing prescriptions opioids constituted deceptive trade practices under applicable law.

103. It is unlawful to represent that goods or services have sponsorship, approval, characteristics, uses, or benefits that they do not have. It is improper to represent that goods are of a standard, quality, or grade if they are of another. Defendants made such deceptive and unlawful misrepresentations.

104. Defendants have engaged in repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in the conduct of commerce in this State and in Toria's community.

105. Each Defendant failed to report and/or prevent the diversion of highly addictive prescription drugs.

106. Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective for ordinary pain management when such representations were untrue, false,

and misleading, all of which was an integral part of Defendants wrongful, improper and misleading marketing.

107. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted a violation of State and Federal law.

108. Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

109. Defendants acted intentionally and were contrary to statutory regulations and common law duties.

110. Defendants' actions directly and proximately caused injury to Toria, as alleged herein, including damages for Toria's wrongful death and for Toria's bodily injury, and associated damages, pre-death. To the extent necessary, the claim for pre-death damages may be considered a survival action or survival claim.

111. Defendants' actions affected commerce and constituted commercial activity.

112. Defendants' violations of Federal law, regulations, and statutes constitute per se violations of N.C. Gen. Stat. § 75-1, et seq.

113. Plaintiff seeks all damages pursuant to N.C. Gen. Stat. § 75-1, et seq., trebled, and attorney's fees, for injuries sustained because of Defendants' violation of statutory and common law, and all legal and equitable relief as allowed by law.

FIFTH CAUSE OF ACTION
Breach of Express Warranty
(Manufacturing Defendants)

114. Plaintiff incorporates each of the previous paragraphs as if fully restated and realleged herein.

115. Upon information and belief, Defendants expressly warranted to Toria and Toria's physicians and pharmacists that the opioids were indicated for use as marketed and prescribed, they were safe and effective for their stated purposes, and that addiction, complications, or problems with the opioids were very rare.

116. Toria was a user and consumer of Defendants' products, and Toria and Toria's physicians initially used Defendants' products in the way Defendants intended they be used.

117. Defendants breached their express warranty by failing to provide opioids that were safe, effective, and properly designed and manufactured for their stated purpose.

118. Defendants breached their express warranty by designing, manufacturing, marketing, and selling opioids in such a way that, when used as advertised, marketed, and prescribed, caused addiction and death.

119. Defendants' breaches were the direct and proximate cause of the damages suffered by Toria, including damages for Toria's wrongful death and for Toria's bodily injury, and associated damages, pre-death. To the extent necessary, the claim for pre-death damages may be considered a survival action or survival claim.

120. As a result of Defendants' breaches, Plaintiff is entitled to recover an amount in excess of \$25,000.00.

SIXTH CAUSE OF ACTION
Breach of the Implied Warranty of Fitness for a Particular Purpose
(All Defendants)

121. Plaintiff incorporates each of the previous paragraphs as if fully restated and realleged herein.

122. Defendants knew that the opioids would be provided to patients for pain management and other purposes and that physicians and patients were relying on Defendants' judgment to furnish suitable goods.

123. Defendants knew or should have known that the opioids did not meet the capabilities as Defendants represented and marketed them, were more addictive than Defendants represented and marketed them, and were less effective than Defendants represented and marketed them.

124. Toria initially used the opioids for the particular purpose and in the manner intended by Defendants, eventually resulting in her addiction and death by overdose.

125. Toria and Toria's physicians, by the use of reasonable care, would not have discovered the breached warranty and realized the danger of the breach.

126. Defendants' breaches of the implied warranty were a direct and proximate cause in bringing about Toria's injuries and death, including damages for Toria's wrongful death and for Toria's bodily injury, and associated damages, pre-death. To the extent necessary, the claim for pre-death damages may be considered a survival action or survival claim.

127. As a direct and proximate result of Defendants' actions, Toria suffered injury and death and Defendants are liable to Plaintiff in an amount in excess of \$25,000.00.

SEVENTH CAUSE OF ACTION
Breach of the Implied Warranty of Merchantability
(All Defendants)

128. Plaintiff incorporates each of the previous paragraphs as if fully restated and realleged herein.

129. Defendants, as the manufacturers, marketers, and sellers of the opioids, are merchants with respect to their own products.

130. By manufacturing, marketing, and selling the opioids, Defendants warranted that the opioids would be merchantable, in that they would be fit for the ordinary purposes for which such products are used; namely, for effective and non-addictive pain management.

131. Toria was a user and consumer of Defendants' opioids, and Toria and Toria's physicians initially used Defendants' products in the way Defendants intended they be used, resulting in Toria's addiction and death.

132. As the purchaser of the opioids, Toria reasonably relied upon Defendants' implied warranties.

133. Defendants breached their implied warranties by designing, marketing, manufacturing, and selling the opioids in such a way that they caused addiction and treated pain less effectively than advertised, without Toria and other users' awareness of these risks.

134. Defendants' breaches were the direct and proximate cause of the damages suffered by Toria, including damages for Toria's wrongful death and for Toria's bodily injury, and associated damages, pre-death. To the extent necessary, the claim for pre-death damages may be considered a survival action or survival claim.

135. As a result of Defendants' breaches, Plaintiff is entitled to recover an amount in excess of \$25,000.00.

EIGHTH CAUSE OF ACTION
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1961,
et seq.
(Against Defendants named herein)

136. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

137. Plaintiff brings this Count on behalf of itself against the following Defendants, as defined above: Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, the Sackler Defendants, and AmerisourceBergen (collectively, for purposes of this Count, the “RICO Defendants”).

138. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were “persons” under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

139. Section 1962(c) of RICO makes it unlawful “for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity or collection of unlawful debt.” 18 U.S.C. § 1962(c).

140. The term “enterprise” is defined as including “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” The definition of “enterprise” in 18 U.S.C. § 1961(4) includes legitimate and illegitimate enterprises within its scope.

141. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As “registrants,” the RICO Defendants operated and continue to operate

within the “closed-system” created under the Controlled Substances Act, 21 U.S.C. § 821, et seq. (the “CSA”). The CSA restricts the RICO Defendants’ ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

142. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from “legitimate channels of trade” to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances].”

143. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. As discussed in detail below, through the RICO Defendants’ scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

144. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants and executed in perfect harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, deceiving the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while people like Toria and communities like Toria's experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. The RICO Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

145. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA") is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4).

146. On information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

147. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. Moreover, the HDA serves the interests of distributors and manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

148. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

A. THE OPIOID DIVERSION ENTERPRISE

149. Recognizing that there was a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” Moreover, the closed system was specifically designed to

ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants -- manufacturers and distributors alike -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

150. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders. The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to “know their customers.”

151. Central to the closed system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.” When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of disposal of the basic class;
- d. An applicant’s production cycle and current inventory position;
- e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.

152. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

153. At all relevant times, the RICO Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

154. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased thirteen-fold, four-fold, and nine-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month. On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.

155. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. It Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. It was

not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

156. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

157. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.

158. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants,

through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating state and federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

159. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

160. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

161. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and

continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

162. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

163. The Pain Care Forum (“PCF”) has been described as a coalition of drugmakers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

164. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.” Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.

165. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF. In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen

Pharmaceuticals), Actavis (i.e., Allergan), and Teva (the parent company of Cephalon). Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA. Plaintiff is informed and believes that the Distributor Defendants participated directly in the PCF as well.

166. The 2012 Meeting Schedule for the Pain Care Forum indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were “encouraged to attend in person” at the monthly meetings.

167. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drugmakers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

168. Second, the HDA -- or Healthcare Distribution Alliance -- led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (i.e., Allergan), Endo, Purdue, Mallinckrodt, and Cephalon were members of the HDA. The HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

169. The HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.” Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

170. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants. The manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.

171. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”

b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business

solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel."

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.

i. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation includes Distributor and Manufacturer Members.

172. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise’s organization.

173. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.” The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.” The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

174. Third, the RICO Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

175. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids. As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the

HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales. Upon information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

176. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

177. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain

Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants was in communication and cooperation.

178. From 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over \$740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures. Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.

179. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

180. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

181. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

182. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

183. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

184. Defendants paid nearly \$800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

185. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

186. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."

187. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiff is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. Plaintiff is informed and believes that the

Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

188. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the RICO Defendants.

189. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids. On information and belief, the "know your customer" questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

190. The RICO Defendants refused to identify, investigate, and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012 and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six actions involving orders to show cause and forty-one actions involving immediate suspension orders -- all for failure to report suspicious orders.

191. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

192. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

193. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;
- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical

need” for and the net disposal of their drugs did not justify the production quotas set by the DEA.

194. The scheme devised and implemented by the RICO Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

C. PATTERN OF RACKETEERING ACTIVITY.

195. The RICO Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1. The RICO Defendants Engaged in Mail and Wire Fraud.

196. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

197. The RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to

each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

198. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

199. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

200. The RICO Defendants’ predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to

design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

201. The RICO Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

- g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;
- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- l. Payments to Defendants' lobbyists through the Pain Care Forum;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

202. On information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

203. Purdue manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.

204. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.

205. Cephalon manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.

206. The Distributor Defendants shipped Teva's prescription opioids throughout this jurisdiction.

207. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

208. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

209. Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydane. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

210. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

211. Actavis manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

212. The Distributor Defendants shipped Actavis' prescription opioids throughout this jurisdiction.

213. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone.

214. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

215. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

216. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

217. Plaintiff is also informed and believes that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

218. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

219. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions

of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

220. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden and cannot be alleged without access to Defendants' books and records. But Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

221. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Defendants.

222. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

223. The RICO Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the RICO Defendants were filling on a daily basis -- leading to the diversion of a tens of millions of doses of prescriptions opioids into the illicit market.

224. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

225. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

226. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

227. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

228. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

229. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue unless enjoined by this Court.

230. Many of the precise dates of the RICO Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

231. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers in this jurisdiction, its citizens or the Plaintiff. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

232. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

233. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

234. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

2. The RICO Defendants Manufactured, Sold and/or Dealt in Controlled Substances and Their Crimes Are Punishable as Felonies.

235. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

236. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony.

237. Each of the RICO Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant.

238. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

239. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

240. For example, The DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.

241. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA. The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring." Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several

years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals.”

242. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012. After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt’s response was that everyone knew what was going on in Florida, but they had no duty to report it.

243. Plaintiff is informed and believes that the foregoing examples reflect the RICO Defendants’ pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants. For example:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against

diversion of hydrocodone. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;

g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford

Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at several of its facilities.

244. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

245. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint.

246. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

247. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and Toria. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or Toria. The Defendants were aware that Toria and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

248. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

249. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Toria and other consumers by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

250. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

3. The Actions of the Sackler Defendants

251. Upon information and belief, the Sackler Defendants exercised enormous control over the Purdue Entities, including approving, directing, or otherwise exerting control over Purdue's deceptive marketing practices.

252. At all times relevant to this action, the Sackler Defendants knew the Purdue opioid products were dangerous, addictive, and being abused. Rather than address these issues, however, the Sackler Defendants instead planned to blame those who became addicted and, possibly, selling the Purdue Entities to avoid financial sanctions for their acts following a criminal investigation.

253. The Sackler Defendants, through the Purdue Entities, intending to defraud or mislead, marketed opioids as less addictive and more effective than they actually knew or should have known the opioids were.

254. The Sackler Defendants each signed an agreement with the U.S. government ensuring that the Purdue Entities did not deceive doctors or patients regarding opioids.

255. Even after making representations to the U.S. government, the Sackler Defendants knew that the Purdue Entities continued to market and sell opioids in a deceptive or fraudulent manner, including, for example, assertions that physical dependence on opioids was beneficial for improving patients' lives and was not dangerous.

256. Over time, the Sackler Defendants expressed great concern for increasing the number of prescriptions and the sales numbers for opioids while expressing little or no concern for data on addiction, abuse, or death from opioids.

257. The Sackler Defendants and Purdue Entities knew that there were serious concerns with addiction, resulting in part from their sales strategies, but rather than address the concerns they simply looked for new ways to profit from addiction treatment for patients

addicted to the products for which the Sackler Defendants oversaw and approved the deceptive marketing and sales.

258. In the past ten-plus years, the Sackler Defendants, through their control of the board of the Purdue Entities, approved the transfer of billions of dollars to themselves in anticipation of the Purdue Entities being held liable for criminal or civil liability and judgment.

D. DAMAGES

259. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Toria's addiction and eventual death, as described above in language expressly incorporated herein by reference.

260. Plaintiff's damages were proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Toria would not have become addicted and died, in addition to the other damages he suffered, as described above and incorporated herein, including damages for Toria's wrongful death and for Toria's bodily injury, and associated damages, pre-death. To the extent necessary, the claim for pre-death damages may be considered a survival action or survival claim.

261. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

**NINTH
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C.
1962(d), et seq.
(Against All RICO Defendants)**

262. Plaintiff hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

263. Plaintiff brings this claim on its own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for “any person to conspire to violate” Section 1962(d), among other provisions.

264. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

A. THE OPIOID DIVERSION ENTERPRISE.

265. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set forth above concerning the “Opioid Diversion Enterprise.”

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.

266. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set forth above concerning the “Conduct of the Opioid Diversion Enterprise.”

C. PATTERN OF RACKETEERING ACTIVITY.

267. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set forth above concerning the “Pattern of Racketeering Activity.”

D. DAMAGES.

268. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Toria's addiction and eventual death, as described above in language expressly incorporated herein by reference.

269. Plaintiff's damages were proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Toria would not have become addicted and died, in addition to the other damages he suffered, as described above and incorporated herein, including damages for Toria's wrongful death and for Toria's bodily injury, and associated damages, pre-death. To the extent necessary, the claim for pre-death damages may be considered a survival action or survival claim.

270. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

TENTH CAUSE OF ACTION

Nuisance (Against all Defendants)

271. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here.

272. Defendants' unlawful actions have created a nuisance under North Carolina law, and Toria's addiction and death were the direct result of Defendants' failure to abate that nuisance.

273. The Defendants have intentionally and/or unlawfully created a nuisance.

274. Toria and the residents of Toria's Community had a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be

free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

275. Defendants intentionally, unlawfully, and recklessly manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will be diverted, causing widespread distribution of prescription opioids in and/or to Toria's Community, resulting in addiction and abuse, an elevated level of crime, death and injuries to the residents of Toria's Community, a higher level of fear, discomfort and inconvenience to the residents of Toria's Community, and direct costs to Toria's Community.

276. Defendants unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the Toria's Community and its residents.

277. Defendants unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct was illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

278. Defendants' conduct in illegally distributing and selling prescription opioids, or causing such opioids to be distributed and sold, where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally Toria's Community is of a continuing nature.

279. A violation of any rule or law controlling the distribution of a drug of abuse in Toria's Community and the State is a public nuisance.

280. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

281. Defendants' ongoing conduct produced an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Toria's Community were diverted, leading to abuse, addiction, crime, and public health costs.

282. Defendants knew, or reasonably should have known, that their conduct had an ongoing detrimental effect upon the public health, safety and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

283. Defendants knew, or reasonably should have known, that their conduct caused an unreasonable invasion of the public right to health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

284. Defendants were aware, and at a bare minimum certainly should have been aware, of the unreasonable interference that their conduct caused in Toria's Community. Defendants are in the business of manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal law.

285. Defendants' conduct in marketing, distributing, and selling prescription opioids which the defendants know, or reasonably should know, were likely to be diverted for non-legitimate, non-medical use, created a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents in Toria's Community and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

286. It was, or should have been, reasonably foreseeable to defendants that their conduct would cause deaths and injuries to residents in Toria's Community, and would otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the

public's right to be free from disturbance and reasonable apprehension of danger to person and property.

287. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Toria's Community not only caused deaths and injuries, but also created a palpable climate of fear among residents in Toria's Community where opioid diversion, abuse, addiction are prevalent and where diverted opioids tend to be used frequently.

288. Defendants' conduct made it easier for persons to divert prescription opioids, constituting a dangerous threat to the public.

289. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

290. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Toria's Community, however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt

suspicious orders of opioids and caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

291. Defendants knew the prescription opioids had a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance in Toria's Community.

292. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm and did cause substantial harm.

293. Defendants' conduct in creating, maintaining, and failing to abate the nuisance caused by their actions was a direct and proximate cause of injury and death to Toria.

294. As a direct and proximate result of Defendants' actions, Toria suffered injury and death and Defendants are liable to Plaintiff in an amount in excess of \$25,000.00, including damages for Toria's wrongful death and for Toria's bodily injury, and associated damages, pre-death. To the extent necessary, the claim for pre-death damages may be considered a survival action or survival claim.

ELEVENTH CAUSE OF ACTION
Piercing the Corporate Veil
(All Sackler Defendants)

295. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here.

296. At all times relevant to this action, the Sackler Defendants were officers, board members, or otherwise controlled Purdue Pharma L.P., Purdue Pharma Inc., and/or Purdue Frederick Company, Inc. (hereinafter collectively referred to as the “Purdue Entities”).

297. Upon information and belief, the Purdue Entities have filed for Federal bankruptcy protection, shielding them from responsibility or liability for the harms they have caused as a manufacturer, marketer, seller, and distributor of opioids. The foregoing allegations pertaining to Manufacturing Defendants and Distributor Defendants would apply to the Purdue Entities were they not currently in bankruptcy.

298. Upon information and belief, the Sackler Defendants knowingly and fraudulent withdrew or are withdrawing billions of dollars from the Purdue Entities specifically to shield the profits of the Purdue Entities and the wealth of the Sackler Defendants from legal judgment.

299. The Sackler Defendants’ knowing and fraudulent withdrawal of funds disregarded the corporate form of the Purdue Entities, was done to protect the funds from legal judgment or disbursement in bankruptcy, demonstrates their total control over the Purdue Entities, demonstrates their use of the Purdue Entities as the personal bank accounts of the Sackler Defendants, and should bar the Sackler Defendants from relying on the shields of corporate forms and bankruptcy protection.

300. The Sackler Defendants have used the corporate form of the Purdue Entities to shield themselves from exposure to their own wrongful acts and the wrongful acts of the Purdue Entities, as described above.

301. Plaintiff prays that the Court pierce the corporate veil of the Purdue Entities, and pierce the bankruptcy protections offered the Purdue Entities, to the extent necessary to reach the assets of the Sackler Defendants, in that the Sackler Defendants were the alter ego of the Purdue

Entities, and the Sackler Defendants used the Purdue Entities in accomplishing the wrongs described herein and causing Plaintiff's associated damages, including both the wrongful death damages arising from Toria's death and the personal bodily injury damages suffered by Toria. pre-death. To the extent necessary, the claim for pre-death damages may be considered a survival action or survival claim.

WHEREFORE, Plaintiff, having complained of Defendants, respectfully requests this Court grant her the following relief:

1. Plaintiff have and recover a judgment against all Defendants, jointly and severally, for compensatory damages for Toria's wrongful death, in an amount in excess of \$25,000.00;
2. Plaintiff have and recover a judgment against all Defendants, jointly and severally, for compensatory damages for Toria's damages suffered pre-death, in an amount in excess of \$25,000.00
3. Plaintiff have and recover a judgment against Defendants, jointly and severally, for trebled compensatory damages in excess of \$25,000.00, attorneys' fees, and costs, pursuant to Chapter 75 of the North Carolina General Statutes;
4. Plaintiff have and recover punitive damages against Defendants, jointly and severally, for the gross, intentional, willful, and wanton conduct, described above, in the greatest amount permitted by law and Chapter 1D of the North Carolina General Statutes;
5. Plaintiff have and recover all applicable costs, interest, and attorneys' fees, in the greatest amount permitted by law;
6. For a trial by jury on all issues so triable; and
7. For such further relief as this Court deems just and proper.

This the ____ day of January, 2020.


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EXHIBIT 2

**COMMONWEALTH OF KENTUCKY
JOHNSON COUNTY CIRCUIT COURT
CIVIL DIVISION ____**

CASE NO. _____

PAINTSVILLE HOSPITAL COMPANY, LLC; JENNIE
STUART MEDICAL CENTER, INC.; HARDIN
MEMORIAL HOSPITAL; T.J. SAMSON COMMUNITY
HOSPITAL; SAINT JOSEPH HEALTH SYSTEM, INC.;
FLAGET HEALTHCARE, INC.; HOSPITAL OF
LOUISA, INC.; and JACKSON HOSPITAL
CORPORATION.

PLAINTIFFS

v.

**COMPLAINT
JURY TRIAL DEMANDED**

AMNEAL PHARMACEUTICALS, LLC; AMNEAL
PHARMACEUTICALS, INC.; AMNEAL
PHARMACEUTICALS OF NEW YORK LLC; IMPAX
LABORATORIES, LLC; TEVA PHARMACEUTICAL
INDUSTRIES, LTD.; TEVA PHARMACEUTICALS
USA, INC.; CEPHALON, INC.; WATSON
LABORATORIES, INC.; WARNER CHILCOTT
COMPANY, LLC; ACTAVIS PHARMA, INC. f/k/a
WATSON PHARMA INC.; ACTAVIS SOUTH
ATLANTIC LLC; ACTAVIS ELIZABETH LLC;
ACTAVIS MID ATLANTIC LLC; ACTAVIS TOTOWA
LLC; ACTAVIS LLC; ACTAVIS KADIAN LLC;
ACTAVIS LABORATORIES UT, INC.; ACTAVIS
LABORATORIES FL, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.; ORTHO-
MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a
JANSSEN PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; NORAMCO, INC.;
TASMANIAN ALKALOIDS PTY. LTD.; ABBVIE,
INC.; ABBOTT LABORATORIES; ABBOTT
LABORATORIES, INC.; ASSERTIO THERAPEUTICS,
INC.; ENDO HEALTH SOLUTIONS, INC.; ENDO
PHARMACEUTICALS, INC.; PAR
PHARMACEUTICAL, INC.; PAR
PHARMACEUTICALS COMPANIES, INC.;

DEFENDANTS

MALLINCKRODT, LLC; MALLINCKRODT PLC;
SPECGX LLC; ALLERGAN PLC; ALLERGAN
FINANCE, LLC; ALLERGAN SALES, LLC;
ALLERGAN USA, INC.; ANDA, INC.; H.D. SMITH,
LLC f/k/a H.D. SMITH WHOLESALE DRUG CO.;
SMITH DRUG COMPANY; HENRY SCHEIN, INC.;
KVK-TECH, INC.; PRACTICE FUSION, INC.;
ALLSCRIPTS HEALTHCARE SOLUTIONS, INC.;
AMERISOURCEBERGEN DRUG CORPORATION;
CARDINAL HEALTH, INC.; THE KROGER CO.;
KROGER LIMITED PARTNERSHIP I; KROGER
LIMITED PARTNERSHIP II; CVS HEALTH
CORPORATION; CVS PHARMACY, INC.;
KENTUCKY CVS PHARMACY, L.L.C.; RITE AID OF
KENTUCKY, INC.; WALGREENS BOOTS
ALLIANCE, INC.; WALGREEN CO.; WALGREEN
EASTERN CO., INC.; WAL-MART INC.; and WAL-
MART STORES EAST, LP.

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Presiding Judge: HON. JOHN DAVID PRESTON (624234)

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Presiding Judge: HON. JOHN DAVID PRESTON (624234)

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“The opioid epidemic is the deadliest drug crisis in American history, and Appalachia has suffered the consequences more than perhaps any other region,” Attorney General William P. Barr announced in a press release on April 17, 2019.¹

The decade of the 1990s was the era of the blockbuster drug, the billion-dollar pill, and a pharmaceutical sales force arms race was part of the excess of the time ... A pharmaceutical Wild West emerged. Salespeople stampeded into offices. They made claims that helped sell the drugs to besieged doctors. Those claims also lead years later to blockbuster lawsuits and criminal cases against their companies.²

COMPLAINT

Plaintiffs Paintsville Hospital Company, LLC, Jennie Stuart Medical Center, Inc., Hardin Memorial Hospital, T.J. Samson Community Hospital, Saint Joseph Health System, Inc., Flaget Healthcare, Inc., Hospital Of Louisa, Inc., and Jackson Hospital Corporation bring this Complaint against Defendants Amneal Pharmaceuticals, LLC; Amneal Pharmaceuticals, Inc.; Amneal Pharmaceuticals of New York LLC; Impax Laboratories, LLC; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc.; Actavis Laboratories FL, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Tasmanian Alkaloids Pty. Ltd.; AbbVie, Inc.; Abbott Laboratories; Abbott

¹ Press Release, U.S. Dep’t of Justice, Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals (Apr. 17, 2019), available at <https://www.justice.gov/opa/pr/appalachian-regional-prescription-opioid-arpo-strike-force-takedown-results-charges-against>

² Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* at 133 (Bloomsbury Press 2015) (“Dreamland”).

Laboratories, Inc.; Assertio Therapeutics, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceuticals Companies, Inc.; Mallinckrodt, LLC; Mallinckrodt Plc; SpecGx LLC; Allergan Plc; Allergan Finance, LLC; Allergan Sales, LLC, Allergan USA, Inc.; Anda, Inc.; H.D. Smith, LLC f/k/a H.D. Smith Wholesale Drug Co.; Smith Drug Company; Henry Schein, Inc.; KVK-Tech, Inc.; Practice Fusion, Inc.; Allscripts Healthcare Solutions, Inc.; AmerisourceBergen Drug Corporation; Cardinal Health, Inc.; The Kroger Co.; Kroger Limited Partnership I; Kroger Limited Partnership II; CVS Health Corporation; CVS Pharmacy, Inc.; Kentucky CVS Pharmacy, L.L.C.; Rite Aid of Kentucky, Inc.; Walgreens Boots Alliance, Inc.; Walgreen Co.; Walgreen Eastern Co., Inc.; Wal-Mart Inc.; and Wal-Mart Stores East, LP (collectively “Defendants”) under the Kentucky Consumer Protection Act (the “KCPA”) as codified at K.R.S § 367.170(1); Nuisance; Negligence; Wanton Negligence; Negligence *Per Se*; Fraud; Civil Conspiracy; and Unjust Enrichment seeking judgment against Defendants and in favor of Plaintiffs; compensatory damages; treble damages; punitive damages; pre-judgment and post-judgment interest; cost of suit; and equitable relief, including injunctive relief and alleges as follows:

I. INTRODUCTION

A. The Opioid Crisis in Kentucky

1. Plaintiffs operate hospitals located throughout Kentucky. The service areas of Plaintiffs’ hospitals have been hit hard by the opioid crisis.

2. No state has been hit harder by the opioid epidemic than Kentucky.³

³ *Confronting the Opioid Epidemic*, University of Kentucky, available at <http://www.uky.edu/president/opioid>.

3. The opioid epidemic poses an ongoing crisis in Kentucky. Opioid use has had tragic consequences for communities across Kentucky. Thousands of Kentucky residents have died from opioid overdoses, and many thousands more suffer from opioid use disorders and related health conditions.

4. During the period from 2006 to 2014, approximately 2,452,373,586 pills of hydrocodone and oxycodone were supplied to Kentucky.⁴ That is enough pills for all of the 4,339,367 Kentuckians⁵ to each have approximately 565 pills.

5. The rate of overdose deaths involving opioid prescriptions in Kentucky rose steadily from 1.0 deaths per 100,000 persons in 1999 to 10.2 deaths per 100,000 persons in 2017.⁶ According to the CDC, in 2015, Kentucky and Ohio shared the 2nd highest overdose rate in the country. Data from 2013 onward shows that Kentucky has the 3rd highest drug overdose mortality rate in the country.⁷ Altogether, between 2012 and 2016, drug overdoses caused a total of 5,822 deaths in Kentucky. In 2017, there were 1,565 fatal drug overdoses in Kentucky, which is an increase to approximately 130 deaths per month. According to the National Institute on Drug Abuse, Kentucky has double the overdose rate of the national average.

6. Drug overdoses have become the leading cause of accidental death in Kentucky. In 2015, 102 opioid prescriptions were written for every 100 Kentucky residents, which was 1.5 times the national average. Kentucky's overdose fatalities, which were already high, increased

⁴ *Drilling into the DEA's pain pill database*, Washington Post, Jan. 17, 2019, available at <https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/>.

⁵ 2010 Demographic Profile Census, Kentucky, U.S. Census Bureau, available at https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml?src=bkml.

⁶ National Institute on Drug Abuse, Virginia Opioid Summary, (last updated March 2019), available at <https://www.drugabuse.gov/opioid-summaries-by-state/kentucky-opioid-summary>

⁷ See <http://www.healthyamericans.org/reports/drugabuse2013/release.php?stateid=KY>.

dramatically in 2015. Overdose deaths of Kentucky residents, regardless of where the death occurred, and non-residents who died in Kentucky, numbered 1,249 in 2015.⁸ In 2015, drug overdoses accounted for 51.17% of Kentucky's statewide accidental deaths, more than motor vehicle accidents, fire, drowning and gunshot wounds combined. In 2015, opioids accounted for 46.63% of the statewide total of drug related fatal overdose victims.⁹ In 2016, the number of lives lost statewide to drug overdoses was nearly five-times that of car accidents.

7. Opioid abuse has reached epidemic levels in Kentucky. From February 1, 2016, to January 31, 2017, pharmacies in Kentucky filled prescriptions for 307,234,816 doses of Schedule II prescription drugs, which breaks down to 69 doses of Schedule II narcotics for every man, woman, and child in Kentucky. The progression from prescription opioids to the use of illicit drugs, particularly injectable heroin, is well documented, with approximately 75% of heroin users reporting that their initial drug use was through prescription.¹⁰ As Kentucky citizens who become addicted to prescription opioids have predictably migrated to illicit, but less expensive, opioids, namely heroin and fentanyl, overdoses have dramatically increased. Opioid-overdose

⁸ 2015 Overdose Fatality Report, Kentucky Office of Drug Control Policy, *available at* <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>.

⁹ 2015 Annual Report, Office of the Kentucky State Medical Examiner, *available at* <https://odcp.ky.gov/Reports/2016%20annual%20report.pdf>.

¹⁰ Theodore J. Cicero, PhD et al., *The Changing Face of Heroin Use in The United States: A Retrospective Analysis of The Past 50 Years*, JAMA Psychiatry (2014); 71(7):821-826, doi:10.1001/jamapsychiatry.2014.366, *available at* <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575>.

reversal drug naloxone was administered in four out of every seven Emergency Medical Services runs; and on average, seven response calls per day were to drug-related incidents.¹¹

8. Opioids have endangered public health in Kentucky even beyond addiction and overdose. Addicts who are not killed by drug addiction experience a variety of health consequences (including non-fatal overdoses) and engage in a variety of risky drug-seeking behaviors. Widespread drug addiction imposes costs on the community including health care and substance abuse treatment costs – a substantial portion of which were provided by Plaintiffs – as well as other costs borne by the community, increased costs and burdens imposed on the criminal justice system and the costs associated with the lost productivity of addicts.¹² Since 2017, Kentucky Attorney General has brought nine lawsuits against opioid manufacturers, distributors and pharmacies for flooding Kentucky communities with dangerous prescription drugs.¹³

9. A study by the American Enterprise Institute concluded that, in 2015, Kentucky’s “cost per capita” resulting from the opioid crisis was \$2,412,¹⁴ or approximately \$10.5 billion total.

10. Children have been especially vulnerable to the opioid epidemic. Along with overdose deaths, the number and rate of neonatal abstinence syndrome (“NAS”) – a condition

¹¹ New Online Tool Uses Data to Show Impact of Opioids, (Oct. 9, 2016), *available at* <https://nkyhealth.org/2016/10/09/new-onlinetool-uses-data-to-show-impact-of-opioids/?search=opioid>.

¹² Alex Brill & Scott Ganz, *The Geographic Variation in the Cost of the Opioid Crisis*, at 1-4, Am. Enter. Inst. (Mar. 20, 2018), *available at* https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf

¹³ Office of the Kentucky Attorney General, *Litigation Against Pharmaceutical Industry*, <https://ag.ky.gov/fighting-drug-abuse/litigation>

¹⁴ Alex Brill & Scott Ganz, *The Geographic Variation in the Cost of the Opioid Crisis*, at 1-4, American Enter. Inst. (Mar. 20, 2018), *available at* https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf.

suffered by babies born to mothers addicted to opioids – has also increased dramatically in Kentucky. Kentucky has had one of the highest rates of pregnant women using opioids in the country. In 2014, Kentucky had the third-highest rate of pregnant women with opioid use disorder. In just one 12-month period, between August 1, 2014 and July 31, 2015, 1,234 infants in Kentucky were born addicted to opioids, more than 100 newborns per month. The number of NAS cases in Kentucky totaled 1,115 in 2016 based on hospital discharge data.¹⁵ In 2017, the number of babies born with NAS in Kentucky had increased by 375% since 2007. These infants usually will spend weeks in neonatal intensive care units while they painfully withdraw from the drugs – a process so painful that it traps many adults on opioids. Research has indicated that these children are likely to suffer from continued serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

11. Children are also left orphaned by multiple generations of family members lost to addiction.¹⁶ As of June 2017, there were over 8,000 children in foster care in Kentucky, compared to 6,000 in 2012, most commonly because of parent's abuse of drugs or alcohol. According to one foster-parent recruiter, the increasing number of children in foster care in

¹⁵ Kentucky Department of Public Health Division of Maternal and Child Health, *Annual Report, Neonatal Abstinence Syndrome In Kentucky*, (Jan. 2018), available at <https://chfs.ky.gov/agencies/dph/dmch/Documents/DPHNASReport2016.pdf>

¹⁶ Opioids orphan kids in Kentucky, Dec. 12, 2014, available at <https://www.cnn.com/2012/12/14/health/kentucky-overdoses/>.

Ashland, Kentucky has reached a “crisis point” as a result of the opioid epidemic.¹⁷ Children are also injured by the removal from their homes due to opioid abuse and opioid dependence.

12. Kentucky has seen an increase in blood-borne diseases caused by intravenous drug use, including hepatitis C (HCV) and human immunodeficiency (HIV). Intravenous use of opioids, which has been a particular problem with easy-to-inject Opana ER, has led to a surge in HCV in the state and created a risk of an even broader epidemic. Kentucky and other states in the central Appalachian region of the country experienced a 364% increase in reported acute HCV among individuals aged 30 years old or below between 2006 and 2012.¹⁸ Among the 220 U.S. counties identified by the CDC as the most vulnerable to HIV and HCV infections among people who inject drugs in the context of the national opioid epidemic, 54 were in Kentucky, primarily in rural communities.¹⁹ If untreated, hepatitis C continues to be transmitted, including in childbirth, and can ultimately cause liver cancer, fibrosis, or cirrhosis, and is the leading cause of liver transplants in the country.

13. The widespread use of opioids and corresponding increases in addiction and abuse have led to increased emergency room visits, emergency responses to overdoses, and emergency medical technicians’ administration of naloxone—an antidote to opioid overdose. In Louisville, the police force administered 123 doses of naloxone in just the first six weeks of 2017

¹⁷ States hit hard by opioid crisis see increase in foster care kids, North Jefferson News, Jan. 19, 2017.

¹⁸ Jon E. Zibbell, PhD et al., *Increases in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged ≤ 30 Years—Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012*, Morbidity and Mortality Weekly Report (May 2015); 64(17):453–58, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4584548/>.

¹⁹ Michelle Van Handel et al., *County-Level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infections Among Persons Who Inject Drugs, United States, 2016* JAIDS 73(3):323–331, (Nov. 2016), doi: 10.1097/QAI.0000000000001098, available at <https://insights.ovid.com/pubmed?pmid=27763996>.

— representing approximately three overdoses each day. It also has resulted in dramatic growth in drug-related crimes. There have been increases in domestic violence, robberies, burglaries, and thefts, among other crimes across Kentucky. An estimated 90% of defendants in Floyd County are prosecuted for crimes related to prescription drug abuse or diversion.

14. Over the last decade, Kentucky has lost over 11,000 coal mining jobs, according to the Kentucky Department of Energy. When the mining industry plummeted, other local businesses were also forced to close. The collapse of the coal industry forced many of the town's residents into joblessness and triggered a sense of hopelessness, which exacerbated the opioid crisis in the region. Abuse of prescription pain medication is especially widespread among the growing ranks of out-of-work miners, who were often prescribed opioid medications to deal with the rigors of the job.

15. From 2006 to 2014, certain Defendants and their co-conspirators topped the ARCOS data lists for the number of hydrocodone and oxycodone opioid pills that were tracked entering Kentucky from distributors: AmerisourceBergen Drug (584,198,415 pills); Cardinal Health (328,472,955 pills); Walgreen Co. (276,846,260 pills); Walmart (185,434,100 pills); and from manufacturers: Actavis Pharma, Inc. (1,047,559,999 pills); SpecGx LLC (716,919,264 pills); Par Pharmaceutical (435,584,240 pills); Amneal Pharmaceuticals LLC (81,686,293 pills); and Purdue Pharma LP (45,208,206 pills).

16. Across Kentucky, families and communities face heartbreaking tragedies that cannot be adequately conveyed by statistics, and they have faced them all too often. Many grieving families have been financially tapped out by the costs of repeated cycles of addiction treatment programs; others have lost hope and given up. The increasing number of cases takes both a physical and mental toll on investigators, first-responders, and hospitals such as Plaintiffs.

B. The Opioid Crisis Nationally

17. The United States is in the midst of an opioid epidemic caused by Defendants' unlawful marketing, sale, and distribution of opioids that has resulted in opioid dependence, criminal activity, serious health issues, and the loss of life.²⁰ According to the Centers for Disease Control and Prevention ("CDC"), from 1999 to 2014, the sales of opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.²¹

18. The United States constitutes 4.6% of the world's population, but consumed 80% of the world's opioid supply in 2011.²² According to the Centers for Disease Control and Prevention ("CDC"), from 1999 to 2014, the sales of opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.²³

19. It is undisputed that opioids are both addictive and deadly. Between 1999 and 2014, more than 165,000 Americans died of opioid overdose.²⁴ Deaths related to opioids are

²⁰ As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

²¹ Centers for Disease Control and Prevention, *Prescribing Data*, available at <https://www.cdc.gov/drugoverdose/data/prescribing.html>, (last accessed August 1, 2018).

²² Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications*, available at <https://www.colorado.gov/pacific/sites/default/files/Psychological%20and%20Physical%20Side%20Effects%20Teater%20NSC.pdf> (citing Daneshvari R. Solanki et al., *Monitoring Opioid Adherence in Chronic Pain Patients: Assessment of Risk of Substance Abuse*, PAIN PHYSICIAN JOURNAL, 14:E119-E131, (2011), available at, <https://www.painphysicianjournal.com/current/pdf?article=MTQ0NQ%3D%3D&journal=60>).

²³ Centers for Disease Control and Prevention, *Prescribing Data*, available at <https://www.cdc.gov/drugoverdose/data/prescribing.html>, (last accessed Aug. 1, 2018).

²⁴ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65(1) Morbidity and Mortality Weekly Report (Mar. 2016), at 2, available at <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf> ("Dowell, CDC Guideline").

accelerating. In 2011, the CDC declared that opioid deaths had reached “epidemic levels.”²⁵ That year, 11,693 people died of opioid overdoses.²⁶ Since then, opioid deaths have *more than quadrupled*, reaching 47,600 Americans in 2017—more than ten times the number of Americans who died in the entire Iraq War.²⁷

20. According to the CDC, opioid overdoses killed more than 45,000 people over a 12-month timeframe that ended in September 2017. It is already the deadliest drug epidemic in American history.²⁸ If current trends continue, lost lives from opioid overdoses will soon represent the vast majority of all drug overdose deaths in the United States.

²⁵ Press Release, Centers for Disease Control and Prevention: Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), *available at* https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html (“Prescription Painkiller Overdoses at Epidemic Levels”).

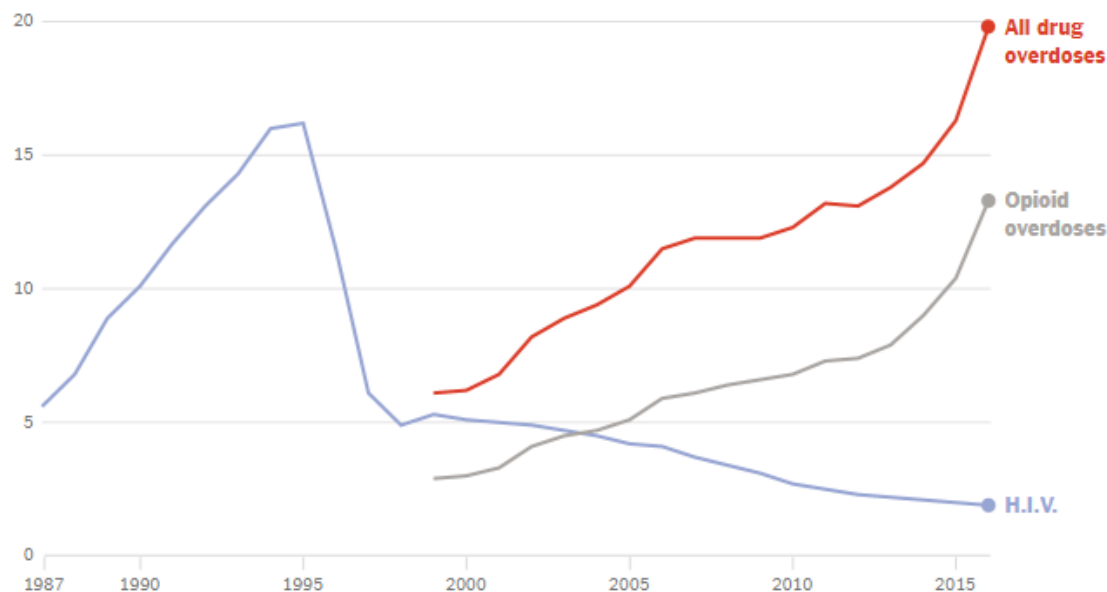
²⁶ Li Hui Chen et al., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999-2011*, 166 NCHS Data Brief (Sept. 2014), *available at* <https://www.cdc.gov/nchs/data/databriefs/db166.pdf>.

²⁷ U.S. Dep’t of Health and Human Services, *What is the U.S. Opioid Epidemic?* (Jan. 2019), <https://www.hhs.gov/opioids/about-the-epidemic/index.html>; German Lopez, *2017 was the worst year ever for drug overdose deaths in America*, VOX, Aug. 16, 2018, *available at* <https://www.vox.com/science-and-health/2018/8/16/17698204/opioid-epidemicoverdose-deaths-2017>.

²⁸ The Editorial Board, *An Opioid Crisis Foretold*, THE NEW YORK TIMES (April 21, 2018), *available at* <https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html>.

Lost Lives

Deaths in the U.S. per 100,000 people



Note: Drug overdose data available since 1999. Source: Centers for Disease Control and Prevention | By THE NEW YORK TIMES.²⁹

21. Between the start of the century and the year 2014, opioid-related death rates have increased by 200%, with 14% of that increase occurring between 2013 and 2014.

22. The opioid epidemic is killing scores of individuals each and every day and is having a similarly drastic impact on the total cost of medical care.

23. A particular tragedy of the opioid epidemic is that it has caused law-abiding citizens who experience routine injuries to become dependent on opioids, and, in many cases, has resulted in the total ruination of their lives.

24. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”³⁰ In many cases, heroin abuse starts with prescription opioid

²⁹ *Id.*

dependence. An inflated volume of opioids invariably leads to increased diversion and abuse. Indeed, there is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”³¹ For most people who misuse opioids, the source of their drugs can typically be found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes. Filling an opioid prescription is a significant risk factor for overdose.³²

25. According to the CDC, the United States is currently seeing the highest overdose death rate ever recorded.³³ Aside from overdose, long-term opioid use is associated with a significant increase in mortality from other causes.³⁴ As opioid-related deaths increase, the life expectancy in the United States decreases.³⁵

³⁰ See Robert M. Califf, *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (Apr. 14, 2016), doi: 10.1056/NEJMSr1601307, available at <https://www.nejm.org/doi/full/10.1056/NEJMSr1601307> (“Califf *et al.*”).

³¹ Dart, Richard C., *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015), DOI: 10.1056/NEJMSa1406143, available at <https://www.nejm.org/doi/full/10.1056/nejmsa1406143>.

³² Dowell, CDC Guideline, *supra* n. 24, at 22-24.

³³ Jessica Glenza, *Opioid crisis: overdoses increased by a third across US in 14 months*, says CDC, The GUARDIAN (March 6, 2018), available at <https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc>.

³⁴ Wayne A. Ray, *et al.*, *Prescription of Long-Acting Opioids and Mortality in Patients With Chronic Noncancer Pain*, 315(22):2415-2423, JAMA (Jun. 2016), doi:10.1001/jama.2016.7789, available at <https://jamanetwork.com/journals/jama/fullarticle/2528212>.

³⁵ National Center for Health Statistics, *Life Expectancy*, available at <https://www.cdc.gov/nchs/fastats/life-expectancy.htm>, (last accessed August 1, 2018); Centers for Disease Control and Prevention, U.S. drug overdose deaths continue to rise; increase fueled

26. On October 28, 2017, the President of the United States declared the opioid crisis a public health emergency.³⁶

27. This suit takes aim at the primary cause of the opioid crisis: A False Narrative marketing scheme, in which the Supply Chain Defendants joined and conspired, involving the false and deceptive marketing of prescription opioids, which was designed to dramatically increase demand for and sale of opioids and opioid prescriptions.

28. On the demand side, the Defendants who manufacture, sell and market opioid pain killers (the “Marketing Defendants and Purdue³⁷”) precipitated the crisis. These opioids have various brand names and generic names, and include OxyContin, fentanyl, hydrocodone, oxycodone, and others mentioned in this Complaint. Through a massive marketing campaign premised on false and incomplete information, the Marketing Defendants and Purdue engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients.

29. The Marketing Defendants and Purdue relentlessly and methodically—but untruthfully—asserted that the risk of opioid dependence was low when opioids were used to treat chronic pain and overstated the benefits and trivialized the risk of the long-term use of opioids. Contrary to these assertions, opioids are extremely addictive. Studies have found

by synthetic opioids, (March 18, 2018), *available at* <https://www.cdc.gov/media/releases.2018/p0329-drug-overdose-deaths.html>.

³⁶ Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a ‘Health Emergency’ but Requests No Funds*, THE NEW YORK TIMES (Oct. 26, 2017), *available at* <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html>.

³⁷ The Purdue entities and individuals described in this Section are Co-Conspirators with the other Defendants charged in this Complaint. They are not charged as Defendants.

diagnosed opioid dependence rates in primary care settings as high as 26%.³⁸ Among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-use disorder.³⁹ Because opioids cause tolerance and dependence, patients who take the drugs for even a short time become a physiologically captured market. According to the U.S. Department of Health and Human Services, more than two million Americans are opioid-dependent.⁴⁰ The difficulty in stopping use is particularly true for patients first prescribed an extended release opioid. Patients who initiated treatment on an extended release opioid – such as OxyContin – have a 27.3% likelihood to be using opioids one year later, and a 20.5% likelihood of using opioids three years later.⁴¹

30. Opioids pose high risks for children and adolescents. Most of the use in this population is off-label as opioids are not approved for children. Use of prescription opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse. The misuse of opioids in adolescents strongly predicts the later onset of heroin

³⁸ Dowell, CDC Guideline, *supra* n. 24, at 22-24.

³⁹ Joseph A. Boscarino, *et al.*, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates*, 6:83-91, Substance Abuse and Rehabilitation (Aug. 2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548725/>; see also Joseph A. Boscarino, *et al.*, *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3):185-94, *Journal of Addictive Diseases* (Sept. 2011), available at <https://www.ncbi.nlm.nih.gov/pubmed/21745041> (showing a 34.9% lifetime opioid use disorder).

⁴⁰ U.S. Dept. of Health and Human Services, *What is the U.S. Opioid Epidemic?* (Jan. 2019), available at <https://www.hhs.gov/opioids/about-the-epidemic/index.html>.

⁴¹ Anuj Shah *et al.*, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66(10):265-269, *Morbidity and Mortality Weekly Report* (Mar. 2017), available at <https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm>.

use.⁴² Nonetheless, the 2016 CDC guidelines found that there have been significant increases in opioid prescribing for children and adolescents, for conditions such as headaches and sports injuries.

31. The Marketing Defendants' and Purdue's goal was simple: dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pain, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

32. The Supply Chain Defendants saw the profit potential in opioid sales, participated in the conspiracy by ignoring their legal responsibilities, and flooded affected areas with opioids while knowing they were contributing to, and profiting from, widespread opioid dependence and human misery. The Supply Chain Defendants, through their willingness to uncritically supply whatever quantities of opioids pharmacies ordered, normalized overprescribing and caused widespread proliferation and availability of these dangerous drugs throughout communities in Kentucky.

33. Defendants succeeded. Opioid abuse has quickly become one of the nation's most pressing health management issues, not only because of its toll on patients, but increasingly because of the financial impact on hospitals and the rest of the healthcare system.⁴³

⁴² Dowell, CDC Guideline, *supra* n. 24.

⁴³ Jennifer Bresnick, *Hospitals Face Higher Costs, More ED Visits from Opioid Abuse*, HEALTHIT Analytics (Dec. 21, 2016), available at <https://healthitanalytics.com/news/hospitals-face-higher-costs-more-ed-visits-from-opioid-abuse> (last accessed on August 1, 2018).

34. The Marketing Defendants and Purdue and the Supply Chain Defendants extract billions of dollars of revenue from the opioid-dependent American public while hospitals sustain billions of dollars in losses caused as a result of the reasonably foreseeable consequences of the opioid dependence epidemic. In fact, Defendants depend on hospitals to mitigate the health consequences of their illegal activities – at no cost to Defendants – thereby permitting Defendants to perpetuate their wrongful scheme. Defendants knew that but for the hospitals providing at least some aspect of a safety net, the number of overdose deaths and other related health consequences arising from opioid dependence would have been far greater than actually occurred, and the public outcry and political backlash threatening their profitmaking activities would have been swifter and far more certain.

35. The Marketing Defendants and Purdue and Supply Chain Defendants have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct has caused and/or is continuing to cause a national, state, and local opioid epidemic.

36. The deceptive marketing campaign of the Marketing Defendants and Purdue substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45 have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include an opioid.

37. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, dependence, overdose, and death throughout the United States, including Kentucky. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora

Volkow explained that “aggressive marketing by pharmaceutical companies” is “likely to have contributed to the severity of the current prescription drug abuse problem.”⁴⁴

38. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this “urgent health crisis” and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the “devastating” results that followed, had “coincided with heavy marketing to doctors [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain.”⁴⁵

39. In a 2016 report, the CDC explained that “[o]pioid prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.”⁴⁶ Patients receiving opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the use of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”⁴⁷

⁴⁴ *America’s Addiction to Opioids: Heroin and Prescription Drug Abuse*, U.S. Senate, Caucus on International Narcotics Control, 113th Cong., at 3 (May 14, 2014) (statement). Testimony of Dr. Nora D. Volkow, Director, National Institute on Drug Abuse, *available at* <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

⁴⁵ Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *available at* <http://www.turntheridex.org/> (last accessed July 23, 2018).

⁴⁶ Rose A. Rudd, *et al.*, Centers for Disease Control and Prevention, Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014, 64(50); 1378-82, Morbidity and Mortality Weekly Report, *available at* <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (“2000-2014 Increases in Drug and Opioid Overdose Deaths”).

<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.

⁴⁷ *Id.*

40. Defendants' practice of continually filling opioid prescriptions, including from suspicious prescribers, and failing to report suspicious orders of opioids has enabled an oversupply of opioids to communities, including in the communities that Plaintiffs serve. The Supply Chain Defendants had financial incentives to distribute higher volumes of opioids and not to report suspicious orders or guard against diversion. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit.

41. Further, either explicitly or implicitly, all Defendants in this action worked together to stifle the reporting of suspicious orders. This is because even one defection and reporting to the DEA could have reduced the overall quantity of opioids allowed to be dispensed within the United States. Therefore, to ensure that profits remained artificially high, the Defendants worked together to ensure oversupply of the market.

42. The widespread use of opioids and corresponding increases in opioid dependence and abuse have led to increased emergency room visits, emergency responses to overdoses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose.

43. As communities work to restore their lives, the opioid epidemic continues to outpace their efforts.

C. The Impact of Opioids on Kentucky Hospitals

44. Hospitals—legally and morally—are compelled to act and treat patients with opioid-related conditions⁴⁸ and, as a result, are directly and monetarily damaged by the opioid epidemic. In addition to the cost of the opioid drugs themselves, hospitals have incurred and continue to incur millions of dollars in damages for the costs of unreimbursed, uncompensated and/or undercompensated care as a result of the unlawful marketing, distribution, and sale of opioids. Arguably, more than any other institution, hospitals directly and monetarily bear the brunt of the opioid crisis.

45. Because of defendants’ conduct, the opioid epidemic is placing an increasing strain on the overburdened health care system in Kentucky.

46. Plaintiffs are struggling from the relentless and crushing financial burdens caused by the epidemic of opioid dependence.

47. The effects of the opioid epidemic on hospitals may soon become even worse. The coverage rules under the Affordable Care Act (“ACA”) are in transition, thus creating the possibility of increased costs for hospitals for treatment of opioid-dependent patients admitted under the Emergency Medical Treatment and Labor Act (“EMTALA”), 42 U.S.C. § 1395dd.⁴⁹

⁴⁸ “Opioid-related conditions” include but are not limited to opioid addiction and overdose; psychiatric and mental health treatment; NAS or other opioid-related conditions of newborns; illnesses associated with opioid use, such as endocarditis, hepatitis-C, and HIV; surgical procedures that are more complex and expensive due to opioid addiction; illnesses or conditions claimed by a person with opioid addiction in order to obtain an opioid prescription; and any other condition identified in Plaintiffs’ records as related to opioid use and abuse.

⁴⁹ American Hospital Association, *AHA Priorities to Address the Opioid Crisis*, <https://www.aha.org/guidereports/2018-03-02-aha-priorities-address-opioid-crisis>, (last accessed August 1, 2018).

48. As a result of these statutes, hospitals in Kentucky must admit opioid-dependent patients who present themselves in need of intensive care or who display symptoms of mental illness. In addition, if an opioid-dependent patient is pregnant, and presents herself for treatment, hospitals also have to provide care for both the opioid-dependent mother and her opioid-dependent baby. As a result of the opioid dependence epidemic, including in the areas Plaintiffs serve, opioid-dependent patients routinely occupy beds in hospitals, including hospitals operated by Plaintiffs. Opioid-dependent mothers and babies routinely present themselves for admission at ERs and occupy beds in the NICUs, including those operated by Plaintiffs. Many of those patients have no insurance and do not pay for their care.

49. Plaintiffs encounter patients with opioid dependence on a daily basis. They must try to help patients who have serious medical conditions that require extra care and expense because the patient is dependent on opioids.

50. The statistics are startling. Adult hospitalizations due substantially to opioid-related medical conditions doubled from 2000 to 2012. From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.⁵⁰

51. Between 2005 and 2014 there was a dramatic increase nationally in hospitalizations involving opioids: the rate of opioid-related inpatient stays increased 64%, and the rate of opioid-related emergency department (“ED”) visits nearly doubled.⁵¹

⁵⁰ *Id.*

⁵¹ Audrey J. Weiss, *et al.*, *Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014* (June 2017), available at <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb224-Patient-Characteristics-Opioid-Hospital-Stays-ED-Visits-by-State.pdf>.

52. The average health care costs for those diagnosed with an opioid use disorder were eight times higher than those without an opioid use disorder.⁵²

53. The cost to hospitalize opioid-dependent patients has more than tripled in a decade, up to nearly \$15 billion in 2012. Similarly, the number of patients hospitalized due to the effects of these drugs surged by more than 72% in 2012, although overall hospitalizations during that time stayed relatively flat.⁵³

54. Private insurance covers only a portion of those costs. The burden is carried by hospitals, patients, and government programs.⁵⁴ In 2012, hospitals provided almost \$15 billion for opioid-related inpatient care, more than double of what they billed in 2002.⁵⁵ A substantial portion of these costs were under-insured or unreimbursed, uncompensated, and/or undercompensated.

55. In 2012, an average hospital stay for a patient with an opioid-related condition cost about \$28,000 and only about 20% of the hospital stays related to those incidents were covered by private insurance. The number increased to \$107,000 if there was an associated infection, with merely 14% covered by insurance.⁵⁶

⁵² Alen G. White, PhD, *et al.*, *Direct Costs of Opioid Abuse in an Insured Population in the United States*, published in *Journal of Managed Care Pharmacy*, Vol. 11, No. 6, at 469 (July/August 2005), available at <http://www.amcp.org/data/jmcp/3.pdf>.

⁵³ Marty Stempniak, *Opioids Add to a Sharp Rise in Hospitalizations, Costs*, (May 5, 2016), <https://www.hhnmag.com/articles/7231-opioids-contribute-to-a-sharp-rise-in-hospitalizations-health-care-costs>, (last accessed on July 11, 2018).

⁵⁴ *Id.*

⁵⁵ Shefali Luthra, *Opioid Epidemic Fueling Hospitalizations, Hospital Costs*, KAISER HEALTH NEWS (May 2, 2016), available at <https://khn.org/news/opioid-epidemic-fueling-hospitalizations-hospital-costs/>.

⁵⁶ *Id.*

56. Patients with opioid dependence-related histories (medically and psychosocially) often cannot get treatment at skilled nursing facilities if they are discharged by hospitals. In Kentucky, there is nowhere for these patients to go other than hospitals due to the behavioral and security issues that are often associated with those who are dependent on opioids. As a result, they wind up staying in hospitals longer, resulting in the cost of care going up.

57. The cost of treating opioid overdose victims in hospital intensive care units jumped 58% in a seven-year span. Between 2009 and 2015, the average cost of care per opioid overdose admission increased from \$58,000 to \$92,400. This was during a period when the overall medical cost escalation was about 19%. This cost increase also highlights a troubling trend: overdose patients are arriving in worse shape, requiring longer stays and a higher level of treatment.⁵⁷

58. Pregnant women and their children have been significantly impacted by the opioid epidemic. There are negative consequences of drug use for pregnant women including increased risks of assault and abuse, miscarriage, and contracting hepatitis or HIV. Each year, thousands of infants are exposed to opioids while in the womb. Infants who are chronically exposed to opioids and other drugs will often experience a constellation of withdrawal signs after birth, collectively referred to as NAS.

59. The rates of opioid abuse during pregnancy have increased nationally and in Kentucky. There has been an almost four-fold increase in admissions to NICUs for NAS over the past decade: from seven cases per 1,000 NICU admissions in 2004, to 27 cases per 1,000 NICU admissions in 2012. Costs have been increasing rapidly.

⁵⁷ Casey Ross, *The Cost of Treating Opioid Overdose Victims is Skyrocketing*, STAT NEWS (August 11, 2017), available at <https://www.statnews.com/2017/08/11/opioid-overdose-costs/>.

60. NAS is such a problem in Kentucky that the Kentucky General Assembly enacted KRS § 211.676, which requires the reporting of NAS cases to the Department for Public Health, and KRS § 211.678, which calls for an annual report of de-identified, aggregate statistical data from this reporting.

61. The misconduct of Marketing Defendants and Purdue, Supply Chain Defendants, and others prompted Kentucky health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, the Marketing Defendants and Purdue and Supply Chain Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks, benefits, and sustainability of long-term opioid use. These harms were compounded by supplying opioids beyond what the market could bear, funneling so many opioids into Kentucky communities that the only logical conclusion was that the product was being diverted and used illicitly. The massive quantities of opioids that flooded into Kentucky as a result of Defendants' wrongful conduct has devastated communities across this State, including the communities served by Plaintiffs.

D. Financial Impact of Defendants' Activities on Plaintiffs

62. Plaintiffs have treated, and continue to treat, numerous patients for opioid-related conditions, including: (1) opioid overdose; (2) opioid dependence; (3) hepatitis C, HIV and other infections occurring as a result of intravenous drug use; (4) neonatal treatment in their NICU for babies born opioid-dependent, for which treatment is specialized, intensive, complex, lengthy and highly expensive; and (5) psychiatric and related treatment for patients with opioid dependence who present in need of mental health treatment programs.

63. Plaintiffs have incurred and continue to incur substantial unreimbursed, uncompensated, and/or undercompensated costs for their treatment of patients with opioid-

related conditions. These patients with opioid-related conditions seek treatment from Plaintiffs as a proximate result of the opioid epidemic created and engineered by Defendants. As a result, Plaintiffs' monetary losses with respect to treatment of these patients were and are foreseeable to Defendants and were and are the proximate result of Defendants' acts and omissions specified herein.

64. Plaintiffs also have incurred and continue to incur operational costs in the form of surgical procedures and other care that have been and are more complex and expensive than would otherwise be the case if the patients were not opioid affected. Surgical procedures on opioid affected patients have been and are complicated and costly and require special protective measures and related prescription drugs.

65. Additionally, individuals with opioid dependence have presented and continue to present themselves to Plaintiffs claiming to have illnesses and medical problems in an effort to obtain opioids. Plaintiffs have incurred and continue to incur operational costs related to the time and expenses in diagnosing, testing, and otherwise attempting to treat these individuals.

66. Increased numbers of opioid-dependent patients have continued to cause substantial financial burden on Plaintiffs. Plaintiffs have borne substantial reimbursement shortages when they have continued to treat opioid-dependent patients with opioid-related conditions or comorbidities. Plaintiffs' effective treatment of all patients has been affected by their treatment of opioid-dependent patients.

67. The costs incurred by Plaintiffs are the direct and proximate result of the opioid epidemic created and engineered by Defendants.

68. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the increase in the use of opioids would result in a corresponding epidemic of

patients with opioid-related conditions going to hospitals for treatment, including to Plaintiffs. It was foreseeable to Defendants that Plaintiffs would suffer substantial monetary losses because of the opioid epidemic, because hospitals are on the front line of treatment for these patients and must bear the additional costs of treatment.

69. Plaintiffs have purchased and continue to purchase and administer opioids marketed and sold by Defendants. Defendants have marketed and continue to market their opioid products directly to Plaintiffs, their pharmacy representatives and their doctors. Defendants directly marketed their opioid products through the False Narrative campaign. Plaintiffs are direct customers and victims of Defendants' false, deceptive, and unfair marketing of opioids described hereafter.

70. Plaintiffs have purchased opioids from Defendants, have used them as falsely and deceptively marketed by Defendants, and have suffered damages as a direct and proximate result of Defendants' acts and omissions as described in this Complaint.

71. Plaintiffs would not have purchased the quantity of opioids they had from Defendants had they known the truth about Defendants' false marketing scheme, *i.e.* that Defendants' claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded, as described herein.

72. Plaintiffs bring this civil action to recover monetary losses that they have incurred as a direct and proximate result of Defendants' false, deceptive, unfair marketing and distribution of opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' unlawful actions and omissions.

73. Plaintiffs bring this suit against the manufacturers of opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that

patients would only rarely succumb to drug dependence. These pharmaceutical companies aggressively advertised to and persuaded hospitals and their doctors to purchase and prescribe highly addictive, dangerous opioids, and turned patients into opioid-dependent patients for their own corporate profit. Such actions were unlawful.

74. Plaintiffs also bring this suit against the Supply Chain Defendants of these highly addictive drugs. In addition to participating in the False Narrative campaign, the Supply Chain Defendants (along with the Manufacturers) unlawfully breached their legal duties under Kentucky law to monitor, detect, investigate, report, and refuse to fill suspicious orders of opiates, which enabled the manufacturers' deceptive advertising to increase sales and distribution of their products to hospitals, including Plaintiffs.

E. The Role of Defendants in Causing and Perpetuating the Opioid Crisis

75. The Marketing Defendants' and Purdue's push to increase opioid sales worked. Through publications and websites, endless streams of sales representatives, "education" programs, and other means, the Marketing Defendants and Purdue dramatically increased their sales of opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of opioids sold in the U.S. has nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

76. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers and distributors, who failed to maintain effective controls over the distribution of opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of opioids than they know should be necessary for legitimate medical uses, while failing to report, and take steps to halt, suspicious orders when they were

identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

77. From the day they made the pills to the day those pills were consumed in each community, the Marketing Defendants and Purdue had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring those doctors into prescribing their products by arguing, among other things, that no one should be in pain, especially chronic pain, the Marketing Defendants and Purdue created a population of opioid-dependent patients who sought opioids at never-before-seen rates. The scheme worked, although perversely, and through it the Marketing Defendants and Purdue caused their profits to soar as more and more people became dependent on opioids.

78. Defendants systematically and repeatedly disregarded the health and safety of the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

79. Corporate greed and callous indifference to the known, serious potential for human suffering and death have caused this public health crisis. Defendants unleashed a healthcare crisis that has had far-reaching financial and social consequences in this country, including opioid dependence and death.

80. The Marketing Defendants and Purdue falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudo addiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing

addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; (6) promoted the falsehood that long-term opioid use improves functioning; (7) misrepresented the effectiveness of time-released dosing, and, in particular, the effectiveness of a version of OxyContin that purportedly provided twelve hours of pain relief; and (8) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse, addiction and death.

81. The Marketing Defendants and Purdue disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians who were recruited by and paid by the Marketing Defendants and Purdue for their support of the Marketing Defendants’ and Purdue’s marketing messages.

82. The Marketing Defendants and Purdue also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as “key opinion leaders” (“KOLs”) and (b) creating, funding, assisting, directing, and/or encouraging seemingly neutral and credible professional societies and patient advocacy groups (hereinafter “Front Groups”). The Marketing Defendants and Purdue then worked together with those KOLs and Front Groups to profoundly influence, and at times control, the sources that doctors, and patients relied on for ostensibly “neutral” guidance, such as treatment guidelines, continuing medical education (“CME”) programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Marketing Defendants and Purdue persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

83. Each Marketing Defendant and Purdue knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the CDC, including by CDC's *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.⁵⁸

84. The Supply Chain Defendants facilitated the supply of far more opioids than could have been justified to serve the legal and appropriate market. The failure of Supply Chain Defendants to Maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, breached both their statutory and common law duties.

85. For over a decade, the Supply Chain Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Supply Chain Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, multiple sources impose duties on the Supply Chain Defendants to maintain effective controls against diversion and to prevent oversupply into the illicit market.

86. As facilitated and caused by Supply Chain Defendants' actions, opioids' distribution has skyrocketed.

⁵⁸ See Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids For Chronic Pain*, available at https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf (last accessed August 1, 2018); Pat Anson, *FDA Endorses CDC Opioid Guidelines*, PAIN NEWS NETWORK (Feb. 4, 2016), available at <https://www.painnewsnetwork.org/stories/2016/2/4/fda-endorses-cdc-opioid-guidelines>.

II. JURISDICTION AND VENUE

87. This Court has subject matter jurisdiction pursuant to KRS § 23A.010.

88. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in Kentucky and purposefully directed their actions towards Kentucky, voluntarily submitted to the jurisdiction of Kentucky when obtaining a manufacturer or distributor license and have the requisite minimum contacts with Kentucky necessary to constitutionally permit this Court to exercise jurisdiction.

89. Venue is proper in Johnson County on multiple grounds: (a) under KRS § 452.450 for the reason that one or more of Defendants has a place of business in the Commonwealth or has an agent who resides in the Commonwealth and such Defendant(s) has committed tortious conduct in Johnson County; (b) under KRS § 452.460 for the reason that the injuries to Plaintiffs occurred, in part, in Johnson County; (c) for Defendants subject to Kentucky's long-arm jurisdiction, under KRS 454.210(4) for the reason that one of the Plaintiff hospitals has legal residence in Johnson County and, for all Plaintiff hospitals, because Defendants' tortious conduct occurred, in part, in Johnson County; (d) under KRS § 367.190(1) for the reason that unlawful methods, acts and/or practices of Defendants were committed in Johnson County; or (e) under KRS § 452.480 for the reason that one or more of Defendants reside or may be summoned in Johnson County.

90. This action is non-removable because there is incomplete diversity of residents and no substantial federal question is presented.

III. PARTIES

A. Plaintiffs

91. Plaintiff Paintsville Hospital Company, LLC is a Kentucky limited liability company with its principal business office located in Paintsville, Kentucky. Quorum Health

Investment Company, LLC, a Delaware limited liability company, is a member of Paintsville Hospital Company, LLC. Paintsville Hospital Company, LLC operates and does business as Paul B. Hall Regional Medical Center (“PBHRM”) located in Paintsville, Kentucky. PBHRM is licensed for a total of 72 acute-care beds, serving patients in Johnson County, Kentucky and surrounding areas.

92. Plaintiff Jennie Stuart Medical Center, Inc. is a Kentucky nonprofit corporation with its principal business office located in Hopkinsville, Kentucky. Jennie Stuart Medical Center, Inc. operates and does business as Jennie Stuart Medical Center located in Hopkinsville, Kentucky, a facility licensed for a total of 182 acute-care beds and 12 geriatric psychiatric beds, serving patients in Christian County, Kentucky and surrounding areas.

93. Plaintiff Hardin County, Kentucky d/b/a Hardin Memorial Hospital (“Hardin Memorial”) is a non-profit, county-owned hospital located in Elizabethtown, Kentucky whose Board of Trustees consist of members of the Hardin County Fiscal Court. Hardin Memorial is licensed for a total of 270 acute-care beds and 15 adult psychiatric beds, serving patients in Hardin County, Kentucky and surrounding areas.

94. Plaintiff T.J. Samson Community Hospital (“T.J. Samson”) is a Kentucky nonprofit corporation with its principal business office located in Glasgow, Kentucky. T.J. Samson is licensed for a total of 180 acute-care beds, serving patients in Barren County, Kentucky and surrounding areas.

95. Plaintiff Saint Joseph Health System, Inc. is a Kentucky nonprofit corporation with its principal business office located in Lexington, Kentucky. Saint Joseph Health System, Inc. operates and does business as CHI Saint Joseph Health – Saint Joseph Hospital, CHI Saint Joseph Health – Saint Joseph Berea, CHI Saint Joseph Health – Saint Joseph East, CHI Saint

Joseph Health – Saint Joseph London, and CHI Saint Joseph Health – Saint Joseph Mount Sterling. Saint Joseph Health System, Inc. is licensed for a total of 842 acute-care beds and 25 critical access beds, serving patients in Madison, Fayette, Laurel, and Montgomery counties in Central and Southern Kentucky and surrounding areas.

96. Flaget Healthcare, Inc. d/b/a Flaget Memorial Hospital (“Flaget”) is a Kentucky nonprofit corporation with its principal business office located in Lexington, Kentucky. Flaget is licensed for a total of 40 acute-care beds, serving patients in Nelson County, Kentucky and surrounding areas.

97. Plaintiff Hospital of Louisa, Inc. is a Kentucky profit corporation with its principal business office located in Louisa, Kentucky. Hospital of Louisa, Inc. operates and does business as Three Rivers Medical Center located in Louisa, Kentucky, a facility licensed for a total of 90 acute-care beds, serving patients in Lawrence County, Kentucky and surrounding areas.

98. Plaintiff Jackson Hospital Corporation is a Kentucky corporation with its principal business office located in Jackson, Kentucky. Jackson Hospital Corporation operates and does business as Kentucky River Medical Center located in Jackson, Kentucky. Kentucky River Medical Center is licensed for a total of 55 acute-care beds, serving patients in Breathitt County, Kentucky and surrounding areas.

B. Defendants and Co-Conspirators

1. Marketing Defendants and Co-Conspirators

a. Purdue

99. The Purdue entities and individuals described in this Section are Co-conspirators with the other Defendants charged in this complaint. They are not charged as Defendants.

i. Purdue Co-Conspirators⁵⁹

100. Co-conspirators Purdue Pharma L.P. (“PPL”) is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

101. Co-conspirators Purdue Pharma Inc. (“PPI”) is a New York corporation with its principal place of business in Stamford, Connecticut, and is the general partner of Purdue Pharma, L.P.

102. Co-conspirators The Purdue Frederick Company, Inc. (“PFC”) is a New York corporation with its principal place of business in Stamford, Connecticut.

103. Co-conspirator Rhodes Pharmaceuticals L.P., is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. Rhodes Pharmaceuticals L.P. has one general partner, Rhodes Pharmaceuticals, Inc.; and one limited partner, Coventry Technologies L.P., which holds Rhodes Pharmaceuticals L.P.’s shares. Coventry Technologies L.P. is a Delaware limited partnership with its principal place of business in Stamford, Connecticut. Its general partner is Purdue Pharma, Inc.

104. Co-conspirator Rhodes Technologies Inc. is a corporation organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. Rhodes Technologies is a Delaware general partnership with its principal place of business in Coventry, Rhode Island. Rhodes Technologies Inc. is the general partner of Rhodes Technologies and is a subsidiary of Purdue Pharma, L.P. (Rhodes Technologies and Rhodes Pharmaceuticals are collectively referred to as “Rhodes”). Rhodes manufactures and distributes generic opioids, including authorized generic versions of OxyContin and Butrans. Rhodes Technologies also

⁵⁹ Purdue Pharma Inc. and certain affiliated business entities have filed for bankruptcy protection. Plaintiffs do not intend to name any of the Purdue entities as defendants in this action, but identify them as Co-Conspirators with certain persons who are named as defendants.

manufacturers the active pharmaceutical ingredient in drugs including Purdue's OxyContin.⁶⁰ Among the drug products manufactured by Rhodes is buprenorphine, a drug used to treat opioid dependence.

105. PPL, PPI, PFC, Rhodes and their subsidiaries and affiliates (collectively, "Purdue-Co-conspirators") engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Kentucky including OxyContin, MS Contin, Dilaudid, Dilaudid-HP, Butrans, Hysingla ER and Targiniq ER.

ii. Purdue Individual Co-Conspirators

106. The following individuals, all members of the Sackler family that beneficially owns Purdue, have served on the Board of Purdue during the relevant times indicated in parenthesis:

- 107. Richard Sackler (at all pertinent times until 2018⁶¹), a resident of Florida;
- 108. Beverly Sackler (all pertinent times until 2017), a resident of Connecticut;
- 109. David Sackler (2012-18), a resident of New York;
- 110. Ilene Sackler Lefcourt (all pertinent times), a resident of New York;
- 111. Jonathan Sackler (all pertinent times), a resident of Connecticut;
- 112. Kathe Sackler (all pertinent times), a resident of Connecticut;
- 113. Mortimer D.A. Sackler (all pertinent times), a resident of New York⁶²; and

⁶⁰ At various times, Defendant Mallinckrodt also supplied Purdue with oxycodone.

⁶¹ Defendant Beverly Sackler left the Board in 2017. Defendants Richard, David and Theresa Sackler left the Board in 2018. Defendants Jonathan Sackler, Ilene Sackler Lefcourt, Kathe Sackler, and Mortimer D.A. Sackler remain on the Board.

114. Theresa Sackler (all pertinent times until 2018), a resident of the United Kingdom.

115. The foregoing individuals (collectively, the “Sackler Co-Conspirators”) controlled Purdue’s misconduct. Each of them took a seat on the Board of Directors of Purdue Pharma Inc. Together, the Sackler Co-Conspirators, at all pertinent times, constituted a majority of Board, which gave them full power over Purdue. They directed and otherwise participated in Purdue’s deceptive sales and marketing practices, sending hundreds of orders to executives and other employees.

116. While the Sackler Co-Conspirators relinquished their officer titles in or around 2003 to try to shield themselves from future criminal and civil liability, they remained Purdue’s owners, in control of its Board of Directors, and thus in firm control.

117. At all pertinent times, at least through the end of 2018, the Sackler Co-Conspirators controlled Purdue’s deceptive sales campaign. They directed the company to hire hundreds more sales representatives to visit doctors thousands more times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered Purdue staff to implement these unlawful tactics. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to

⁶² References to “Mortimer D.A. Sackler” in this Complaint are to Mortimer David Alfons Sackler. Mortimer Sackler’s father, the late Mortimer D. Sackler, was also involved in Purdue Pharma during his lifetime.

promote opioids to doctors and supervise representatives face to face. In connection with a single meeting in 2011, for example, sales and marketing staff scrambled to prepare responses to questions from the Sackler Co-Conspirators as follows: Co-Conspirator Mortimer D.A. Sackler asked about launching a generic version of OxyContin to “capture more cost sensitive patients;” Co-Conspirator Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert; and Co-Conspirator Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

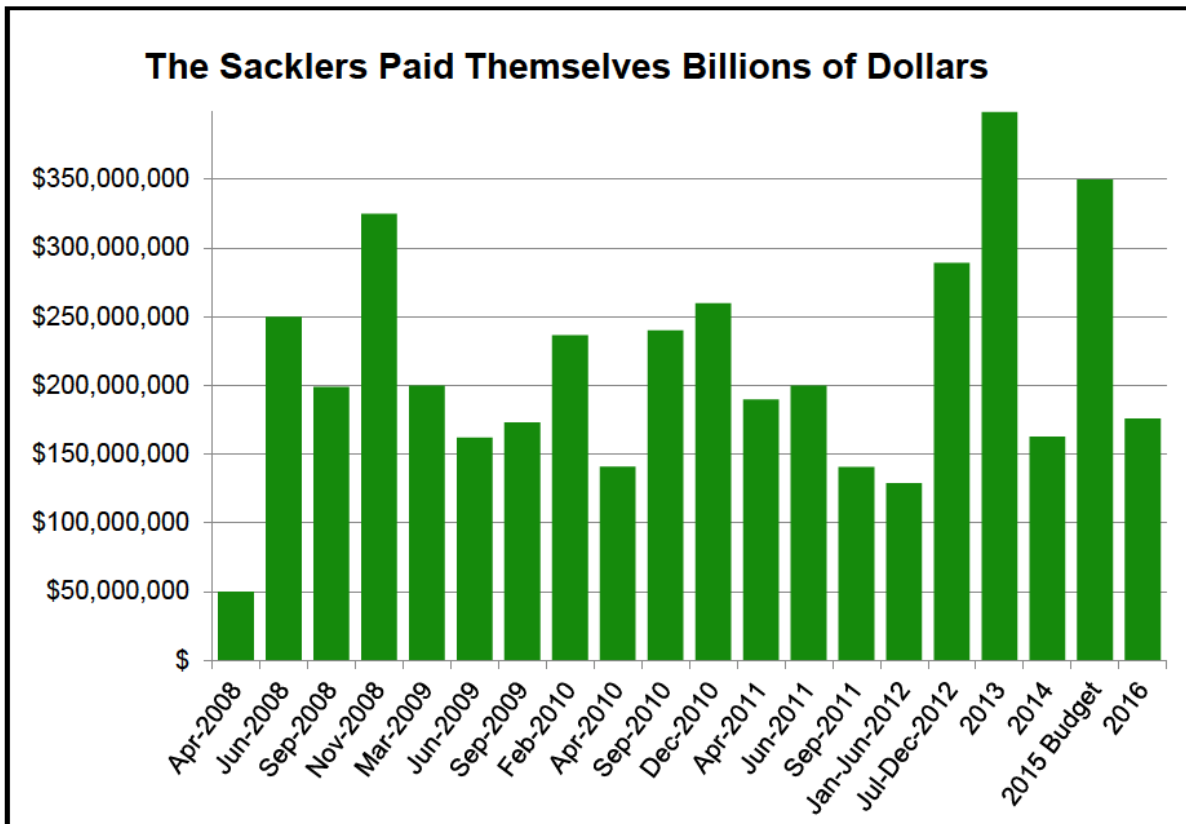
118. The Sackler Co-Conspirators’ micromanagement was so intrusive that staff begged for relief. Co-Conspirator Gasdia (identified below) wrote to the CEO: “Anything you can do to reduce the direct contact of Richard into the organization is appreciated.” To convince the Sackler Co-Conspirators to make him CEO, Co-Conspirator Landau wrote a plan that he titled: “SACKLER PHARMA ENTERPRISE.” He started by admitting that the Sackler Co-Conspirators in fact controlled the company like chief executive officers. The family ran “the global Sackler pharmaceutical enterprise ... with the Board of Directors serving as the ‘de-facto’ CEO.”

119. The Sackler Co-Conspirators concealed their extensive involvement at all costs. In 2000, the Sackler Co-Conspirators were warned that a reporter was “sniffing about the OxyContin abuse story.” The Sackler Co-Conspirators put the threat on the agenda for the next Board meeting and began covering their tracks. They planned a response that “deflects attention away from the company owners.” More recently, in November 2016, staff prepared statements to the press denying the Sackler Co-Conspirators’ involvement in Purdue. Their draft claimed: “Sackler family members hold no leadership roles in the companies owned by the family trust.”

A staff member reviewing the draft knew what was up and commented with apparent sarcasm: “Love the ... statement.” Staff eventually told the press: “Sackler family members hold no management positions.” Some employees worried about the deception. When journalists asked follow-up questions about the Sackler Co-Conspirators, communications staff deliberated about whether to repeat the “no management positions” claim. They double-checked that Purdue’s top lawyers had ordered the statement. Then they arranged for one of the Sackler Co-Conspirators’ foreign companies to issue it, so U.S. employees would not be blamed: “The statement will come out of Singapore.”

120. Most of all, the Sackler Co-Conspirators cared about money. Millions of dollars were not enough. They wanted billions. They cared more about money than about patients, or their employees, or the truth. In 1999, when employee Michael Friedman reported to Co-Conspirator Richard Sackler that Purdue was making more than \$20,000,000 per week, Richard replied immediately, at midnight, that the sales were “not so great.” “After all, if we are to do 900M this year, we should be running at 75M/month. So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?” Missives of this nature from Richard to Purdue’s ostensible management were a routine, if not daily, occurrence. There was no such thing as enough.

121. From the money that Purdue collected as a result of its wrongful conduct, they paid themselves and their family billions of dollars. From the 2007 convictions (of certain Purdue officers) until 2018, the Sackler Co-Conspirators voted dozens of times to pay out Purdue’s opioid profits to their family - in total ***more than four billion dollars***.



122. When the Sackler Co-Conspirators directed Purdue to pay their family, they knew and intended that they were paying themselves from opioid sales in Kentucky. Purdue and the Sackler Co-Conspirators tracked revenue from Kentucky.

123. In order to enhance their own and Purdue's social standing and prestige, the Sackler Co-Conspirators endowed many cultural, educational and scientific institutions, many of which bear their family name, including many academic programs at Harvard University and Tufts University in Massachusetts, the New York Academy of Sciences, Columbia University, Dia Art Foundation, the Metropolitan Museum of Art and the Guggenheim art museum, all in New York, London's Victoria and Albert Museum, and the Louvre in Paris. There is a Sackler gallery at the Princeton University Art Museum and Sackler museums at Harvard University and Peking University in Beijing. The Sackler Co-Conspirators and their relatives include many prominent New York and international socialites.

124. Co-Conspirators John Stewart (CEO from 2007 to 2013), Mark Timney (2014 to 2017), a resident of Connecticut, and Co-Conspirator Craig Landau (2017 to the present), a resident of Connecticut, each directed Purdue's deception as CEO of Purdue Pharma Inc. and Russell Gasdia, a resident of Massachusetts and Vice President of Sales and Marketing for Co-Conspirator Purdue Pharma L.P. at all pertinent times until June 2014, carried out the misconduct. The Co-Conspirators named in this paragraph are collectively referred to as the "Purdue Officer Co-Conspirators."

125. The Sackler Co-Conspirators and the Purdue Officer Co-Conspirators are collectively referred to as the "Purdue Individual Co-Conspirators." Purdue Co-Conspirators and Purdue Individual Co-Conspirators are collectively referred to as "Purdue."

126. The Purdue Co-Conspirators all actively participated in the common law torts and statutory violations of Purdue and benefited therefrom. The tortious conduct of the Purdue Individual Co-Conspirators was not, and could not have been, through the exercise of due diligence, known to the public until their conduct was detailed in recent court filings by the Attorney General of Massachusetts.

127. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States, including to Plaintiffs. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

128. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million – one of the largest settlements with

a drug company for marketing misconduct. In the same year, Purdue settled with 27 states for its Consumer Protection Act violations regarding Purdue's extensive off-label marketing of OxyContin and Purdue's failure to adequately disclose abuse and diversion risks associated with the drug. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long-term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year. Substantially all of the Sackler Co-Conspirators (all of those except David Sackler) were heavily involved in the conduct that led to the fines and criminal convictions in 2007. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was particularly unfair, deceptive, unreasonable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they directed a decade of misconduct, which led to criminal convictions, court judgment, and commitments that Purdue would not deceive doctors and patients again. That background confirms that their misconduct since 2007 was knowing, purposeful, reckless, and intentional.

129. Each of the Purdue Individual Co-Conspirators acted directly and through agents to transact business and cause injury in Kentucky.

130. Purdue employed scores of sales representatives in Kentucky to promote Purdue's opioids in Kentucky and sold hundreds of millions of dollars of opioids in Kentucky.

131. The Sackler Co-Conspirators and Purdue Officer Co-Conspirators voted for and/or directed sales representatives to go door-to-door, making thousands of visits to doctors in Kentucky. Although they did not knock on the doors to clinics and family practices themselves, these individuals voted for and/or ordered sales representatives to deceptively promote Purdue's

dangerous drugs in person, as a central facet of their deceptive marketing scheme that killed hundreds of people in Kentucky.

132. The Sackler Co-Conspirators and Purdue Officer Co-Conspirators voted for and/or directed payments to Kentucky doctors to promote Purdue's drugs.

133. The Sackler Co-Conspirators and Purdue Officer Co-Conspirators all directed the dissemination of tens of thousands of copies of unfair or deceptive marketing materials to doctors and other health care providers throughout Kentucky for the purpose of getting more and more prescribers to put their patients on Purdue's drugs for longer and longer periods of time at higher and higher doses. These individuals voted for and/or managed a chain-of-command causing these mailings in Kentucky because they meant increased sales and profits for the Sackler Co-Conspirators and their executives.

134. This misconduct caused tortious injury in Kentucky by killing hundreds of people and injuring many more.

b. Cephalon and Associated Companies

135. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Ltd. Acquired Cephalon in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Defendant Teva Ltd.

136. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd. is traded on the New York Stock Exchange (NYSE: TEVA). In its 2018 Form 10-K filed with the Securities and Exchange Commission, Teva Ltd. stated that it is the leading generic drug company in the United States. Teva Ltd. operates globally, with significant business transactions in the United States. In 2018, its gross profit from North American operations was \$4.979 million.

137. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, and is a wholly owned subsidiary of Teva, Ltd.

138. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Since its acquisition of Cephalon in October 2011, Teva USA has conducted all sales and marketing activities for Cephalon in the United States, through its “specialty medicines” division. Teva USA and Cephalon, Inc. worked together to manufacture, promote, sell, and distribute opioids such as Actiq and Fentora in the United States. Teva USA holds out Actiq and Fentora as Teva products to the public. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.⁶³

139. Teva USA’s parent company, Teva Pharmaceuticals Industries, Ltd. lists Cephalon and Teva USA’s sales as its own on its financial reports, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including sales of Fentora.⁶⁴ Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent

⁶³ *E.g.*, ACTIQ, available at <http://www.actiq.com/> (displaying logo at bottom-left) (last accessed August 1, 2018).

⁶⁴ Teva Ltd., Annual Report (Form 20-F), at 62 (Feb. 12, 2013), available at http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

cancer pain.”⁶⁵ Fentora has been approved by the FDA only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”⁶⁶ In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay a \$425 million fine.⁶⁷

140. Teva USA also sells generic opioids in the United States, including generic opioids previously sold by Allergan plc, whose generics business Teva Ltd., Teva USA’s parent company based in Israel, acquired in August 2016.

141. Teva USA and Cephalon Inc. are collectively referred to herein as “Cephalon.”

142. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but, in fact, these activities were used by Cephalon to deceptively promote and maximize the use of opioids.

⁶⁵ *Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009)*, ACTIQ PI/Med Guide, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf (last accessed August 1, 2018).

⁶⁶ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011)*, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf (last accessed August 1, 2018).

⁶⁷ Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

c. Actavis Entities

143. Defendant Allergan plc (“Allergan”) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Shares of Allergan are traded on the New York Stock Exchange (NYSE: AGN). In its 2018 Form 10-K filed with the SEC, Allergan plc stated that it does business in the United States through its U.S. Specialized Therapeutics and U.S. General Medicine segments, which generated nearly 80% of the company’s \$15.8 billion in net revenue during the year ended December 31, 2018.

144. Before the entities defined below as Actavis were sold to Teva Ltd. in August 2016, Actavis was part of the same corporate family as Allergan and sold and marketed opioids as part of a coordinated strategy to sell and market the branded and generic opioids of Allergan and Actavis. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.’s common shares were converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the “successor issuer” to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

145. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of defendant Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

146. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application ("NDA") holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications ("ANDAs") for Norco. Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc. The Norco ANDAs are currently held by Allergan Pharmaceuticals International Limited, which is incorporated in Ireland.

147. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

148. Defendant Allergan plc has, at all times, exercised control over these marketing and sales efforts and profits from the sale of its subsidiaries' products ultimately inure to its benefit, including those sales by Actavis during the period of its ownership and control by Allergan. Allergan is or has been in the business of manufacturing, selling, promoting, and/or

distributing both brand name and generic opioids throughout the United States, including to Plaintiffs.

149. Defendant Watson Laboratories, Inc. (“Watson”) is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc., (n/k/a Allergan Finance, LLC). Between 2000 and 2015, Watson Laboratories, Inc. held the ANDAs for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

150. Defendant Warner Chilcott Company, LLC is a limited liability company incorporated in Puerto Rico. Since 2015, Warner Chilcott Company, LLC has been the manufacturer of Norco. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva.

151. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma Inc.) (“Actavis Pharma”) is a Delaware corporation with its principal place of business in New Jersey.

152. Actavis Pharma was previously responsible for sales of Kadian and Norco. Actavis Pharma was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva. According to ARCOS data, from 2006 through 2014, Actavis Pharma, Inc. sold 1,047,559,999 pills of oxycodone and hydrocodone into Kentucky. Among all manufacturers, Actavis Pharma, Inc. manufactured the most oxycodone and hydrocodone pills sold into Kentucky during that eight-year period.

153. Defendant Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

154. Defendant Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. From December 19, 2005, until it purchased the medication in December 2008, Actavis Elizabeth LLC served as the contract manufacturer of Kadian for Alpharma. Actavis Elizabeth LLC held the ANDA for Kadian from 2008 to 2013. Actavis Elizabeth LLC was also the holder of ANDAs for the following opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

155. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. As part of Allergan plc's 2016 sale of its generic businesses to Teva.

156. Defendant Actavis Totowa LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the

ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride.

157. Defendant Actavis LLC (f/k/a Actavis Inc.) (“Actavis LLC”) is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of defendant Watson. Watson, in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva.

158. Defendant Actavis Kadian LLC is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC has been identified on Kadian’s label as a manufacturer or distributor of Kadian. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva.

159. Defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt Lake City, Utah. Actavis Laboratories UT, Inc. was the Kadian NDA holder from 2013 to 2016 and was listed as the NDA holder for morphine sulfate capsule. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc’s 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

160. Defendant Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida.

Actavis Laboratories FL, Inc. was a Norco ANDA holder in 2015 and was the ANDA holder of the following opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

161. Each of these Defendants and entities currently is or was previously owned by Defendant Allergan plc., which uses them to market and sell its drugs in the United States. Collectively, these defendants and entities, and their subsidiaries and affiliates that manufacture, promote, distribute, and sell opioids, are referred to as "Actavis."

162. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

d. Janssen and Associated Companies

163. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

164. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

165. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

166. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco, Inc. is or had

been part of J&J's opium processing. It makes active pharmaceutical ingredients ("APIs") for opioid painkillers.

167. Defendant, Tasmanian Alkaloids Pty. Ltd. ("Tasmanian Alkaloids") is an Australian private company based in Westbury, Australia and incorporated in Tasmania, Australia. Tasmanian Alkaloids Pty. Ltd. was a wholly owned subsidiary of J&J until July 2016 when J&J sold its interests to SK Capital Partners LP, a limited partnership incorporated in Delaware.

168. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

169. J&J, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Tasmanian Alkaloids Pty. Ltd., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

170. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

171. Janssen made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but, in

fact, these activities were used by Janssen to deceptively promote and maximize the use of opioids.

172. On August 26, 2019, a judge in Oklahoma ruled that Johnson & Johnson had intentionally played down the dangers and oversold the benefits of opioids, and ordered it to pay the state \$572 million in the first trial of a drug manufacturer for the destruction wrought by opioid painkillers.⁶⁸ The judge found that the state had proven that Johnson & Johnson had created a public nuisance by exaggerating the benefits of narcotic painkillers and minimizing their addiction risks. The Oklahoma Court also found that “the public in general are currently experiencing an opioid crisis and epidemic.”⁶⁹

173. According to the Oklahoma Court, Johnson & Johnson’s marketing and promotion activities included, among other things, their sales representatives providing education, literature they funded in medical journals and publications, materials from professional societies/patient advocacy groups, continuing medical education they funded, unbranded marketing materials, and paid speakers.⁷⁰ The key messages in this marketing strategy included promoting the concept that chronic pain was undertreated, and the solution to this problem was increasing opioid use.⁷¹ They used the phrase, “pseudoaddiction,” to describe patients returning to the doctor before a prescription should have run out, not as individuals suffering from addiction but rather as suffering from the undertreatment of their pain, which

⁶⁸ Jan Hoffman, *Johnson & Johnson Ordered to Pay \$572 Million in Landmark Opioid Trial*, THE NEW YORK TIMES (Aug. 26, 2019), available at <https://www.nytimes.com/2019/08/26/health/oklahoma-opioids-johnson-and-johnson.html>. See also Judgment After Non-Jury Trial, Aug. 26, 2019, Case No. CJ-2017-816 (Okla. Cleveland Cty. Dist. Ct.) (“Okla. Judgment”).

⁶⁹ Okla. Judgment, Findings of Fact, ¶1.

⁷⁰ Okla. Judgment, Findings of Fact, ¶19.

⁷¹ Okla. Judgment, Findings of Fact, ¶20.

could best be solved by prescribing those patients more opioids.⁷² Sales representatives did not, however, receive training regarding “pill mill” red flags, such as “pain clinics with patients lined up out the door or patients passed out in the waiting room.”⁷³

174. According to the Oklahoma Court, Johnson & Johnson, through its wholly owned subsidiaries, Tasmanian Alkaloids Limited and Noramco, Inc., supplied opioid manufacturers with active pharmaceutical ingredients (“APIs”) from the 1990s until at least 2016. Tasmanian Alkaloids Limited “cultivated and processed opium poppy plants to manufacture narcotic raw materials that were imported into the U.S. to be processed and made into APIs for manufacturing opioids.” Noramco, Inc. imported the raw materials from Tasmanian Alkaloids Limited, processed these materials into APIs for manufacturing opioids, and sold the APIs to other opioid manufacturers in the United States.⁷⁴

175. According to the Oklahoma Court, drug manufacturers in the United States, including Purdue and Teva, were supplied the following opioid APIs through Johnson & Johnson’s operations: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.⁷⁵ Noramco sold its APIs, including oxycodone, hydrocodone, morphine, codeine, buprenorphine, hydromorphone, and naloxone, through long-term agreements with all 7 of the top U.S. generic manufacturing companies.⁷⁶

⁷² Okla. Judgment, Findings of Fact, ¶22.

⁷³ Okla. Judgment, Findings of Fact, ¶33.

⁷⁴ Okla. Judgment, Findings of Fact, ¶6.

⁷⁵ Okla. Judgment, Findings of Fact, ¶7.

⁷⁶ Okla. Judgment, Findings of Fact, ¶14.

176. According to the Oklahoma Court, in 2015, Johnson & Johnson's operations, comprised of Noramco and Tasmanian Alkaloids, and called "Noramco World Wide Narcotics Franchise," held the distinction of being "the #1 supplier of Narcotic APIs in the United States, the world's largest market."⁷⁷ "Noramco grew to become the No. 1 narcotic API supplier of oxycodone, hydrocodone, codeine and morphine in the United States."⁷⁸

177. Janssen, like many other companies, has a corporate code of conduct, which sets forth the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. Johnson & Johnson imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J.⁷⁹ Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "*Ethical Code for the Conduct of Research and Development*," names only J&J and does not mention Janssen anywhere within the document. The "*Ethical Code for the Conduct of Research and Development*" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

178. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise

⁷⁷ Okla. Judgment, Findings of Fact, ¶8.

⁷⁸ Okla. Judgment, Findings of Fact, ¶15.

⁷⁹ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case. J&J made payments to thousands of physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but, in fact, these activities were used by J&J to deceptively promote and maximize the use of opioids.

e. Endo and Associated Companies

179. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

180. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

181. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

182. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively, "Par Pharmaceutical"). Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc.

183. According to ARCOS data, from 2006 to 2014, Par Pharmaceutical manufactured and sold 435,584,240 pills of oxycodone and hydrocodone in Kentucky. Among all

manufacturers, Par Pharmaceutical manufactured the third highest number of pills of oxycodone and hydrocodone sold into Kentucky during that eight-year period.

184. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, “Endo”) are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

185. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, generic versions of oxycodone, oxymorphone, hydromorphone and hydrocodone in the United States. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo’s total revenue in 2012. On June 8, 2017, the FDA requested that Endo remove Opana ER from the market because of a “serious outbreak” of HIV and hepatitis C due to abuse of the drug after the reformulation of Opana from a nasal spray to an injectable.⁸⁰ In response to the FDA’s request, Endo removed Opana ER from the market in July 2017, the first time the agency had ever moved to pull an opioid medication from sale.⁸¹ Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

186. Endo made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers’ bureaus, providing

⁸⁰ Press Release, U.S. Food & Drug Administration, FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), *available at* <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

⁸¹ Press Release, Endo International PLC, Endo Provides update on Opana ER (July 6, 2017), *available at* <http://investor.endo.com/news-releases/news-release-details/endo-provides-update-opanar-er>.

consulting services, assisting in post-marketing safety surveillance and other services, but, in fact, these activities were used by Endo to deceptively promote and maximize the use of opioids.

f. Abbott Laboratories

187. Defendant AbbVie, Inc. (“AbbVie”), is a corporation organized under the laws of Delaware, with its principal place of business in North Chicago, Illinois. AbbVie, at times relevant to this Complaint, manufactured, promoted, sold, and distributed branded and generic opioids in the United States and Kentucky.

188. Defendant Abbott Laboratories, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business in Chicago, Illinois. Before splitting from AbbVie in 2013, Abbott Laboratories, Inc. manufactured, promoted, sold, and distributed branded and generic opioids in the United States and Kentucky.

189. Defendant Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Defendant Abbott Laboratories, Inc. is a subsidiary of Abbott Laboratories, whose principal place of business is also in Abbott Park, Illinois. Defendants Abbott Laboratories and Abbott Laboratories, Inc. are referred to collectively as “Abbott.”

190. Abbott was primarily engaged in the promotion and distribution of opioids nationally due to the co-promotional agreement with Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue’s opioid products as set forth above.

191. Abbott, as part of the co-promotional agreement, helped turn OxyContin into the largest selling opioid in the nation. Abbott, a much larger company than Purdue, had a sales force entrenched in hospitals and surgical centers, and had existing relationships with anesthesiologists, emergency room doctors, surgeons, and pain management teams. Abbott

devoted at least 300 sales representatives to OxyContin sales – about the same number of people Purdue initially dedicated to the drug – as part of a co-promotional agreement with Purdue.⁸² Winning Abbott’s help was so important to Purdue that it agreed to indemnify the larger company from any legal costs that might arise from the selling of the drug. It was a provision that ended up saving Abbott millions of dollars, and also kept the company out of the headlines as Purdue was forced to pay huge fines and settlements from the illegal marketing of Oxycontin.⁸³

192. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received 25% to 30% of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of 6% of net sales up through at least 2006.

193. With Abbott’s help, sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.2 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

194. Abbott and Purdue’s conspiring with Pharmacy Benefit Managers (PBMs) to drive opioid use is well established. As described in an October 28, 2016, article from Psychology Today entitled *America’s Opioid Epidemic*:

Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts] and other pharmacy benefits managers on condition that they eased

⁸² “Secret trove reveals bold ‘crusade’ to make OxyContin a blockbuster” by David Armstrong. STAT. September 22, 2016.

⁸³ *Id.*

availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction.... One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scene, however, as one Purdue official openly acknowledged, the drug maker was “working with Medco (PBM) [now Express Scripts] to try and make parameters [for prescribing] less stringent.”⁸⁴

g. Amneal

195. Defendant Amneal Pharmaceuticals, LLC (“Amneal LLC”) is a Delaware limited liability company with its principal place of in New Jersey.

196. Defendant Amneal Pharmaceuticals, Inc. (“API”) is a Delaware corporation with its principal place of business in New Jersey. API is the managing member of Amneal LLC, and conducts and exercises full control over all activities of Amneal LLC.⁸⁵

197. Impax Laboratories, LLC, formerly known as Impax Laboratories, Inc., is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey. Upon information and belief, in May 2018, Impax Laboratories, Inc. merged with and into Amneal Pharmaceuticals LLC to form Defendant, Amneal Pharmaceuticals, Inc.

198. Defendant Amneal Pharmaceuticals of New York LLC is a Delaware limited liability company with its principal place of business in Hauppauge, New York.

199. API, Impax Laboratories, LLC, Amneal Pharmaceuticals of New York LLC and Amneal LLC are referred to herein as “Amneal.”

⁸⁴ American Society of Addiction Medicine, *America’s Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing*, Psychology Today, Oct. 28, 2016, <https://www.psychologytoday.com/blog/side-effects/201610/america-s-opioid-epidemic>.

⁸⁵ *Id.*

200. At all relevant times, Amneal has sold prescription drugs including opioids in Kentucky and across the United States.

201. According to ARCOS data, between 2006 and 2014, Amneal sold 81,686,293 pills of oxycodone and hydrocodone in Kentucky. Among all manufacturers, Amneal manufactured the fourth highest number of pills of oxycodone and hydrocodone sold in Kentucky during that eight-year period.

202. Defendant Amneal breached its duties under Kentucky law. As shown by the ARCOS Data, Amneal sold an extraordinary amount of opioids into Kentucky and the areas served by Plaintiffs. Amneal's excessive sales were made possible by, and are evidence of, Amneal's failures to comply with its duties under applicable state law and regulations. Further, Amneal failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under Kentucky law. These breaches contributed substantially to the harms borne by Plaintiffs as alleged in the Complaint.

h. Assertio

203. Defendant Assertio Therapeutics, Inc. f/k/a Depomed, Inc. ("Assertio" or "Depomed") is a Delaware corporation with its principal place of business in Lake Forest, Illinois. Assertio describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Assertio develops, markets, and sells prescriptions drugs in Kentucky and across the United States. Assertio acquired the rights to Nucynta and Nucynta ER for \$1.05 billion from Janssen pursuant to a January 15, 2015, Asset Purchase Agreement. This agreement closed on April 2, 2015.

i. Mallinckrodt Entities

204. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

205. Defendant Mallinckrodt LLC is a Delaware corporation with its headquarters in Hazelwood, Missouri.

206. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc.

207. Mallinckrodt LLC, Mallinckrodt plc, and SpecGx LLC are referred to as “Mallinckrodt.” Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States, and to Plaintiffs. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

208. According to ARCOS data, SpecGx LLC sold 716,919,264 pills of oxycodone and hydrocodone into Kentucky between 2006 and 2014. Among all manufacturers, SpecGx LLC manufactured the second highest number of pills of oxycodone and hydrocodone sold in Kentucky during that eight-year period.

209. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo

for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

210. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health⁸⁶ data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.⁸⁷

211. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

212. Among the drugs Mallinckrodt manufactures or has manufactured are the following: Schedule II: Exalgo (hydromorphone hydrochloride, extended release), Roxicodone

⁸⁶ "IMS Health was a [provider of] information, services and technology for the healthcare industry, including U.S. physician prescribing data." It has changed its corporate form and is now known as "IQVIA."

⁸⁷ Mallinckrodt plc 2016 Annual Report (Form 10-K), *available at* <http://www.mallinckrodt.com/investors/annual-reports/>.

(oxycodone hydrochloride), Xartemis XR (oxycodone hydrochloride and acetaminophen), Methadose (methadone hydrochloride), Generic (morphine sulfate, extended release, morphine sulfate oral solution, fentanyl transdermal system, oral transmucosal fentanyl citrate, oxycodone and acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride, hydromorphone hydrochloride, extended release, oxymorphone hydrochloride, methadone hydrochloride. Schedule III: buprenorphine and naloxone. Unscheduled: naltrexone hydrochloride.

213. Mallinckrodt made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but, in fact, Mallinckrodt used these activities to deceptively promote and maximize the use of opioids

j. KVK Tech

214. Defendant KVK-Tech, Inc. is a privately held Pennsylvania corporation with its principal place of business in Pennsylvania. KVK-Tech, Inc. is a manufacturer of generic prescription opioid, including many Schedule II controlled substances such as oxycodone and hydrocodone.

215. KVK-Tech, Inc. has engaged in the manufacture, promotion, distribution, and sale of the generic prescription opioid drugs sold throughout the country, including into Kentucky.

216. Collectively, the Purdue Individual Co-Conspirators, Actavis, Amneal, Cephalon, Janssen, Assertio, Endo, Abbott, Actavis, Mallinckrodt, and KVK-Tech, Inc. are referred to as "Marketing Defendants."

k. Practice Fusion

217. Defendant Practice Fusion, Inc. (“Practice Fusion”) was a Delaware corporation with headquarters in San Francisco, California.

218. Defendant Allscripts Healthcare Solutions, Inc. (“Allscripts”) is a Delaware corporation, with headquarters in Chicago, Illinois, and, through merger completed February 13, 2018, acquired Practice Fusion, Inc.

219. Defendant Practice Fusion, Inc. was a cloud-based electronic health records (“EHR”) company that provides its cloud-based EHR products to traditionally hard-to-reach small independent physician practices without charge.

220. Practice Fusion and Allscripts are referred to as “Practice Fusion” throughout the Complaint.

221. Beginning in and around 2013, Practice Fusion solicited remuneration from Purdue Pharma in exchange for creating and embedding an alert, known as a clinical decision support (referred to hereafter as the “Pain CDS”), in Practice Fusion’s EHR to prompt doctors to make certain clinical decisions for the purpose of increasing Purdue’s extended-release opioid prescriptions. The Pain CDS suggested that doctors focus on assessing and treating a patient’s pain symptoms and provided the doctor with a list of potential care plan treatment options, including extended-release opioids medications.

222. Practice Fusion understood and has admitted that Purdue Pharma provided remuneration in exchange for the Pain CDS because the Pain CDS could boost sales of Purdue Pharma’s extended-release opioid products.

223. Practice Fusion understood and has admitted that it was unlawful to sell clinical decision support programs based upon anticipated returns on investment that a pharmaceutical company clients like Purdue Pharma could achieve through the programs, and that any clinical

decision support programs must be consistent with any applicable evidence-based medical guidelines and department of Health and Human Services (“HHS”) Centers for Medicare and Medicaid Services (“CMS”) Clinical Quality Measures (“CQM”).

224. Practice Fusion has admitted that it and Purdue Pharma did not pursue a clinical decision support alert to assist doctors in screening patients; instead the parties developed the Pain CDS to increase sales of Purdue Pharma’s extended-release opioid products.

225. Practice Fusion and Purdue Pharma entered into a written statement of work contracting for the Pain CDS effective March 1, 2016, pursuant to which Purdue Pharma paid Practice Fusion \$959,700 for a program directed at chronic pain management treatment with immediate release opioids and chronically used NSAIDs that would support the identification and/or treatment of patients who are recommended to be screened for and receive the treatment specified in what the contract described as “gold standard evidence based clinical guidelines.”

226. The Pain CDS that Practice Fusion and Purdue jointly developed in the next three months violated clinical guidelines current at that time and that have been developed during the time of its use and did not incorporate the recommendations contained in the CDC’s Guidelines for Prescribing Opioids for Chronic Pain issued on March 15, 2016, nor did it implement the recommendations provided by the New England Journal of Medicine (“NEJM”) 2016 article entitled “Opioid Abuse in Chronic Pain-Misconceptions and Mitigation Strategies”.

227. The Pain CDS went live on Practice Fusion’s platform on or about July 6, 2016. It deviated from the various evidence-based guidelines in several material respects, including advocating for the use of Purdue’s extended -release opioid products for patients with less than severe pain; listing those products as an option for patients with pain without regard to whether the pain could be adequately treated by non-opioid products; listing Purdue’s extended-release

opioid products as an option for patients who had not previously received opioid therapy; and suggesting Purdue's extended-release opioid products as a treatment option for patients whose pain was not chronic, but who presented with separate complaints of acute pain within three months.

228. In so doing, at a time when evidence-based guidelines issued by the CDC and by scientific journals such as the NEJM were advocating for *limited* use of Purdue's extended-release opioid products, Practice Fusion solicited payment from Purdue to use its EHR platform to cause the healthcare professionals who used that platform to *increase* prescriptions of such products in situations that violated those Guidelines. In sum, the Pain CDS on Practice Fusion's platform was not consistent with the guidelines such as the CDC Guidelines; the Pain CDS was inconsistent with applicable CQM; and the Pain CDS was funded by Purdue Pharma's marketing department and Purdue Pharma's drug marketers were involved in its design.

229. On November, 6, 2017, Practice Fusion and Purdue Pharma employees publicly announced at a national American Medical Informatics association ("AMIA") Annual Symposium held in Washington, D.C. that they had begun to study the effectiveness of the CDS Pain Program on Practice Fusion's platform. The researchers tested pain alerts for roughly 13 million patients per year. They concluded that such reminders "may have a sustained influence on the rate of opioid prescribing."

230. The CDS Pain Program that went live on July 2016 continued until the spring of 2019, more than a year after Defendant Allscripts Healthcare Solutions, Inc.'s acquisition of Practice Fusion. The rigged alerts popped up on doctors' computers more than 230 million times between July 2006 and the spring of 2019 when criminal charges were filed. The healthcare

providers who received them prescribed extended-release opioids at a higher rate than those who did not receive them.

231. On information and belief, at the time of Practice Fusion's merger with Allscripts and for some time before the merger, Allscripts was aware of Practice Fusion's arrangement with Purdue Pharma described herein and the investigation of the illegality of Practice Fusion's conduct under that arrangement by the U.S. Attorney for the District of Vermont, but took no steps to stop Practice Fusion's conduct until the U.S. Attorney charged Practice Fusion with unlawful criminal conduct in the spring of 2019.

232. On January 27, 2020, Practice Fusion paid a total of \$145 million to resolve criminal and civil investigations that asserted that the arrangement described above and thirteen others like it constituted illegal kickback schemes under the Anti-Kickback Statute, 42 U.S.C. sections 1320(a)-7(b)(1) and that it had conspired with Purdue Pharma to violate Section 371 of that statute. Practice Fusion admitted only to its opioids agreement with Purdue Pharma. It paid a total of \$118.6 million to the federal government and to the states to resolve allegations that it accepted kickbacks from Purdue Pharma and other pharmaceutical companies and also caused its users to submit false claims for federal incentive payments by misrepresenting the capabilities of its EHR software.

2. Distributor Defendants

233. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants, who are wholesale distributors that engaged in the chain of distribution or resale of Schedule II controlled substances, universally failed to comply with Kentucky law regulating that activity. Plaintiffs allege the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiffs' communities.

a. **AmerisourceBergen Drug Corporation**

234. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including to Kentucky.

235. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of \$147 billion in 2016.

236. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."⁸⁸

⁸⁸ AmerisourceBergen, 2016 Summary Annual Report, *available at* <http://investor.amerisourcebergen.com/static-files/37daf1ed-4d41-4547-bb87-86d501087dbb> (last accessed August 1, 2018).

237. AmerisourceBergen, at all relevant times, operated as a licensed distributor wholesaler in Kentucky, licensed by the Kentucky Board of Pharmacy.

238. According to ARCOS data, between 2006 and 2014, AmerisourceBergen distributed 584,198,415 pills of hydrocodone and oxycodone into Kentucky during this eight-year period, making AmerisourceBergen the top distributor of these opioid pills during that eight-year period.

b. Anda, Inc.

239. Defendant Anda, Inc., (“Anda”) through its various DEA registrant subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its principal place of business in Weston, Florida. In October 2016, Defendant Teva Ltd. acquired Anda from Allergan plc (i.e. Defendant Actavis), for \$500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in Kentucky and within the communities served by Plaintiffs.

c. Cardinal

240. Defendant Cardinal Health, Inc. (“Cardinal”) is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal generated revenues of \$121.5 billion.

241. Cardinal is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. It has annual resources of over \$120 billion. Additionally, in December 2013, Cardinal formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal has, at all relevant times, had distribution centers throughout the United States, including Kentucky, and has distributed opioids nationwide.

242. Cardinal Health at all relevant times, operated as a licensed distributor wholesaler in Kentucky, licensed by the Kentucky Board of Pharmacy.

d. H.D. Smith, LLC

243. Defendant H. D. Smith, LLC f/k/a H. D. Smith Wholesale Drug Co. (“H. D. Smith”) through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including Kentucky and the communities served by Plaintiffs. H. D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic and specialty pharmaceuticals and is a Delaware corporation with its principal place of business in Illinois. H. D. Smith Wholesale Drug Co. has been restructured and is currently doing business as H. D. Smith, LLC. H.D. Smith LLC’s sole member is H. D. Smith Holdings, LLC, and its sole member is H. D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. H. D. Smith is the largest independent wholesaler in the United States. In January 2018, Defendant AmerisourceBergen acquired H. D. Smith. At all relevant times, H. D. Smith distributed prescription opioids throughout the United States including in Kentucky.

e. Henry Schein

244. Henry Schein, Inc. (“Henry Schein”) describes its business as providing a products and services to integrated health systems, designed specifically for and focused exclusively on, the non-acute care space. Henry Schein is incorporated in Delaware, with its principal place of business located in Melville, New York.

245. Henry Schein distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health practices and clinics, and office-based medical practitioners, ambulatory surgery centers, and other institutions.

246. At all relevant times, Henry Schein was in the business of distributing, and redistributing, pharmaceutical products to consumers within Kentucky.

247. In 2015, Henry Schein reported that its sales reached a record \$10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

f. Smith Drug Company

248. Defendant Smith Drug Company is a South Carolina business entity with its principal place of business in South Carolina.

249. At all times relevant to this Complaint, Smith Drug Company was in the business of distributing and redistributing prescription opioids throughout the United States, including in Kentucky.

250. Based on ARCOS data, opioids sold and distributed by Smith Drug Company represent a substantial market share in Kentucky during the relevant time period. Between 2006 and 2014, Smith Drug company was one of the top five distributors of hydrocodone and oxycodone in thirty-eight (38) Kentucky counties, distributing 117,073,140 pills of hydrocodone and oxycodone in just those Kentucky counties during that eight-year period.

251. Cardinal, Anda, H. D. Smith, Henry Schein, AmerisourceBergen, and Smith Drug Company are collectively referred to as the "Distributor Defendants."

3. National Retail Pharmacies

a. CVS

252. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business in Rhode Island.

253. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Rhode Island.

254. Defendant Kentucky CVS Pharmacy, L.L.C. is Kentucky limited liability company with its principal place of business in Rhode Island.

255. CVS Health Corporation, CVS Pharmacy Inc., Kentucky CVS Pharmacy, L.L.C. are collectively referred to as “CVS.” CVS distributed prescription opioids throughout the United States, including in Kentucky.

256. As a vertically integrated seller of opioids, CVS knew or should have known that an excessive volume of pills was being sold into Kentucky.

257. According to ARCOS data, from 2006 to 2014, CVS was a top five distributor of oxycodone and hydrocodone pills in twenty Kentucky counties, distributing approximately 36,763,200 pills into Kentucky in just those counties during that eight-year period. Kentucky CVS Pharmacy, L.L.C. was also was one of the top five pharmacies selling oxycodone and hydrocodone pills in twenty-five Kentucky counties. In just those counties, Kentucky CVS Pharmacy, L.L.C. sold approximately 73,251,195 pills into Kentucky during that eight year period.

258. Discovery will reveal that CVS knew or should have known that its pharmacies in Kentucky were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians;

and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

259. At all relevant times, and as the parent company of Defendants CVS Pharmacy, Inc., and Kentucky CVS Pharmacy, L.L.C., Defendant CVS Health Corporation established national policies and procedures governing the distribution and sales of controlled substances throughout the United States that it directed and intended that those policies and procedures would be implemented on a nationwide basis including in, specifically, Kentucky. At all times relevant to this Complaint, CVS was responsible for directing and implementing policies and procedures governing the distribution and sales of controlled substances by its subsidiaries throughout the United States, including in Kentucky and Plaintiffs' communities specifically.

260. CVS Pharmacy, Inc. had complete access to, and full visibility of, all opioid distribution data related to CVS pharmacies in and around Kentucky.

261. CVS Pharmacy, Inc. had complete access to, and full visibility of, all prescription opioid dispensing data related to CVS pharmacies in and around Kentucky.

262. CVS Pharmacy, Inc. had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in CVS pharmacies in and around Kentucky.

263. CVS Pharmacy, Inc. had complete access to information revealing the opioid and non-opioid prescriptions dispensed by CVS pharmacies in Kentucky, including those which were being paid for in cash. CVS Pharmacy, Inc. had complete access to information revealing the

geographic location of out-of-state prescriptions for opioids that were being filled in and around Kentucky.

b. The Kroger Co.

264. Defendant The Kroger Co. is an Ohio corporation with headquarters in Cincinnati, Ohio.

265. Defendant, Kroger Limited Partnership I, an Ohio corporation with its principal place of business located in Cincinnati, Ohio.

266. Defendant, Kroger Limited Partnership II, is an Ohio limited partnership with its principal place of business located in Columbus, Ohio.

267. The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II are collectively referred to as “Kroger.” Kroger operates 2,268 pharmacies in the United States, including in Kentucky. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in Kentucky.

268. As a vertically integrated dispenser of prescription opioids, Kroger knew or should have known that an excessive volume of pills was being sold into Kentucky.

269. Discovery will reveal that Kroger knew or should have known that its pharmacies in Kentucky were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and

dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

270. At all relevant times, and as the parent company, Defendant The Kroger Co. established national policies and procedures governing the distribution and dispensing of controlled substances throughout the United States that it directed and intended that those policies and procedures would be implemented on a nationwide basis including, specifically, Kentucky. At all times relevant to this Complaint, Defendant The Kroger Co. was responsible for directing and implementing policies and procedures governing the distribution and dispensing of controlled substances by its subsidiaries throughout the United States, including in Kentucky and Plaintiffs' Community specifically.

271. Kroger had complete access to, and full visibility of, all prescription opioid distribution data related Kroger pharmacies in and around Kentucky.

272. Kroger had complete access to, and full visibility of, all prescription opioid dispensing data related to Kroger pharmacies in and around Kentucky.

273. Kroger had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in Kroger pharmacies in and around Kentucky.

274. Kroger had complete access to information revealing the opioid and non-opioid prescriptions dispensed by Kroger pharmacies in Kentucky, including those which were being paid for in cash. Kroger had complete access to information revealing the geographic location of out-of-state prescriptions for opioids that were being filled in and around Kentucky.

c. Rite-Aid of Maryland, Inc.

275. Defendant Rite Aid of Kentucky, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. (“Rite Aid”), is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid distributed prescription opioids throughout the United States, including in Kentucky.

d. Walgreens

276. Defendant Walgreen Co. (“Walgreen Co.”) is an Illinois corporation with its principal place of business in Deerfield, Illinois. Walgreen Co. conducted business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreen Co. distributed opioids throughout the United States, including into Kentucky.

277. Defendant Walgreen Eastern Co., Inc. (“WEC”) is a New York corporation with its principal place of business in Deerfield, Illinois. WEC conducted business as a licensed wholesale distributor. At all times relevant to this Complaint, WEC distributed opioids throughout the United States, including into Kentucky.

278. Defendant Walgreens Boots Alliance, Inc. (“WBA”) is a Delaware corporation with its principal place of business in Illinois. WBA acted by and through its own subsidiaries and affiliated entities to distribute opioids throughout the country, including in Kentucky.

279. Walgreens Co., WBA, and WEC are collectively referred to herein as “Walgreens.” At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in Kentucky.

280. According to ARCOS data, Walgreen Co. was the fourth largest distributors of pills of oxycodone and hydrocodone in Kentucky between 2006 and 2014. During this eight-year period, Walgreens distributed 276,846,260 pills of oxycodone and hydrocodone into Kentucky.

Walgreens pharmacies were also top opioid sellers in Kentucky, with two Walgreens pharmacies in Louisville ranking in the top five sellers of oxycodone and hydrocodone.

281. As a vertically integrated dispenser of prescription opioids, Walgreens knew or should have known that an excessive volume of pills were being distributed in Kentucky.

282. Discovery will reveal that Walgreens knew or should have known that its pharmacies in Kentucky were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

283. At all relevant times, Walgreens established national policies and procedures governing the distribution of controlled substances throughout the United States that it directed and intended that those policies and procedures would be implemented on a nationwide basis including, specifically, Kentucky. At all times relevant to this Complaint, Walgreens was responsible for directing and implementing policies and procedures governing the distribution of controlled substances by its subsidiaries throughout the United States, including in Kentucky and Plaintiffs' Community specifically.

284. Walgreens had complete access to, and full visibility of opioid distribution data related to its pharmacies in and around Kentucky.

285. Walgreens had complete access to, and full visibility of, all prescription opioid dispensing data related to Walgreens pharmacies in and around Kentucky.

286. Walgreens had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in Walgreens pharmacies in and around Kentucky.

287. Walgreens had complete access to information revealing the opioid and non-opioid prescriptions dispensed by Walgreens pharmacies in Kentucky, including those which were being paid for in cash. Walgreens had complete access to information revealing the geographic location of out-of-state prescriptions for opioids that were being filled in and around Kentucky.

e. Wal-Mart Inc.

288. Defendant Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Arkansas.

289. Defendant Wal-Mart Stores East, LP is a Delaware limited partnership with its principal place of business in Arkansas.

290. Wal-Mart, Inc. and Wal-Mart Stores East, LP are collectively referred to as “Wal-Mart.” At all times relevant to this Complaint, Walmart distributed prescription opioids throughout the United States, including in Kentucky.

291. According to ARCOS data, between 2006 and 2014 Walmart was the fifth largest seller of oxycodone and hydrocodone pills in Kentucky. Walmart distributed 185,434,100 pills of oxycodone and hydrocodone in Kentucky, including in Plaintiffs’ communities during that

eight-year period. Walmart's noncompliant sales were made possible by, and are evidence of, Walmart's failures to comply with its duties under state and federal controlled substance laws.

292. From 1996 to 2010, Walmart utilized employees at its distribution centers to review orders for controlled substances, speak to pharmacies about the orders, and escalate any order needing further review. However, Walmart had no written criteria regarding how to identify orders that needed further review. Walmart simply relies on the experience of hourly associates reviewing hundreds of orders each day to recall what an unusual order would be for one of Walmart's more than 4000 pharmacies. Under this system, few, if any orders were ever identified by distribution center employees as needing further review or followed up on.

293. Walmart's policies during this time period failed to identify suspicious orders before shipment or anytime, and, as a consequence, Walmart routinely shipped suspicious orders. Walmart failed to use available reports and information to monitor for suspicious orders. Walmart further did not have a process to monitor or keep track of any order that was flagged.

294. Walmart conducted very little due diligence during the relevant time period. Even once Walmart put policy in place requiring flagged orders to be reviewed, Walmart failed to follow its own policy and the review of these orders failed to occur.

295. Though Walmart had access to significant information about red flags due to its vertical integration with its stores, Walmart failed to use available information from indicating red flags in order to more effectively prevent diversion.

296. As a National Pharmacy, Walmart knew or should have known that its pharmacies in Illinois were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling orders of unusual size and frequency for the same patient (d) filling orders of unusual size and

frequency from out-of-state patients; (e) filling orders of unusual size and frequency paid for in cash (f) filling orders of unusual size and frequency from the same prescribing physician (g) filling orders of unusual size and frequency from out-of-state physicians.

297. Because of its vertically integrated structure, Walmart has access to complete information regarding red flags of diversion across its pharmacies in and around Illinois, including Plaintiffs' Community, but Walmart failed to utilize this information to effectively prevent diversion.

298. Collectively, Defendants CVS, Kroger, Rite Aid, Walgreens, and Walmart are referred to as "National Retail Pharmacies."

299. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale and/or dispensing of opioids.

300. The Distributor Defendants and the National Retail Pharmacies are collectively referred to as the "Supply Chain Defendants."

4. Defendants' Agents and Affiliated Persons

301. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

302. The true names and capacities, whether individual, corporate, associate, or otherwise of certain vendors, distributors and/or their alter egos, sued herein as DOES 1 through 100 inclusive, are presently unknown to Plaintiffs, who therefore sues these Defendants by fictitious names. Plaintiffs will seek leave of this Court to amend this Complaint to show their

true names and capacities when they become ascertained. Each of the Doe Defendants has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein, and therefore are liable for the same.

IV. FACTUAL BACKGROUND

A. The History of Opioids

303. The synthetic opioids manufactured and distributed by Defendants are related to the opium poppy, which has been used to relieve pain for centuries.

304. The opium poppy was a well-known symbol which signified both sleep and death in Roman Civilization. The Romans used opium not only as a medicine but also as a poison.⁸⁹

305. During the Civil War, opioids, then known as “tinctures of laudanum,” gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain on the battlefield. They were also used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

306. Kentucky law imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence; Schedule III drugs are deemed to have a lower potential for abuse, but their abuse may lead to moderate or low physical dependence or high psychological dependence. *See* KRS § 218A.060; KRS § 218A.080.

307. The strength of various opioids is defined by medical professionals in terms of morphine milligram equivalents (“MME”). Opioids provide varying levels of MMEs. For

⁸⁹ Martin Booth, *Opium: A History*, at 20 (Simon & Schuster Ltd. 1996).

example, just 33 mg of oxycodone provides 50 MME. According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day. Thus, at OxyContin's twice-daily dosing, the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

308. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Subsys (a product of nonparty and co-conspirator, Insys Therapeutics, Inc. ("Insys")), are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Marketing Defendants and Purdue promoted the idea that non-cancer related pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

309. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest

respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

310. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

311. Opioids provide effective treatment for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain when use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, marketed, and distributed opioids for the management of chronic pain by misleading consumers and medical providers, such as hospitals, through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

312. As one doctor put it, the widespread, long-term use of opioids “was an experiment on the population of the United States. It wasn’t randomized, it wasn’t controlled, and no data was collected until they started gathering death statistics.”

B. The Opioid Epidemic

313. Opioids have become widely used. In 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone

every 4 hours for 1 month.⁹⁰ Marketing Defendants and Purdue manufacture, market, sell, and distribute branded and/or generic prescription opioid pain medications. Some of the relevant brand-name drugs include OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydene, Nucynta/Nucynta ER, Duragesic, Exalgo, and Xartemis XR. Marketing Defendants and Purdue used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.

314. Despite the enormous number of prescriptions, recent studies have concluded that treatment with opioids is not superior to treatment with non-opioid medications for improving pain-related function.⁹¹ Even for patients presenting to the emergency room with acute extremity pain, there is no significant or clinically important difference in pain reduction at 2 hours among single-dose treatment with ibuprofen and acetaminophen or with three different opioid and acetaminophen combination analgesics.⁹²

315. In 2011, the CDC declared prescription painkiller overdoses at epidemic levels. The News Release noted:

⁹⁰ Katherine M. Keyes, et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52-e59 (2014), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935688/>.

⁹¹ Erin E. Krebs, M.D., et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain*, 319 JAMA 872-882 (2018), doi: 10.1001/jama.2018.0899, available at <https://jamanetwork.com/journals/jama/article-abstract/2673971?redirect=true>.

⁹² Andrew K. Chang, M.D., et al., *Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department*, 318 JAMA 1661-1667 (2017), doi: 10.1001/jama.2017.16190, available at <https://jamanetwork.com/journals/jama/article-abstract/2661581?widget=personalizedcontent&previousarticle=2673971&redirect=true>.

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
- c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
- e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
- f. Almost 5,500 people start to misuse prescription painkillers every day.⁹³

316. The CDC has also identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are dependent on prescription opioid painkillers – which, at the molecular level and in their effect, closely resemble heroin - are forty times more likely to be addicted to heroin.⁹⁴ According to a recent study, among young urban heroin users, 86% used opioid pain relievers prior to using heroin.⁹⁵

⁹³ See Prescription Painkiller Overdoses at Epidemic Levels, *supra* n. 28.

⁹⁴ See Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, available at <https://www.cdc.gov/vitalsigns/heroin/index.html> (last accessed August 1, 2018).

⁹⁵ Nat'l Inst. on Drug Abuse, *Prescription Opioids and Heroin* (Jan. 2018), available at <https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/19774-prescription-opioids-and-heroin.pdf>.

317. The synthetic opioid fentanyl has been a driving force behind the nation's opioid epidemic, killing tens of thousands of Americans in overdoses. The drug is so powerful that it is now being used to execute prisoners on death row.⁹⁶

318. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.⁹⁷

319. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among the 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.⁹⁸

320. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.⁹⁹

321. The National Institute on Drug Abuse identifies misuse and dependence on opioids as “a serious national crisis that affects public health as well as social and economic

⁹⁶ Mitch Smith, *Fentanyl Used to Execute Nebraska Inmate*, in *First for U.S.*, (Aug. 14, 2018), available at <https://www.nytimes.com/2018/08/14/us/carey-dean-moore-nebraska-execution-fentanyl.html>.

⁹⁷ Rudd *et al.*, Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, doi: <http://dx.doi.org/10.15585/mmwr.mm655051e1>, available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

⁹⁸ See Rudd *et al.*, Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, DOI: <http://dx.doi.org/10.15585/mmwr.mm655051e1>, available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

⁹⁹ See Nora D. Volkow, M.D. & A. Thomas McLellan, M.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N Engl J Med 1253-1263 (2016), DOI: 10.1056/NEJMra1507771, <http://www.nejm.org/doi/full/10.1056/NEJMra1507771>, (“Volkow & McLellan”).

welfare.”¹⁰⁰ The economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.¹⁰¹

322. In 2016, the President of the United States officially declared an opioid and heroin epidemic.¹⁰²

C. Congressional Response to the Opioid Crisis

323. Congressional interest in the opioid crisis has been intense. Multiple committees in both the House and Senate have conducted dozens of hearings exploring the issue from almost every angle, including effects on the health care system, people and their communities, law enforcement, workplaces, schools, and the Native American community. Congressional efforts culminated in the passage of the “Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act,” or the “SUPPORT for Patients and Communities Act.” This Bill passed the House by a vote of 396-14 on June 22, 2018, passed the Senate by a vote of 99-1 on September 17, 2018, and was signed into law by the President on October 24, 2018. Among other provisions, the Bill made it easier to intercept drugs being shipped into the country, authorized new funding for more comprehensive treatment, sped up research on non-addictive painkillers, and provided for broader coverage for substance abuse

¹⁰⁰ *Id.*

¹⁰¹ *Id.* (citing at note 2, Florence CS, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States*, 2013 (Oct. 2016), 54 Med. Care 901-906 (2016), DOI: 10.1097/MLR.0000000000000625, available at <https://www.ncbi.nlm.nih.gov/pubmed/27623005>).

¹⁰² See Proclamation No. 9499, 81 Fed. Reg. 65173 (Sept. 16, 2016) (proclaiming “Prescription Opioid and Heroin Epidemic Awareness Week”), available at <https://www.gpo.gov/fdsys/pkg/FR-2016-09-22/pdf/2016-22960.pdf>.

under Medicare and Medicaid regulations that have occasionally stood in the way of treatment. Congressional interest in the issue is ongoing.

V. THE MARKETING DEFENDANTS' AND PURDUE'S FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS

324. The opioid epidemic did not happen by accident.

325. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

326. Each Marketing Defendant and Purdue has conducted a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Marketing Defendant and Purdue spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny, trivialize, or materially understate the risks of opioids while overstating the benefits of using them for chronic pain.

327. The Marketing Defendants and Purdue have disseminated these common messages to reverse the generally accepted medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker

groups led by physicians that the Marketing Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded Front Groups.

328. The Marketing Defendants' and Purdue's efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009.¹⁰³ In an open letter to the nation's physicians in August 2016, the then U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."¹⁰⁴ This epidemic has resulted in a flood of opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

329. The Marketing Defendants and Purdue promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history, research, as well as clinical experience over the last 20 years of opioids, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Marketing Defendants and Purdue of these risks. The Marketing Defendants and Purdue had access to scientific studies, detailed prescription data, and reports of adverse events,

¹⁰³ See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, FORTUNE (Nov. 9, 2011), available at <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>; David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, FINANCIAL TIMES (Aug. 10, 2016).

¹⁰⁴ Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *supra* n. 48.

including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients were suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

330. The Marketing Defendants and Purdue intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

331. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance. The harm and endangerment to the public health, safety, and the environment created by this public nuisance is ongoing and has not been abated.

332. The public nuisance— *i.e.*, the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm can be ameliorated by (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

333. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they must do so. It is the manufacturer of a drug that has primary responsibility to ensure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. All companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not

diverted. These responsibilities to ensure that their products and practices meet state controlled substances and consumer protection laws and regulations, exist independent of any FDA or DEA regulation. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility, and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

334. The Marketing Defendants and Purdue spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States. The Marketing Defendants and Purdue also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout Kentucky.

335. Across the pharmaceutical industry, “core message” development is funded and overseen on a national basis by the drug manufacturer’s corporate headquarters. This comprehensive approach ensures that the Marketing Defendants and Purdue’s messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Marketing Defendants and Purdue consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

336. The Marketing Defendants and Purdue ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Marketing Defendants and Purdue’s sales representatives and physician speakers were required to stick to prescribed talking points, sales

messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

A. The Marketing Defendants' and Purdue's False and Deceptive Statements About Opioids

337. The Marketing Defendants' and Purdue's misrepresentations fall into the following ten categories:

- a. The risk of addiction from chronic opioid therapy is low;
- b. To the extent there is a risk of addiction, it can be easily identified and managed;
- c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids;
- d. Blaming persons dependent on opioids as "abusers" of opioids;
- e. Opioid withdrawal can be avoided by tapering;
- f. Opioid doses can be increased without limit or greater risks;
- g. Long-term opioid use improves functioning;
- h. Alternative forms of pain relief pose greater risks than opioids;
- i. A version of OxyContin marketed by Purdue was effective in providing 12-hour pain relief; and
- j. New formulations of certain opioids successfully deter abuse.

338. Each of these propositions was false. The Marketing Defendants and Purdue knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

339. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants and Purdue made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant's liability. While each Marketing Defendant and Purdue deceptively promoted their opioids specifically, and,

together with other Marketing Defendants and Purdue, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's and Purdue's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risks and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant's and Purdue's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant and Purdue.

1. **Falsehood #1: The Risk of Addiction from Chronic Opioid Therapy is Low**

340. Central to the Marketing Defendants' and Purdue's promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants and Purdue advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and Purdue and substantially contributing to the opioid epidemic.

341. Each of the Marketing Defendants and Purdue claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

342. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at

recommended dose,”¹⁰⁵ and the risk substantially increases with more than three months of use.¹⁰⁶ As the CDC Guideline states, “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” (a diagnostic term for addiction).¹⁰⁷

a. **Purdue and Abbott’s Misrepresentations Regarding Addiction Risk**

36. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the New England Journal of Medicine (“NEJM”) in 1980.

37. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction “rare” for patients treated with opioids.¹⁰⁸ They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients’ records.

¹⁰⁵ FDA announces safety labeling changes and post market study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013). *See also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016).

¹⁰⁶ Dowell, CDC Guideline, *supra* n. 24, at 27.

¹⁰⁷ *Id.* at 2.

¹⁰⁸ Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), available at <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER

HERSHEL JICK, M.D.

Boston Collaborative Drug

Surveillance Program

Waltham, MA 02154

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.

2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

38. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.¹⁰⁹

39. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.¹¹⁰ Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, “that’s not in any shape or form what we suggested in our letter,” according to Dr. Jick.

¹⁰⁹ Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail Of Addiction And Death*, 174 (Rodale 2003) (herein after “Pain Killer”).

¹¹⁰ J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New. Eng. J. Med. 123 (1980).

40. Purdue specifically used the Porter and Jick Letter in its 1998 promotional video “I got my life back,” in which Dr. Alan Spanos states “In fact, the rate of addiction amongst pain patients who are treated by doctors is *much less than 1%*.”¹¹¹ Purdue trained its sales representatives to tell prescribers that less than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was 13%).¹¹²

41. Other Defendants relied on and disseminated the same false and deceptive messaging. The enormous impact of Defendants’ misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy.¹¹³

¹¹¹ Our Amazing World, *Purdue Pharma OxyContin Commercial*, available at <https://www.youtube.com/watch?v=Er78Dj5hyeI>, (last accessed August 1, 2018) (emphasis added).

¹¹² Patrick R. Keefe, *The Family that Built an Empire of Pain*, *The New Yorker* (Oct. 30, 2017), available at <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain> (“*Empire of Pain*”).

¹¹³ Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), available at <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article>.

42. “It’s difficult to overstate the role of this letter,” said Dr. David Juurlink of the University of Toronto, who led the analysis. “It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern.”¹¹⁴

43. Alongside its use of the Porter and Jick Letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, “The fear of addiction is exaggerated.”¹¹⁵

44. Abbott sales staff were instructed about the euphoria patients were receiving on the shorter-acting painkiller Vicodin; they should tell physicians that “OxyContin has fewer such effects.” Abbott’s “King of Pain” taught his staff of “Royal Crusaders” that OxyContin would “minimize[e] the risk of dependence” and “lower[] euphoria,” when, in fact, he had little knowledge of pharmacology and no basis for these statements.

45. In an internal memo, Abbott told representatives to highlight the “less abuse/addiction potential” of the drug, which could be taken just twice a day because of its time-release formulation.¹¹⁶

46. Abbott’s sales representatives were also given a graphic to show doctors that depicted levels of its pain-killing ingredient in the bloodstream holding steady, but it looked

¹¹⁴ Marilyn Marchione, *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017), available at <https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

¹¹⁵ Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996) available at <http://documents.latimes.com/oxycontin-press-release-1996/>.

¹¹⁶ “Secret trove reveals bold ‘crusade’ to make OxyContin a blockbuster” by David Armstrong. STAT. Sept. 22, 2016.

“flatter” than the levels actually were, according to the court records. The use of a similar graph was cited in the federal case against Purdue as a key part of evidence that it falsely marketed OxyContin as having less euphoric effects and abuse potential than shorter-acting opioids.¹¹⁷

47. A “coaching sheet” prepared for Abbott sales personnel advised discussing the potential abuse of OxyContin only if a doctor brought it up, and to tell physicians that “street users” were misusing the drug not “true pain patients.”¹¹⁸

48. The more Abbott generated in sales, the higher the reward for the company, as well. Under the agreement with Purdue, Abbott received 25 percent of all net sales, up to \$10 million, for prescriptions written by doctors its sales reps called on, and 30 percent of sales above \$10 million, according to court records. Purdue deducted an unspecified amount for costs related to items such as shipping and distribution.¹¹⁹

49. Abbott refused to provide West Virginia’s lawyers figures showing its earnings from OxyContin, according to the court records, but documents obtained by the state in its lawsuit “show millions of dollars in earnings to Abbott.”¹²⁰

50. In an attached letter from an Abbott executive to Purdue’s vice president of marketing, Abbott pledged to take the relationship between the companies to “new heights with our positioning of OxyContin as a key component of Abbott Pain Management.”¹²¹

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

51. The sales forces of Abbott and Purdue worked in tandem. They held regular strategy sessions, alternating meeting locations between Purdue's headquarters and Abbott's corporate offices in Illinois, according to the court records.¹²²

52. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."¹²³

53. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called *A Guide to Your New Pain Medicine and How to Become a Partner Against Pain*. In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?" Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

¹²² *Id.*

¹²³ *Oxycontin: Its Use and Abuse: Hearing Before the House Subcommittee on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), available at <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm>.

54. Sales representatives marketed OxyContin as a product “to start with and to stay with.”¹²⁴ Sales representatives also received training in overcoming doctors’ concerns about addiction with talking points they knew to be untrue about the drug’s abuse potential. One of Purdue’s early training memos compared doctor visits to “firing at a target,” declaring that “[a]s you prepare to fire your ‘message,’ you need to know where to aim and what you want to hit!”¹²⁵ According to the memo, the target is physician resistance based on concern about addiction: “The physician wants pain relief for these patients without addicting them to an opioid.”¹²⁶

55. Purdue, through its unbranded website *Partners Against Pain*,¹²⁷ stated the following: “Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids.”

56. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors’ objections to prescribing opioids. The most common objection he heard about prescribing

¹²⁴ Keefe, *Empire Of Pain*, *supra* n. 112.

¹²⁵ *Pain Killer*, *supra* n. 109, at 102.

¹²⁶ *Id.*

¹²⁷ *Partners Against Pain* consists of both a website, styled as an “advocacy community” for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

OxyContin was that “it’s just too addictive.”¹²⁸ May and his coworkers were trained to “refocus” doctors on “legitimate” pain patients, and to represent that “legitimate” patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less “habit-forming” than painkillers that need to be taken every four hours.

57. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

58. With regard to addiction, Purdue’s label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have “abuse potential” and that the “risk of abuse is increased in patients with a personal or family history of substance abuse.”

59. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

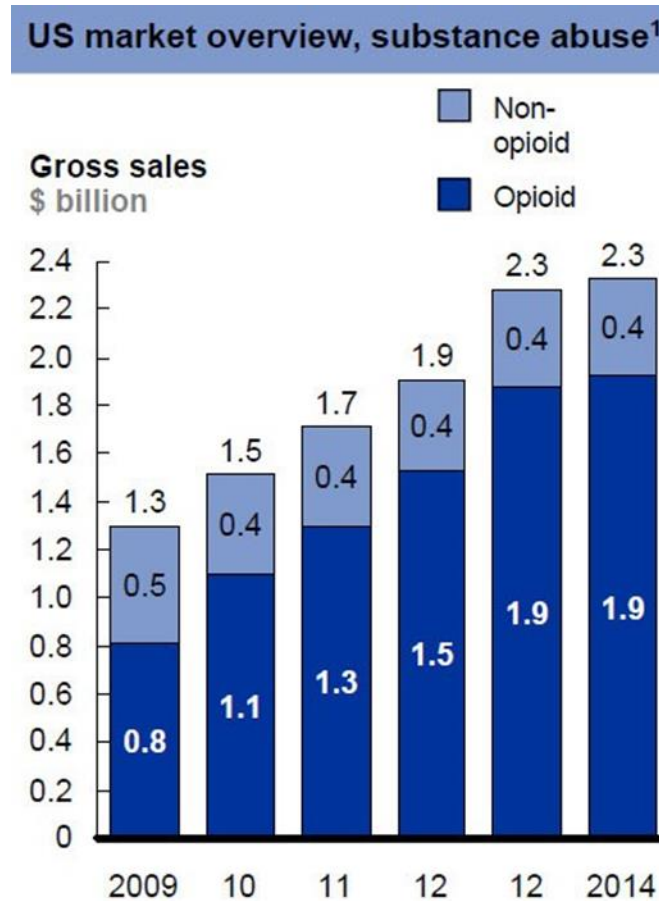
60. In 2001, Purdue revised the indication and warnings for OxyContin.

61. In the end, Purdue narrowed the recommended use of OxyContin to situations when “a continuous, around-the-clock analgesic is needed for an extended period of time” and added a warning that “[t]aking broken, chewed, or crushed OxyContin tablets” could lead to a “potentially fatal dose.” However, Purdue did not, until 2014, change the label to indicate that

¹²⁸ David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), *The New Yorker* (Oct. 27, 2017), available at <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers.

62. Purdue's awareness of the addictive properties of their opioid products is exemplified by their cynical attempts to profit from addiction treatment. In 2007, Co-Conspirator Richard Sackler filed an application for a patent for a purported treatment for opioid addiction. In September 2014, Co-Conspirator Kathe Sackler dialed in to a confidential call about Project Tango -- a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, Ms. Sackler and staff wrote down what Purdue publicly denied for decades: that addictive opioids and opioid addiction are "naturally linked." They determined that Purdue should expand across "the pain and addiction spectrum," to become "an end-to-end pain provider." Purdue illustrated the end-to-end business model with a picture of a dark hole labeled "Pain treatment" that a patient could fall into — and "Opioid addiction treatment" waiting at the bottom. Ms. Sackler and the *Project Tango* team reviewed their findings that the "market" of people addicted to opioids, measured coldly in billions of dollars, had doubled from 2009 to 2014:



Purdue's measure of the opioid addiction "market"

63. Co-Conspirator Kathe Sackler and the staff found that the catastrophe provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010." Ms. Kathe Sackler and the staff revealed in their internal documents that Purdue's tactic of blaming addiction on untrustworthy patients was a lie. Instead, the truth is that opioid addiction can happen to anyone who is prescribed opioids.

- *“This can happen to any-one – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor”*

Purdue’s “Project Tango” patient and clinical rationale

64. Ms. Kathe Sackler and the staff concluded that millions of people who became addicted to opioids were the Sackler Co-Conspirators’ next business opportunity. Staff wrote: “It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction.” The team identified eight ways that Purdue’s experience getting patients *on* opioids could now be used to sell treatment for opioid addiction.

65. In June 2017, the Sackler Co-Conspirators met to discuss a revised version of *Project Tango* - another try at profiting from the opioid crisis. This time, they considered a scheme to sell the overdose antidote NARCAN. The need for NARCAN to reverse overdoses was rising so fast that the Sackler Co-Conspirators calculated it could provide a growing source of revenue, tripling from 2016 to 2018.

b. Endo’s Misrepresentations Regarding Addiction Risk

66. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

67. Until April 2012, Endo’s website for Opana, www.opana.com, stated that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”

68. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER.

69. One of the Front Groups with which Endo worked most closely was the American Pain Foundation (“APF”), described more fully below.

70. APF conveyed through its National Initiative on Pain Control (“NIPC”) and its website www.Painknowledge.com, which claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”

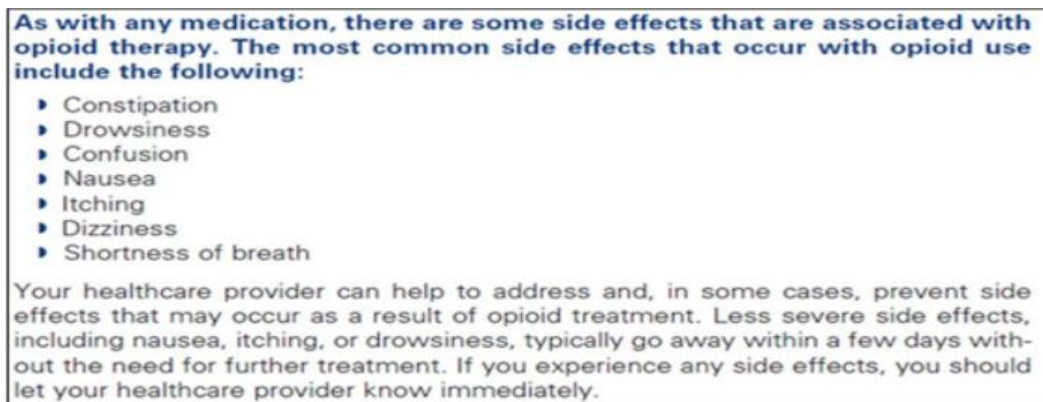
71. Another Endo website, www.PainAction.com, stated: “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”

72. A brochure available on www.Painknowledge.com titled “*Pain: Opioid Facts*,” an Endo- sponsored NIPC, stated that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.” In numerous patient education pamphlets, Endo repeated this deceptive message.

73. In a patient education pamphlet titled “*Understanding Your Pain: Taking Oral Opioid Analgesics*,” Endo answers the hypothetical patient question — “What should I know about opioids and addiction?” — by focusing on explaining what addiction is (“a chronic brain disease”) and is not (“Taking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed

for pain relief is not addiction.” This publication is still available online and was edited by KOL Dr. Russell Portenoy.¹²⁹

74. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on www.Painknowledge.com, omitted addiction from the “common risks” of opioids, as shown below:



c. Janssen’s Misrepresentations Regarding Addiction Risk

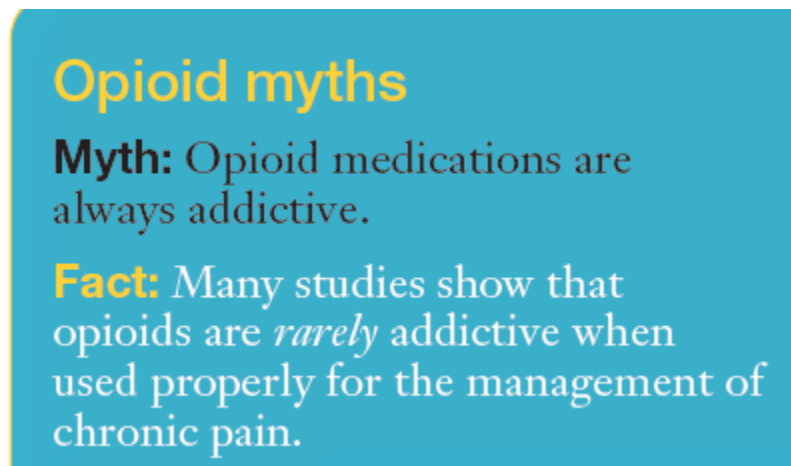
75. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let’s Talk Pain*, states, among other things, that “the stigma of drug addiction and abuse” associated with the use of opioids stemmed from a “lack of understanding addiction.”

76. The *Let’s Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as “drug seeking,” “clock watching,” and “even illicit drug use or deception” with undertreated pain which can be resolved with “effective pain management.”

¹²⁹ Margo McCaffery, RN MS, FAAN & Chris Pasero, RN, MS FAAN, *Understanding Your Pain, Taking Oral Opioid Analgesics*, available at http://www.thblack.com/links/rsd/understand_pain_opioid_analgesics.pdf (last accessed October 26, 2018)

77. A Janssen unbranded website, www.PrescribeResponsibly.com, states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”¹³⁰

78. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as “myth” that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain” (emphasis in original). Until recently, this guide was still available online.



79. Janssen’s website for Duragesic included a section addressing “Your Right to Pain Relief” and a hypothetical patient’s fear that “I’m afraid I’ll become a drug addict.” The website’s response: “Addiction is relatively rare when patients take opioids appropriately.”

d. Cephalon’s Misrepresentations Regarding Addiction Risk

80. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient’s Guide*, which included claims that “patients without a

¹³⁰ Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, available at <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

history of abuse or a family history of abuse do not commonly become addicted to opioids.” Similarly, Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

81. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the non-cancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to under treatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.¹³¹

e. Actavis’s Misrepresentations Regarding Addiction Risk

82. Through its “Learn More about customized pain control with Kadian” material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is “less likely” to happen in those who “have never had an addiction problem.” The piece goes on to advise that a need for a “dose adjustment” is the result of tolerance, and “not addiction.”

¹³¹ Michael J. Brennan, et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape (Feb. 26, 2003), available at <http://www.medscape.org/viewarticle/449803>, (last accessed July 27, 2017).

83. Training for Actavis sales representatives deceptively minimized the risk of addiction by: (i) attributing addiction to “predisposing factors” like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described below, dismisses evidence of addiction as the undertreatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.

84. Actavis conducted a market study on takeaways from prescribers’ interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives’ discussion of the low-abuse potential. Actavis’ sales representatives’ misstatements on the low- abuse potential was considered an important factor to doctors, and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives use during the visits, and Actavis noted that doctors associate Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis’s messaging about Kadian’s purported low addiction potential, and that it had less abuse potential than other similar opioids.

85. A guide for prescribers under Actavis’s copyright deceptively represented that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) “unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users,” and 2) KADIAN may be less likely to be abused by health care providers and illicit users” because of “Slow onset of action,” “Lower peak plasma morphine levels than equivalent doses of other formulations of morphine,” “Long duration of action,” and “Minimal fluctuations in peak to

trough plasma levels of morphine at steady state.” These statements convey both that (1) Kadian does not cause euphoria and therefore is less addictive and that (2) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

f. Mallinckrodt’s Misrepresentations Regarding Addiction Risk

86. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the “C.A.R.E.S. Alliance” it created and led.

87. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as “a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits.” The “C.A.R.E.S. Alliance” itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

88. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online.¹³² The false claims and misrepresentations in this book include the following statements:

¹³² Available at https://books.google.com/books?id=VcSQGYKXWdYC&printsec=frontcover&source=gbs_ViewAPI#v=snippet&q=only%20rarely%20does%20opioid%20medication&f=false

- a. “Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- b. “It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.”
- c. “When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving.”
- d. “Only a minority of chronic pain patients who are taking long-term opioids develop tolerance.”
- e. “The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- f. “Here are the facts. It is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”
- g. “Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.”

89. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, “[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated” and cites to a report that concludes that “the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others.”

90. Marketing Defendants’ and Purdue’s suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who “doctor-shop”—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid

prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

2. Falsehood #2: To the Extent There is a Risk of Addiction, It Can Be Easily Identified and Managed

91. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Marketing Defendants and Purdue assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

92. Purdue shared its *Partners Against Pain* “Pain Management Kit,” which contains several screening tools and catalogues of Purdue materials.

93. Janssen, on its website www.PrescribeResponsibly.com, states that the risk of opioid addiction “can usually be managed” through tools such as opioid agreements between patients and doctors.¹³³ The website, which directly provides screening tools to prescribers for

¹³³ Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, available at <https://web.archive.org/web/20171003105720/> (“What a Prescriber Should Know Before Writing the First Prescription”).

risk assessments,¹³⁴ includes a “[f]our question screener” to purportedly help physicians identify and address possible opioid misuse.¹³⁵

94. Purdue and Cephalon sponsored the APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can “ensure that you take the opioid as prescribed” and counseled patients that opioids “give [pain patients] a quality of life we deserve.”

95. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, entitled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.”

96. Purdue sponsored a similar 2011 CME program titled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.”

97. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

¹³⁴ Risk Assessment Resources, *PRESCRIBE RESPONSIBLY*, available at <http://www.prescriberesponsibly.com/risk-assessment-resources> (last accessed August 1, 2018).

¹³⁵ *Id.*

98. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* (ORT) created by Dr. Webster and linked to Janssen or (b) the *Screening and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. The ORT was linked to Endo-supported websites, as well.

99. There are three fundamental flaws in the Marketing Defendants' and Purdue's representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

100. The CDC Guideline confirmed the falsity of marketing Defendants' and Purdue's claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies — such as screening tools or patient contracts — "for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for

[opioid] abuse or misuse” and counseled that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”¹³⁶

3. Falsehood #3: Signs of Addictive Behavior are “Pseudoaddiction” Requiring More Opioids

101. The Marketing Defendants and Purdue instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term “pseudoaddiction,” which he characterized as “the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management.”¹³⁷ In other words, people on prescription opioids who exhibited classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain.

102. In the materials and outreach they produced, sponsored, or controlled, the Marketing Defendants and Purdue made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

103. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards’ (“FSMB”) *Responsible Opioid Prescribing* (2007) written by Dr. Scott Fishman and discussed in more detail below, which taught that behaviors such as “requesting drugs by name,” “demanding

¹³⁶ Dowell, CDC Guideline, *supra* n. 24, at 28.

¹³⁷ David E. Weissman and J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) *Pain* 363-66 (Mar. 1989) available at <https://www.ncbi.nlm.nih.gov/pubmed/2710565> (“Iatrogenic” describes a condition induced by medical treatment).

or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of “pseudoaddiction.”

104. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *PartnersAgainstPain.com*, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including “illicit drug use and deception” that it claimed was not evidence of true addiction but “pseudoaddiction” caused by untreated pain:

A term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may ‘clock watch,’ and may otherwise seem inappropriately ‘drug-seeking.’ Even such behaviors as illicit drug use and deception can occur in the patient’s efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.

105. Purdue again urged doctors to prescribe higher doses, stating that opioids “are frequently underdosed - or even withheld due to a widespread lack of information ... about their use among healthcare professionals.”

106. Purdue’s *Pain Management Kit* is another example of publication used by Purdue’s sales force that endorses pseudoaddiction by claiming that “pain-relief seeking behavior can be mistaken for drug-seeking behavior.” In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the kit was in use from roughly 2011 through at least June 2016.

107. A Purdue presentation for doctors titled *Medication Therapy Management* recited what had been the consensus view for decades: “Many medical students are taught that if opioids are prescribed in high doses or for a prolonged time, the patient will become an addict.” Purdue then assured doctors that this traditional concern about addiction was wrong — that patients

instead suffer from “pseudoaddiction” because “opioids are frequently prescribed in doses that are inadequate.” Doctors on Purdue’s payroll admitted in writing that pseudoaddiction was used to describe “behaviors that are clearly characterized as drug abuse” and put Purdue at risk of “ignoring” addiction and “sanctioning abuse.” Purdue, nevertheless, urged doctors to respond to signs of addiction by prescribing higher doses of Purdue’s drugs.

108. Purdue publications touting the concept of “pseudoaddiction” were regularly provided to the Purdue Individual Co-Conspirators by Purdue staff. Staff also regularly reported on the distribution of such materials to the Purdue Individuals.

109. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed “[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction” as an element to be considered in awarding grants to CME providers.

110. Endo itself has repudiated the concept of pseudoaddiction. In finding that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the New York Attorney General, in a 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’”¹³⁸ Endo thereafter agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York.

¹³⁸ Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc., Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7, *available at* https://www.ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

111. The FAQs section of *www.pain-topics.org*, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to “keep in mind” that signs of potential drug diversion, rather than signaling “actual” addiction, “may represent pseudoaddiction,” which the website described as behavior that occurs in patients when pain is “undertreated” and includes patients becoming “very focused on obtaining opioid medications and may be erroneously perceived as ‘drug seeking.’”

112. Janssen sponsored, funded, and edited a website called *Let’s Talk Pain*, which in 2009 stated “pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.” This website was accessible online until at least May 2012. Janssen also currently runs a website, *www.Prescriberresponsibly.com*, which claims that concerns about opioid addiction are “overestimated,” and describes pseudoaddiction as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases.”¹³⁹

113. Marketing Defendants and Purdue also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

114. The CDC Guideline for prescribing opioids for chronic pain, a “systematic review of the best available evidence” by a panel excluding experts with conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends opioid doses be increased if a

¹³⁹ *What a Prescriber Should Know Before Writing the First Prescription*, *supra* n. 133.

patient is not experiencing pain relief. To the contrary, the Guideline explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”¹⁴⁰

115. Dr. Lynn Webster, a KOL discussed below, admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

4. Falsehood #4: Blaming Addicted Patients as “Untrustworthy” “Abusers”

116. A recurring strategy employed by the Purdue Individual Co-Conspirators, over a period of decades, was to blame any negative consequences from opioid use on moral failings of a minority of users, who would be labeled as “abusers” or “untrustworthy” people.

117. In 2001, Co-Conspirator Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death: blame and stigmatize people who become addicted to opioids. Richard Sackler wrote in a confidential email: “we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.” The Sackler Co-Conspirators chose to stigmatize people who were hurt by opioids, calling them “junkies” and “criminals.”

118. In December 2011, Co-Conspirator John Stewart gave a speech titled Providing Relief, Preventing Abuse in Connecticut, which deceptively blamed the addiction, overdose, and death on “abuse.” A Purdue pamphlet titled “*Responsible Opioid Prescribing*” told doctors that

¹⁴⁰ Dowell, CDC Guideline, *supra* n. 24, at 13.

only “a small minority of people seeking treatment may not be reliable or trustworthy” and not suitable for addictive opioid drugs.

119. Purdue managers praised sales representatives for pitching doctors on the idea that prescribing to “trustworthy” patients was safe. A sales rep reported that one doctor: “let me know that she will Rx OxyContin when the pts [patients] has chronic pain and are trustworthy.” The rep added that he would “Follow up with Dr and ask what pts does she consider ‘trust worthy?’” A Purdue district manager responded: “Great follow up question on what patients does he consider trustworthy.”

120. Purdue managers praised sales representatives for pitching doctors on the idea that prescribing to “trustworthy” patients was safe. Co-Conspirator Richard Sackler, in a 2007 patent application he filed for a purported treatment for opioid addiction, referred to addicts as “junkies.” In the application, he asks for a monopoly on the treatment of addicts. He received the patent in January 2018.

5. Falsehood #5: Opioid Withdrawal Can Be Avoided by Tapering

121. In an effort to underplay the risk and impact of addiction, the Marketing Defendants and Purdue falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering a patient’s dose to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

122. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days.

123. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

124. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

125. To this day, the Marketing Defendants and Purdue have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

6. Falsehood #6: Opioid Doses Can Be Increased Without Limit or Greater Risk

126. In materials they produced, sponsored or controlled, Marketing Defendants and Purdue instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Marketing Defendants' and Purdue's claims was deceptive in that they omitted warnings of increased adverse effects that occur at higher doses that were confirmed by scientific evidence.

127. These misrepresentations were integral to the Marketing Defendants' and Purdue's promotion of prescription opioids. As discussed above, patients develop a tolerance to

opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. Patients who take larger doses, and who escalate to larger doses faster, are much more likely to remain on opioids for a longer period of time, resulting in increased revenue.

128. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."

The next week the representative would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Stronger doses were more expensive and increased the likelihood of addiction.

129. These misrepresentations were particularly dangerous. Opioid doses at or above 50 MME (morphine milligram equivalents)/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

130. In its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be

increased by 25% to 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration.”¹⁴¹

131. Purdue, for years, used a marketing theme dubbed “Individualize the Dose,” which was a euphemism for “Increase the Dose,” as a means of propounding the false notion that increasing doses of painkillers was in patients’ best interests. Staff regularly reported to the Sackler Co-Conspirators that Purdue’s sales representatives were continuing the *Individualize the Dose* campaign.

132. Endo sponsored a website, www.Painknowledge.com, which claimed that opioids may be increased until “you are on the right dose of medication for your pain,” at which point further dose increases would not be required.

133. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased . . . You won’t ‘run out’ of pain relief.”

134. Marketing Defendants and Purdue were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events” and that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.” A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

¹⁴¹ Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., available at <https://web.archive.org/web/2/https://www.fda.gov/downloads/Drugs/DrugSafet%20y/Postmarke%20DrugSafetyInformationforPatientsandProviders/UCM220990.pdf>, (last modified Nov. 2010).

7. **Falsehood #7: Long-Term Opioid Use Improves Functioning**

135. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants and Purdue consistently promoted opioids for patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

136. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork, uninterrupted," "[l]ife, uninterrupted," "[g]ame, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] . . . physical and social functioning."

137. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine. . . . We do not have such data to support OxyContin promotion In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.¹⁴²

138. Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users' function. This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your

¹⁴² *Pain Killer*, *supra* n. 109, at 281.

November ad would tout ‘Life With Relief’ yet fail to warn that patients can die from taking OxyContin.”¹⁴³

139. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids.”

140. A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes”—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively.

141. Similarly, since at least May of 2011, Endo has distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

142. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through

¹⁴³ Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, WALL STREET JOURNAL (Jan. 23, 2003, 12:01am), available at <https://www.wsj.com/articles/SB1043259665976915824>.

the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’” Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online.

143. In addition, Janssen’s *Let’s Talk Pain* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to “continue to function,” falsely implying that her experience would be representative.

144. Endo’s NIPC website, www.Painknowledge.com, claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” In addition to “improved function,” the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make claims of functional improvement.

145. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

146. Mallinckrodt’s website, in a section on responsible use of opioids, claims that “[t]he effective pain management offered by our medicines helps enable patients to stay in the

workplace, enjoy interactions with family and friends, and remain an active member of society.”¹⁴⁴

147. The Marketing Defendants’ and Purdue’s claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients’ function and quality of life.¹⁴⁵ Based upon a review of the existing scientific evidence, the CDC Guideline concluded that “there is no good evidence that opioids improve pain or function with long-term use.”¹⁴⁶

148. Consistent with the CDC’s findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients’ health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term

¹⁴⁴ Mallinckrodt Pharmaceuticals, Responsible Use, *available at* <http://www.mallinckrodt.com/corporate-responsibility/responsible-use>, (last accessed July 16, 2018).

¹⁴⁵ The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis’ opioid, Kadian, had an “overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that “patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”). The FDA’s warning letters were available to Defendants on the FDA website.

¹⁴⁶ Dowell, CDC Guideline, *supra* n. 24, at 20.

studies of opioid use had “consistently poor results,” and “several studies have showed that Opioids for chronic pain may actually worsen pain and functioning . . .”¹⁴⁷ along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

149. On the contrary, the available evidence indicates opioids may worsen patients’ health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.”¹⁴⁸ According to the CDC, “for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”¹⁴⁹

150. Assessing existing evidence, the CDC Guideline found that there is “insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain.”¹⁵⁰ In fact, the CDC found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-

¹⁴⁷ Thomas Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med., 4/21/16, at 1503. (April 21, 2016).

¹⁴⁸ Dowell, CDC Guideline, *supra* n. 24, at 2, 18.

¹⁴⁹ Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med. 1501-1504 (Apr. 21, 2016), doi: 10.1056/NEJMp1515917, available at <http://www.nejm.org/doi/full/10.1056/NEJMp1515917>.

¹⁵⁰ Dowell, CDC Guideline, *supra* n. 24, at 10.

controlled randomized trials $\leq$ 6 weeks in duration)”¹⁵¹ and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well- controlled studies of opioids use longer than 12 weeks.”¹⁵² As a result, the CDC recommends that opioids not be used in the first instance and for treatment of chronic pain; rather, opioids should be used only after prescribers have exhausted alternative treatments. Nevertheless, upon information and belief, Marketing Defendants and Purdue touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

151. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.”¹⁵³ In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.¹⁵⁴ Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six

¹⁵¹ Dowell, CDC Guideline, *supra* n. 24, at 9.

¹⁵² Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013), at 10.

¹⁵³ Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at <http://www.nbcms.org/en-us/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747>.

¹⁵⁴ Jeffrey Dersh, *et al.*, *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) *Spine* 2219-27 (Sept. 15, 2008), available at <https://www.ncbi.nlm.nih.gov/pubmed/18725868>.

weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.¹⁵⁵ Yet, Marketing Defendants and Purdue have not acknowledged, retracted, or corrected their false statements.

8. Falsehood #8: Alternative Forms of Pain Relief Pose Greater Risks Than Opioids

152. In materials they produced, sponsored or controlled, the Marketing Defendants and Purdue omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription non-steroidal anti-inflammatory drugs (“NSAIDs”).

153. For example, in addition to failing to disclose the risks of addiction, overdose, and death in promotional materials, the Marketing Defendants and Purdue routinely ignored the risks of hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time,”¹⁵⁶ hormonal dysfunction,¹⁵⁷ decline in immune function; mental clouding, confusion, and dizziness, increased falls and fractures in the elderly;¹⁵⁸ NAS (when an infant exposed to opioids prenatally suffers

¹⁵⁵ Franklin, GM, *et al.*, *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199, 201-202 (Jan. 15, 2008) doi: 10.1097/BRS.0b013e318160455c, available at <https://www.ncbi.nlm.nih.gov/pubmed/18197107>.

¹⁵⁶ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

¹⁵⁷ H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001), available at <https://www.ncbi.nlm.nih.gov/pubmed/14622741>.

¹⁵⁸ See Bernhard M. Kuschel, *et al.*, *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, 25 Eur. J. Pub. H. 527-32

withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.¹⁵⁹

154. The APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Teva, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is actually closer to 3,200.¹⁶⁰

155. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009) that listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks from increased doses of opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

156. Endo's NIPC website, www.Painknowledge.org, contained a flyer called "Pain: Opioid Therapy." This publication listed opioids' adverse effects but with significant omissions,

(July 31, 2014), doi: 10.1093/eurpub/cku120, available at <https://www.ncbi.nlm.nih.gov/pubmed/25085470>.

¹⁵⁹ Karen H. Seal, et al., *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940-47, (March 7, 2012) doi:10.1001/jama.2012.234, available at <https://jamanetwork.com/journals/jama/fullarticle/1105046>.

¹⁶⁰ Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004), available at <https://www.ncbi.nlm.nih.gov/pubmed/14704592>.

including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

157. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled “Case Challenges in Pain Management: Opioid Therapy for Chronic Pain.”¹⁶¹ The article asserted:

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.¹⁶²

158. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

159. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

¹⁶¹ Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, *Pain Med. News*, available at http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf.

¹⁶² *Id.*

160. As a result of the Marketing Defendants' and Purdue's deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.¹⁶³

9. Falsehood #9: OxyContin Provides Twelve Hours of Pain Relief

161. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provided the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

162. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials.

¹⁶³ M. Daubresse, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013) available at <https://insights.ovid.com/pubmed?pmid=24025657> ("For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady."). See also, J. Mafi, *et al.*, *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013) available at <https://www.ncbi.nlm.nih.gov/pubmed/23896698>.

OxyContin PI Figure, Linear y-axis

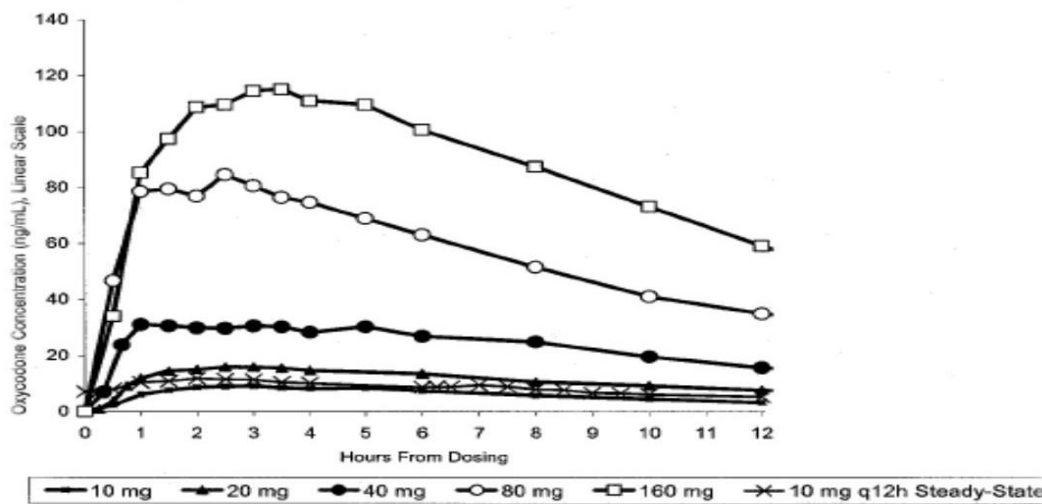


Figure 1

163. The reduced release of the drug over time means that the OxyContin no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promoted it — a fact that Purdue had known at all times relevant to this action.

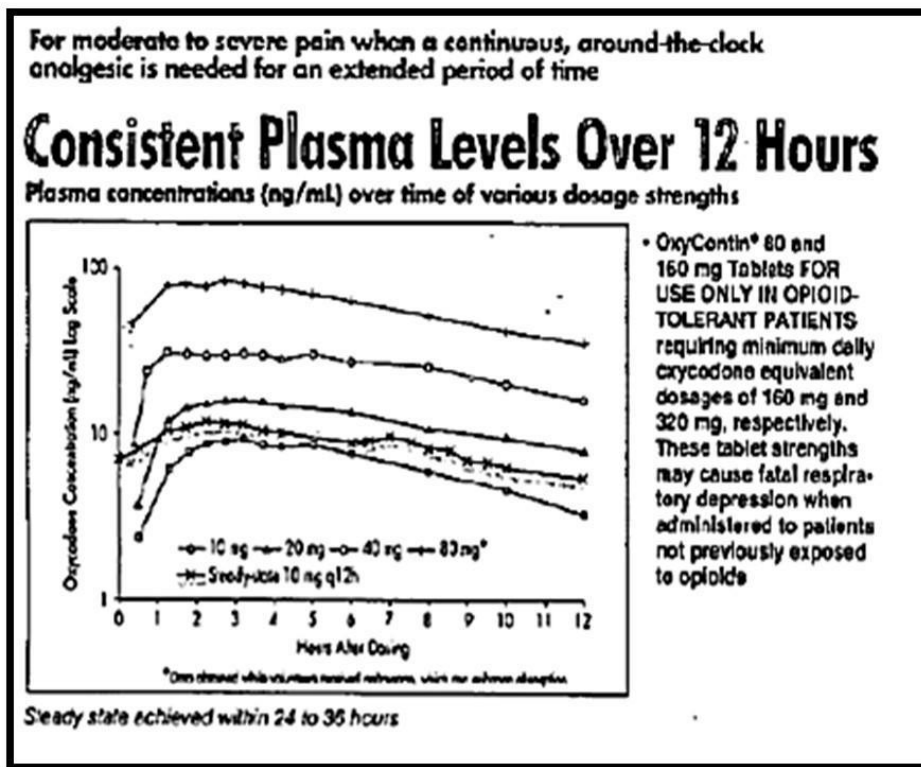
164. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug's not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure. (The FDA found in 2008 that a "substantial number" of chronic pain patients will experience end-of-dose failure with OxyContin.)

165. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin’s 12-hour dosing “the perfect recipe for addiction.”¹⁶⁴ Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall quantity of opioids they are taking.

166. It was Purdue’s decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that “[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours,” that is because Purdue has conducted no such studies.

167. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides “Consistent Plasma Levels Over 12 Hours.” That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table’s y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:

¹⁶⁴ Harriet Ryan, *et al.*, ‘*You Want a Description of Hell?*’ *OxyContin’s 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (“*You Want a Description of Hell?*”).



168. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."¹⁶⁵

169. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of

¹⁶⁵ Purdue Meeting Memo, *OxyContin launch*, LOS ANGELES TIMES (May 5, 2016), available at <http://documents.latimes.com/oxycontin-launch-1995/>.

acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. Higher Dosing also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the LOS ANGELES TIMES, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED (morphine equivalent dose) that the CDC Guideline urges prescribers to “avoid” or “carefully justify.”¹⁶⁶

170. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue’s competitors, but was not disclosed to prescribers. Purdue’s knowledge of some pain specialists’ tendency to prescribe OxyContin three times per day instead of two is apparent from MEDWATCH Adverse Event reports for OxyContin.

171. Even Purdue’s competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering “durable” pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists’ citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to “real” 12-hour dosing.

172. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should “convinc[e] the physician that there is no need” for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and

¹⁶⁶ Dowell, CDC Guideline, *supra* n. 24, at 16.

instead the solution is prescribing higher doses.”¹⁶⁷ One sales manager instructed her team that anything shorter than 12-hour dosing “needs to be nipped in the bud. NOW!!”¹⁶⁸

173. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue’s competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

10. Falsehood #10: New Formulations of Certain Opioids Successfully Deter Abuse

174. Rather than take the widespread abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as an opportunity to compete. These companies developed and oversold “abuse-deterrent formulations” (“ADF”) opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants’ false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

175. The CDC Guideline confirms that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting

¹⁶⁷ Southern Region Memo to Mr. B. Gergely, *Sales manager on 12-hour dosing*, LOS ANGELES TIMES (May 5, 2016), available at <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/>.

¹⁶⁸ *You Want a Description of Hell?*, *supra* n. 164.

that the technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes.” Tom Frieden, the former Director of the CDC, reported that his staff could not find “any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death.”

a. **Purdue’s Deceptive Marketing of Reformulated OxyContin and Hysingla ER**

176. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

177. Purdue introduced reformulated ADF OxyContin shortly before generic versions of OxyContin were to become available. By so doing, Purdue anticipated and countered a threat to its market share and the price it could charge for OxyContin. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

178. Internal documents reveal that Purdue knew, and in fact discussed, the fact that the “crush-proof” ADF reformulation would not prevent the vast majority of opioid abuse, which comes from swallowing pills, and that they introduced the product solely for purposes of extending their patent. In 2008, Purdue’s then CEO, wrote to Defendant Richard Sackler that reformulating OxyContin “will not stop patients from the simple act of taking too many pills.”

179. Despite its self-proclaimed good intention, Purdue merely continued its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

- a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;
- b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;
- c. asserted or suggested that its ADF opioids are non-addictive or less addictive;
- d. asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and
- e. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

180. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

181. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with.

182. In 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to

OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

183. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to do so orally after the reformulation rather than shift to other drugs.

184. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but ignored important negative findings. The article revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were more harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

185. Websites and message boards used by drug abusers, such as www.bluelight.org and www.reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

186. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

187. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue “evaluating the misuse and/or abuse of reformulated OxyContin” and whether those studies “have demonstrated that the reformulated product has a meaningful impact on abuse.”¹⁶⁹ In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin’s ADF properties reduced abuse or misuse.

188. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue’s ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue’s ADF opioids are being abused in large numbers. Purdue’s recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

b. Endo’s Deceptive Marketing of Reformulated Opana ER

189. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower “bioavailability” than other opioids, meaning that the active pharmaceutical ingredient (the “API” or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism

¹⁶⁹ Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

190. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

191. Even prior to its approval, the FDA advised Endo that it could not market the new Opana ER as abuse-deterrent.

192. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant to injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

193. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to \$135 million per year. Endo also claimed that if the FDA did not block generic competition, \$125 million, the amount Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.¹⁷⁰ The FDA responded that:

¹⁷⁰ Pl's Opp. to Defs.' and Intervenor's Mots. to Dismiss and Pl's Reply in Supp. of Mot. for Prelim. Inj. ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).

“Endo’s true interest in expedited FDA consideration stems from business concerns rather than protection of the public health.”¹⁷¹

194. Despite Endo’s purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be “proud” that “almost all remaining inventory” of the original Opana ER had “been utilized.”¹⁷²

195. In its citizen petition, Endo asserted that redesigned Opana ER had “safety advantages.” Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, “where children unintentionally chew the tablets prior to an accidental ingestion.”¹⁷³

196. However, in a 2013 decision rejecting the petition, the FDA found that “study data show that the reformulated version’s extended-release features can be compromised when subjected to ... cutting, grinding, or chewing.” The FDA also determined that “reformulated Opana ER” could also be “readily prepared for injections and more easily injected[.]” In fact, the FDA warned that preliminary data—including in Endo’s own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

¹⁷¹ Defs.’ Resp. to the Court’s November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

¹⁷² *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).

¹⁷³ Citizens Petition, FDA Docket 2012-8-0895, at 2.

197. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER has increased by more than 500%. Endo's own data, presented in 2014, found that between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.¹⁷⁴ The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

198. Publicly, Endo sought to minimize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Ohio from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

199. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

200. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the

¹⁷⁴ Theresa Cassidy, *et al.*, *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Inflexxion (Sept. 7, 2014)), available at <https://www.inflexxion.com/changing-abuse-ecology-extended-release-oxymorphone/>.

advantages of Opana ER, according to participating doctors, was its “low abuse potential.” For example, a June 14, 2012 Endo press release announced “the completion of the company’s transition of its Opana ER franchise to the new formulation designed to be crush resistant.”

201. The press release further stated that: “We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers. The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed “INTAC Technology” and continued to describe the drug as “designed to be crush-resistant.”

202. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was “designed to be crush resistant.” A January 2013 article in *Pain Medicine News*, based in part on an Endo press release, described Opana ER as “crush-resistant.” This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

203. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of Opana, the first documented HIV outbreak in the United States associated with injection of a prescription painkiller.

204. In March 2017, because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.¹⁷⁵ Endo

¹⁷⁵ FDA requests removal of Opana ER, *supra* n. 80.

announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER.¹⁷⁶ However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it “has taken significant steps over the years to combat misuse and abuse.”

**c. Other Marketing Defendants’ and Purdue’s
Misrepresentations Regarding Abuse Deterrence**

205. A guide for prescribers under Actavis’s copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide declares that “unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users,” and “KADIAN may be less likely to be abused by health care providers and illicit users” because of its “[s]low onset of action.” Kadian, however, was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

206. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt’s promotional materials stated that “the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving.”¹⁷⁷ One member of the FDA’s Controlled Substance Staff, however, noted in 2010 that hydromorphone has “a high abuse potential comparable to oxycodone” and further stated that “we predict that Exalgo will have high levels of abuse and diversion.”

¹⁷⁶ Endo Provides Update on Opana ER, (July 6, 2017), *supra* n. 81.

¹⁷⁷ Mallinckrodt Press Release, Medtronic, *FDA Approves Mallinckrodt’s EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), available at <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159>

207. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."¹⁷⁸ In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."¹⁷⁹

208. While Marketing Defendants and Purdue promoted patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

209. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was either not supported by or was contrary to the scientific evidence. In addition, the Defendants' misrepresentations and omissions as set in this Complaint are misleading and contrary to the Marketing Defendants' and Purdue's products' labels.

B. The Marketing Defendants and Purdue Directly Targeted Hospitals

210. From the beginning, hospitals were directly targeted by the Marketing Defendants. Internal documents from the 1995 "OxyContin Launch" orchestrated by Defendants Purdue and Abbott (1) identified "hospital pharmacists" as among their "audience," (2) identified "hospitals" among their "institutional targets," (3) identified an objective of "[f]ormulary

¹⁷⁸ Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

¹⁷⁹ Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, ST. LOUIS BUSINESS JOURNAL (Dec. 30, 2013), available at <http://argentscapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>.

acceptance in 75% of hospitals for first twelve months,” and (4) identified an objective of developing a “successful distribution program” to “hospitals.”

211. In 1996, Purdue made a deal with Defendant Abbott under which Abbott’s sales force would promote Purdue’s lead opioid, OxyContin, in hospitals. Abbott’s co-promotion of OxyContin was, in the words of Abbott’s counsel, by terms of its contract, dedicated to “hospitals, surgical centers and hospital-based surgeons.” Promoting the use of OxyContin for “postoperative pain” and “support[ing] the Abbott agreement” were paramount objectives identified in Purdue’s internal documents. “Abbott and Purdue consciously targeted hospitals. [Purdue] representatives will work with their Abbott counterparts to make calls on all Pharmacy and Therapeutic (P&T) communities.” “[S]ales force will provide the *appropriate* clinical data necessary to continue to add OxyContin Tablets to hospital formularies.”¹⁸⁰

212. Initial plans called for marketing to “[a]ll 1,200 cancer centers,” “[a]ll 1,200 major teaching institutions,” and “[a]ll 2,500 community hospitals with $\geq$ 100 beds.” The hospital marketing plan further entailed the following actions:

- a. The Purdue Frederick sales force should call on all hospital P&T committees to gain hospital formulary acceptance during the first three months of launch. This effort would entail contacting directors of pharmacies in an effort to gain formulary acceptance of OxyContin.
- b. Educate MD’s/RN’s/RPH’s regarding the advantages of OxyContin over other Step 2 opioids for cancer patients. The promotional effort should focus on the ease of use and the reduced administration time. If available,

¹⁸⁰ 2002 Purdue Budget Plan, *available at* <https://khn.org/news/purdue-and-the-oxycontin-files/> (last visited Aug. 20, 2018) (emphasis added).

clinical outcomes studies, showing improved quality of life and cost effectiveness, should be used to convince the house staff to use OxyContin as their opioid of choice.

- c. Educational lectures should be held through the Speakers' Bureau program during grand rounds, tumor boards, etc. The Purdue Frederick Speakers' Bureau should educate the house staff about the benefits of OxyContin, while presenting clinical study data.
- d. Educational symposia should be conducted through the use of satellite teleconferencing to various cancer centers and major teaching institutions across the country, offering CME credits to MD's/RN's/RPH's and focus on the implementation of the AHCPR Clinical Practice Guideline for the Management of Cancer Pain and the results of clinical trials with OxyContin.
- e. Target the top 100 MS CONTIN/Duragesic hospitals and offer them a special pain management day where our OxyContin clinical investigators will train the staff on the use of OxyContin.

213. Defendant Abbott, in a 1997 document, indicated that prescriptions written by "Abbott MD's" comprised 25% of all OxyContin prescriptions. In addition, Purdue's budget records reveal details of the payments to Abbott for its OxyContin work, which were termed "commissions." From 1996 through 2002, Abbott was paid \$374 million in commissions, according to those documents. Total sales of the drug during that time were nearly \$5 billion. From 2003 to 2006, OxyContin sales were nearly \$6 billion. From 1996 to 2005, inclusive, Abbott's "commissions" exceeded \$500 million.

214. The importance of targeting hospital emergency rooms was illustrated by a study that demonstrated that patients who receive an opiate prescription within 7 days of surgery are 44% more likely to still be using the medication one year after surgery than patients who do not receive an opioid prescription.”¹⁸¹

C. The Marketing Defendants and Purdue Disseminated Their Misleading Messages About Opioids Through Multiple Direct and Indirect Channels

215. The Marketing Defendants and Purdue utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) direct, targeted communications with prescribers by sales representatives or “detailers;” (2) “Front Groups” with the appearance of independence from the Marketing Defendants and Purdue; (3) so-called KOLs, that is, doctors who were paid by the Marketing Defendants and Purdue to promote their pro-opioid message; (4) disseminating their misleading messages through reputable organizations; (5) CME programs controlled and/or funded by the Marketing Defendants and Purdue; (6) branded advertising; (7) unbranded advertising; (8) publications; and (9) speakers bureaus and programs.

1. The Marketing Defendants and Purdue Used “Detailers” To Directly Disseminate Their Misrepresentations to Prescribers

216. The Marketing Defendants’ and Purdue’s sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors and hospitals with centrally orchestrated messages. The Marketing Defendants’ and Purdue’s sales representatives also distributed third-party marketing material to their target audience that was deceptive. The Marketing Defendants’ and Purdue’s direct contact with

¹⁸¹ Cheryl Genord et al., *Opioid exit plan: A pharmacist’s role in managing acute postoperative pain*, Journal of the American Pharmacists Association (Jan. 2017), at 593, available at [https://www.japha.org/article/S1544-3191\(17\)30016-X/fulltext](https://www.japha.org/article/S1544-3191(17)30016-X/fulltext) (“Opioid Exit Plan”).

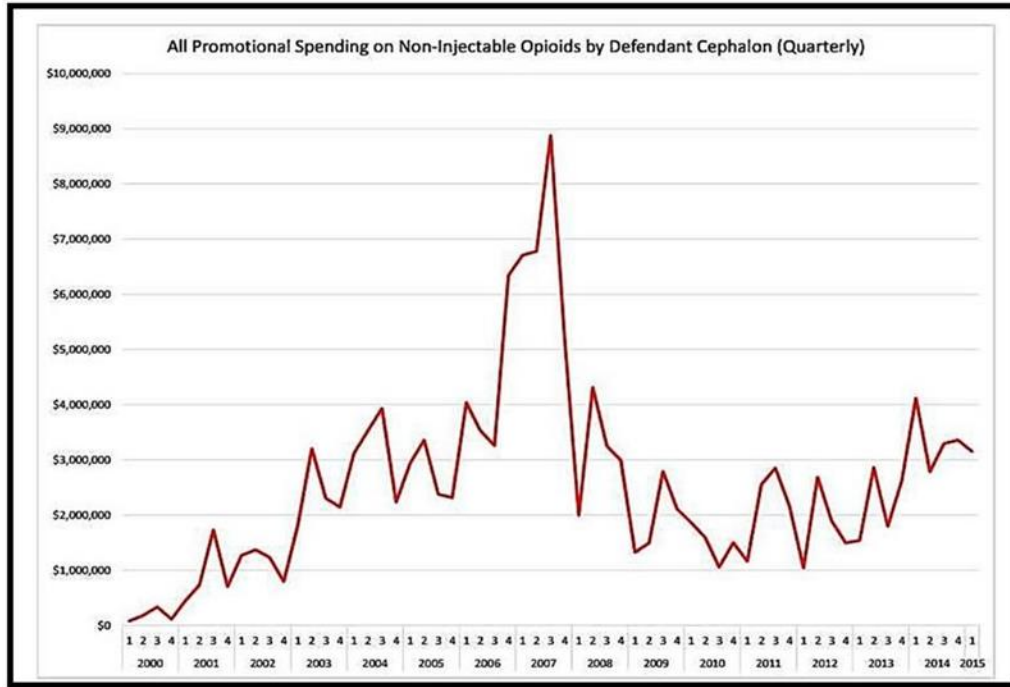
prescribers was, by far, their most important means of disseminating the False Narrative and increasing opioid prescriptions, and, accordingly, their sales.

217. Each Marketing Defendant and Purdue promoted opioids through sales representatives (also called “detailers”) and, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that small group speaker programs were designed to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants and Purdue were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

218. In accordance with common industry practice, the Marketing Defendants purchased and closely analyzed prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allowed them to precisely track the rates of initial and renewal prescribing by individual doctors, which allowed them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

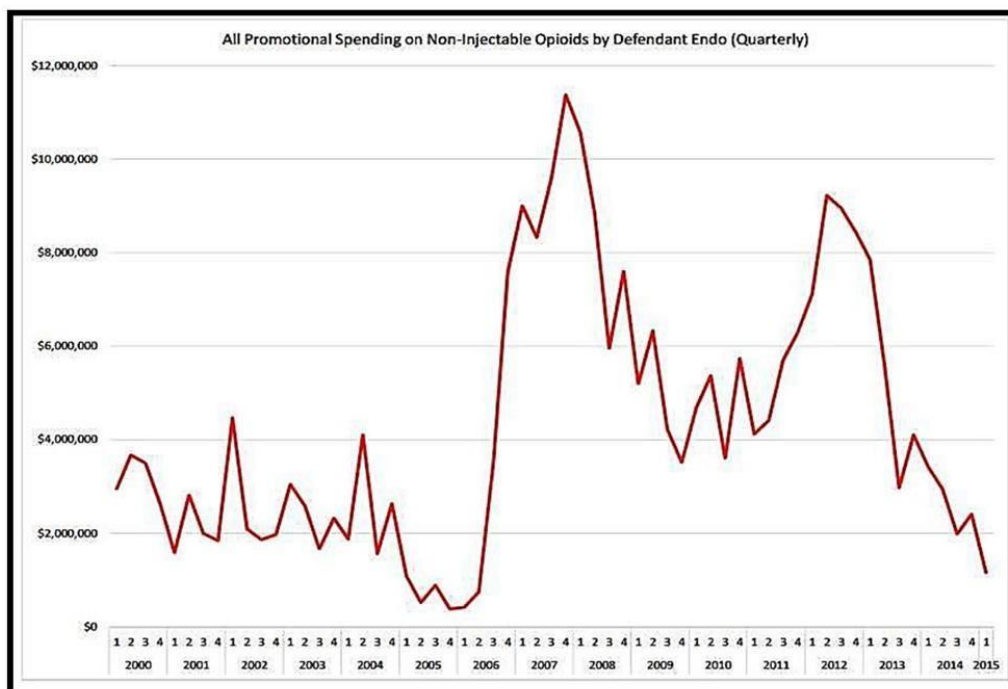
219. Marketing Defendants and Purdue devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants and Purdue spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants and Purdue spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.

220. Cephalon’s quarterly spending steadily climbed from below \$1 million in 2000 to more than \$3 million in 2014 (and more than \$13 million for the year), with a peak, coinciding with the launch of Fentora, of more than \$27 million in 2007, as shown below:

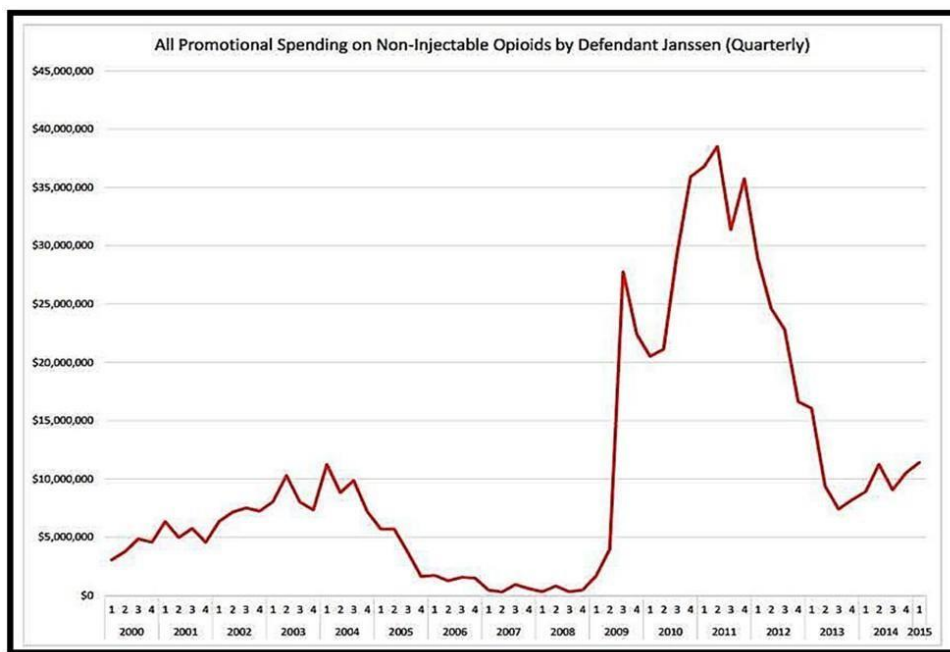


221. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

222. Endo's quarterly spending went from the \$2 million to \$4 million range in 2000-2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38 million for the year in 2007) and more than \$8 million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year), as shown below:



223. Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011), as shown below:



224. Abbott, which was tasked with marketing Purdue's products to hospitals, heavily incentivized its staff to push OxyContin, offering \$20,000 cash prizes and luxury vacations to top performers. Abbott's almost religious zeal to sell the drug is evident in the wide use of terminology from the Middle Ages Crusades: Sales reps were called "royal crusaders" and "knights" in internal documents, and they were supervised by the "Royal Court of OxyContin" – executives referred to in memos as the "Wizard of OxyContin," "Supreme Sovereign of Pain Management," and the "Empress of Analgesia." The head of pain care sales, Jerry Eichhorn, was the "King of Pain," and signed memos simply as "King."



225. At Purdue, aggressive and frequent visits to prescribers was always its most important marketing technique. The Sackler Co-Conspirators set targets for each representative to visit over 7 prescribers per day, and closely monitored actual data. Some doctors were visited multiple times per week. The pressure on sales representatives, and on prescribers, was relentless, and was dictated by the Sackler Co-Conspirators.

226. Each of these in-person sales visits cost Purdue money — on average more than \$200 per visit. But Purdue made that money back many times over, because it convinced doctors to prescribe its addictive drugs. When Purdue identified a doctor as a profitable target, Purdue visited the doctor frequently: often weekly, sometimes almost every day. Purdue salespeople, asked doctors to list specific patients they were scheduled to see and pressed the doctors to commit to put the patients on Purdue opioids. By the time a patient walked into a clinic, the doctor, in Purdue’s words, had already “guaranteed” that he would prescribe Purdue’s drugs.

227. Purdue judged its sales representatives by how many opioids they got doctors to prescribe. Sales representatives who generated the most prescriptions won bonuses and prizes. These incentives included a “Toppers Club sales contest” for sales representatives to win bonuses, based on how much a representative increased OxyContin use in her territory and how much the representative increased the broader prescribing of opioids — the same “availability of product” and “prescribing practices” factors that worsen the risk of diversion and abuse.

228. Purdue continued to incentivize its representatives to sell opioids even after some competitors had ended that practice. Representatives who failed to get enough patients on opioids were placed on probation, put on performance improvement plans, and they would be threatened with loss of their jobs if they did not generate more opioid sales. Those unable to generate more sales were fired. In 2015 alone, Purdue replaced 14% of its sales representatives and 20% of its District Managers for failing to create enough opioid sales.

229. Sales representatives focused on prolific (and potentially prolific) prescribers, described internally at Purdue as “core,” “super core,” and “high potential” prescribers at times, even though the Marketing Defendants and Purdue were all well aware of the heightened risk of improper prescriptions and diversion through these prescribers. Purdue Co-Conspirator Richard

Sackler once chastised his senior marketing officer, Co-Conspirator Gasdia, for Purdue's managers permitting sales representatives to target "non-high potential prescribers," asking "[h]ow can our managers have allowed this to happen?" Co-Conspirator Richard Sackler personally insisted that sales representatives push the doctors who prescribed the most drugs.

230. To make sure doctors prescribed more opioids, Purdue tracked doctors' prescriptions, visited their offices, bought them meals, and asked them to put specific patients on Purdue drugs. Purdue selected doctors for target lists based on its estimates of which doctors could be influenced to increase opioid prescriptions the most. Purdue managers told representatives to visit most often the doctors who were most likely to change their prescribing to benefit Purdue. Purdue Sales representatives visited Purdue's targets, including top targets in Kentucky. Those visits cost Purdue more than \$40,000 for each doctor. Purdue did not spend \$40,000 per doctor so sales representatives could watch doctors write prescriptions that they were already going to write anyway. Instead, Purdue paid to lobby these doctors because Purdue knew its representatives would convince them to put more patients on opioids, at higher doses, for longer periods. Those extra prescriptions paid back Purdue's investment many times over.

231. Compared to Kentucky doctors and nurses who prescribed Purdue opioids without lobbying from sales reps, Purdue's top targets wrote far more dangerous prescriptions. Purdue's top targets prescribed Purdue opioids to more of their patients, at higher doses, and for longer periods of time. Compared to doctors and nurses who prescribed Purdue opioids without seeing reps, Purdue's top targets were ***at least ten times more likely*** to prescribe Purdue opioids to patients who overdosed and died.

232. As of the fourth quarter of 2013, Purdue employed 632 sales representatives and, during that quarter they visited prescribers 176,227 times – an annualized rate of over 700,000

visits. These statistics were regularly reported to the Sackler Co-Conspirators and Purdue Officer Co-Conspirators. Purdue's budget for Sales and Promotion for 2013 was \$312,563,000. In 2013, Purdue spent over \$9 million on meals alone for its prescribers.

233. The sales visits of its staff were so important to the Sackler Co-Conspirators that Co-Conspirator Richard Sackler himself went into the field in 2013 to promote opioids to doctors alongside a sales representative. Co-Conspirator Gasdia and Purdue's Chief Compliance Officer were well aware that this was "a potential compliance risk." To make sure the Sackler Co-Conspirators' involvement in marketing stayed secret, staff instructed: "Richard needs to be mum and be anonymous." When he returned, Richard Sackler argued to the Vice President of Sales that a legally required warning about Purdue's opioids wasn't needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." Richard Sackler insisted there should be "less threatening" ways to describe Purdue opioids.

234. Purdue intensified its marketing efforts in subsequent years, in an effort to counteract decreasing sales (sales of OxyContin peaked in 2010, and decreased somewhat in subsequent years). For 2018, the Sacklers approved a target for sales representatives to visit prescribers 1,050,000 times – which would include thousands of visits to Kentucky prescribers — almost double the number of sales visits they had ordered during the peak of OxyContin sales in 2010.

2. **The Marketing Defendants and Purdue Deceptively Directed Front Groups to Promote Opioid Use**

235. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants and Purdue exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put

out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated the benefits of opioids, and understated their risks.¹⁸² Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of the Front Groups own constituencies.

236. “Patient advocacy organizations and professional societies like the Front Groups ‘play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.’”¹⁸³ “Even small organizations—with ‘their large numbers and credibility with policymakers and the public’—have ‘extensive influence in specific disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”¹⁸⁴ Indeed, the U.S. Senate’s report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,¹⁸⁵ which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, “provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of

¹⁸² U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 12, 2018), available at <https://www.hsdl.org/?abstract&did=808171> (“*Fueling an Epidemic*”), at p. 3.

¹⁸³ *Id.* at p. 2.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.* at p. 1.

Office opioids policy,”¹⁸⁶ found that the Marketing Defendants and Purdue made millions of dollars’ worth of contributions to various Front Groups.¹⁸⁷

237. The Marketing Defendants and Purdue also “made substantial payments to individual group executives, staff members, board members, and advisory board members” affiliated with the Front Groups subject to the Senate Committee’s study.¹⁸⁸

238. As the Senate’s Report *Fueling an Epidemic* found, the Front Groups “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”¹⁸⁹ They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding.”¹⁹⁰

239. The Marketing Defendants and Purdue took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each working with the other to deceptively promote the use of opioids for the treatment of chronic pain.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at p. 3.

¹⁸⁸ *Id.* at p. 10.

¹⁸⁹ *Id.* at 12-15.

¹⁹⁰ *Id.* at 12.

a. **American Pain Foundation**

240. The most prominent of the Front Groups was APF. While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from Purdue, Endo, Janssen and Cephalon. APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.

241. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain* and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed *supra*.

242. APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or www.painknowledge.org. Endo estimated it would reach 60,000 prescribers through NIPC.

243. APF was often called upon to provide “patient representatives” for the Marketing Defendants’ and Purdue’s promotional activities, including for Purdue’s “*Partners Against Pain*” and Janssen’s “*Let’s Talk Pain*.” Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants and Purdue, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue’s desire to strategically align its investments in nonprofit organizations that shared its business interests.

244. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

245. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF’s work related to a specific promotional project. Moreover, based on the assignment of particular Purdue “contacts” for each project and APF’s periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF’s funding) for any reason.

246. APF’s Board of Directors was largely comprised of doctors who were on the Marketing Defendants’ and Purdue’s payrolls, either as consultants or as speakers for medical events. The close relationship between APF and the Marketing Defendants and Purdue demonstrates APF’s lack of independence in its finances, management, and mission, and APF’s

willingness to allow Marketing Defendants and Purdue to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants’ messages contradicted APF’s internal conclusions.

247. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF’s board voted to dissolve the organization “due to irreparable economic circumstances.” APF then “cease[d] to exist, effective immediately.” Without support from Marketing Defendants and Purdue, to whom APF could no longer be helpful, APF was no longer financially viable.

b. American Academy of Pain Medicine and the American Pain Society

248. The American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.¹⁹¹ The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM’s website.

¹⁹¹ *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), available at <http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf> (last accessed August 1, 2018).

249. AAPM's corporate council includes Purdue, Assertio, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

250. Fishman, who also served as a KOL for Marketing Defendants and Purdue, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."¹⁹²

251. AAPM has received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

252. More specifically, Purdue paid \$725,584.95 from 2012-2017 to AAPM.¹⁹³ Janssen paid \$83,975 from 2012-2017 to AAPM.¹⁹⁴ Insys paid \$57,750 from 2012-2017 to AAPM.¹⁹⁵ Endo funded AAPM CMEs. Teva is on AAPM's corporate relations council.

253. As to APS, Purdue paid \$542,259.52 from 2012-2017.¹⁹⁶ Janssen paid \$88,500 from 2012-2017.¹⁹⁷ Insys paid \$22,965 from 2012-2017.¹⁹⁸

¹⁹² Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

¹⁹³ *Id.*

¹⁹⁴ *Fueling an Epidemic*, *supra* n. 182.

¹⁹⁵ *Id.*

254. AAPM describes its annual meeting as an “exclusive venue” for offering CME programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

255. AAPM’s staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

256. In 1996, AAPM and APS jointly issued a consensus statement, “The Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain and claimed that the risk of a patients’ addiction to opioids was low. Dr. David Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011.

257. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”) AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine,

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

received support from Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

258. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

259. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the Journal of Pain, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants and Purdue promoted opioids, and whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines.

260. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."¹⁹⁹

261. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

262. The Marketing Defendants and Purdue widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of

¹⁹⁹ Dowell, CDC Guideline, *supra* n. 24.

these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS 2009 Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

c. Federation of State Medical Boards

263. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

264. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

265. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies.” The 1998 Guidelines—that the pharmaceutical companies helped author—taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

266. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Kentucky.

267. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. Purdue paid \$100,000 for printing and distribution of FSMB's Guidelines.²⁰⁰

268. The publication also received support from the American Pain Foundation (APF) and the American Academy of Pain Medicine (AAPM). The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards.²⁰¹ The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.²⁰²

269. The Marketing Defendants and Purdue relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to

²⁰⁰ John Fauber, *Follow the Money: Pain, Policy, and Profit*, MILWAUKEE JOURNAL SENTINEL/MEDPAGE TODAY (Feb. 19, 2012), available at <https://www.medpagetoday.com/neurology/painmanagement/31256>.

²⁰¹ Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), available at <https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf>.

²⁰² Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).

opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

270. Dr. Fishman said that he did not receive any payments from FSMB or any royalties from the publisher because he wanted to avoid the perception of a potential conflict of interest in his authorship of the book or for the ongoing efforts of FSMB. This is because prior to 2011, he had been scrutinized for his involvement with the front groups/manufacturers and accepting payments.²⁰³

271. The Manufacturing Defendants made additional contributions to the FSMB to further their misleading advertising. For example, Purdue paid FSMB \$822,400.06 over 8 years.²⁰⁴ Cephalon paid FSMB \$180,000 over a 3-year period 2007-2008, and 2011.²⁰⁵ Endo paid FSMB \$371,620 over a 5-year period.²⁰⁶ Mallinckrodt paid FSMB \$100,000 in 2011.²⁰⁷

d. The Alliance for Patient Access

272. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical

²⁰³ Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), *available at* <https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf>.

²⁰⁴ Letter from Humayun J. Chaudhry, President and CEO, FSMB, to the Hon. Max Baucus and Hon. Charles Grassley, U.S. Senate (June 8, 2012), *available at* <https://www.documentcloud.org/documents/3109089-FSMB-Response-Letter-to-US-Senate.html>.

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.*

care.”²⁰⁸ It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.²⁰⁹ As of June 2017, the APA listed 30 “Associate Members and Financial Supporters.” The list includes J&J, Endo, Mallinckrodt, Purdue and Cephalon.

273. APA’s board members have also directly received substantial funding from pharmaceutical companies.²¹⁰ For instance, board vice president Dr. Srinivas Nalamachu (“Nalamachu”), who practices in Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from defendants Endo, Purdue and Cephalon, and nonparty Insys. Nalamachu’s clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.²¹¹ Other board members include Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and

²⁰⁸ The Alliance for Patient Access, *About AfPA*, available at <http://allianceforpatientaccess.org/about-afpa/#membership> (last accessed August 1, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

²⁰⁹ Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma’s agenda*, Health News Review (Oct. 2, 2017), available at <https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/> (“Jaklevic, *Non-profit Alliance for Patient Access*”).

²¹⁰ All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica’s Dollars for Docs database, available at <https://projects.propublica.org/docdollars/>.

²¹¹ Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, KANSAS CITY STAR (July 19, 2017), available at <http://www.kansascity.com/news/business/health-care/article162569383.html>.

Cephalon; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Mallinckrodt, Cephalon, and nonparty Insys; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

274. Among its activities, APA issued a “white paper” titled “Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.”²¹² Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.²¹³

²¹² Institute for Patient Access, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, (Oct. 2013), available at http://1yh21u3cjpgtv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/01/PT_White-Paper_Finala.pdf.

²¹³ *Id.* at 4-5 (footnote omitted).

275. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.²¹⁴

276. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.²¹⁵

277. In conclusion, the white paper states that “[p]rescription pain medications, and specifically opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”²¹⁶

278. The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation

²¹⁴ *Id.* at 5-6.

²¹⁵ *Id.* at 6.

²¹⁶ *Id.* at 7.

from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they were generally given to members of Congress who supported the APA's agenda.²¹⁷

279. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801, *et seq.* ("CSA" or "Controlled Substances Act").²¹⁸ The AAPM is also a signatory to this letter. An internal DOJ memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'"²¹⁹ and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like Defendants here, in the courts.²²⁰ The law passed both Houses of Congress and was signed into law in 2016.

²¹⁷ Jaklevic, *Non-profit Alliance for Patient Access*, *supra* n. 209.

²¹⁸ Letter from Alliance for Patient Access, *et al.*, to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015).

²¹⁹ Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS NEWS (last updated Oct. 17, 2017), available at <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/> ("Whitaker, Opioid Crisis Fueled by Drug Industry").

²²⁰ John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. 333 (2017), available at <https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html>.

e. **The U.S. Pain Foundation**

280. The U.S. Pain Foundation (“USPF”) was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants and Purdue. The USPF was one of the largest recipients of contributions from the Marketing Defendants and Purdue, collecting nearly \$3 million in payments between 2012 and 2015 alone.²²¹ The USPF was also a critical component of the Marketing Defendants’ and Purdue’s lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertised its ties to the Marketing Defendants and Purdue, listing opioid manufacturers such as Pfizer, Teva, Assertio, Endo, Purdue, McNeil (*i.e.*, Janssen), and Mallinckrodt as “Platinum,” “Gold,” and “Basic” corporate members.²²² Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

281. More specifically, Purdue paid \$359,300 from 2012-2017;²²³ Janssen paid \$41,500 from 2012-2017;²²⁴ and Insys paid \$2,500,000 from 2012-2017 to the USPF.²²⁵

f. **American Geriatrics Society**

282. The AGS was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants and Purdue. The AGS was a large recipient of contributions from the Marketing Defendants and Purdue, including Endo, Purdue and Janssen.

²²¹ *Fueling an Epidemic*, *supra* n. 182, at p. 4.

²²² *Id.* at 12; U.S. Pain Foundation, *Transparency*, available at <https://uspainfoundation.org/transparency/>. (last accessed on August 1, 2018).

²²³ *Id.*

²²⁴ *Id.*

²²⁵ *Id.*

AGS contracted with Purdue, Endo, and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter “2002 AGS Guidelines”) and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*,²²⁶ hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009.²²⁷ AGS’s complicity in the common purpose with the Marketing Defendants and Purdue is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

283. More specifically, Purdue paid \$11,785 from 2012-2017²²⁸ and provided \$40,000 in “corporate roundtable dues” to AGS’s Health in Aging Foundation, a 501(c)(3) organization affiliated with the group between 2012 and 2015.²²⁹

284. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of

²²⁶ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331 (2009), available at <https://www.ncbi.nlm.nih.gov/pubmed/19573219> (last accessed on August 1, 2018) (“2009 AGS Guidelines”).

²²⁷ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), available at <https://www.medpagetoday.com/geriatrics/painmanagement/32967> (“Narcotic Painkiller Use Booming Among Elderly”).

²²⁸ *Fueling an Epidemic*, *supra* n. 182.

²²⁹ Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

addiction is manageable for patients, even with a prior history of drug abuse.²³⁰ These Guidelines further recommended that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 500 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

285. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

286. Dr. Bruce Farrell was an AGS task force chairman for the 2009 Guidelines, but was also a paid speaker for Endo, and he helped conduct a CME for treating osteoarthritis pain, which was funded by Purdue.²³¹

287. Representatives of the Marketing Defendants and Purdue, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

²³⁰ 2009 AGS Guidelines, *supra* n. 226, at 1342.

²³¹ *Narcotic Painkiller Use Booming Among Elderly*, *supra* n. 227.

288. Members of AGS Board of Directors were doctors who were on the Marketing Defendants' and Purdue's payrolls, either as consultants or as speakers for medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

g. American Chronic Pain Association

289. The Manufacturer Defendants also made substantial payments to the American Chronic Pain Association ("ACPA"). Founded in 1980, the ACPA offers support and education for people suffering with chronic pain.

290. Contributions to the ACPA from the Manufacturing Defendants include \$312,470 from Purdue and \$50,000 from Janssen from 2012-2017.²³² Between 2013 and 2016, 10 members of ACPA's Advisory Board received more than \$140,000 from opioid manufacturers, including Endo.

3. The Marketing Defendants and Purdue Deceptively Paid KOLs to Promote Opioid Use

291. To falsely promote their opioids, the Marketing Defendants and Purdue paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants and Purdue for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants' and Purdue's well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception that science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine and Dr. Scott Fishman.

292. Although these KOLs were funded by the Marketing Defendants and Purdue, the KOLs were used extensively to present the appearance that unbiased and reliable medical

²³² *Fueling an Epidemic*, *supra* n. 182.

research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

293. As the Marketing Defendants' and Purdue's false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that developed, selected, and presented CMEs.

294. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants and Purdue were able to exert control of each of these modalities through which doctors receive their information.

295. In return for their pro-opioid advocacy, the Marketing Defendants' and Purdue's KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

296. The Marketing Defendants and Purdue carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' and Purdue's agenda. The Marketing Defendants and Purdue also kept close tabs on the content of the materials published by these KOLs. Of course, the Marketing Defendants and Purdue also kept these KOLs well-funded enabling them to push the Marketing Defendants' and Purdue's deceptive message out to the medical community.

297. Once the Marketing Defendants and Purdue identified and funded KOLs and those KOLs began to publish “scientific” papers supporting the Marketing Defendants’ and Purdue’s false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants and Purdue poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescriptions of opioids for chronic pain. The Marketing Defendants and Purdue cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants and Purdue did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

298. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants’ and Purdue’s KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants and Purdue.

a. Dr. Russell Portenoy

299. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”²³³

²³³ Russell Portenoy & Kathy Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986), available at <https://www.ncbi.nlm.nih.gov/pubmed/2873550>.

300. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

*The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*²³⁴

(emphasis added). According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”²³⁵

301. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious- like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak.

²³⁴ Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

²³⁵ *Id.*

It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”²³⁶

302. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”²³⁷

303. Dr. Portenoy was also a critical component of the Marketing Defendants’ and Purdue’s control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

304. In recent years, some of the Marketing Defendants’ and Purdue’s KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.²³⁸ Dr. Portenoy has now admitted that he minimized the risks of opioids,²³⁹ and that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that

²³⁶ *Dreamland*, *supra* n. 2, at 314.

²³⁷ *Id.* at 136.

²³⁸ See, e.g., John Fauber, *Painkiller boom fueled by networking*, MILWAUKEE JOURNAL SENTINEL (Feb. 18, 2012), available at <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (reporting that a key Endo KOL acknowledged that opioid marketing went too far).

²³⁹ Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, THE NEW YORKER (Nov. 8, 2013), available at <https://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic> (“Gounder, *Who Is Responsible*”).

weren't true."²⁴⁰ He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ."²⁴¹

305. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*²⁴²

306. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."²⁴³

b. Dr. Lynn Webster

307. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was

²⁴⁰ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012, 11:36am), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

²⁴¹ *Id.*

²⁴² Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER (May 26, 2016), available at <http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5>; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), available at <https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

²⁴³ *Pain Killer*, *supra* n. 109, at 277.

President in 2013 and was a board member of AAPM, a Front Group that ardently supported chronic opioid therapy. He was a Senior Editor of Pain Medicine, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

308. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool ("ORT") appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors at hospitals such as Plaintiffs.

309. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' and Purdue's promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

310. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent

buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results.” The presentation’s agenda description states: “Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment.” The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the “[i]nterim results of this study suggest that [fentanyl buccal] is safe and well-tolerated in patients with chronic pain and [breakthrough pain].” This CME effectively amounted to off-label promotion of Cephalon’s opioids, even though they were approved only for cancer pain.

311. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

c. Dr. Perry Fine

312. Dr. Perry Fine’s ties to the Marketing Defendants and Purdue have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue’s advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline

Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.²⁴⁴

313. Multiple videos feature Dr. Fine's delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith before her death for pain did not make her an addict.

314. Dr. Fine has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under \$5,000 in 2010 from Johnson & Johnson for providing “educational” services, but Johnson & Johnson's website states that the company paid him \$32,017 that year for consulting, promotional talks, meals and travel.²⁴⁵

315. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

At clinically appropriate doses . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for

²⁴⁴ Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), available at <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true>.

²⁴⁵ Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), available at <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>.

acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.²⁴⁶

316. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.”²⁴⁷ In that article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for non-cancer pain.”²⁴⁸ The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic non-cancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”²⁴⁹

317. The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases,

²⁴⁶ Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), available at <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

²⁴⁷ Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

²⁴⁸ *Id.*

²⁴⁹ *Id.*

predictable, manageable, and tolerable.” They also conclude that the number of abuse-related events was “small.”²⁵⁰

318. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but also for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain.²⁵¹ He states the “goal is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events *over the course of years*.”²⁵² The entire program assumes that opioids are appropriate treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”²⁵³

e. Dr. Scott Fishman

319. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are manifold. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid

²⁵⁰ *Id.*

²⁵¹ Perry A. Fine, M.D., *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI

²⁵² *Id.*

²⁵³ *Id.*

prescribing, which were funded by the Marketing Defendants and Purdue. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non- cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled “Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion.”²⁵⁴

320. Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled “Responsible Opioid Prescribing,” in 2007 which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

321. In 2012, Dr. Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it’s critical to remember that the problem of unrelieved pain remains as urgent as ever.²⁵⁵

322. The updated guide still assures that “[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins.”²⁵⁶

323. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: “I believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a

²⁵⁴ *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, supra n. 244.

²⁵⁵ Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).

²⁵⁶ *Id.*

‘chemical coper’ and an addict.”²⁵⁷ The guide also continues to present symptoms of addiction as symptoms of “pseudoaddiction.”

4. The Marketing Defendants and Purdue Also Spread Their Misleading Messages to Reputable Organizations

324. The Defendants also manipulated reputable organizations like the Joint Commission on Accreditation of Healthcare Organizations (the “Joint Commission”) in order to further advance their unlawful marketing of opioids. The Joint Commission certifies over 21,000 health care organizations and is the nation’s oldest and largest standards-setting and accrediting body in health care.²⁵⁸

325. In 2000, Purdue sponsored a book through the Joint Commission which claimed “there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”²⁵⁹ It also called doctors’ concerns about addiction side effects “inaccurate and exaggerated.”²⁶⁰ Dr. David W. Baker, the Joint Commission’s executive vice president for health care quality evaluation, has acknowledged that “[t]he Joint Commission was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information.”²⁶¹

²⁵⁷ Scott M. Fishman, *Listening to Pain: A Physician’s Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

²⁵⁸ Joint Commission, *FAQ Page*, available at <https://www.jointcommission.org/about/jointcommissionfaqs.aspx?CategoryId=10#2274> (last accessed August 1, 2018).

²⁵⁹ Sonia Moghe, *Opioid history: From ‘wonder drug’ to abuse epidemic*, CNN (Oct. 13, 2016), available at <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/>.

²⁶⁰ *Id.*

²⁶¹ *Id.*

326. In 2001, due to the influence of the Marketing Defendants and Purdue, the Joint Commission, along with the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies²⁶²) "introduced standards for [hospitals] to improve their care for patients with pain." The new standards for hospitals put patient pain front and center as the "fifth vital sign." This monograph, entitled *Pain: Current Understanding of Assessment, Management and Treatments* required assessment of pain in all patients.

327. The Joint Commission's first pain management standards placed responsibility for pain control on health care organizations (hospitals); and, emphasized the need for hospitals to do systematic assessments and use quantitative measures of pain which was consistent with the position of the Front Group APS.

328. As a result of the Marketing Defendants' and Purdue's efforts to manipulate the standard of care, many hospitals, including Plaintiffs, risked loss of their Joint Commission accreditation if they did not incorporate the "fifth vital sign" standard and put pain at the forefront of their treatment. Loss of accreditation by The Joint Commission can result in the loss of a huge amount of hospital resources to become reaccredited, despite having a patient satisfaction rating of 99% for the same period.²⁶³

329. Since 2001, The Joint Commission standards relating to pain assessment and management have been revised to lessen emphasis on pain. However, the damage caused by the Marketing Defendants' and Purdue's marketing campaigns could not be undone. Dr. Baker

²⁶² Currently funded by Johnson & Johnson, Purdue and Teva, among others.

²⁶³ Testimony of Tim Westlake, MD, FFSMB, FACEP, U.S. Senate Comm. on Homeland Sec. and Gov't Affairs (Apr 15, 2016) *available at* <https://www.hsgac.senate.gov/imo/media/doc/Testimony-Westlake-2016-04-15-REVISED.pdf>.

explains that “the concept that iatrogenic addiction was rare and that long acting opioids were less addictive had been greatly reinforced and widely repeated, and studies refuting these claims were not published until several years later.”

5. **The Marketing Defendants and Purdue Disseminated Their Misrepresentations Through CME Programs**

330. Now that the Marketing Defendants and Purdue had both a group of physician promoters and had built a false body of “literature,” Defendants needed to make sure their false marketing message was widely distributed.

331. One way the Marketing Defendants and Purdue aggressively distributed their false message was through countless CME programs.

332. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are generally delivered in person, often in connection with professional organizations’ conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians’ medical expertise, they can be especially influential with doctors.

333. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants’ and Purdue’s deceptions.

334. The Marketing Defendants and Purdue sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

335. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC (“Medscape”) and which disseminated false and misleading information to physicians across the country.

336. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who “previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis.” He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using “targeted pharmaco therapeutics to affect multiple points in the pain-signaling pathway.”²⁶⁴ The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process.²⁶⁵ Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

²⁶⁴ Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, available at <http://www.medscape.org/viewarticle/461612> (last accessed August 1, 2018).

²⁶⁵ *Id.*

337. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

338. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Fishman.

339. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

340. The American Medical Association (“AMA”) recognized the impropriety that pharmaceutical company-funded CMEs create, stating that support from drug companies with a financial interest in the content being promoted “creates conditions in which external interests could influence the availability and/or content” of the programs and urged that “[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter.”²⁶⁶

341. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

²⁶⁶ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass’n (Nov. 2011).

342. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants and Purdue expected and understood that instructors would deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants and Purdue for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendants and Purdue-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Marketing Defendants and Purdue both measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

6. **The Marketing Defendants and Purdue Used “Branded” Advertising to Promote Their Products to Doctors and Consumers**

343. The Marketing Defendants and Purdue engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants and Purdue published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the Journal of Pain and Clinical Journal of Pain, to journals with wider medical audiences, such as the Journal of the American Medical Association. The Marketing Defendants and Purdue collectively spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

344. The Marketing Defendants and Purdue also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient

specifically requests it.²⁶⁷ They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.²⁶⁸ Endo's research, for example, found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants and Purdue thus increasingly took their opioid sales campaigns directly to consumers, including through patient- focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

7. **The Marketing Defendants and Purdue Used "Unbranded" Advertising to Promote Opioid Use for Chronic Pain Without FDA Review**

345. The Marketing Defendants and Purdue also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's

²⁶⁷ In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4151257/>.

²⁶⁸ *Id.*

FDA-approved label. Through unbranded materials, the Marketing Defendants and Purdue expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

346. Many of the Marketing Defendants and Purdue utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

8. The Marketing Defendants and Purdue Funded, Edited and Distributed Publications That Supported Their Misrepresentations

347. The Marketing Defendants and Purdue created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was calculated to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

348. To accomplish their goal, the Marketing Defendants and Purdue — sometimes through third-party consultants and/or Front Groups — commissioned, edited, and arranged for the placement of favorable articles in academic journals.

349. The Marketing Defendants' and Purdue's plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their

effects on patients; rather, they originated in the Marketing Defendants' and Purdue's marketing departments.

350. The Marketing Defendants and Purdue made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants and Purdue knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants and Purdue also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

351. The Marketing Defendants and Purdue published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

352. For example, in 2007, Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"²⁶⁹ published in the nationally circulated Journal of Pain Medicine, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Webster, discussed above) stated that the "OTFC [fentanyl] has been shown to relieve BTP [breakthrough pain] more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality

²⁶⁹ Donald R. Taylor, *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007), available at <https://academic.oup.com/painmedicine/article/8/3/281/1829094>.

of life] of non-cancer pain patients.” The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with chronic non-cancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.²⁷⁰

9. The Marketing Defendants and Purdue Used Speakers’ Bureaus and Programs to Spread Their Deceptive Messages.

353. In addition to making sales calls, the Marketing Defendants’ and Purdue’s detailers also identified doctors to serve, for payment, on their speakers’ bureaus and to attend programs with speakers with meals paid for by the Marketing Defendants and Purdue. These speaker programs and associated speaker trainings served three purposes: they provided 1) an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; 2) an opportunity for doctors to be selected to attend a forum at which the drug companies could further market to the speaker himself or herself; and 3) an opportunity for the doctors to market to their peers. The Marketing Defendants and Purdue graded their speakers, and future opportunities were based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers’ bureaus, providing consulting services, and other services.

VI. THE MARKETING DEFENDANTS’ AND PURDUE’S GOAL WAS FOR MORE PATIENTS TO TAKE MORE OPIOIDS AT HIGHER DOSES FOR LONGER PERIODS OF TIME

²⁷⁰ *Id.*

A. Increasing the Patient Population

1. The Marketing Defendants and Purdue Focused on Vulnerable Populations

354. The Marketing Defendants and Purdue specifically targeted their marketing at two particularly vulnerable populations—the elderly and veterans – who tend to suffer from chronic pain.

355. Internal Purdue documents demonstrate that the Purdue Individual Co-Conspirators focused on elderly patients because they are frequent pain sufferers, and, of equal importance, are likely to be covered by Medicare. Purdue internal documents reflected that if it targeted “Patients over the age of 65 ... more Medicare Part D coverage is achieved.”

356. Elderly patients frequently suffer from osteoarthritis, but opioids are not approved to treat the condition. Purdue conducted a single study on osteoarthritis for its Butrans opioid, and it failed. Purdue admitted in internal documents that its opioids “are not indicated for a specific disease” and “it is very important that you never suggest to your HCP [health care professional] that OxyContin is indicated for the treatment of a specific disease state such as Rheumatoid Arthritis or Osteoarthritis.” Nevertheless, to meet its business goals, Purdue trained its representatives to mislead doctors by promoting opioids for osteoarthritis without disclosing Purdue’s failed trial. Purdue even measured how often it targeted osteoarthritis patients. A Purdue marketing presentation concluded that its sales reps were “identifying appropriate patients” because osteoarthritis was specifically mentioned during 35% of sales visits. Purdue also directed sales reps to use marketing materials that highlight patients with osteoarthritis, even though Purdue drugs were never indicated for that disease and Purdue’s Butrans trial had failed. At one point, the Purdue Individual Co-Conspirators wanted to know if sales reps could sell more by remaining silent about the failed trial: “What can be said in response to a prescriber who

asks directly or indirectly, ‘can this product be prescribed for my patient with OA?’ In responding are we required to specifically mention the failed trials in OA?”

357. The Marketing Defendants and Purdue targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, a 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.²⁷¹ Elderly patients taking opioids have also been found to have a greater risk for hospitalizations and increased vulnerability to adverse drug effects and interactions, such as respiratory depression. The 2016 CDC Guideline concludes that there must be “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients.²⁷²

2. **The Marketing Defendants and Purdue Focused on Having Opioids Perceived as a “First Line” of Medication for “Opioid-Naïve” Patients, Rather Than as a Last Resort for Cancer Patients and the Terminally Ill**

358. From the very beginning, Purdue and Abbott intended to position OxyContin as useful for more than just cancer pain. Internal documents from the 1995 “OxyContin Launch” indicate that they also intended it for a “secondary market . . . for non-malignant pain (musculoskeletal, injury and trauma)” and that it must be “reinforced that we do not want to niche OxyContin just for cancer pain.”

359. In 1996, Purdue envisioned OxyContin’s being prescribed for a long laundry list of conditions, and literally generated a “wish list” of clinical studies to support its prescription in

²⁷¹ Dowell, CDC Guideline, *supra* n. 24.

²⁷² *Id.* at 27.

a variety of contexts, including: (1) postoperative pain, with specific objectives of supporting the “Abbott agreement” to market to hospitals, removing “the prohibition of giving the product during the 12-24 hour immediate postop period,” and removing “the qualification limiting the indication to pain for more than a few days;” (2) “nonmalignant pain” (including low back pain, osteoarthritis); and (3) HIV/AIDS treatment.

360. Purdue, particularly after its overall OxyContin sales began to slow after 2010, instructed its sales representatives to focus on expanding the patient base, by promoting its drugs specifically for patients who had not previously taken opioids, who it described as “opioid-naïve” or simply “naïve” patients:

- “Your opportunity here is with the naïve community, let’s use the naïve trial to make your case.”
- “You created an epiphany with the doctor today (potentially) by reviewing the opiate naïve patient profile. What made him more pat to write for this patient, being an amiable doctor, is the fact that he would not have to talk patients out of their short acting [opioids].”
- “This was an example of what a good call looks like ... [Dr.] was particularly interested in the RM case study of Marjorie, which generated a robust discussion of opioid naïve patients ...”

361. Purdue also promoted its drugs for “opioid-naïve” patients using the deceptive term “first line opioid.” “First line” is a medical term for the preferred first step in treating a patient. Opioids are not an appropriate first line therapy. Nevertheless, Purdue’s internal documents and testimony from sales representatives shows that Purdue repeatedly promoted OxyContin as “first line” — “the first thing they would take to treat pain.”

362. A particularly insidious aspect of Purdue's focus on "naïve" patients, and on keeping patients on opioids longer, was its savings card program. The cards provided a discount on a patient's first five prescriptions. In 2012, Purdue's internal 10-year plan highlighted its discovery that opioid savings cards kept patients on opioids longer: "more patients remain on OxyContin after 90 days." The savings card program was incredibly lucrative -- the return on investment for Purdue was 4.28, so that every \$1,000,000 Purdue gave away in savings came back to Purdue as \$4,280,000 in revenue because patients stayed on dangerous opioids longer. Discounts could have cut Purdue's revenue *if* patients took opioids for a short time. But Purdue's internal 10-year plan highlighted its discovery that opioid savings cards kept patients on opioids longer: "more patients remain on OxyContin after 90 days."

363. Purdue sales representatives did not disclose to doctors that "opioid naïve" patients faced greater risks of overdose and death. Purdue focused on less sophisticated prescribers, such as its "core" prolific prescribers, and certain nurses and PAs who might be more vulnerable to persuasion by its sales representatives.

3. **Increasing Dosages and Increasing Them Quickly to Keep Patients on Longer**

364. In order to promote long-term sales, the Marketing Defendants and Purdue promoted the prescription of higher dosages of opioids. There were several dimensions to this. First, the Marketing Defendants and Purdue charged more for the higher dosages. More importantly, patients who took higher dosages would stay on opioids longer.

365. At Purdue, staff, from sales representatives to senior management including the Purdue Individual Co-Conspirators, regularly and candidly discussed internally the imperative of increasing prescribed dosages. Accordingly, Purdue's second most important sales tactic (after frequent sales representative visits, the most important strategy employed by Purdue) was to

cause prescribers to prescribe higher doses. This was manifested in Purdue's *Individualize the Dose* campaign, and was communicated to prescribers in sales representatives' visits, including by the sales representatives in Kentucky. Sales representatives were relentlessly pressured to increase the average doses prescribed by the prescribers in their territories. An aspect of this strategy was to encourage faster upward *titration*, that is moving quickly from smaller to larger doses. The lowest dosage of Purdue's Butrans product, for example, was described to prescribers as an "introductory" dose that would presumptively be increased for most if not all patients.

366. Purdue secretly determined that pushing patients to higher doses would keep them on opioids longer. Purdue developed tactics specifically to keep patients hooked on opioids longer, which it called by the euphemism: "*Improving the Length of Therapy*" — sometimes abbreviated as "LOT" or "LoT." Purdue taught its employees that there is "a direct relationship" between getting patients on higher doses and keeping them on Purdue's opioids longer.

367. The Marketing Defendants' and Purdue's focus on increasing dosages, and increasing the duration of opioid usage, had devastating consequences for patients. Patients exposed to higher dosages, and for longer periods of time, are many times more likely to become addicted, and to overdose.

VII. THE MARKETING DEFENDANTS' AND PURDUE'S SCHEME SUCCEEDED, CREATING A PUBLIC HEALTH EPIDEMIC

A. The Marketing Defendants and Purdue Dramatically Expanded Opioid Prescribing and Use

368. The Marketing Defendants and Purdue necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and they worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

369. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated \$15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to “a dedicated sales force for ACTIQ” and “ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists.”²⁷³ Actiq became Cephalon’s second best-selling drug. By the end of 2006, Actiq’s sales had exceeded \$500 million.²⁷⁴ Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that “more than 80 percent of patients who use[d] the drug don’t have cancer.”²⁷⁵

370. Each of the Marketing Defendants and Purdue tracked the impact of their marketing efforts to measure their impact in changing doctors’ perceptions and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors’ prescribing before and after detailing visits, and before and after speaker programs. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants’ opioids), and more generally, Defendants’ marketing changed prescribers’ willingness to prescribe opioids, led them to prescribe more of their

²⁷³ Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), *available at* <https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm>.

²⁷⁴ John Carreyrou, *Narcotic ‘Lollipop’ Becomes Big Seller Despite FDA Curbs*, THE WALL STREET JOURNAL (Nov. 3, 2006), *available at* <https://www.wsj.com/articles/SB116252463810112292>.

²⁷⁵ *Id.*

opioids, and persuaded them not to stop prescribing opioids or to switch to “safer” opioids, such as ADF.

371. This success would have come as no surprise. Drug Company marketing materially impacts doctors’ prescribing behavior.²⁷⁶ The effects of sales calls on prescribers’ behavior is well documented in the literature. One study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals’ formularies.

372. Marketing Defendants and Purdue spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable

²⁷⁶ See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs). See also A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue’s sales force and trebling of annual sales calls (“Commercial Triumph”).

using opioids for chronic non-cancer pain.²⁷⁷ These results are directly due to the Marketing Defendants' and Purdue's fraudulent marketing campaign focused on several misrepresentations.

373. Thus, both independent studies and Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

B. The Marketing Defendants' and Purdue's Deception in Expanding Their Market Created and Fueled the Opioid Epidemic.

374. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."²⁷⁸ It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

375. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."²⁷⁹

376. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients' receiving

²⁷⁷ CS Hwang, *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175 JAMA Intern. Med. 302 (2014), doi: 10.1001/jamainternmed.2014.6520, available at <https://www.ncbi.nlm.nih.gov/pubmed/25485657>.

²⁷⁸ Theodore J. Cicero, *et al.*, *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16 Pharmacopidemiology and Drug Safety, 827-40 (2007), doi: 10.1002/pds.1452, available at <https://www.cdhs.udel.edu/content-sub-site/Documents/Publications/Relationship%20Between%20Therapeutic%20Use%20and%20Abuse%20of%20Opioid%20Analgesics.pdf>.

²⁷⁹ See Califf, *et al.*, *supra* n. 30.

opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

VIII. EACH OF THE MARKETING DEFENDANTS AND PURDUE MADE MATERIALLY DECEPTIVE STATEMENTS AND CONCEALED MATERIAL FACTS

377. As alleged herein, the Marketing Defendants and Purdue made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course of manufacturing, marketing, and selling prescription opioids. The Marketing Defendants’ and Purdue’s actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

378. As a part of their deceptive marketing scheme, the Marketing Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, the Marketing Defendants and Purdue focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Marketing Defendants’ and Purdue’s misrepresentations.

A. Purdue

379. Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the

efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

380. More specifically, Purdue made and/or disseminated deceptive statements, and promoted a culture that mislead doctors and patients into believing opioids were safe for chronic care, including, but not limited to, the following:

In 1998, Purdue distributed 15,000 copies of an OxyContin video to physicians without submitting it to the FDA for review, an oversight later acknowledged by Purdue. In 2001, Purdue submitted to the FDA a second version of the video, which the FDA did not review until October 2002—after the General Accounting Office inquired about its content. After its review, the FDA concluded that the video minimized the risks from

OxyContin and made unsubstantiated claims regarding its benefits to patients.²⁸⁰

According to training materials, Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that “fewer than one per cent” of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)²⁸¹

Andrew Kolodny, the co-director of the Opioid Policy Research Collaborative, at Brandeis University, has worked with hundreds of patients addicted to opioids. He has stated that, though many fatal overdoses have resulted from opioids other than OxyContin, the crisis was initially precipitated by a shift in the culture of prescribing—a shift carefully engineered by Purdue. “If you look at the prescribing trends for all the different opioids, it’s in 1996 that prescribing really takes off,” Kolodny said. “It’s not a coincidence. That was the year Purdue launched a multifaceted campaign that misinformed the medical community about the risks.”²⁸²

“Purdue had a speakers’ bureau, and it paid several thousand clinicians to attend medical conferences and deliver presentations about the merits of the drug. Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton. Such spending was worth the investment: doctors who attended these seminars in 1996 wrote OxyContin prescriptions more than twice as often as those who didn’t. The company advertised in medical journals, sponsored Web sites about chronic pain, and distributed a dizzying variety of OxyContin swag: fishing hats, plush toys, luggage tags. Purdue also produced promotional videos featuring satisfied patients—like a construction worker who talked about how OxyContin had eased his chronic back pain, allowing him to return to work. The videos, which also included testimonials from pain specialists, were sent to tens of thousands of doctors. The marketing of OxyContin relied on an empirical circularity: the company convinced doctors of the drug’s safety

²⁸⁰ *Empire of Pain*, *supra* n. 112.

²⁸¹ *Id.*

²⁸² *Id.*

with literature that had been produced by doctors who were paid, or funded, by the company.”²⁸³

Purdue encouraged sales representatives to increase sales of OxyContin through a lucrative bonus system, which resulted in a large number of visits to physicians with high rates of opioid prescriptions. In 2001, Purdue paid \$40 million in bonuses to its sales representatives.²⁸⁴

Purdue claimed that the risk of addiction from OxyContin was extremely small and trained its sales representatives to carry the message that the risk of addiction was “less than one percent,” while knowing that there was no empirical support for that statement.

By 2003, the Drug Enforcement Administration had found that Purdue’s “aggressive methods” had “very much exacerbated OxyContin’s widespread abuse.” Rogelio Guevara, a senior official at the D.E.A., concluded that Purdue had “deliberately minimized” the risks associated with the drug.²⁸⁵

381. “From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue’s national speaker bureau. It is well documented that this type of pharmaceutical company symposium influences physicians’ prescribing even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.”²⁸⁶

²⁸³ *Id.*

²⁸⁴ *Commercial Triumph*, *supra* n. 276.

²⁸⁵ *Empire of Pain*, *supra* n. 112.

²⁸⁶ *Commercial Triumph*, *supra* n. 276.

382. As noted above, Purdue utilized Front Groups to help disseminate and defend its false messages. Between January 2012 and March 2017, Purdue made the following contributions:

Academy of Integrative Pain Management	\$1,091,024.86
American Academy of Pain Management	\$725,584.95
ACS Cancer Action Network	\$168,500.00 ²⁸⁷
American Chronic Pain Association	\$312,470.00
American Geriatrics Society	\$11,785.00 ²⁸⁸
American Pain Foundation	\$25,000
American Pain Society	\$542,259.52
American Society of Pain Educators	\$30,000
American Society of Pain Management Nursing	\$242,535.00
The Center for Practical Bioethics	\$145,095.00
U.S. Pain Foundation	\$359,300.00
Washington Legal Foundation	\$500,000.00
TOTAL	\$4,153,554.33

²⁸⁷ Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017).

²⁸⁸ The AGS reported that Purdue also provided \$40,000 in “corporate roundtable dues” to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

383. The Purdue Individual Co-Conspirators reinforced Purdue's sales visits with dozens of other deceptive tactics aimed at Kentucky. The Purdue Individual Co-Conspirators wrote deceptive pamphlets and mailed them to doctors in Kentucky. The Purdue Individual Co-Conspirators used all these deceptive tactics to collect money in Kentucky, by getting more Kentucky patients on opioids, at higher doses, for longer periods of time.

384. Purdue streamed videos to Kentucky doctors on its OxyContin Physicians Television Network. Purdue hired the most prolific opioid prescribers in Kentucky as spokesmen to promote its drugs to other doctors.

385. Purdue promoted its opioids to Kentucky patients with marketing that was designed to obscure the risk of addiction and even the fact that Purdue was behind the campaign.

B. Endo

386. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

Providing needed financial support to pro-opioid pain organizations – including over \$5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

C. Janssen

387. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids

to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

D. Assertio

388. Defendant Assertio has, since at least October 2011, made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive with respect to Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER, including, but not limited to:

- a. Promoting the usage of Lazanda with patients not suffering from cancer;
- b. Endorsing, supporting, and pressuring its sales representative to target

pain management physicians, particularly those who historically wrote large numbers of Lazanda-like drugs;

- c. Discouraging sales representatives from promoting sales of Lazanda to cancer patients against the FDA instruction that Lazanda is only indicated “for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain;”
- d. Training of sales representatives on how to deal with pushback from physicians;
- e. Promoting of Nucynta and Nucynta ER for all manner of pain management while downplaying the drug’s addictive nature;
- f. Promoting its drugs as a safer alternative than other opioids;
- g. Telling investors that Depomed is safe. August Moretti, Assertio’s Senior Vice President and Chief Financial Officer, stated that “[a]lthough not in the label, there’s a very low abuse profile and side effect rate.”

E. Cephalon

389. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon’s potent rapid-onset opioids;

- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing and speakers' bureau events.

F. Actavis

390. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

391. A Kadian prescriber guide deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. Kadian's prescriber guide is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.

G. Mallinckrodt

392. Defendant Mallinckrodt made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

393. Creating and promoting publications that misrepresented and trivialized the risks of addiction;

394. Creating and promoting publications that overstated the benefits of opioids for chronic pain; and

395. Making deceptive statements about pseudoaddiction.

**IX. DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY
DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS**

AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS

396. The Marketing Defendants and Purdue created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids than could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

397. Marketing Defendants' and Purdue's scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Marketing Defendants' and Purdue's deceptive marketing caused prescribing not only of their opioids, but also of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and MME per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids.

398. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.”²⁸⁹ Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these

²⁸⁹ Centers for Disease Control and Prevention, Increases in Drug and Opioids Overdose Deaths — United States, 2000–2014, 64(50): 1378–82, Morbidity and Mortality Weekly Report (Jan. 2016), *available at* <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.

reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”²⁹⁰

X. **ALL DEFENDANTS HAVE, AND BREACHED, DUTIES TO GUARD AGAINST, AND REPORT, UNLAWFUL DIVERSION AND TO REPORT AND PREVENT SUSPICIOUS ORDERS**

399. Multiple sources impose duties on Defendants with respect to the supply of opioids, including the common law duty to exercise reasonable care. Each Defendant was also required to obtain a license from Kentucky’s Board of Pharmacy, and certify compliance with Kentucky law. The Defendants also had legal duties under Kentucky common law, statutes, and regulations to maintain adequate records, and prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids. This includes the common law of fraud, statutes designed to generally prohibit unfair and deceptive acts in commerce, as well as statutes specifically prohibiting deceptive practice relating to drugs.

400. Each Defendant was required to register with the Commonwealth of Kentucky. 201 KAR 2:320, 2:105; KRS § 315.005.

401. The Defendants also had legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids under Kentucky law.

402. Pursuant to KRS § 218A.170(8), Defendants must adhere to Kentucky’s controlled substances law in the sale of controlled substances. See KRS § 218A.170(8) (“All sales and distributions shall be in accordance with KRS § 218A.200 and the federal controlled substances laws, including the requirements governing the use of order forms.”). Thus, all

²⁹⁰ *Id.*

Defendants have a duty to report suspicious orders in order to prevent diversion.²⁹¹ Pharmacies are required to ensure that opioid prescriptions they fill are written for a legitimate patient for a legitimate medical need. See KRS § 218A.180(3)(a) (“[T]o be valid, a prescription for a controlled substance shall be issued only for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice[.]”).

403. Further, “[m]anufacturers and wholesalers shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them.” KRS § 218A.200(2). “The record of controlled substances received shall in every case show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The record of all controlled substances sold, administered, dispensed, or otherwise disposed of, shall show the date of selling, administering, or dispensing, the name and address of the person to whom, or for whose use, or the owner and species of animal for which the drugs were sold, administered, or dispensed, and the kind and quantity” KRS § 218A.200(4).

404. Each Defendant’s actions were in violation of Chapter 218A of the Kentucky Revised Statutes, as set out above, and also including § 218A.1404(3), which forbids unlawful distribution of controlled substances; § 218A.1404(1), which forbids the trafficking of controlled substances; and, KRS §§ 506.040, and 218A.1402, which forbid criminal drug conspiracies; and

²⁹¹ Federal requirements impose a non-delegable duty upon registrants to design and operate a system to disclose to the registrant suspicious orders of controlled substances. “The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

KRS § 218A.1405, which forbids receipt of income from trafficking and utilizing that income to operate a commercial enterprise.

405. In addition to reporting all suspicious orders, the Supply Chain Defendants must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the recipient can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F. 3d 206 (D.C. 2017). Regardless, all flagged orders must be reported.

406. These prescription drugs are regulated for the purpose of providing a “closed” system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.²⁹²

²⁹² See 1970 U.S.C.C.A.N. 4566, 4571-72.

407. “Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant’s role and responsibilities.”²⁹³

408. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction, with costs and damages necessarily inflicted on and incurred by Plaintiffs and others.

409. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality, along with the costs imposed upon Plaintiffs and others associated with the treatment of these conditions and related health consequences caused by opioid abuse.

410. Finding it impossible to legally achieve their ever-increasing sales ambitions, Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

411. Wholesale distributors such as Supply Chain Defendants had close financial relationships with Marketing Defendants, Purdue, and customers, for whom they provide a broad

²⁹³ Brief for Healthcare Distribution Mgmt. Association and National Ass’n of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf’t Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 (“Brief for HDMA and NACDS”). The Healthcare Distribution Mgmt. Ass’n (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation and Cardinal Health, Inc. *See generally*, HDA, *About*, available at <https://www.healthcaredistribution.org/about> (last accessed Aug. 1, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, available at <https://www.nacds.org/%20about/mission/> (last accessed Aug. 1, 2018).

range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, “[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers’ stock.” *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able “to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers.” Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

412. Distributor Defendants had financial incentives from the Marketing Defendants and Purdue to distribute higher volumes and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

413. The Marketing Defendants and Purdue engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The Washington Post has described the practice as industry-wide, and the Healthcare Distribution Alliance (“HDA”) includes a “Contracts and Chargebacks Working Group,” suggesting a standard practice.

414. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors).” The transaction information contains data relating to the direct customer sales of controlled substances to “downstream registrants”, meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants and Purdue buy data from pharmacies as well. This exchange of information, upon information and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

415. A dramatic example of the use of prescription information provided by IMS Health was described in Congressional testimony:

Mr. Greenwood: Well, why do you want that [IMS Health] information then?

Mr. Friedman: Well, we use that information to understand what is happening in terms of the development of use of our product in any area.

Mr. Greenwood. And so the use of it--and I assume that part of it--a large part of it you want is to see how successful your marketing techniques are so that you can expend money in a particular region or among a particular group of physicians-- you look to see if your marketing practices are increased in sales. And, if not, you go back to the drawing board with your marketers and say, how come we spent “X” number of dollars, according to these physicians, and sales haven't responded. You do that kind of thing. Right?

Mr. Friedman: Sure.²⁹⁴

416. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The Defendants negotiated agreements

²⁹⁴ *Oxycontin: Its Use and Abuse*, *supra* n. 123.

whereby the Marketing Defendants and Purdue installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

417. Under the common law, Defendants had a duty to exercise reasonable care in manufacturing and distributing dangerous narcotic substances. National Pharmacies further had a duty to exercise reasonable care in supervising the sale of such drugs. By flooding Kentucky with opioids and failing to effectively prevent diversion, including failing to monitor for red flags, Defendants breached their duties. By filling and failing to report or halt orders that they knew or should have realized were likely being diverted for illicit uses, Supply Chain Defendants further breached their duties. These breaches by Defendants both created and failed to prevent a foreseeable risk of harm to the Plaintiffs.

418. Defendants also assumed a duty, when speaking publicly about opioids and their efforts and commitment to combat diversion of prescription opioids, to speak accurately and truthfully. They breached the duty by making inaccurate or untruthful statements on their efforts to combat diversion. They also breached the duty by misrepresenting the efficacy of opioids, as stated in this complaint.

A. Defendants' Use of Trade and Other Organizations

419. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA.

1. Pain Care Forum

420. PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that

lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

421. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”²⁹⁵ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.²⁹⁶

422. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF.²⁹⁷ In 2012, membership and participating organizations included Endo, Purdue, Actavis and Cephalon. Each of the Marketing Defendants and Purdue worked together through the PCF. But the Marketing Defendants and Purdue were not alone. The Distributor Defendants actively participated, and continue to participate, in the PCF through, at a minimum, their trade organization, the HDA.²⁹⁸ The Distributor Defendants participated directly in the PCF as well.

²⁹⁵ Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (Sept. 19, 2017, 12:01 a.m.), available at <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

²⁹⁶ *Id.*

²⁹⁷ *PAIN CARE FORUM 2012 Meetings Schedule*, (last updated Dec. 2011), available at <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>.

²⁹⁸ *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc. and the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation. *Executive Committee*, Healthcare Distribution Alliance (last accessed on Aug. 1, 2018), available at <https://www.healthcaredistribution.org/about/executive-committee%20>.

2. Healthcare Distribution Alliance (“HDA”)

423. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants, including Actavis, Endo, Purdue, Mallinckrodt, Cephalon, and Purdue were members of the HDA.²⁹⁹ Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Marketing Defendants and Purdue by advocating for the many benefits of members, including “strengthening . . . alliances.”³⁰⁰

424. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”³⁰¹ The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Marketing and Distributor Defendants.

425. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other’s

²⁹⁹ *Manufacturer Membership*, Healthcare Distribution Alliance, available at <https://www.healthcaredistribution.org/about/membership/manufacturer> (last accessed Aug. 1, 2018).

³⁰⁰ *Id.*

³⁰¹ *Id.*

businesses.³⁰² For example, the manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

426. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their “most recent year end net sales” through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Anda, Cardinal, and Henry Schein and their subsidiaries.

427. The closed meetings of the HDA’s councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

428. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants and Purdue as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”³⁰³ The conferences also gave the Marketing and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all

³⁰² *Id.*

³⁰³ *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, available at <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers> (last accessed Aug. 1, 2018, and no longer available).

levels of the healthcare distribution industry.”³⁰⁴ The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. The Marketing Defendants and Purdue embraced this opportunity by attending and sponsoring these events.³⁰⁵

429. After becoming members of the HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributor and manufacturer members.
- c. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributor and manufacturer members.
- d. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.

³⁰⁴ *Id.*

³⁰⁵ *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, available at <https://www.healthcaredistribution.org/events/2015-distribution-management-conference> (last accessed Aug. 1, 2018).

- e. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation in this group includes manufacturer and distributor members.

430. The Distributor Defendants, Marketing Defendants, and Purdue also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.³⁰⁶ For example, on April 27, 2011, the HDA offered a Webinar to “accurately and effectively exchange business transactions between distributors and manufacturers...” The Marketing Defendants and Purdue used this information to gather high-level data regarding overall distribution and to direct the Distributor Defendants on how to most effectively sell prescription opioids.

431. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

432. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

³⁰⁶ *Webinars*, Healthcare Distribution Alliance, (last accessed on Sept. 14, 2017), *available at* <https://www.healthcaredistribution.org/resources/webinar-leveraging-edl>.

433. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the “Industry Compliance Guidelines”) regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of “[a] committee of HDMA members contribut[ing] to the development of this publication” beginning in late 2007.

434. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their legal duties with respect to the distribution of controlled substances. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion. Discovery, including discovery of meeting minutes within the HDA, will further reveal that Defendants utilized the HDA to combat their legal duties and avoid compliance with the law and regulations.

435. The Defendants worked together to control the flow of information and to influence governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

436. The Defendants also had obligations to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

437. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be revealed. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency.

438. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

B. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

439. The reason for the reporting rules is to create a “closed” system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.³⁰⁷

³⁰⁷ See Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Holder*, 1:12-cv-00185-RBW, Doc. No. 14-2 (D.D.C. Feb. 10, 2012).

440. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

C. **Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers**

441. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's Confidential Automation of Reports and Consolidated Orders System (ARCOS) database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants, Marketing Defendants, and Purdue but has not been disclosed to the public.

442. Publicly available information confirms that Distributor Defendants, Marketing Defendants, and Purdue funneled far more opioids into Kentucky and communities across the United States than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor Defendants, Marketing Defendants, and Purdue, would have alerted them to potentially suspicious orders of opioids.

443. This information includes the following facts:

- a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;
- b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
- c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;

- d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and
- e. Marketing Defendants and Purdue purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

444. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

445. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber-and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”).

446. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.³⁰⁸ The “know your customer” questionnaires informed the Defendants of

³⁰⁸ *Suggested Questions a Distributor should ask prior to shipping controlled substances, available at https://www.dea diversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr. & Kathleen H. Dooley, Esq. *Pharmaceutical Product Diversion: Beyond the PDMA*,*

the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy purchased opioids from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and others. These questionnaires put the recipients on notice of suspicious orders.

447. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.³⁰⁹

448. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.³¹⁰

449. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by Cardinal (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.³¹¹

Purdue Pharma and McGuireWoods LLC, available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

³⁰⁹ A Verispan representative testified that the Distributor Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 661712, *9-10 (Feb. 22, 2011).

³¹⁰ Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, available at <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf>, Figure 2 at p. 3 (last accessed Aug. 1, 2018).

³¹¹ *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, at *467-471 (Feb. 22, 2011).

450. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.³¹² Defendants were, therefore, collectively aware of the suspicious orders that flowed from their facilities.

451. Defendants refused to identify, investigate, and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012³¹³ and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders, all for failure to report suspicious orders.³¹⁴

452. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

³¹² In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vender, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.* See also Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).

³¹³ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> ("The Drug Enforcement Administration's Adjudication of Registrant Actions").

³¹⁴ *Id.*

Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

453. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.³¹⁵ In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."³¹⁶

454. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked

³¹⁵ *Pain Killer*, *supra* n. 109, at 298-300.

³¹⁶ *Id.*

like gang members,” and that she felt “very certain that this an organized drug ring[.]”³¹⁷ She wrote, “This is clearly diversion. Shouldn’t the DEA be contacted about this?” But her supervisor at Purdue responded that while they were “considering all angles,” it was “really up to [the wholesaler] to make the report.”³¹⁸ This pill mill was not only distributing opioids locally - over a million pills were transported to the City of Everett, Washington, a city of around 100,000 people. Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle. The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

455. At Purdue, the Purdue Individual Co-Conspirators were well aware of the importance of prolific prescribers, which they and their staff referred to internally, at times, as “core,” “super core,” “high value” and “high potential” prescribers. In fact, it was an explicit, and significant, sales strategy to pay particular attention to actual and potential prolific prescribers, which the Purdue Individual Co-Conspirators understood to account for approximately 10% of overall revenues. At Purdue, Sackler Co-Conspirators and Purdue Officer Co-Conspirators were aware that Purdue regularly received “Reports of Concern” about abuse and diversion of opioids, as well as reports of other adverse events, and also calls to Purdue’s compliance “hotline.” In July 2007, staff told the Sackler Co-Conspirators and Purdue Officer Co-Conspirators that more than 5,000 cases of adverse events had been reported to

³¹⁷ Harriet Ryan, *et al.*, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew*, LOS ANGELES TIMES (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

³¹⁸ *Id.*

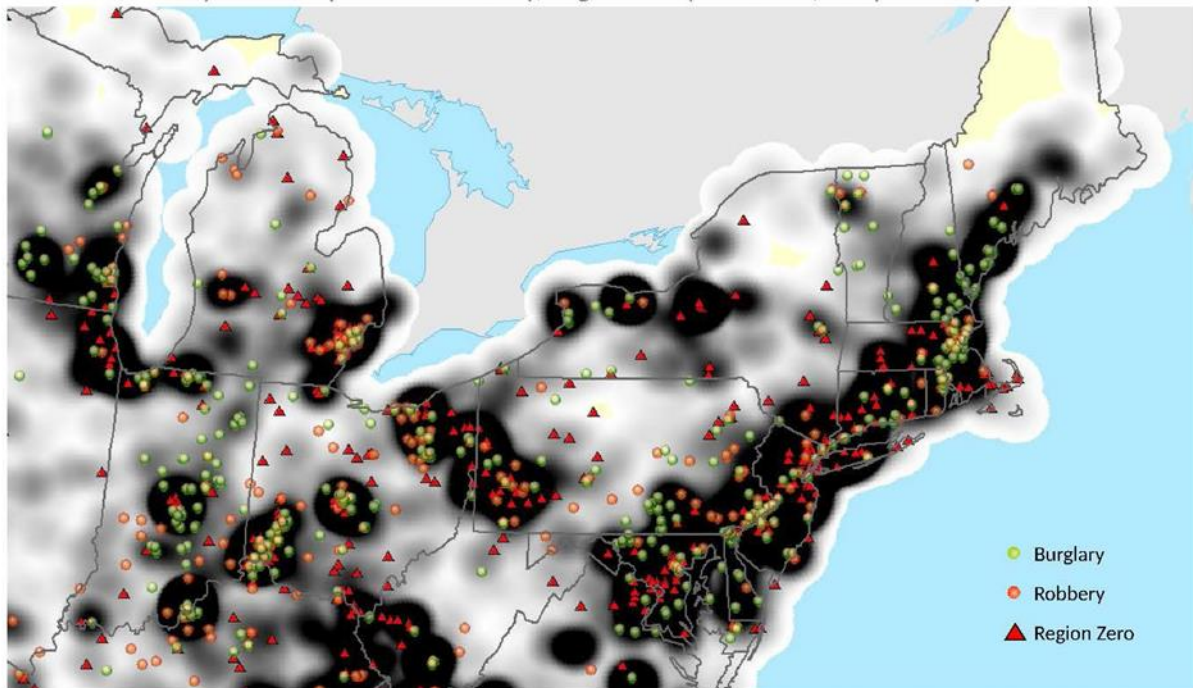
Purdue in just the first three months of 2007. Staff also told the Sackler Co-Conspirators and Purdue Officer Co-Conspirators that Purdue received 572 Reports of Concern about abuse and diversion of Purdue opioids during Q2 2007. Staff reported to the Sackler Co-Conspirators that they completed only 21 field inquiries in response. Staff also told the Sackler Co-Conspirators that they received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities. Purdue's self-interested failure to report abuse and diversion would continue, quarter after quarter, even though the 2007 Judgment required Purdue to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or even directing sales reps to stop visiting them, the Sackler Co-Conspirators chose to keep pushing opioids to whoever prescribed the most.

456. Purdue also tracked prescribers from whom there was a substantial possibility of opioids having been diverted, or, at a minimum, grossly over-prescribed. It described these prescribers as, collectively, "Region Zero," and even generated a map, given to members of the Board, correlating these prescribers with poison control calls and pharmacy thefts.

We are examining the spatial relationship between different aspects of the abuse environment

ILLUSTRATIVE

Poison Control oxycodone exposure call density, Region Zero prescribers, and pharmacy theft



SOURCE: AAPCC, PPLP, RxPatrol

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Map presented to the Purdue Board in 2011

457. Once prescribers were categorized as part of “Region Zero,” Purdue would eventually stop promoting to them, but it would *not* stop selling to them, and it would *not* report them to authorities. This would have been costly. Staff told Co-Conspirator Stewart, the Sackler Co-Conspirators and the Board that the company was receiving a steadily rising volume of hotline calls and other compliance matters in this timeframe, reaching an all-time high during

October, November, and December 2010. Purdue made a calculated economic decision *not* to report suspicious prescribers and orders. Indeed, an internal Purdue study showed that the financial penalties imposed on drug companies for illegal marketing were “relatively small” when “compared to the perpetrating companies’ profits.” When the CDC issued a national warning against the highest and most dangerous doses of opioids, Purdue studied prescription data to calculate how much profit it would lose if doctors followed the CDC’s advice, and it elected not to.

458. Defendants’ obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers. However, this was done not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement.

459. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors’ sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

460. This focus on marketing to the highest prescribers demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

461. Whenever examples of opioid diversion and abuse have drawn media attention, Co-Conspirator Purdue and other Marketing Defendants and Purdue have consistently blamed “bad actors.” For example, in 2001, during a Congressional hearing, Purdue’s attorney Howard

Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was “fooled” by the doctor: “The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us.”³¹⁹

462. But given the closeness with which they monitored prescribing patterns through IMS Health data, the Defendants either knew or chose not to know of the obvious drug diversions. In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino’s clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue’s tracking system and database as a “gold mine” and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

463. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company’s policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

464. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Marketing Defendants and their employees turned a collective blind eye, allowing certain

³¹⁹ *Pain Killer*, *supra* n. 109, at 179.

clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

D. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

465. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities across America. Despite the notice described above, Defendants continued to pump massive quantities of opioids into communities in disregard of their legal duties to control the supply, prevent diversion, and report and take steps to halt suspicious orders.

466. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

467. For example, in 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances - orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”

468. On December 23, 2016, Cardinal agreed to pay the United States \$44 million to resolve allegations that it violated reporting requirements in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA.

In the settlement agreement, Cardinal admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- a. “timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b);”
- b. “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA’s regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5);” and
- c. “execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA ‘Form 222’ order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21.F.R. Part 1305.”

469. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection laws, antitrust laws, and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with Cardinal, shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities demonstrate that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for \$16 million to the state; Cardinal settled for \$20 million.

470. Henry Schein, too, is a repeat offender. Since the company’s inception, it has been subjected to repeated disciplinary actions across the United States for its sale and/or

distribution of dangerous drugs to persons or facilities not licensed or otherwise authorized to possess such drugs.

471. In 2014, Henry Schein Animal Health was investigated by the State of Ohio Board of Pharmacy due to its sale/distribution of wholesale dangerous drugs to an entity not holding a valid Ohio license. It reached a settlement with the Ohio Board of Pharmacy related to this investigation in 2015.

472. Records from a disciplinary proceeding against a Wisconsin-licensed medical practitioner reveal that from May 2005 through September 2006, Henry Schein continued to deliver opioids to the provider, despite the fact that his license had been suspended for inappropriate prescribing of opioids.

473. Thus, Defendants have admitted to disregarding their duties. They have admitted that they pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

474. The National Retail Pharmacies continuously paid other Defendants to supply large quantities of prescription opioids and continuously dispensed them in order to satisfy demand for the drugs, despite knowing of their illegitimate or, at best, suspicious nature, despite knowing that Manufacturer Defendants and Distributor Defendants were habitually violating state law, and despite Retail Defendants' duty to prevent diversion.

E. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

475. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and

results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action - or may not know to take action at all.

476. After being caught failing to comply with particular obligations at particular facilities, Supply Chain Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens.

477. More generally, Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: “We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing ‘the right thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along the same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription-controlled medications that do not meet [its] strict criteria.” Defendant Cardinal also promotes funding it provides for “Generation Rx,” which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

478. Along the same lines, Defendant AmerisourceBergen has taken the public position that it is “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find

solutions that will support appropriate access while limiting misuse of controlled substances.” A company spokeswoman also provided assurance that: “At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients.”

479. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an amicus brief in *Masters Pharmaceuticals*, which made the following statements:³²⁰

- a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
- b. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.”

480. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further asserted that their conduct was in compliance with those obligations.

481. Defendant Mallinckrodt similarly claims to be “committed . . . to fighting opioid misuse and abuse,” and further asserts that: “In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . .”

³²⁰ Brief for HDMA and NACDS, *supra* n. 293, 2016 WL 1321983, at *3-4, *25.

482. Other Marketing Defendants and Purdue also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its “constructive role in the fight against opioid abuse,” including its commitment to ADF opioids and its “strong record of coordination with law enforcement.”³²¹

483. At the heart of Purdue’s public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue’s recent pronouncements in response to the opioid epidemic.

484. Touting the benefits of ADF opioids, Purdue’s website asserts: “[W]e are acutely aware of the public health risks these powerful medications create That’s why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse”³²² Purdue’s statement on “Opioids Corporate Responsibility” likewise states that “[f]or many years, Purdue has committed substantial resources to combat opioid abuse

³²¹ Purdue, *Setting The Record Straight On OxyContin’s FDA-Approved Label* (May 5, 2016), available at <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontin-fda-approved-label/>; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), available at <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/>.

³²² Purdue website, *Opioids With Abuse-Deterrent Properties*, available at <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/> (last accessed Aug. 1, 2018).

by partnering with . . . communities, law enforcement, and government.”³²³ And, responding to criticism of Purdue’s failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue “ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion.”³²⁴

485. These public pronouncements create the false impression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

486. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

XI. THE MARKETING DEFENDANTS’ AND PURDUE’S UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS

487. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Supply Chain Defendants

³²³ *Id.*

³²⁴ *Setting The Record Straight*, *supra* n. 321. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

were also legally required of the Marketing Defendants and Purdue under Kentucky law. Like the Supply Chain Defendants, the Marketing Defendants and Purdue were required to register with the Kentucky Board of Pharmacy and the DEA to manufacture and distribute Schedule II controlled substances, like prescription opioids. *See* KRS § 218A.010(10), (11), (12), (38); KRS § 218A.150(1) (repealed 2018); KRS § 218.170(1), (2); KRS § 315.010; KRS § 315.400(9); 902 KAR 55:010 Section 1(4), 201 KAR 2:230. Under Kentucky state law, it has been declared that “[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health.” KRS § 218A.005(1).

488. Like the Supply Chain Defendants, the Marketing Defendants breached these duties. Kentucky state law requires that a “manufacturer, distributor, or wholesaler” must comply with “KRS § 218A.200 and the federal controlled substances laws.” KRS § 218A.170.

489. Pursuant to KRS § 218A.200, manufacturers and wholesalers of opioids “shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and all of controlled substances received and disposed of by them.”

490. The Marketing Defendants and Purdue have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors’ offices and pharmacies, and from the data they purchase from commercial sources, such as IMS Health (now IQVIA). Their extensive boots-on-the-ground through their sales force, allows them to observe the signs of suspicious prescribing and dispensing discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few.

491. In addition, Marketing Defendants and Purdue had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. Marketing Defendants and Purdue regularly mine data, including, upon information and belief, chargeback data, that allows them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusually high dose prescribing, that would have alerted them, independent of their sales representatives, to suspicious prescribing.

492. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, Marketing Defendants and Purdue knew – just as the Supply Chain Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Marketing Defendants and Purdue built receipt of this information into the payment structure for the opioids provided to the opioid distributors. These information points give Manufacturer Defendants insight into prescribing and dispensing conduct that enables them to play a valuable role in preventing diversion and fulfilling their obligations under the law.

493. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.³²⁵

³²⁵ See Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for

494. In the press release accompanying the settlement, the Department of Justice stated: “[Mallinckrodt] did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone.” . . . “Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . .”³²⁶

495. Among the allegations resolved by the settlement, the government alleged “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”³²⁷

496. The Memorandum of Agreement entered into by Mallinckrodt (“2017 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to

Recordkeeping Violations (July 11, 2017), available at <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

³²⁶ *Id.*

³²⁷ *Id.*

maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.”³²⁸

497. Mallinckrodt further stated that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and agreed that it would “design and operate a system that meets the requirements of 21 C.F.R. § 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product.” Mallinckrodt specifically agreed “to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”

498. The 2017 Mallinckrodt MOA further details the DEA’s allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer:

- a. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt’s alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt’s alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt’s alleged failure to: conduct adequate due diligence of its customers;
- b. Detect and report to the DEA orders of unusual size and frequency;
- c. Detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
 - i. orders that resulted in a disproportionate amount of a substance which is most often abused going to a

³²⁸ Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), available at <https://www.justice.gov/usao-edmi/press-release/file/986026/download> (“2017 Mallinckrodt MOA”).

particular geographic region where there was known diversion,

- ii. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and
- iii. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
- d. Use “chargeback” information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
- e. Take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.³²⁹

499. Mallinckrodt agreed that its “system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and would “design and operate a system that meets the requirements of 21 C.F.R. 1301.74(b) [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”³³⁰

³²⁹ *Id.* at 2-3.

³³⁰ *Id.* at 3-4.

500. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”³³¹

501. The same duties imposed by law on Mallinckrodt were imposed upon all Marketing Defendants and Purdue.

502. The same business practices utilized by Mallinckrodt regarding “charge backs” and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including the other Marketing and Distributor Defendants.

503. Through the charge back data, the Marketing Defendants could monitor suspicious orders of opioids.

504. The Marketing Defendants and Purdue failed to monitor, report, and halt suspicious orders of opioids as required by law.

505. The Marketing Defendants’ and Purdue’s failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

506. The Marketing Defendants and Purdue have misrepresented their compliance with the laws regulating controlled substances.

507. The wrongful actions and omissions of the Marketing Defendants and Purdue that caused the diversion of opioids and which were a substantial contributing factor to and/or

³³¹ *Id.* at 5.

proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' allegations of Defendants' unlawful acts below.

508. The Marketing Defendants' and Purdue's actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States, including in Kentucky.

XII. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS

509. The Distributor Defendants owe a duty under Kentucky common law and statutory law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

510. The foreseeable harm from a breach of these duties was the medical, social, and financial consequences rippling through society, arising from the abuse of diverted opioids for nonmedical purposes.

511. Each Distributor Defendant repeatedly and purposefully breached its duties under Kentucky law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes, with the resultant medical and financial damages.

512. For over a decade, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

513. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality, with social and financial costs borne by, among others, individuals, families and hospitals.

514. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

A. The Distributor Defendants Breached Their Duties

515. Opioids are a controlled substance. Schedule II controlled substances have “high potential for abuse,” which “may lead to severe psychic or physical dependence.” *See* KRS § 218A.060; KRS § 218A.070; KRS § 218A.080.

516. Each Distributor Defendant was required to obtain a license from Kentucky’s Board of Pharmacy. Each Distributor Defendant is a wholesaler that engaged in the chain of distribution or resale of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. In failing to maintain effective controls against their diversion and illegitimate use, it is foreseeable that controlled substances will be prescribed for illegitimate purposes, diverted by corrupt retailers, and abused by the public that have fallen victim to their “high potential for abuse.” *See* KRS § 218A.070.

517. Each Distributor Defendant has an affirmative duty to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. In addition, the Kentucky law imposes specific record-keeping requirements on manufacturers and wholesalers who are required to maintain detailed records of all inventory of narcotic drugs received by and disposed of by them. *See, e.g.*, KRS § 315.0351; KRS § 315.036; KRS § 315.402 The information required to be collected and maintained includes dates of production and

distribution and contact information of the persons to whom or for whose use the drugs were sold, administered or dispensed.

518. “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

519. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

520. These prescription drugs are regulated for the purpose of providing a “closed” system intended to reduce the widespread diversion of these drugs out of legitimate channels

into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

521. Because distributors are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on them to maintain effective controls to prevent diversion of controlled substances.

522. As the DEA advised the Distributor Defendants in a letter dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”³³²

523. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.³³³

524. The DEA’s September 27, 2006 letter also warned the Distributor Defendants that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a “statutory

³³² See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) (“This letter is being sent to every commercial entity in the United States registered with the Drug Enf’t Admin. (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, ECF No. 14-51 (D.D.C. Feb. 10, 2012) (“Rannazzisi Letter to Cardinal Health”).

³³³ See Brief for HDMA and NACDS, *supra* n. 293, 2016 WL 1321983, at *4 (“[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”).

responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”³³⁴ The letter also instructs that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”³³⁵ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

525. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.³³⁶ This letter reminds the Distributor Defendants of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”³³⁷ The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive.

³³⁴ Rannazzisi Letter to Cardinal Health, *supra* note 332, at 2.

³³⁵ *Id.* at 1.

³³⁶ *Id.* at 2.

³³⁷ See Rannazzisi Letter to Cardinal Health, *supra* n. 332.

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.³³⁸

526. Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”³³⁹

527. The Distributor Defendants admit that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”³⁴⁰

528. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association (now known as the HDA, a front group of the Defendants, discussed below), the trade association of pharmaceutical distributors, explain that distributors are “[a]t the

³³⁸ *Id.*

³³⁹ *Id.*

³⁴⁰ See Amicus Curiae Brief of Healthcare Distribution Mgmt. Ass'n in Support of App. Cardinal Health, Inc., *Cardinal Health, Inc. v. U.S. Dep't of Justice*, No. 12- 5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 (“Brief of HDMA in Support of Cardinal”).

center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process, and note in particular: If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.³⁴¹

529. The FTC has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC’s motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the

³⁴¹ Healthcare Distribution Mgmt. Ass’n (HDMA)), Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, *filed in Cardinal Health, Inc. v. Holder*, Doc. No. 1362415 (App’x B), No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B).

potential anti-competitive effect of a proposed merger between Cardinal, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

530. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

531. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which the Distributor Defendants knew prescription opioids were likely to be diverted.

532. Each Distributor Defendant owes a duty to monitor, detect and refuse suspicious orders of prescription opioids, to report suspicious orders of prescription opioids and to prevent the diversion of prescription opioids into illicit markets.

533. The laws at issue here concerning the sale and distribution of controlled substances are also the public safety statutes and regulations of states in which Plaintiffs' hospitals operate.

534. The Distributor Defendants' violations of public safety statutes constitute *prima facie* evidence of negligence under state law.

535. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by state law which are required to legally acquire and maintain a license to distribute prescription opiates.

536. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

B. Inadequate Compliance, Staffing and Training

537. First, the Distributor Defendants routinely failed to staff their compliance functions with qualified personnel, and failed to provide those compliance employees and their sales representatives with appropriate training. Even front-line compliance functions, such as approving threshold increases, detecting, blocking, and reporting suspicious orders, and terminating and/or suspending customers, were often assigned to operations, sales and administrative employees who had no experience with regulatory compliance of any kind.

C. Inadequate Scrutiny of Customers

538. None of the Distributor Defendants had a consistent practice of conducting appropriate due diligence of either prospective new customers or their existing customers. New customers were routinely on-boarded despite the acknowledged presence of unresolved red flags, and none of the Distributor Defendants ensured that additional investigations were conducted

when existing customers made suspicious orders, even when compliance staff flagged those orders as suspicious, blocked them, and reported them to the State.

539. Indeed, the Distributor Defendants routinely allowed their customers to make multiple suspicious orders within the same month, week, or even year, without conducting any additional due diligence of those customers. In fact, salespeople would warn customers when they were approaching their monthly threshold limits for ordering certain categories of controlled substances, putting them in a position to assist their customers in *evading* compliance reviews that would have otherwise occurred by manipulating the timing and volume of their orders.

540. Even where customers had to be blocked from ordering opioids in excess of their monthly threshold allowance multiple times within that month, the Distributor Defendants would allow those customers to resume ordering opioids the next month, at the same volume levels as before, without requiring any follow up investigation.

541. And none of the Distributor Defendants conducted periodic, unexpected due diligence audits of their customers, even among the easily identifiable and relatively small groups of pharmacies that consistently ordered the highest volumes of opioids. Instead, these pharmacies could go for years without the Distributor Defendants updating their knowledge of those customers' prescriber base, customer traffic patterns, and other relevant store conditions. Even when those pharmacies were scrutinized, the customer was often warned in advance.

D. Failure to Detect, Block and Report Suspicious Orders

542. The Distributor Defendants failed to report "suspicious orders," which the Distributor Defendants knew were likely to be diverted, to the relevant governmental authorities.

543. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

544. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

545. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

546. The Distributor Defendants breached their duty to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and failed to inform the authorities, including the DEA, of suspicious orders when discovered in violation of their duties under state law.

547. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific, and industrial channels.³⁴²

548. While the Distributor Defendants’ policies nominally allowed for compliance staff to identify any order as suspicious, as a matter of practice, only orders that exceeded a customer’s monthly threshold limit for a particular category of controlled substances would actually trigger a compliance review. As a result, untold numbers of opioid orders that should have been reviewed due to their unusual size or frequency, or their departure from the customers’ normal ordering patterns, were never even checked to determine whether they were suspicious. Because the Distributor Defendants routinely allowed their customers to obtain information about the monthly threshold limits governing their orders of opioid products, orders customers made within the limits after being enabled to “game” them were improperly excluded from

³⁴² See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

compliance review, when they all should have been checked to see whether the customers were deliberately structuring their orders to evade scrutiny.

549. Even as to orders that exceeded customers' monthly thresholds, the Distributor Defendants, over varying time periods, routinely failed to accurately identify those orders as suspicious. Instead, they released those orders for delivery based on perfunctory and unverified information provided by the customer, or for no documented reason at all. Moreover, even when the Distributor Defendants did identify orders as suspicious and did block them from delivery to customers, they routinely failed to report those suspicious orders to the State, sometimes going months or years without reporting any at all. When they did make suspicious-order reports, the reports were routinely incomplete, for example, by failing to identify all of the relevant suspicious orders for a customer, even when they were made within the same month, week, or even day.

550. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.³⁴³

E. Distributor Defendants Failed to Suspend Suspicious Customers

551. The Distributor Defendants failed to act to suspend customers from ordering controlled substances, let alone terminate their accounts, even after compliance staff had blocked and reported dozens, or even hundreds, of suspicious orders from those customers. In the

³⁴³ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy*, Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

relatively rare instances where a customer had been terminated or suspended, the Distributor Defendants allowed them to reinstate their accounts, or open accounts under new business names, without investigating and resolving the issues that had led to the initial termination or suspension.

F. Distributor Defendants Failed to Adequately Maintain Accessible Data Concerning Customers and Prescribers

552. None of the Distributor Defendants systematically stored, organized, and made accessible for reference information about their customers or their owners, pharmacists, and top prescribers, in order to allow for meaningful future compliance efforts.

553. The Distributor Defendants did not require compliance staff to obtain customers' prescriber information, and some actually changed their policies to *forbid* such inquiries, willfully blinding themselves to one of the most important indicators of diversion. While compliance staff and/or third-party investigators retained by the Distributor Defendants would sometimes flag prescribers as suspicious in the course of conducting due diligence of a pharmacy, that information was not stored or shared in any useable format. As a result, when the same suspicious prescriber appeared among another pharmacy's top prescribers, the compliance staff handling that subsequent due diligence investigation would have no way of knowing about this risk that had already been identified, unless they had personally handled the earlier investigation, and happened to remember the prescriber's name. Similarly, they made no effort to collect and compare information about pharmacies that made high-volume orders of opioids, had been flagged for making suspicious orders, or had been suspended or terminated for suspicious or illegal practices. As a result, compliance staff had no way of knowing that a pharmacy they were investigating shared ordering patterns or top prescribers with another risky, suspicious, and/or previously disciplined customer.

G. The Distributor Defendants Failed to Report Violations to Government Authorities

554. The Distributor Defendants failed to promptly report compliance violations to the Commonwealth of Kentucky, and other governments. Indeed, even when they actually detected failures in their compliance systems, they made no effort to report those known incidents. More broadly, due to the combination of systematic failures riddling their compliance systems described above, none of the Distributor Defendants had the competence to effectively detect their own violations.

555. For example, if any of the relevant Distributor Defendants had conducted periodic audits of their own records of customers' orders, those customers' patterns of ordering in excess of their monthly threshold allowance for opioid products, the number of times those orders were released without justification, and the number of times those orders were blocked as suspicious without being reported to government agencies and/or triggering additional investigations, suspensions, or terminations, they would have each been obliged to report hundreds, if not thousands, of violations at a time.

556. In short, the Distributor Defendants deliberately lied to Kentucky and other states, both expressly and by omission, year in and year out, about the effectiveness of their compliance systems and the incidence of violations, so that they could fraudulently maintain their licenses to continue doing business in Kentucky and elsewhere.

557. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

H. Each of the Distributor Defendants Engaged in Wrongful Conduct

1. Cardinal

558. Defendant Cardinal Health breached its duties under federal and state law.

559. As shown by the ARCOS Data, Cardinal Health distributed an extraordinary amount of prescription opioids into Plaintiffs' communities. From 2006 to 2014, Cardinal Health distributed 328,472,955 pills of hydrocodone and oxycodone into Kentucky, making it the third largest distributor of these opioid pills during this eight-year period. Cardinal Health's excessive distribution was made possible by, and is evidence of, Cardinal Health's failures to comply with its duties under state and federal law.

560. From 1996 to 2008, Cardinal Health did not have an anti-diversion program that could adequately monitor and detect suspicious orders of opioids or timely report any suspicious orders.

a. Cardinal's Flawed Written Policies Enabled Opioid Diversion

561. Cardinal's written policies for compliance were and are contained in Standard Operating Procedures ("SOPs") that apply to its various operating and sales departments. These SOPs were first implemented in 2008 and have since undergone several revisions.

562. These policies were fundamentally flawed in that they were not coordinated within the context of a consistent, unified umbrella policy to prevent the diversion of controlled substances, resulting in employees governed by one of the SOPs being unaware of the obligations imposed by other SOPs on other employees, even when effective anti-diversion measures required that understanding and coordination. Furthermore, these documents are not readily available even to the employees charged with implementing them.

563. In addition, Cardinal's SOPs and policies contained numerous gaps that would have prevented them from effectively preventing diversion, even if enforced. For example, these policies:

- a. Allowed new accounts with no formal mechanism to ensure review and approval by a supervisor;
- b. Allowed onboarding of new accounts even where customers failed to provide requested information about other suppliers, dispensing data, and top prescriber information; and
- c. Allowed compliance staff to release a customer's first order in excess of its monthly threshold, regardless of whether the customer made other orders in excess of the same drug threshold at the same time.

b. Cardinal's Failure to Effectively Prevent Diversion in Practice

564. At all relevant times, Cardinal failed to employ qualified compliance staff to implement these policies, failed to adequately train those compliance staff or its sales representatives concerning Cardinal's anti-diversion duties, and failed to enforce even the defective policies it had in place.

565. Cardinal failed to install qualified personnel in key compliance positions. For example, Cardinal's front-line "New Account Specialists" and "Analysts," responsible for onboarding new customers and monitoring existing customers, respectively, were routinely recruited from the ranks of the company's existing pool of administrative assistants. These employees, who had no experience in regulatory compliance, were generally supervised by pharmacists or other professionals with no prior experience in supervising investigative functions.

566. Moreover, Cardinal failed to provide meaningful training to either these unqualified compliance personnel or sales representatives. Instead, Cardinal expected the compliance staff to "learn on the job" through informal in-person "team meetings." Due to the

lack of proper training and clear guidelines, compliance staff did not fully understand critical components of their jobs and often developed their own procedures and benchmarks for reviewing customers.

567. Unsurprisingly, these unqualified and untrained staff routinely failed to follow even the most basic procedures required under the company's various SOPs. In addition, Cardinal allowed customers to reinstate their accounts through the new account onboarding process despite having compliance red flags.

568. Even to staff charged with investigations and anti-diversion, the message was clear: without sales, there is no Cardinal. Indeed, many of Cardinal's policies and practices have prioritized sales over regulatory obligations.

569. In 2012 and 2013, Cardinal took significant steps to renew focus on increased sales at the cost of a robust and responsible compliance structure, thereby keeping as customers pharmacies that it knew or should have known were high risk for diversion of opioids. For example, Cardinal:

- a. Continuously reduced the due diligence information collected from prospective and existing customers, diluting the customer questionnaire, removing the requirements to collect photos of the pharmacies, and ceasing to ask about top prescribers;
- b. Expanded the geographic scope of investigators with essential regional knowledge of, for example, top prescribers and their locations relative to the pharmacies where their prescriptions were being filled, thus reducing the investigators' efficacy;
- c. Restricted the information reviewed from site visits by first removing the investigator comment section and for a time eliminating written reports entirely; and
- d. Demoted, moved to non-compliance functions, or let go several staff members who articulated an interest in expanding the company's compliance functions, aggressively scrutinizing pharmacy customers, and/or terminating problematic customers.

570. As to existing customers, Cardinal routinely failed to follow the SOP's procedures for detecting, monitoring, and reporting suspicious orders. Cardinal's compliance staff routinely released orders in excess of a customer's threshold without conducting the follow-up investigation and providing the detailed written justification called for by the SOPs.

571. Even when Cardinal did block customers' orders and report them as, it routinely took no steps to suspend or terminate those customers pending further investigation, and instead allowed them to continue receiving their threshold amount of opioids month after month thereafter, regardless of whether the customer continued to make additional suspicious orders.

572. Between 2012 and 2017, for example, Cardinal reported twelve or more opioid related suspicious orders for at least one year-the equivalent of one per month-for hundreds of pharmacies nationwide. Those pharmacies had several known red flags in their shipment orders and prescription data. More than half of these pharmacies: (a) exceeded the 90th percentile in the State in terms of opioid volume shipped; (b) exceeded the 90th percentile in the State in terms of oxycodone volume shipped; and (c) exceeded the 90th percentile in the State in terms of median strength of opioids prescribed per day. Nonetheless, even after reporting twelve or more opioid-related suspicious orders for one of these pharmacies, Cardinal continued to ship opioids, on average, for *more than three years*. Within this group of suspect pharmacies that Cardinal did nothing to control, these included particularly egregious cases in which Cardinal reported more than 50 opioid-related suspicious orders per year-the equivalent of *one suspicious order per week* to the authorities for *three or more consecutive years*.

573. In still other instances, neither Cardinal nor other distributors reported numerous suspicious orders, but almost certainly should have, given that a handful of prescribers were responsible for writing an unusually high percentage of the pharmacy's opioid prescriptions. By

itself, having a high concentration of opioid prescriptions written by a small number of providers is a known red flag for opioid diversion. Subsequently, these pharmacies had among the highest percentage of prescriptions written by providers who were indicted or convicted on opioid-related prescribing and distribution charges.

574. Examples of egregious cases identified in an investigation by a state attorney general included:

- a. A pharmacy in the 99th percentile in the state, to which Cardinal reported an average of 85 suspicious orders per year for five years, the equivalent of more than once a week, yet as of 2018, as of 2018, this pharmacy continued to receive opioids from Cardinal.
- b. A pharmacy in the 95th percentile in the state, to which Cardinal, from 2012 to 2018, shipped more than 20,000 grams of opioids, the equivalent of about thirteen 30mg oxycodone pills for every person in the county.
- c. A pharmacy in the 90th percentile where more than 20% of its customers have received opioid prescriptions by three or more doctors in a six-year period, and to which Cardinal continued to ship opioids after other distributors had issued 223 SORs.
- d. A pharmacy in the 99th percentile where approximately 60% of prescriptions were written by prescribers who were later indicted or convicted, and to which Cardinal has failed to issue a single SOR as of December 2017.

575. Finally, even if Cardinal had conducted due diligence to investigate its high-volume opioids customers, Cardinal's failure to implement any system to store and share information about their suspicious customers and/or suspicious prescribers would have compromised the effectiveness of any such investigation.

576. Due to these flaws, Cardinal routinely continued to supply pharmacies that filled prescriptions for prescribers that had been flagged in its own (infrequent) investigations of other pharmacies as likely sources of diversion.

c. **Cardinal Was Put on Notice of its Wrongful Conduct**

577. In addition to numerous instances, including examples cited above, in which Cardinal's own employees acknowledged failures in its compliance systems, the company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties.

578. To date, Cardinal has paid a total of \$98 million in fines and other amounts involving multiple DEA and various state actions relating to its improper management and distribution of opioids to pharmacies across the United States.

579. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven warehouses³⁴⁴ around the United States (the “2008 Cardinal Settlement Agreement”).³⁴⁵ These allegations included failing to report to the DEA thousands of suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.³⁴⁶

³⁴⁴ Including its Lakeland, Florida facility. See <https://www.dea.gov/pubs/pressrel/pr100608.html>. In 2012, Cardinal described the Lakeland facility as shipping “an average of about 4 million dosage units of prescription drugs, including about 500,000 dosage units of controlled substances, on a monthly basis to more than 5,200 customers in Florida, Georgia and South Carolina. The volume of prescription drugs distributed makes the Lakeland facility the largest prescription drug wholesaler in Florida.” *Cardinal Health, Inc. v. Eric Holder, Jr., Att’y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-1, at 6; 3-13 at 2; 3-15 (Feb. 3, 2012).

³⁴⁵ Settlement and Release Agreement and Administrative Memorandum of Agreement (Sept. 30, 2008), a cached version is available at https://webcache.googleusercontent.com/search?q=cache:O7Te0HbVfpIJ:https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf+&cd=2&hl=en&ct=clnk&gl=us; Press Release, U.S. Att’y Office, Dist. of Colo., Cardinal Health Inc., Agrees to Pay \$34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

³⁴⁶ *Id.*

580. In connection with the 2008 Cardinal Settlement Agreement, the DEA stated that “[d]espite [its] repeated attempts to educate Cardinal on diversion awareness and prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for controlled substances filled by its distribution facilities located throughout the United States.”³⁴⁷ The DEA concluded that “Cardinal’s conduct allowed the ‘diversion’ of millions of dosage units of hydrocodone from legitimate to non-legitimate channels.”³⁴⁸

581. As part of the 2008 Cardinal Settlement Agreement, Cardinal agreed to “maintain a compliance program designed to detect and prevent diversion of controlled substances as required by the CSA and applicable DEA regulations.”³⁴⁹ However, in 2012, the DEA issued an “immediate suspension order,” suspending Cardinal’s registration with respect to Cardinal’s drug distribution facility in Lakeland, Florida. That order stated that “Despite the [2008 Cardinal Settlement Agreement], the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA].”³⁵⁰ For example, from “2008-2009, Cardinal’s sales to its top four retail pharmacies [in the State of

³⁴⁷ U.S. Att’y Office, Dist. of Colo., *Cardinal Health Inc. Agrees to Pay \$34 Million to Settle Claims that It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* (Oct. 2, 2008), available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

³⁴⁸ *Id.*

³⁴⁹ *Cardinal Health, Inc. v. Eric Holder, Jr., Att’y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-4, at ¶ 2 (Feb. 3, 2012).

³⁵⁰ *Id.* at ¶ 3.

Florida] increased approximately 803%. From 2009 to 2010, Cardinal's sales to its top four retail pharmacies [in the State of Florida] increased 162%.”³⁵¹

582. In 2012, Cardinal reached another settlement with the DEA relating to its failure to “conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels” resulting in systemic opioid diversion in its Florida distribution center (the “2012 Cardinal Settlement Agreement”).³⁵² Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area pharmacies, nearly fifty times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years.³⁵³ The DEA found that Cardinal's own investigator warned Cardinal against selling opioids to these pharmacies, but that Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacies.³⁵⁴ Instead, Cardinal's opioid shipments to the pharmacies increased.³⁵⁵

583. In the 2012 Cardinal Settlement Agreement, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances as required by the CSA, on

³⁵¹ *Id.* at ¶ 4.

³⁵² Administrative Memorandum of Agreement (May 14, 2012), *available at* https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed August 1, 2018); Press Release, Drug Enf't Admin., DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), *available at* <https://www.dea.gov/pubs/pressrel/pr051512.html>.

³⁵³ *Id.*

³⁵⁴ *Id.*

³⁵⁵ *Id.*

or before May 14, 2012; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.³⁵⁶

584. In December 2016, Cardinal again settled charges that it had violated the CSA by failing to prevent diversion of oxycodone for illegal purposes, this time for \$44 million (the “2016 Cardinal Settlement Agreement”).³⁵⁷ The settlement covered DEA allegations that Cardinal had failed to report suspicious orders across Washington, Maryland, New York, and Florida.³⁵⁸ The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case.³⁵⁹ The settlement also covered a Cardinal subsidiary, Kinray, LLC, which failed to report a single suspicious order despite shipping oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate.³⁶⁰

d. Cardinal Actively Marketed Prescription Opioids

585. Cardinal worked to increase sales of opioids through a range of in-house marketing platforms directed at prescribers, pharmacists, and consumers, implemented nationally.

³⁵⁶ Administrative Memorandum of Agreement, *supra* n. 352.

³⁵⁷ U.S. Att’y Office, Dist. of Md., *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016), available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act>.

³⁵⁸ *Id.*

³⁵⁹ *Id.*

³⁶⁰ *Id.*

586. Cardinal not only offers marketing services to its drug manufacturer clients, it incentivizes and encourages manufacturers to use these marketing channels as a way of building their business and increasing sales of prescription opioids.

587. Purdue and other manufacturers worked hand-in-glove with Cardinal to promote their products through the distributors to pharmacies and pharmacists.

588. Cardinal profited in two ways from its marketing activities: (1) it was paid by the drug manufacturers to promote their prescription opioids, and/or (2) it was paid from increases in pharmacy drug sales that resulted from these marketing efforts.

589. The targeting of pharmacists by Cardinal in its marketing activities was particularly problematic because of Cardinal's existing and often long-term business relationships with pharmacies—with whom Cardinal shared a legal responsibility to prevent diversion. Opioid distributors, like Cardinal, were in a unique and trusted position in the controlled substances supply chain from which they could have spoken truthfully to their pharmacy customers about the serious risks posed by opioids (including the risk of diversion). They could have remained silent about the benefits and risks of opioids, and simply filled orders and shipped drugs. Instead, Cardinal abused its unique position for profit, by contributing to the chorus of deception surrounding opioids.

590. To engage in the promotion of controlled substances at all, under the circumstances detailed in this Complaint, was a dereliction of Cardinal's duties to prevent opioid diversion. Through these marketing activities, Cardinal contributed to and reinforced the deceptive and misleading marketing messages that healthcare providers received about opioids through other channels. Moreover, much of the Cardinal's marketing content was deceptive, because it either affirmatively misrepresented the benefits and risks of prescription opioids, or it

omitted important information about the risks of prescription opioids. Cardinal knew or should have known that these marketing messages—particularly those that misrepresented or omitted material information about the potential for diversion or risks of addiction associated with prescription opioids—were deceptive.

591. Through marketing activities, Cardinal built upon, reinforced, and profited from the drug manufacturers' campaign to deceive healthcare providers about the risks and benefits of prescription opioid use—a campaign that encouraged and normalized over-prescribing and over-dispensing of prescription opioids.

592. Cardinal made false statements that it had no role in influencing the prescribing or dispensing of prescription opioids and did not promote and market any pharmaceuticals-including opioids-directly to consumers.

2. AmerisourceBergen

593. Defendant AmerisourceBergen breached its duties under federal and state law.

594. As shown by the ARCOS Data, AmerisourceBergen distributed an extraordinary amount of prescription opioids into Plaintiffs' communities. AmerisourceBergen's excessive distribution was made possible by, and is evidence of, AmerisourceBergen's failures to comply with its duties under state and federal law.

a. AmerisourceBergen's Flawed Written Policies Enabled Opioid Diversion

595. AmerisourceBergen is the nation's third largest drug distributor. AmerisourceBergen's written policies for compliance were and are contained within its Diversion Control Program and its Order Monitoring Program ("COMP"). The programs are administered by AmerisourceBergen's Corporate Security and Regulatory Affairs ("CSRA"). From 2007 to 2015, the program's specifics were scattered through a series of policy and

procedure documents, and which were not uniform for AmerisourceBergen and its subsidiary, Bellco Health, which it acquired in 2007.

596. AmerisourceBergen compliance policies are flawed from the point of initial new customer on boarding. Since 2007, AmerisourceBergen has generally required a customer questionnaire, a site visit, license verification, and online investigation as part of its new customer due diligence process. A central component of AmerisourceBergen's new customer procedure is its Retail Pharmacy Questionnaire ("590 Form"). The form asks for information about other distributors, disciplinary history, customer payment methods, percentages of controlled substances, usage numbers for specific high-risk drugs, and top prescribers of opioids, among other questions. Though the form requests information about prescribing physicians, it is not AmerisourceBergen's policy to perform news searches on those prescribers as part of the new customer procedure, and controlled substances could account for up to-of prescriptions dispensed before triggering additional investigation.

597. AmerisourceBergen does not require new customers to provide usage reports or dispensing data as part of the on boarding process. By relying on these customers to self-report without any documented verification, AmerisourceBergen does not fulfill its obligation of truly knowing its customers' business practices.

598. Both prior to and after program revision, AmerisourceBergen's policies have allowed for frequent threshold manipulation to avoid orders being held for review, rejected from shipment, or reported as suspicious. Staff reviewing the form have high benchmarks for these numbers before considering them red flags.

599. AmerisourceBergen's policies are not sufficient to comply with the requirements of Kentucky law and regulations and similar requirements of other states. Under

AmerisourceBergen's deficient policies, it does not hold for review orders that only meet one of these qualifications. By limiting the orders even held for review, AmerisourceBergen's policy does not fulfill its obligation to identify even orders of interest, much less suspicious orders.

600. Examples of egregious cases identified recently in a complaint filed by a state attorney general included:

- a. A pharmacy at or above both the 99th percentile in terms of both number of opioid orders and total opioid weight, at which, between 2014 and 2016, more than 10% of its prescriptions were written by prescribers who were later indicted or convicted of opioid-related prescribing and distribution charges, concerning which AmerisourceBergen reported nearly 200 SORs in 2013-14, and to which as of 2018, AmerisourceBergen was still serving as this pharmacy's primary opioid distributor;
- b. A pharmacy where, between 2013 and 2017, 77% of its prescriptions, on average, were written by prescribers who were later indicted or convicted, including 90% in 2014, and to which Amerisource appears to have only stopped shipping in 2017; and
- c. A pharmacy that exceeded the 95th percentile for the percentage of oxycodone volume shipped for five years straight (2012 to 2016), where on average 58% of its opioid prescriptions were paid in cash (99th percentile), where for three consecutive years (2013 to 2015) approximately half of all opioid scripts were filled by prescribers who were later convicted, and which, as of 2018, was still a customer of AmerisourceBergen.

b. AmerisourceBergen's Failure to Effectively Prevent Diversion in Practice

601. At all relevant times, AmerisourceBergen failed to employ sufficient numbers of qualified compliance staff to implement these policies, failed to ensure those compliance staff were meeting AmerisourceBergen's anti-diversion duties, and failed to enforce even the defective policies it had in place. Among other deficiencies, AmerisourceBergen failed to sufficiently staff its compliance departments.

602. Since the integration of Bellco into AmerisourceBergen and the revamp of its Diversion Control Program in 2015, the company has increased anti-diversion staffing, but has not significantly increased the number of fully trained ground level employees. Since that time, AmerisourceBergen has maintained only five to seven front-line employees on its Diversion Control Team, responsible for reviewing new customers and monitoring its existing customers.

603. Many of AmerisourceBergen's compliance violations begin with its new customer policy. The process relies heavily on the customer 590 Form, given that AmerisourceBergen only requests dispensing information from new customers when it already knows of potential issues. For example, dispensing data was requested recently in considering customers moving from distributor Morris & Dickson Company-including customers that prompted a DEA investigation because of their high-volume opioid purchasing.

604. Despite the 590 Form's being so critical to understanding its customers and ensuring it can fulfill its regulatory obligations, and despite numerous other AmerisourceBergen procedures relying on reviewing or updating this form, AmerisourceBergen has had significant issues related to failing to perform even this baseline screening. Bellco Generics customers, for example, regularly completed the 590 Form independently, submitted it to Bellco, and were on boarded thereafter without receiving a site visit.

605. Disjunction between AmerisourceBergen and Bellco has led to many compliance failures. Until system integration in or around November 2015, staff had no systematic way of identifying dual customers. The lack of an integrated system also meant that thresholds were not coordinated between AmerisourceBergen and Bellco at any point. As a result, a dual customer could have high thresholds set with both, could be exceeding both thresholds, or even having its threshold periodically increased with both, without detection. In or around April 2013,

AmerisourceBergen implemented a policy for dual customers that prevented both AmerisourceBergen and Bellco from supplying controlled substances to the same customer, but implementation was spotty, and, in practice, only a small percentage of orders flagged for review are cancelled, and even fewer are deemed suspicious.

606. AmerisourceBergen has a high tolerance for apparent compliance issues before it will terminate a customer. It lacked an internal rule or policy that requires investigation of a customer based on a specific number of suspicious order reports. Even when customers were restricted, blocked, or terminated, AmerisourceBergen's system failed to ensure their accounts were de-activated.

607. The one area in which AmerisourceBergen has consistently stood out as compared to its major competitors is its unwillingness to identify suspicious orders, even among customers that regularly exceeded their thresholds and presented multiple red flags of diversion. During this time, numerous AmerisourceBergen opioid customers exhibited several common indicators of suspicious activity for multiple years. These flags included:

- a. Scoring above the 90th percentile in the county for opioid order volume;
- b. Scoring above the 90th percentile in the county for total opioid orders;
- c. Scoring above the 90th percentile in the county for oxycodone order volume;
- d. Scoring above the 90th percentile in the county for total oxycodone orders;
- e. Scoring above the 90th percentile in the state for the percentage of oxycodone volume shipped out of all controlled substances shipped;
- f. Filling prescriptions by prescribers who were later indicted or convicted on opioid-related prescribing and distribution charges;
- g. Scoring above the 90th percentile in terms of percentage of patient doctor-shoppers;

- h. Scoring above the 90th percentile in terms of percentage of cash payments; and
- i. Scoring above the 90th percentile in terms of the median MME prescribed per day.

c. **AmerisourceBergen Was Put on Notice of its Wrongful Conduct**

608. AmerisourceBergen's deficiencies and failures did not go undetected. The company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties.

609. AmerisourceBergen has paid \$16 million in settlements and had certain licenses revoked as a result of allegations related to the diversion of prescription opioids.

610. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.³⁶¹ Over the course of one year, AmerisourceBergen had distributed 3.8 million dosage units of hydrocodone to "rogue pharmacies."³⁶² The DEA suspended AmerisourceBergen's registration after determining that "the continued registration of this company constitutes an imminent danger to public health and safety."³⁶³

³⁶¹ Press Release, Drug Enf't Admin., *DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances* (Apr. 24, 2007), available at <https://www.dea.gov/divisions/mia/2007/mia042407p.html>.

³⁶² *Id.*

³⁶³ *Id.*

611. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.³⁶⁴

3. H.D. Smith

612. Defendant H.D. Smith breached its duties under federal and state law.

613. As shown by the ARCOS Data, H.D. Smith distributed an extraordinary amount of prescription opioids into Plaintiffs' community. H.D. Smith's excessive distribution was made possible by, and is evidence of, H.D. Smith's failures to comply with its duties under state and federal law.

614. According to ARCOS Data, H.D. Smith was one of the top five distributors of oxycodone and hydrocodone pills in twenty-three Kentucky counties during the eight-year period from 2006 to 2014. In just these twenty-three Kentucky Counties, H.D. Smith distributed 33,313,840 pills during this eight-year period.

a. H.D. Smith's Flawed Written Policies Enable Opioids Diversion

615. Through 2008, H.D. Smith only had two undated policies that were at least nominally in place that covered suspicious order monitoring. These policies were little used. The fact that these policies even existed was not well known by many employees of H.D. Smith.

616. In or around 2008, H.D. Smith began developing a computer based suspicious order monitoring system which H.D. Smith calls CSOMP. The system did not include pattern and frequency as considerations. Another flaw in the program provided for automatic release of all orders by new pharmacies in order for them to "ramp up." Orders which hit CSOMP limits

³⁶⁴ Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion*, Law360.com (Aug. 9, 2012), available at <https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion>.

were automatically released, allowing the customer to build a high-volume sales “history.” Further, hundreds of people within the company had authority to release a held order.

617. In or around 2014, H.D. Smith hired a new compliance officer and began to create an improved CSOMP program to comply with law requirements. However, in 2016, the new compliance officer was terminated before any enhancements went into effect. H.D. Smith rehired their former Vice President of Compliance, as of May 31, 2016.

b. H.D. Smith’s Failure to Effectively Prevent Diversion in Practice

618. Lori Kirbach worked in the Compliance Department at H.D. Smith until she resigned in February of 2015. When she resigned, she participated in an exit interview, in which she stated that the main reason she wanted to leave H.D. Smith was because she felt that the company, “Is and has been breaking the law for some time.” She did not understand why this was being tolerated. Specifically, Ms. Kirbach stated that CSOMP had not been working correctly since OPUS Go Live and that no one would listen to compliance personnel when the issue was brought up. She confirmed that, “Compliance is releasing orders that they should not be releasing.”³⁶⁵

I. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties

619. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants’ compliance with their legal duties.

³⁶⁵ See HDS_MDL_00510236.

620. Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017), the Healthcare Distribution Management Association, n/k/a HDA, a trade association run by the Distributor Defendants, and the National Association of Chain Drug Stores (“NACDS”) submitted amicus briefs regarding the legal duty of wholesale distributors. Denying - inaccurately - the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (*e.g.*, by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”³⁶⁶
- b. The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it is changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”³⁶⁷
- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”³⁶⁸
- d. The Associations complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”³⁶⁹

³⁶⁶ Brief for HDMA and NACDS, *supra* n. 293, 2016 WL 1321983, at *4–5.

³⁶⁷ *Id.* at *8 (citations and quotation marks omitted).

³⁶⁸ *Id.* at *14.

³⁶⁹ *Id.* at *22.

- e. The Associations alleged (inaccurately) that “DEA’s regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”³⁷⁰
- f. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”³⁷¹

621. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.³⁷²

622. The Court of Appeals for the District of Columbia Circuit recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. In *Masters Pharmaceuticals*, the Court upheld the revocation of Masters Pharmaceutical’s license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must “decline to ship the order, or conduct some ‘due diligence’ and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order.” Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. A distributor’s investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties.

³⁷⁰ *Id.* at *24–25

³⁷¹ *Id.* at 26.

³⁷² See Brief of HDMA in Support of Cardinal, *supra* n. 340, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry “does not know the rules of the road because” they claim (inaccurately) that the “DEA has not adequately explained them”).

623. Because of the Distributor Defendants' refusals to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.³⁷³ As noted above, the Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.³⁷⁴ These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

³⁷³ *The Drug Enforcement Administration's Adjudication of Registrant Actions*, *supra* n. 313.

³⁷⁴ *Id.*

- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On September 30, 2008, Cardinal entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- g. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone; and
- h. On December 23, 2016, Cardinal agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

624. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.³⁷⁵

³⁷⁵ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.2f757833e3c4; Lenny Bernstein & Scott Higham,

625. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

626. For example, a Cardinal executive claimed that it uses “advanced analytics” to monitor its supply chain and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”³⁷⁶ Given the sales volumes and the company’s history of violations, this executive was either not telling the truth, or, if Cardinal had such a system, it ignored the results.

627. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert.

628. The Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

Investigations: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, WASHINGTON POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.7007bf2b9455; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL (Feb. 18, 2017), https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

³⁷⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* WASHINGTON POST (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.a5f051722a7a.

629. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' allegations of Defendants' unlawful acts below.

630. The Distributor Defendants have abandoned their duties imposed under Kentucky law, taken advantage of a lack of adequate law enforcement, and abused the privilege of distributing controlled substances.

XIII. THE NATIONAL RETAIL PHARMACIES WERE ON NOTICE OF AND CONTRIBUTED TO ILLEGAL DIVERSION OF OPIOIDS

631. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids.³⁷⁷ They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

632. Each of the National Retail Pharmacies does substantial business throughout the United States and Kentucky. This business includes the distribution of prescription opioids.

633. Data shows that the National Retail Pharmacies distributed substantial quantities of opioids, including fentanyl, hydrocodone, and oxycodone in Kentucky. In addition, they distributed substantial quantities of opioids in other states, and these drugs were diverted from these other states to Kentucky. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

³⁷⁷ Plaintiffs' allegations of wrongdoing are pointing to the National Retail Pharmacies not the pharmacy industry who in general serve a vital healthcare function in the United States.

634. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, and use of opioids in communities throughout the country, and in Kentucky in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided other Defendants with the data in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion, but failed to do so.

A. The National Retail Pharmacies Have a Duty to Prevent Diversion

635. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

636. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under Kentucky law. Pharmacy registrants are required to ensure that opioid prescriptions filled by them are written for a legitimate patient for a legitimate medical need in the usual course of practice for the prescriber. *See* KRS § 218A.180(3)(a). In addition, “[e]ach pharmacy shall comply with KRS § 218A.202,” which requires that “Every practitioner or pharmacy which dispenses a controlled substance to a person in Kentucky, or to a person at an address in Kentucky, shall report to the Cabinet for Health and Family Services the data required by this section, which includes the reporting of any Schedule II controlled substance dispensed at a facility licensed by the cabinet and a Schedule II through Schedule V controlled substance regardless of dosage when dispensed by the emergency department of a hospital to an emergency department patient.” KRS § 315.035(7); KRS § 218A.202(3). Because pharmacies themselves

are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

637. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

638. Suspicious pharmacy orders include orders unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

639. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

640. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of sales and distribution that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper conduct.

641. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

642. Despite their legal obligations as registrants under state law, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly. They knew that they made money by distributing opioids under suspicious orders.

643. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. For instance, under CVS's Metrics System, pharmacists are directed to meet high goals that make it difficult, if not impossible, to

comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many orders that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country and in Kentucky. The policies remained in place even as the epidemic raged.

644. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that this problem was compounded by the National Retail Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle orders for opioid painkillers, including what constitutes a proper inquiry into whether an order is legitimate, whether an order is likely for a condition with an approved treatment with opioids, and what measures and/or actions to take when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

645. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to adequately use data available to them to identify pill-mills that were ordering suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of suspicious orders that have contributed to the opioid crisis.

646. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies failed to analyze: (a) the number of opioid orders filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid orders

filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

647. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

648. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid orders.

649. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

B. Multiple Enforcement Actions Against the National Retail Pharmacies Confirm their Compliance Failures.

650. The National Retail Pharmacies have long been on notice of their failure to abide by the law and regulations governing the distribution of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal practices. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

1. CVS

651. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

652. CVS is a repeat offender; the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines as the cost of doing business and has allowed distribution of opioids in quantities significantly higher than any plausible legitimate need would require, and to continue violating its obligations under the law.

653. As recently as March 2019, CVS entered into a \$535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island regarding allegations that its pharmacies in Rhode Island violated federal law "including by... in 39 instances between September 9, 2015 and June 18, 2017, filling a prescription for a Schedule II drug under circumstances ... that the CVS pharmacist filling the prescription knew or had reason to know that the prescription in question was invalid or unauthorized..."

654. This fine was preceded by numerous others throughout the county.

655. In July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.³⁷⁸

³⁷⁸ Press Release, U.S. Attorney's Office E. Dist. of Cal., CVS Pharmacy Inc. Pays \$5M to Settle Alleged Violations of the Controlled Substance Act, U.S. Dep't of Just. (July 11, 2017), available at <https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violationscontrolled-substance-act>.

656. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling orders with no legitimate medical purpose.³⁷⁹

657. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.³⁸⁰

658. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's drug use history before sales of certain opioid drugs.³⁸¹

659. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.³⁸²

³⁷⁹ Press Release, U.S. Attorney's Office Dist. of Md., United States Reaches \$8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances, U.S. Dep't of Just. (Feb. 12, 2016), *available at* <https://www.justice.gov/usao-md/pr/united-states-reaches-8-millionsettlement-agreement-cvs-unlawful-distribution-controlled>.

³⁸⁰ Press Release, U.S. Attorney's Office Dist. of Conn., CVS Pharmacy Pays \$600,000 to Settle Controlled Substances Act Allegations, U.S. Dep't of Just. (Oct. 20, 2016), *available at* <https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-actallegations>.

³⁸¹ Dialynn Dwyer, *CVS will pay \$795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), *available at* <https://www.boston.com/news/localnews/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-inagreement-with-state>.

³⁸² Press Release, U.S. Attorney's Office Dist. of Mass., CVS to Pay \$3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions, U.S. Dep't of Just. (June 30, 2016), <https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filledfake-prescriptions>.

660. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.³⁸³

661. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had sold opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."³⁸⁴

³⁸³ Press Release, U.S. Attorney's Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved With \$450,000 Civil Settlement, U.S. Dep't of Just. (Aug. 10, 2015), *available at* <https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement>.

³⁸⁴ Press Release, U.S. Attorney's Office M. Dist. of Fla., United States Reaches \$22 Million Settlement Agreement with CVS For Unlawful Distribution of Controlled Substances, U.S. Dep't of Just. (May 13, 2015), *available at* <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution>.

662. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.³⁸⁵

663. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.³⁸⁶

664. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.³⁸⁷

2. Walgreens

665. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

666. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of violations of the CSA, including

³⁸⁵ Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News (Sept. 5, 2014), *available at* <http://www.expressnews.com/business/local/article/H-E-B-CVS-fined-over-prescriptions-5736554.php>.

³⁸⁶ Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NEWSOK (May 3, 2015), *available at* <http://newsok.com/article/5415840>.

³⁸⁷ Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay \$11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act, U.S. Dep't of Just. (Apr. 3, 2013), *available at* <https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penaltyclaims-involving-violations-controlled>.

negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.³⁸⁸

667. As part of the settlement, Walgreens admitted that it failed to uphold its obligations as a DEA registrant regarding the above-described conduct.³⁸⁹

668. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

669. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.³⁹⁰

670. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens' corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not

³⁸⁸ Press Release, U.S. Attorney's Office S. Dist. of Fla., Walgreens Agrees to Pay a Record Settlement of \$80 Million for Civil Penalties Under the Controlled Substances Act, U.S. Dep't of Just. (June 11, 2013), *available at* <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-recordsettlement-80-million-civil-penalties-under-controlled>.

³⁸⁹ *Id.*

³⁹⁰ Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

documenting our own potential noncompliance,” underscoring Walgreens’ attitude that profit outweighed compliance with the law or the health of communities.³⁹¹

671. Defendant Walgreens’ settlement with the DEA stemmed from the DEA’s investigation into Walgreens’ distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens’ corporate headquarters pushed to increase the number of oxycodone sales to Walgreens’ Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.³⁹²

672. The six retail pharmacies in Florida that received the suspicious drug shipments from the Jupiter Distribution Center, in turn, filled customer prescriptions that they knew or should have known were not for legitimate medical use.³⁹³

673. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).³⁹⁴

³⁹¹ *Id.*

³⁹² *Id.*

³⁹³ *Id.*

³⁹⁴ *Walgreens to pay \$200,000 settlement for lapses with opioids*, APhA (Jan. 25, 2017) available at <https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids>. .

674. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

675. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when distributing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.³⁹⁵

3. Rite Aid

676. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.

677. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.³⁹⁶

678. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid

³⁹⁵ *Id.*

³⁹⁶ Press Release, Dep't of Justice, Rite Aid Corporation and Subsidiaries Agree to Pay \$5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act, U.S. Dep't of Just. (Jan. 12, 2009), <https://www.justice.gov/opa/pr/rite-aid-corporation-andsubsidiaries-agree-pay-5-million-civil-penalties-resolve-violations>.

pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R 1301.76(b).³⁹⁷

679. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

680. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

681. Throughout the country and in Kentucky in particular, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

682. On information and belief, from the catbird seat of their retail pharmacy operations, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into Kentucky and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

683. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

³⁹⁷ *Id.*

684. On information and belief, because of (among others sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

685. The National Retail Pharmacies' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

XIV. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM AND SUBSTANTIAL DAMAGE ALLEGED HEREIN

686. As the Marketing Defendants' and Purdue's efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the United States. The Supply Chain Defendants have continued to unlawfully ship these massive quantities of opioids.

687. There is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”³⁹⁸

688. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.³⁹⁹

³⁹⁸ See Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241-248 (2015), doi: 10.1056/NEJMsa1406143, available at <http://www.nejm.org/doi/full/10.1056/NEJMsa1406143>.

689. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”⁴⁰⁰

690. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.⁴⁰¹

691. As shown above, the opioid epidemic has escalated with devastating effects: substantial opiate-related substance abuse, hospitalization, and death that goes hand in hand with Defendants’ increased distribution of opioids.

692. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids by Defendants has caused the opioid epidemic to include heroin addiction, abuse, and death.

693. Defendants repeatedly and purposefully breached their duties under federal and Kentucky law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes and the foreseeable, inevitable financial burdens imposed on and incurred by hospitals and other health care providers.

694. Hospitals are integral to the solution to the opioid epidemic, because they can “aid in the proper treatment of postoperative pain while also helping to combat a nationwide epidemic.”⁴⁰² Indeed, “[h]ospital pharmacists...are in an ideal position to help address the

³⁹⁹ See Volkow & McLellan, *supra* n. 99.

⁴⁰⁰ See Califf, *et al.*, *supra* n. 30.

⁴⁰¹ See Press Release, Centers for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., *supra* n. 25.

⁴⁰² Opioid Exit Plan, *supra* n. 181.

opioid epidemic and make sure these agents are used appropriately.”⁴⁰³ But Defendants’ wrongful conduct has jeopardized the ability of Plaintiffs and other hospital purchasers to properly limit their purchasing and dispensing of opioids, particularly at the key junctures of patient admission and discharge. Indeed, by creating and fueling the opioid epidemic, Defendants have impaired the hospitals’ ability to perform their integral responsibilities to patients.

695. During admission, hospital professionals routinely consult with the patient to assess which medications the patient is taking at home. But, due to Defendants’ conduct, hospitals can no longer trust patients to self-report their prescriptions. Hospital pharmacists may also check available databases to ensure that patients are not stockpiling prescription opioids, but such databases often do not record the actual flow of opioids.⁴⁰⁴ Hospital pharmacies’ inability to rely on their patients’ self-reporting, and having to take additional steps to independently verify their patients’ purchases from other sources, imposes additional burdens on hospitals.

696. Then, before discharge, hospital professionals “obtain a list of planned outpatient prescriptions and perform a counseling session on how to safely and effectively control postoperative pain.”⁴⁰⁵ The hospitals’ efforts to provide meaningful counseling is subverted by Defendants’ sales practices described in the Complaint, pursuant to which Defendants have disseminated misinformation throughout all levels of the marketplace and fostered increased demand for their products.

⁴⁰³ Joey Sweeney, *Hospital Pharmacists Can Help Reduce Opioid Prescriptions*, PHARMACY TODAY (July 2016) (emphasis added), available at [https://www.pharmacytoday.org/article/S1042-0991\(16\)30505-9/fulltext](https://www.pharmacytoday.org/article/S1042-0991(16)30505-9/fulltext).

⁴⁰⁴ *Id.* at ¶ 32.

⁴⁰⁵ Opioid Exit Plan, *supra* n. 181.

697. Hospitals must admit opioid users who present in need of intensive care or who display symptoms of mental illness. Defendants knew that federal and state law require hospitals to admit and treat opioid-dependent patients. Similarly, if a pregnant opioid-dependent patient presents for treatment, the hospital must provide care for both the opioid-addicted mother and the opioid-dependent baby. Defendants relied on Plaintiffs to provide a safety net to prevent overdose deaths and treat health consequences arising from opioid dependence and depended on hospitals themselves to mitigate the health consequences of their illegal activities.⁴⁰⁶ In 2011, it is “estimated that [there were] greater than 420[,000 emergency room] visits related to the misuse of abuse of narcotic pain relievers” in the United States.⁴⁰⁷ Hospitals bear an enormous burden in providing care, as insurance covers only a portion of the cost.

698. The increased financial burdens on hospitals include, but are not limited to the following:

- a. Unreimbursed, uncompensated, and/or undercompensated costs for providing healthcare and medical care, additional diagnostic, therapeutic and other treatments for patients suffering from opioid-related addiction or disease, including physical and mental disabilities, overdoses and deaths.;
- b. Costs associated with patient counseling with respect to pain management, necessitated by overprescription to the general population and dissemination of false and misleading information to prospective patients and others; as hospitals and other providers question their patients’ self-reporting, it necessitates further steps to be taken in all phases of treatment and counseling;
- c. Unreimbursed, uncompensated, and/or undercompensated costs of opioids purchased by hospitals themselves, which were direct targets of the

⁴⁰⁶ *Id.* at ¶ 19.

⁴⁰⁷ Cindy Williams, Vice President and Chief Pharmacy Officer, Riverside Health System, *Establishment of an Opioid Stewardship Program*, available at http://www.vshp.org/uploads/6/3/6/0/6360223/williams-opioid_1_per_page.pdf (“Va. Hospital Pharmacists Paper”).

Defendants' marketing campaigns;

- d. Unreimbursed, uncompensated, and/or undercompensated costs of prescription drugs used to treat addiction;
- e. Costs of training additional personnel in the proper treatment of drug overdoses;
- f. Costs associated with obtaining and training staff in the application of naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- g. Additional unreimbursed, uncompensated, and/or undercompensated costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Unreimbursed, uncompensated, and/or undercompensated costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy; and
- i. Substantial reimbursement shortages for patients treated with opioid-related conditions or comorbidities and patients for whom opioid dependence is a condition.

699. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, dependence, morbidity, and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harm to Plaintiffs.

700. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief.

A. Conspiracy Allegations

701. The Defendants conspired with each other and with Purdue (not named in this Complaint as a Defendant), to engage in the wrongful conduct complained of herein and intended to benefit both independently and jointly from their wrongful conduct.

1. Conspiracy Among the Marketing Defendants and Purdue

702. The Marketing Defendants and Purdue agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain. The promotion and marketing network was intended and designed to mislead physicians, patients, health care providers such as hospitals, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids in order to increase sales, revenue, and profit from their opioid products.

703. This interconnected and interrelated network relied on the Marketing Defendants' and Purdue's collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Marketing Defendants and Purdue intended to mislead consumers and medical providers, such as hospitals, of the appropriate uses, risks, and safety of opioids.

704. The Marketing Defendants' and Purdue's collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

705. The Marketing Defendants and Purdue knew that none of these propositions are true.

706. Each Marketing Defendant and Purdue worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, and health care providers, such as hospitals and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

707. What is particularly remarkable about the Marketing Defendants' and Purdue's efforts is the seamless method in which the Marketing Defendants and Purdue joined forces to achieve their collective goal: to persuade consumers and medical providers, such as hospitals, of the safety of opioids, and to hide their actual risks and dangers. In doing so, the Marketing Defendants and Purdue effectively built a new – and extremely lucrative – opioid marketplace for their select group of industry players.

708. The Marketing Defendants' and Purdue's unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network's distinct corporate members.

709. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Marketing Defendant and Purdue to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Marketing Defendants and Purdue.

710. The most unnerving tactic utilized by the Marketing Defendants' and Purdue's network was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by

objective unbiased and disinterested experts in the field, and an unfounded theory or proposition would, or should, never gain traction.

711. Marketing Defendants and Purdue put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Marketing Defendants and Purdue were able to create a false consensus through their materials and references.

712. An illustrative example of the Marketing Defendants' and Purdue's utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

713. Nonetheless, Marketing Defendants and Purdue widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids despite the letter's obvious shortcomings. Marketing Defendants' and Purdue's egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

714. Marketing Defendants' and Purdue's collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers, such as hospitals that opioids were not a concern. The enormous impact of Marketing Defendants' and Purdue's misleading amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly

cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy...

715. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Marketing Defendants committed overt acts in furtherance of their conspiracy.

2. **Conspiracy Among the Marketing Defendants, Purdue, and the Supply Chain Defendants**

716. In addition, and on an even broader level, all the Marketing Defendants and Purdue and Supply Chain Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. The Marketing Defendants and Purdue and Supply Chain Defendants agreed among themselves to increase the supply of opioids and fraudulently increase the quotas that governed the manufacture and supply of prescription opioids. The Marketing Defendants and Purdue and Supply Chain Defendants did so to increase sales, revenue, and profit from their opioid products.

717. The interaction and length of the relationships between and among the Marketing Defendants and Supply Chain Defendants reflects a deep level of interaction and cooperation between the Marketing Defendants and Purdue and Supply Chain Defendants in a tightly knit industry. The Marketing Defendants and Purdue and Supply Chain Defendants were not separate groups operating in isolation or forced to work together in a closed system. The Marketing Defendants and Purdue and Supply Chain Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

718. The Marketing Defendants and Purdue and Supply Chain Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below including, for example, membership in the Healthcare Distribution Alliance.

719. The Marketing Defendants and Purdue and Distributor Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA, as well as under Kentucky and other laws to report suspicious orders. The Marketing Defendants and Purdue and Supply Chain Defendants overwhelmingly agreed on the same approach – to fail to identify, report, or halt suspicious opioid orders, and fail to prevent diversion. The Marketing Defendants and Purdue and Supply Chain Defendants’ understanding to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as the Marketing Defendants and Purdue and Supply Chain Defendants were thus collectively responsible for each other’s compliance with their reporting obligations. The Marketing Defendants and Purdue and Supply Chain Defendants were aware, both individually and collectively, of the suspicious orders that flowed directly from the Marketing Defendants and Purdue and Supply Chain Defendants’ facilities.

720. The Marketing Defendants and Purdue and Supply Chain Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the government’s attention. As a result, the Marketing Defendants and Purdue and Supply Chain Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with the authorities.

721. The desired consistency, and collective end goal were achieved. The Marketing Defendants and Purdue and Supply Chain Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

722. By their participation in this Conspiracy, all of the Defendants are responsible for the actions of the other Conspirators taken in furtherance of the conspiracy, and share liability for the claims for which they are charged as having liability as Conspirators.

723. The countless acts of the Manufacturing Defendants and Purdue in deceptively marketing opioids each constitutes an overt act in furtherance of a conspiracy.

724. The countless acts of the Supply Chain Defendants in filling suspicious orders, in the face of overwhelming evidence of drug diversions, including the acts and practices for which some of the Supply Chain Defendants have been administratively sanctioned, each constitutes acts in furtherance of a conspiracy.

725. The acts of coordination of the Manufacturing Defendants and Purdue, and Supply Chain Defendants, through trade associations such as HAD and through other means, designed to avoid regulatory scrutiny while they attempted to create and supply an ever-expanding market for opioids by creating and supplying an ever-increasing number of opioid-dependent individuals, constitute acts in furtherance of a conspiracy.

726. Through the operation of this Conspiracy, the Defendants are liable for the actions of each other in using unlawful and fraudulent means to pursue the goals, and are liable with each other for the Claims set forth in this Complaint

XV. ADDITIONAL FACTS PERTAINING TO PUNITIVE DAMAGES

727. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants and Purdue knew there was no support for their

claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely “pseudoaddiction,” that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

728. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States. Despite this knowledge, Defendants took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed, as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

729. Defendants’ conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to communities, governments, families, communities, hospitals and health care providers, across the country.

730. As all of the governmental actions against all of the Defendants show, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

731. Defendants, acting in concert, knew or should have known, in light of the surrounding circumstances, that their conduct would naturally and probably result in injury or damage to Plaintiffs, and Defendants continued the conduct with malice or in reckless disregard of the consequences from which malice may be inferred. Defendants intentionally pursued the course of conduct described herein for the purpose of causing injury and damages to Plaintiffs.

A. The Marketing Defendants and Purdue Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions

732. So determined were the Marketing Defendants and Purdue to sell more opioids that they simply ignored multiple admonitions, warnings and prosecutions, as described more fully below.

1. FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic

733. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of “homemade” promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the “homemade” promotional pieces were “false or misleading because they contain misrepresentations of safety information, broaden Duragesic’s indication, contain unsubstantiated claims, and lack fair balance.” The March 30, 2000 letter detailed numerous ways in which Janssen’s marketing was misleading.

734. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to “false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic,” including, specifically, “suggesting that Duragesic has a lower potential for abuse compared to other opioid products.” The September 2, 2004 letter detailed a series of unsubstantiated, false or misleading claims.

735. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been “examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch” and noted the possibility “that patients and physicians might be unaware of the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

2. **Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon From Falsely Marketing Actiq For Off-label Uses**

736. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CMEs to promote off-label uses.

737. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

3. **FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora**

738. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.” Indeed, FDA specifically

denied Cephalon's application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

739. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

740. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

4. **A Guilty Plea and a Large Fine did not Deter Co-Conspirator Purdue from Continuing its Fraudulent Marketing of OxyContin**

741. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay nearly \$635 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. At the time, this was one

of the largest settlements with a drug company for marketing misconduct.⁴⁰⁸ Additionally, Michael Friedman the company's president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.

742. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and to fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued deceptively marketing the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying and political contributions - eight times what the gun lobby spent during that period.

743. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were

⁴⁰⁸ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), available at <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

744. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the Los Angeles Times that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

745. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

746. Indeed, the New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

5. **Endo Continued to Aggressively Promote Opana After Becoming Aware of Its Widespread Abuse**

747. The New York Attorney General found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed

health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

748. Even after the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of the prescription painkiller Opana and requested removal from the market, in 2015, “based on its concern that the benefits of the drug may no longer outweigh its risks,” Endo continued to market the drug until 2017.

6. Repeated Admonishments and Fines Did Not Stop the Supply Chain Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

749. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

750. In a *60 Minutes* interview, former DEA agent Joe Rannazzisi described Defendants’ industry as “out of control,” stating that “[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don’t follow the law in drug supply, people die. That’s just it. People die.” The interview continued:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you’re saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That’s not an implication, that’s a fact. That’s exactly what they did.

751. Another DEA veteran similarly stated that these companies failed to make even a “good faith effort” to “do the right thing.” He explained that “I can tell you with 100 percent

accuracy that we were in there on multiple occasions trying to get them to change their behavior.

And they just flat out ignored us.”⁴⁰⁹

752. Government actions against the Distributor Defendants with respect to their obligations to control the supply chain and prevent diversion include:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On September 30, 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);

⁴⁰⁹ *Id.*

- g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and
- h. On December 23, 2016, Cardinal agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.
- i. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.
- j. In March 2019, CVS entered into a \$535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island regarding allegations that its pharmacies in Rhode Island violated federal law “including by... in 39 instances between September 9, 2015 and June 18, 2017, filling a prescription for a Schedule II drug under circumstances ... that the CVS pharmacist filling the prescription knew or had reason to know that the prescription in question was invalid or unauthorized...” This fine was preceded by numerous others throughout the county.

XVI. JOINT ENTERPRISE ALLEGATIONS

753. Defendants entered into an agreement with respect to the unlawful marketing of opioids and/or distribution of opioids in Kentucky and Plaintiffs' communities.

754. The agreement had a common purpose: to promote the sale and distribution of opioids through the marketing of opioids and/or distribution of opioids into Kentucky and Plaintiffs' community, in violation of the KCPA and the common law of fraud and nuisance, and regulations of Kentucky.

755. The Defendants had a community of pecuniary interest in that common purpose, as all of the Defendants profited from sales of opioids in Kentucky and elsewhere.

756. The Defendants had an equal right to a voice in the direction of the enterprise.

XVII. TOLLING AND FRAUDULENT CONCEALMENT

757. Plaintiffs' claims are equitably tolled because Defendants knowingly and fraudulently concealed from the Plaintiffs the facts and their wrongful acts, and the material information pertinent to their discovery. Plaintiffs did not know, or could not have known through the exercise of reasonable diligence, of their claims, as a result of Defendants' conduct.

758. The fraudulent concealment consists of numerous acts forth throughout this Complaint.

759. The Defendants invented the term "pseudoaddiction" and promoted it to the medical community, including Plaintiffs. Defendants provided the medical community, including Plaintiffs, with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Marketing Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales.

760. Defendants overstated the benefits of and evidence for the use of opioids for chronic pain and understated their very serious risks, including the risk of addiction and death. Defendants falsely promoted abuse-deterrent formulations as reducing abuse, and falsely claimed that OxyContin provides 12 hours of relief. Defendants falsely portrayed their efforts or commitment to rein in the supply and diversion of opioids when, in truth and in fact, they behaved recklessly in disregard of their duties and adopted practices and policies that caused nearly an unchecked supply of opioids. By word and deed, Defendants have engaged in intentional, fraudulent misrepresentations and concealment of material facts.

761. Plaintiffs had no reason to suspect that the Marketing Defendants were perpetrating what was, in essence, a massive fraud on the public. Plaintiffs had no reason to

suspect that the Supply Chain Defendants – including large publicly traded companies – were routinely violating legal and commonsense duties of not distributing addictive drugs in ways that they knew were facilitating and promoting widespread opioid dependence.

762. So long as the Defendants' worked in coordination with each other in pursuit of the common goal of expanding opioid consumption, so that the false statements to create demand went hand in hand with the negligent and unlawful distribution activities to create abundant supply, Plaintiffs were kept unaware of the existence of the facts supporting the causes of actions set forth in this Complaint, and those facts supporting the causes of action could not have been discoverable by reasonable diligence.

763. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful statements and actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiffs were unable to obtain vital information bearing on their claims absent any fault or lack of diligence on their part.

764. The tortious and unlawful conduct by the Defendants is not limited to a single transgression, but constitutes an ongoing and continuous series of acts causing an ongoing and continuous series of injuries to Plaintiffs. The tortious conduct and injury to Plaintiffs occurs each time an individual presents himself or herself to Plaintiffs' hospitals as a result of an opioid-related condition. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The nuisance created by Defendants remains unabated.

XVIII. WAIVER OF CERTAIN CLAIMS FOR RELIEF

765. Plaintiffs expressly disclaim and waive any and all right to recovery, whether financial, injunctive, or equitable, relating to or arising out of the distribution by any person of any product, or the provision of any service, pursuant to McKesson Corporation's Pharmaceutical Prime Vendor Contract with the United States Department of Veteran Affairs ("PPV Contract"). Plaintiffs further commit that they will not, in any forum, rely on or raise the PPV Contract in connection with their allegations and/or prosecution in this matter.

766. Plaintiffs agree that should Defendants present evidence sufficient for the trier of fact to determine that Plaintiffs' injuries were caused, in whole or in part, by the distribution of products or provision of services through the PPV, Defendants are entitled to a reduction of their liability proportionately by the extent to which the trier of fact determines that any injury to Plaintiffs was caused by goods or products distributed and/or services provided through the PPV.

XIX. CLAIMS FOR RELIEF**FIRST CLAIM FOR RELIEF****Violation of Kentucky's Consumer Protection Act (K.R.S 367.120)
(Against All Defendants)**

767. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein. This Claim is brought against all Defendants as principals and as conspirators with each other.

768. This cause of action is brought pursuant to Section 367.120, Kentucky Revised Statutes, which is known as the Consumer Protection Act (the "KCPA").

769. Kentucky has enacted a Consumer Protection Act to ensure that citizens are protected against predatory or inappropriate actions by sellers of goods. "The General Assembly finds that the public health, welfare and interest require a strong consumer protection program to

protect the public interest and the well-being of both the consumer public and the ethical sellers of goods and services...” KRS § 367.120.

770. KRS § 367.170 (1) states that “[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.” Where such practices occur in the course of “trade” and “commerce”, as those terms are defined in KRS § 367.170(1) and KRS § 367.110(2), that being: “the advertising, offering for sale, or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value, and shall include any trade or commerce directly or indirectly affecting the people of this Commonwealth”, the KCPA applies to penalize the seller and to protect the consumer.

771. Specifically, those penalties are monetary and may be enforced per willful violation of KRS § 367.170.

772. As provided under KRS § 367.200, “[t]he court may make such additional orders or judgments as may be necessary to restore to any person in interest any moneys or property, real or personal, which may have been paid out as a result of any practice declared to be unlawful by KRS §§ 367.130 to 367.300.”

773. Plaintiffs are “persons” for purposes of this statute.

774. As alleged herein, and upon information and belief, Defendants committed unfair, false, misleading, and/or deceptive acts with regard to the sale and distribution of opioids within the Commonwealth.

775. Defendants engaged in deception, deceptive or unfair acts or practices, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission, in

connection with the sale or advertisement of prescription drugs in violation of the KCPA, KRS § 367.170(1).

776. During the relevant period and as detailed further herein, the Marketing Defendants have each engaged in unfair and deceptive acts or practices in commerce in violation of the Kentucky Consumer Protection statute by actively promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning opioids' safety and efficacy, and downplaying or omitting the risk of addiction arising from their use.

777. Each of the Defendants have engaged in unfair and/or deceptive trade practices by omitting the material fact of its failure to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required of "registrants" by the federal CSA, 21 C.F.R. § 1301.74(b). The CSA defines "registrant" as any person who is registered pursuant to 21 U.S.C § 823. 21 C.F.R. § 1300.02(b). Section 823(a)-(b) requires manufacturers and distributors of controlled substances Schedule II to register.

778. Defendants' unfair or deceptive acts or practices in violation of the Kentucky KCPA offend Kentucky's public policy, are immoral, unethical, oppressive and unscrupulous, as well as malicious, wanton and manifesting of ill will, and they caused substantial injury to Plaintiffs. Plaintiffs risk irreparable injury as a result of the Marketing and Distributor Defendants', and their agents', acts, misrepresentations and omissions in violation of the KCPA, and these violations present a continuing risk to Plaintiffs, as well as to the general public.

779. As a direct and proximate result of Defendants' violations of the KCPA, Plaintiffs have suffered and continue to suffer injury-in-fact and actual damages.

780. Defendants violated the KCPA because they engaged in false or misleading statements about the efficacy and safety of opioid pharmaceuticals.

781. Defendants, individually and acting through their employees and agents, and in concert with each other, knowingly made material misrepresentations and omissions of facts to Plaintiffs to induce them to purchase and administer opioids as set forth in detail above.

782. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

783. Defendants intended that Plaintiffs, physicians, patients, and/or others would rely on their misrepresentations and omissions.

784. Plaintiffs, physicians, patients, and/or others reasonably relied upon Defendants' misrepresentations and omissions.

785. In the alternate, the Defendants recklessly disregarded the falsity of their representations regarding opioids.

786. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiffs, physicians, patients, and/or others suffered actual pecuniary damage.

787. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

788. Plaintiffs have suffered an ascertainable loss of money or property and/or other things of value as a result of the use or employment by Defendants of an unfair or deceptive act or practices described in the KCPA.

789. Plaintiffs are entitled to recover damages caused by Defendants' fraud in an amount to be determined at trial.

SECOND CLAIM FOR RELIEF**Negligence
(Against All Defendants)**

790. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein. All Defendants are charged in this claim, as principals and as conspirators with each other.

791. This claim is brought under the common law of negligence.

1. Defendants Owed a Duty of Care

792. To establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and loss or damage caused by the breach, and actual loss or damage to another. All such essential elements exist here.

793. Kentucky law has adopted a “universal duty of care,” which requires every person to exercise ordinary care in his activities to prevent foreseeable injury.

794. Each Defendant had a duty to exercise reasonable care in the manufacturing, marketing, selling, and distributing of highly dangerous opioid drugs. These Defendants knew or should have known that opioids were unreasonably dangerous and were likely to cause opioid dependence. These Defendants owed their aforesaid duties to Plaintiffs because the injuries alleged herein were foreseeable by the Defendants.

795. A reasonable person could foresee the probability of occurrence of injury to Plaintiffs. Reasonably prudent wholesale drug manufactures, marketers and distributors of opioids would have anticipated the scourge of opioid dependence, especially when being warned and prosecuted by law enforcement repeatedly. These Marketing and Supply Chain Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of highly dangerous opioid drugs during manufacture and distribution.

2. Defendants Breached Their Duty of Care

a. Defendants' Conduct, in Violation of Applicable Statutes, Constitutes Negligence Per Se

796. The marketing and Supply Chain Defendants' conduct, in violation of Kentucky statutes and regulations (including KRS § 315.005, KRS § 218A.200, and KRS § 218A.1404(3)) in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels. Defendants also violated state law, including KRS § 218A.202, in failing to operate a system to stop orders which is flagged or should have been flagged as suspicious.

797. A manufacturer or wholesaler/distributor of prescription drugs must obtain a license from Kentucky Board of Pharmacy and "shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared drugs, and of all controlled substances received and disposed of by them," among other requirements by the Board. KRS § 218A.200(2). Kentucky state law also requires that a "manufacturer, distributor, or wholesaler" must comply with "KRS § 218A.200 and the federal controlled substances laws." KRS § 218A.170. "No person shall dispense, prescribe, distribute, or administer any controlled substance except as authorized by law." KRS § 218A.1404(2). Defendants have a duty to comply with the law.

798. Each Defendant's actions were in violation of Chapter 218A of the Kentucky Revised Statutes, as set out above, and also including KRS § 218A.1404(3), which forbids unlawful distribution of controlled substances; § 218A.1404(1), which forbids the trafficking of controlled substances; and, KRS § 506.040 and § 218A.1402, which forbid criminal drug conspiracies; and KRS § 218A.1405, which forbids receipt of income from trafficking and utilizing that income to operate a commercial enterprise.

799. Defendants violated both State and Federal Controlled Substances act in failing to report suspicious orders of opioid pain medications in Kentucky. Defendants violated state law in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels. Defendants also violated state law in failing to operate a system to stop orders which is flagged or should have been flagged as suspicious.

800. Defendants' failure to comply with Kentucky law, and the CSA constitutes negligence *per se*.

801. The KCPA and the CSA require that the Defendants know their customers, which includes, an awareness of the customer base, knowledge of the average prescriptions filled each day, the percentage of controlled substances compared to overall purchases, a description of how the dispenser fulfills its responsibility to ensure that prescriptions filled are for legitimate medical purposes, and identification of physicians and bogus centers for the alleged treatment of pain that are the dispenser's most frequent prescribers.

802. The Marketing and Supply Chain Defendants violated Kentucky laws in failing to report suspicious orders of opioid pain medications, in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels, and in failing to operate a system to stop or at least diligently respond to orders which are flagged or should have been flagged as suspicious. The Marketing and Supply Chain Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions controlled substances, thereby creating and continuing opioid dependence on prescription medications.

803. Defendants have willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a

customer base substantially comprised of individuals who are abusing and/or diverting prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted. Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions for controlled substances, thereby creating and continuing addictions to prescription medications in this state.

804. Defendants have, by their acts and omissions, proximately caused and substantially contributed to damages to Plaintiffs by violating Kentucky law, by creating conditions which contribute to violations of Kentucky laws by others, and by their negligent and/or reckless disregard of the customs, standards, and practices within their own industry.

805. Plaintiffs have suffered and will continue to suffer enormous damages as the proximate result of the failure by Defendants to comply with Kentucky law.

806. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties. Plaintiffs are within the class of persons the KCPA and the CSA were intended to protect. The harm that has occurred is the type of harm that the KCPA and the CSA was intended to guard against.

807. Defendants' violations constitute negligence *per se*.

b. Defendants Breached Their Duty of Reasonable Care

808. Alternatively, to the extent that Marketing and Supply Chain Defendants' statutory violations do not obviate the need to show breaches of the duty of care, each Defendant breached its aforesaid duties of care.

i. Negligent Marketing

809. The Marketing Defendants marketed opioids in a negligent and improper manner by:

- a. Overstating the benefits of chronic opioid therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;
- b. Trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose and death;
- c. Overstating opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;
- d. Mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms; and
- e. Marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

810. It was Defendants' marketing – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

811. The Marketing Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Marketing Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Marketing Defendants' branded marketing materials and drug labels. Marketing Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

812. The Marketing Defendants also marketed opioids through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

ii. Negligent Distribution

813. The Marketing and Supply Chain Defendants distributed opioids in an improper manner by:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and selling opioids without maintaining effective controls against diversion;
- c. Choosing not to or failing to effectively monitor for suspicious orders;
- d. Choosing not to or failing to report suspicious orders;
- e. Choosing not to or failing to stop or suspend shipments of suspicious orders; and
- f. Distributing and selling opioids prescribed by “pill mills” when Marketing and Supply Chain Defendants knew or should have known the opioids were being prescribed by “pill mills.”

iii. The Marketing and Supply Chain Defendants’ Breaches of Care Were Intentional, Willful, Wanton and/or Reckless

814. Marketing and Supply Chain Defendants’ breaches of care were intentional, willful, wanton and/or reckless. Marketing and Supply Chain Defendants purposely overstated the benefits of chronic opioid therapy and opioids’ superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; actively and

continuously promoted the use of opioids for improvement in patients' function and quality of life but failed to disclose the lack of evidence supporting the long-term use, as well as mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms; intentionally trivialized or obscured opioids' serious risks and adverse outcomes, including the risk of addiction, overdose, and death; continuously marketed opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

815. Marketing and Supply Chain Defendants willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base substantially comprised of individuals who are abusing and/or diverting prescription medications, many of whom are opioid-dependent addicted and all of whom can reasonably be expected to become opioid dependent. Marketing and Supply Chain Defendants conducted themselves with wanton and conscious disregard for the rights and safety of others. Notwithstanding their conscious and timely knowledge that their conduct posed unusual danger and of common probability of injury to others, including the Plaintiffs.

3. Injury, Causation and Damages

816. As a proximate result of Marketing and Supply Chain Defendants' conduct, Marketing and Supply Chain Defendants have caused Plaintiffs' injury related to the diagnosis and treatment of opioid-related conditions. Plaintiffs have incurred massive costs by providing unreimbursed, uncompensated, and/or undercompensated care as a result of opioid-related conditions.

817. The injuries to Plaintiffs would not have happened in the ordinary course of events had Marketing and Supply Chain Defendants exercise the degree of care, prudence,

watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business in the manufacture, marketing, sale and distribution of opioids.

818. Plaintiffs are entitled to recover compensatory damages as a result of Marketing and Supply Chain Defendants' negligence, in an amount to be determined at trial.

819. The Purdue Individual Co-Conspirators directed and participated in the tortious conduct of Purdue and are individually liable.

820. As a result of Marketing and Supply Chain Defendants' intentional, willful, wanton and/or reckless conduct described herein, Plaintiffs are entitled to treble, punitive, exemplary and/or otherwise enhanced damages to the full extent available under state law, in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF

Nuisance

(Against All Defendants)

821. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

822. All Defendants are charged in this claim, as principals and as conspirators with each other.

823. The Defendants' conduct set forth in this Complaint, consisting of thousands of purposeful and intentional acts directed at vastly expanding the use of opioids, created a nuisance. The conduct caused widespread opioid dependence and related individual and social harms. The conduct injured public health and interfered with the comfortable enjoyment of life and property of thousands of citizens throughout Kentucky and the regions served by Plaintiffs, and, as discussed below, inflicted special pecuniary injury on Plaintiffs.

824. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiffs, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

825. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

826. Defendants' activities unreasonably interfere with and injured the economic rights of Plaintiffs.

827. The Defendants' interference with these rights of Plaintiffs is unreasonable because it:

- a. Has harmed and will continue to harm the public health services of and public peace of Plaintiffs;
- b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiffs serve;
- c. Is proscribed by statutes and regulation, including the CSA and KCPA;
- d. Is of a continuing nature and it has produced long-lasting effects;
- e. Was the result of conduct that the Defendants knew, or had reason to know, would inflict a significant effect upon Plaintiffs; and
- f. Has inflicted substantial costs on Plaintiffs.

828. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of opioid dependence, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

829. The resources of Plaintiffs are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

830. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid dependence and failing to identify, halt, and report suspicious opioid transactions.

831. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Distributor Defendants had the power to shut off the supply of illicit opioids to Plaintiffs and in the geographic area served by Plaintiffs.

832. As a direct and proximate result of the nuisance, Plaintiffs have sustained economic harm by spending a substantial amount of money trying to remedy the harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services and healthcare. In short, the Defendants created a mess, leaving to the Plaintiffs and other hospitals the costs of cleaning it up. This is a classic nuisance.

833. As a result of Defendants' actions, Plaintiffs have suffered a special injury, different from that suffered by the general public at large by individual users and by governmental entities, namely that Plaintiffs have incurred costs by providing unreimbursed, uncompensated, and/or undercompensated care for patients suffering from opioid-related conditions.

834. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

835. Defendants should be required to pay the expenses Plaintiffs have incurred or will incur in the future to fully abate the nuisance.

FOURTH CLAIM FOR RELIEF

**Unjust Enrichment
(Against All Defendants)**

836. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein. All Defendants are charged in this claim, as principals and as conspirators with each other.

837. This claim is brought under the common law of unjust enrichment.

838. Plaintiffs provided unreimbursed, uncompensated, and/or undercompensated healthcare treatment to patients with opioid related conditions that Defendants are responsible for creating. Plaintiffs thereby conferred a benefit on Defendants because Defendants should bear the expense of treating these patients' opioid conditions. This is because Defendants created the opioid epidemic and the patients' opioid conditions, as described above.

839. Defendants appreciated and knew of this benefit because they knew their opioid promotional and marketing policies would cause, and in fact caused, hospitals throughout the United States and Kentucky to provide unreimbursed, uncompensated, and/or undercompensated healthcare treatment to patients with opioid related conditions that Defendants were responsible for creating.

840. The circumstances under which Defendants accepted or retained the benefit, described throughout this Complaint, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

841. Defendants have therefore been unjustly enriched.

842. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and provide restitution to the Plaintiffs.

FIFTH CLAIM FOR RELIEF
Fraud and Deceit
(Against All Defendants)

843. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

844. This claim is brought under the common law of fraud and deceit. All Defendants are charged in this Claim as principals and as conspirators with each other.

845. As alleged herein, Defendants violated their duty not to actively deceive by intentionally and unlawfully making knowingly false representations, intending that the representations be relied upon, and by intentionally and unlawfully omitting and/or concealing information.

846. Defendants made misrepresentations and failed to disclose material facts to physicians and consumers throughout Kentucky and the United States, to induce the physicians to prescribe and administer, and consumers to purchase and consume, opioids as set forth herein.

847. Specifically, the Marketing Defendants' knowing deceptions during the relevant period, which were intended to induce reliance, include but are not limited to:

- a. Marketing Defendants' misrepresentations overstating the benefits of, and evidence for, the use of opioids in chronic pain;
- b. Marketing Defendants' misrepresentations that the risks of long-term opioid use, especially the risk of addiction, were overblown;
- c. Marketing Defendants' misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;

- d. Marketing Defendants' misrepresentations that signs of addiction were "pseudoaddiction" and thus reflected undertreated pain, which should be responded to with more opioids;
- e. Marketing Defendants' misrepresentations that screening tools effectively prevent addiction;
- f. Marketing Defendants' misrepresentations concerning the comparative risks of NSAIDs and opioids;
- g. Marketing Defendants' misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;
- h. Marketing Defendants' misrepresentations that evidence supports the long-term use of opioids for chronic pain;
- i. Marketing Defendants' misrepresentations that chronic opioid therapy would improve patients' function and quality of life;
- j. Marketing Defendants' false portrayal of their efforts and/or commitment to rein in the diversion and abuse of opioids;
- k. Marketing Defendants' misrepresentations that withdrawal is easily managed;
- l. Endo's and Co-Conspirator Purdue's misrepresentations that alleged abuse-deterrent opioids reduce tampering and abuse;
- m. Co-Conspirator Purdue's misrepresentations that OxyContin provides a full 12 hours of pain relief;
- n. Co-Conspirator Purdue's misrepresentations that it cooperates with and supports efforts to prevent opioid abuse and diversion;
- o. Mallinckrodt's misrepresentations that it meets or exceeds legal requirements for controlling against diversion of controlled substances it has been entrusted to handle;
- p. Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use;
- q. Cephalon's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain;

- r. Marketing Defendants' use of front groups to misrepresent that the deceptive statements from the sources described in this Complaint came from objective, independent sources;
- s. Marketing Defendants' creation of a body of deceptive, misleading and unsupported medical and popular literature, advertisements, training materials, and speaker presentations about opioids that (1i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors; and,
- t. Such other misrepresentations and deceptions outlined above.

848. By engaging in the acts and practices alleged herein, Marketing Defendants, in the relevant time period; and with the intent that others rely on their omissions or suppression of information, omitted material facts that Marketing Defendants had a duty to disclose by virtue of these Defendants' other representations, including, but not limited to, the fact that:

- a. Opioids are highly addictive and may result in overdose or death;
- b. No credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;
- c. High dose opioids subject the user to greater risks of opioid dependence, other injury, and/or death;
- d. Opioids present the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, NAS, and potentially fatal interactions with alcohol or benzodiazepines; these omissions were made while Defendants exaggerated the risks of competing products such as NSAIDs;
- e. Claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;
- f. Co-Conspirator Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;
- g. Co-Conspirator Purdue and Defendant Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the common route of abuse (oral), can be defeated with relative ease, and may increase overall abuse;

- h. Marketing Defendants were systematically failing to report suspicious prescribers and/or orders;
- i. Cephalon's products Actiq and Fentora were not approved for non-cancer pain;
- j. Marketing Defendants had substantial financial ties to and a substantial role in connection with KOLs, front groups, and their creation and the contents of deceptive literature and related materials, and their promotion and contents of CME programs, as more fully described above; and
- k. Such other omissions and concealments as described above in this Complaint.

849. In each of the circumstances described *inter alia* the foregoing paragraph, Marketing Defendants knew that their failure to disclose rendered their prior representations untrue or misleading, or would be material to the targets of their false representations.

850. In addition, and independently, Marketing Defendants had a duty not to deceive Plaintiffs because Marketing Defendants had in their possession unique material knowledge that was unknown, and not knowable, to Plaintiffs, their agents, their community, physicians, and the public.

851. Marketing Defendants intended and had reason to expect under the operative circumstances that Plaintiffs, their agents, their community, physicians, and persons on whom Plaintiffs and their agents relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable reliance thereon.

852. Marketing Defendants intended that Plaintiffs, their agents, their communities, physicians, and persons on whom Plaintiffs and their agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and

omissions; and, Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

853. The Marketing Defendants were not alone in this. The Supply Chain Defendants were also knowingly deceptive during the relevant period, and their deception was intended to induce reliance. The Supply Chain Defendants repeatedly made statements acknowledging their roles and responsibilities to guard against diversion, and claiming that they were carrying out those functions. Such statements included but are not limited to:

- a. Acknowledgment of the Distributor Defendants by and through their front group, the HDMA, that distributors are at the center of a sophisticated supply chain and therefore, are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers;
- b. Acknowledgment of the Distributor Defendants that because of their unique position within the “closed” system, they were to act as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market;
- c. Cardinal Health claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse;”
- d. AmerisourceBergen took a same position as its counterpart within the industry and stated that it was “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare to help find solutions that will support appropriate access while limiting misuse of controlled substances;”
- e. More holistically, Distributor Defendants misrepresented that not only do its members (Distributor Defendants) have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society; and
- f. Such other omissions or concealments as described above in this Complaint.

854. In truth and in fact, despite having induced reliance on their purported good faith efforts to protect against diversion, Supply Chain Defendants, in the relevant time period, and with the intent that others rely on their omissions or suppression of information, omitted material

facts that Supply Chain Defendants had a duty to disclose by virtue of the above representations, so as to make those statements true and accurate and complete, including but not limited to:

- a. There being no legitimate medical purpose for the copious amounts of opioids shipped into and distributed around Plaintiffs' communities;
- b. That they failed to report to the DEA suspicious orders;
- c. That they failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain customers;
- d. That they failed to prevent against diversion from legitimate to non-legitimate channels;
- e. That they failed to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels;
- f. That they failed to keep and maintain accurate records of Schedule II – V controlled substances;
- g. That they maintained they were entitled to ship opioids to locations where diversion was obvious so long as the DEA did not actually tell them not to; and
- h. Such other omissions or concealments as alleged above in this Complaint.

855. Supply Chain Defendants intended and had reason to expect under the operative circumstances that Plaintiffs, their agents, community, physicians, and persons on whom Plaintiffs relied would be deceived by their statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable reliance thereon.

856. Supply Chain Defendants intended that Plaintiffs, their agents, communities, physicians, and persons on whom Plaintiffs and their agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and, Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

857. Plaintiffs rightfully, reasonably, and justifiably relied on Defendants' and their Co-Conspirators' representations and/or concealments, both directly and indirectly. As the Defendants and their Co-Conspirators knew or should have known Plaintiffs were directly and proximately injured as a result of this reliance, Plaintiffs' injuries were directly and proximately caused by this reliance.

858. As a result of these representations and/or omissions, Plaintiffs proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants and their Co-Conspirators. As a consequence, Defendants prevented Plaintiffs from a timelier and effective response to the opioid epidemic.

859. Defendants' false representations and omissions were material and were made and omitted intentionally and recklessly.

860. Defendants' misconduct alleged in this case is ongoing and persistent.

861. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort Plaintiffs would reasonably expect to occur and is not part of the normal and expected costs of a hospital's healthcare services. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a hospital can reasonably expect.

862. Plaintiffs have incurred expenditures for special programs over and above ordinary hospital healthcare services.

863. Defendants' conduct was accompanied by wanton and willful disregard of person who foreseeably might be harmed by their acts and omissions.

864. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

865. Plaintiffs have suffered monetary damages as aforesaid. As such Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, including attorney fees and costs, and pre- and post-judgment interest.

SIXTH CLAIM FOR RELIEF

Civil Conspiracy to Violate the KCPA, Commit Fraud and Maintain a Nuisance (Against All Defendants)

866. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

867. Plaintiffs bring this claim under the common law providing for the civil liability of persons who conspire to commit one or more unlawful acts.

868. Defendants engaged in a common design between two or more persons to accomplish by concerted action an unlawful purpose, or a lawful purpose by unlawful means, an overt act in furtherance of the conspiracy, and resulting injury to Plaintiffs.

869. Defendants engaged in a combination and an agreement to act in concert in their tortious and/or otherwise unlawful marketing of opioids and/or distribution of opioids in Kentucky and Plaintiffs' communities.

870. Defendants engaged in one or more unlawful activities to further the conspiracy. The objects of the conspiracy were nuisance, negligence, fraud, misrepresentation, violation of the KCPA, and other unlawful conduct as described above in this Complaint. Defendants knew that these objects were unlawful and would be accomplished by unlawful means such as fraud, misrepresentations, and omissions.

871. Defendants each conspired with various KOLs and Front Groups to commit unlawful or lawful acts in an unlawful manner. Defendants and the various KOLs and Front Groups with which each of them was allied, knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote and distribute opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers. Defendants enlisted various KOLs and Front Groups to make and disseminate these statements in furtherance of their common strategy to increase the sale and distribution of opioids, and Defendants—along with the KOLs and Front Groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

872. By engaging in the conduct described in this Complaint, Defendant Cephalon agreed with Front Groups FSMB and APF that they would deceptively promote the risks, benefits and superiority of opioid therapy. As part of its agreements with FSMB and APF, Cephalon provided support for FSMB's and APF's deceptive statements promoting opioids and FSMB and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Cephalon's drugs. *Responsible Opioid Prescribing* (Cephalon and FSMB) and *Treatment Options: A Guide for People Living with Pain* (Cephalon and APF) are publications that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Cephalon and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

873. By engaging in the conduct described in this Complaint, Defendant Endo agreed with Front Groups APF, NICP, AGS and FSMB that they would deceptively promote the risks,

benefits, and superiority of opioid therapy. As part of its agreements with APF, NIPC, AGS and FSMB, Endo provided support for APF, NIPC, AGS and FSMB's deceptive statements promoting opioids and APF, NIPC, AGS and FSMB used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Endo's drugs. *Persistent Pain in the Older Adult* (Endo, APF, and NIPC), *Persistent Pain in the Older Patient* (Endo, APF, and NIPC), *Painknowledge.com* (Endo, APF, and NIPC), *Exit Wounds* (Endo and APF), *Pharmacological Management of Persistent Pain in Older Persons* (Endo and AGS), and *Responsible Opioid Prescribing* (Endo and FSMB) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Endo and each of these entities in creating and disseminating these publication, CMEs, and websites is further evidence of each conspiracy's existence.

874. By engaging in the conduct described in this Complaint, Defendant Janssen agreed with Front Groups AAPM, AGS and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with AAPM, AGS, and APF, Janssen provided support for AAPM, AGS, and APF's deceptive statements promoting opioids and Conrad & Associates LLC, Medical Writer X, AAPM, AGS, and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Janssen's drugs. *Finding Relief: Pain Management for Older Adults* (Janssen, AAPM, and AGS), a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Janssen and APF), the *Let's Talk Pain* website (Janssen and APF), and *Exit Wounds* (Janssen and APF) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies and the

collaboration between Janssen and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

875. By engaging in the conduct described in this Complaint, Purdue agreed with Front Groups APF, FDMB, and AGS that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, FSMB, and AGS, Purdue provided support for APF, FSMB, and AGS's deceptive statements promoting opioids and APF, FSMB, and AGS used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Purdue's drugs. The *Partners Against Pain* website (Purdue and APF), *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue and APF), *Treatment Options: A Guide for People Living with Pain* (Purdue and APF), *Exit Wounds* (Purdue and APF),⁴¹⁰ *Responsible Opioid Prescribing* (Purdue and FSMB), and a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Purdue and AGS) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Purdue and each of these entities in creating and disseminating these publications, CME's and websites is further evidence of each conspiracy's existence.

876. Each of the participants to the conspiracies outlined above was aware of the misleading nature of the statements they planned to issue and of the role they played in each scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. These Defendants and third parties nevertheless agreed to misrepresent the risks, benefits, and

⁴¹⁰ Purdue's collaboration with APF through APF's "Corporate Roundtable" and Purdue and APF's active collaboration in running PCF constitute additional evidence of the conspiracy between Purdue and APF to deceptively promote opioids.

superiority of using opioids to Plaintiffs in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

877. Each of the participants to the conspiracies outlined above was aware of the nuisance resulting from their conduct, and agreed to continue the practices described above that resulted in the maintenance of that nuisance.

878. Supply Chain Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities.

879. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

880. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

881. The Defendants further worked together in their unlawful failure to act to prevent diversion and failure to monitor for, report, and prevent suspicious order of opioids.

882. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

883. By reason of Defendants' unlawful acts, Plaintiffs have been damaged and continue to be damaged by paying the costs of Defendants' externalities have suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

884. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

885. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

886. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

887. As outlined above, Defendants played an active role in determining the substance of the misleading messages issued by KOLs and Front Groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was and unrelenting stream of misleading information about compliance with state and federal legislation as related to opioid distribution, and the risks, benefits, and superiority of using opioids to treat chronic pain from sources Defendants knew were trusted by prescribers and consumers. Defendants

exercised direct editorial control over most of these statements. However, even if Defendants did not directly disseminate or control the content of these misleading statements, they are liable for conspiring with the third parties who did.

888. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue to engage in their unlawful conduct.

889. Defendants had a meeting of the minds on the object of or course of action for this conspiracy. Defendants knew and agreed upon the unlawful object or course of action for this conspiracy. Defendants also knew that their wrongful actions would inflict injury upon the targets of the conspiracy, including Plaintiffs.

890. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

891. Defendants' misconduct alleged in this case is ongoing and persistent.

892. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergent of the sort a hospital would reasonably expect to occur and is not part of the normal and expected costs of a hospital's healthcare services. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a hospital can reasonably expect.

893. Plaintiffs have incurred expenditures for special programs over and above ordinary healthcare services.

894. Because of Defendants dissemination of false information and misleading information of opioid risks, benefits, and sustainability for chronic pain, and false and misleading statements regarding compliance with Kentucky law concerning the distribution of opioids, Defendants are responsible for the costs.

895. Defendants conspired to create a public nuisance and to commit tortious conduct and are therefore jointly and severally liable for the damages flowing from the conspiracy.

896. Plaintiffs therefore request this Court to enter an order awarding judgment in their favor against Defendants, compelling Defendants to pay the direct and consequential damages, and awarding Plaintiffs such other, further, and different relief as this Court may deem just and proper.

SEVENTH CLAIM FOR RELIEF

Fraudulent Concealment (Against All Defendants)

897. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

898. “One party to a transaction who by concealment or other action intentionally prevents the other from acquiring material information is subject to the same liability to the other, for pecuniary loss as though he had stated the nonexistence of the matter that the other was thus prevented from discovering.” Restatement (Second) of Torts § 550 (1977).

899. Defendants, individually and acting through their employees and agents, knowingly and intentionally concealed material fact and knowledge to Plaintiffs to induce it to purchase and administer opioids as set forth in detail above.

900. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction and death; in falsely

promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; in falsely portraying their efforts or commitment to rein in the supply and diversion of opioids; and doing all of this while knowing full well that their statements were misrepresentations of facts material, Defendants have engaged in intentional, fraudulent misrepresentations and concealment of the material fact, as detailed herein.

901. Defendants intended that Plaintiffs would rely on their misrepresentations, omissions, and concealment, knew that Plaintiffs would rely on their misrepresentations, and that such reliance would cause harm to Plaintiffs.

902. Plaintiffs reasonably relied on Defendants' misrepresentations and omissions in writing and filling prescriptions for Defendants' opioids. The use of Defendants' opioid medicines became widespread and continuous as a result.

903. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Defendants. They do not seek damages which may have been suffered by individual citizens for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

904. Plaintiffs suffered actual pecuniary damages proximately caused by Defendants concealment of material fact, which include but are not limited to, expending funds on emergency services, emergency response, additional training, additional security, and other services Plaintiffs would not have incurred.

905. Plaintiffs have incurred expenditures for special programs over and above their ordinary hospital services.

906. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a hospital would reasonably expect to occur and is not part of the

normal and expected costs of a hospital's existence. Plaintiffs allege wrongful acts which were neither discrete nor of the sort a hospital can reasonable expect.

907. Plaintiffs therefore demand judgment in their favor against Defendants for compensatory, exemplary, and punitive damages in an amount to be determined by a jury, together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that the Court:

- A. Enter judgment against Defendants, jointly and severally, and in favor of Plaintiffs;
- B. Award compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages; treble damages; punitive damages; pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate; and such equitable relief against Defendants as the Court should find appropriate;
- C. Award Plaintiffs their cost of suit, including reasonable attorneys' fees as provided by law; and
- D. Award such further and additional relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Dated: _____

Respectfully Submitted,

/s/ Joseph M. Kramer

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EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

ADVANTAGE BEHAVIORAL HEALTH SYSTEMS; ALBANY AREA COMMUNITY SERVICE BOARD d/b/a ASPIRE BEHAVIORAL HEALTH & DEVELOPMENTAL DISABILITY SERVICES; GEORGIA MOUNTAINS COMMUNITY SERVICES d/b/a AVITA COMMUNITY PARTNERS; CLAYTON COMMUNITY MH/SA/DS SERVICE BOARD; COBB COUNTY COMMUNITY SERVICE BOARD; COMMUNITY SERVICE BOARD OF MIDDLE GEORGIA; GATEWAY COMMUNITY SERVICE BOARD; GEORGIA PINES COMMUNITY SERVICE BOARD; HIGHLAND RIVERS COMMUNITY SERVICE BOARD d/b/a HIGHLAND RIVERS HEALTH; LOOKOUT MOUNTAIN COMMUNITY SERVICE BOARD; MIDDLE FLINT AREA COMMUNITY SERVICE BOARD D/B/A MIDDLE FLINT BEHAVIORAL HEALTHCARE; NEW HORIZONS COMMUNITY SERVICE BOARD; PINELAND BEHAVIORAL HEALTH AND DEVELOPMENTAL DISABILITIES CSB; RIVER EDGE BEHAVIORAL HEALTH; COMMUNITY MENTAL HEALTH CENTER OF EAST CENTRAL GEORGIA d/b/a SERENITY BEHAVIORAL HEALTH SYSTEMS; SATILLA COMMUNITY SERVICES d/b/a UNISON BEHAVIORAL HEALTH; and VIEW POINT HEALTH

Civil Action No.

JURY TRIAL DEMANDED

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; ENDO HEALTH
SOLUTIONS, INC; ENDO
PHARMACEUTICALS INC.,; PAR
PHARMACEUTICAL, INC.; PAR
PHARMACEUTICAL COMPANIES, INC.,
F/K/A PAR PHARMACEUTICAL HOLDINGS,
INC.; QUALITEST PHARMACEUTICALS,
INC.; ALLERGAN PLC F/K/A ACTAVIS,
PLC; ACTAVIS LLC; ACTAVIS PHARMA,
INC. F/K/A WATSON PHARMA, INC.;
ALLERGAN FINANCE, LLC F/K/A ACTAVIS
INC. F/K/A WATSON PHARMACEUTICALS,
INC.; WATSON LABORATORIES, INC.;
ALLERGAN USA, INC.; MALLINCKRODT
LLC; SPECGX LLC; MCKESSON
CORPORATION; CARDINAL HEALTH INC.;
AMERISOURCEBERGEN DRUG
CORPORATION; J M SMITH
CORPORATION; and JOHN DOE
DEFENDANTS 1 through 80,

Defendants.

COMPLAINT

Plaintiffs, Advantage Behavioral Health Systems; Albany Area Community
Service Board d/b/a Aspire Behavioral Health & Developmental Disability
Services; Georgia Mountains Community Services d/b/a Avita Community
Partners; Clayton Community MH/SA/DS Service Board; Cobb County

Community Service Board; Community Service Board of Middle Georgia; Gateway Community Service Board; Georgia Pines Community Service Board; Highland Rivers Community Service Board d/b/a Highland Rivers Health; Lookout Mountain Community Service Board; Middle Flint Area Community Service Board d/b/a Middle Flint Behavioral HealthCare; New Horizons Community Service Board; Pineland Behavioral Health and Developmental Disabilities CSB; River Edge Behavioral Health; Community Mental HealthCenter of East Central Georgia d/b/a Serenity Behavioral Health Systems; Satilla Community Services d/b/a Unison Behavioral Health; and View Point Health (hereinafter collectively referred to as the “Georgia CSBs” or “CSBs”), hereby file this Complaint pursuant to their statutory and common law authority against Defendants Cephalon, Inc.; Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals Inc.; Endo International plc; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.; Qualitest Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis, PLC; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Allergan USA, Inc.; Mallinckrodt LLC; Mallinckrodt plc; SpecGx LLC; McKesson Corporation;

Cardinal Health, Inc.; AmerisourceBergen Drug Corporation; J M Smith Corporation; and John Doe Defendants 1 through 80 (Defendants are sometimes referred to herein as “Manufacturer Defendants,” “Distributor Defendants,” or collectively as “Defendants”) for Defendants’ violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§1961 *et seq.* (“RICO”), creation of a public nuisance, violations of the Georgia Drug Dealer Liability Act, O.C.G.A. §§51-1-46 *et seq.*, and other causes of action related to their past and ongoing campaign of unlawfully, dangerously and deceptively marketing and distributing opioids. The Plaintiff CSBs allege as follows:

INTRODUCTION

1. Dangerous opioid drugs produced and/or distributed by the Defendants are killing people across Georgia at alarming rates, and the CSBs are the first line responders at the center of Georgia’s opioid epidemic.

2. The CSBs’ role as opioid first line responders is even more pronounced as a result of coronavirus, COVID-19, which has upended all facets of American life, including the delivery of health care by the CSBs to those with likely opioid abuse disorder.

3. It is the policy in the State of Georgia that no person shall be denied care and treatment for drug dependency or drug abuse nor shall services be delayed

at a facility of the state or a political subdivision of the state because of the inability to pay for such care and treatment.¹

4. It is further the policy in the State of Georgia to hold those who create and financially benefit from illegal drug markets responsible to pay civil damages to persons who are injured as a result of such illegal drug use and proliferation.² Those persons include “governmental entities, and others who pay for drug treatments.”³

5. The Defendant Drug Manufacturers have generated billions of dollars in drug sales through their deceptive and illegal marketing of opioids as safe and effective with a low risk for addiction, and the Defendant Drug Distributors have generated billions of dollars in drug distribution costs while failing to prevent the diversion of dangerously excessive opioids in the State of Georgia.

6. As a result of the Defendants’ conduct, lives have been forever altered, and the CSBs have suffered excessive expenditures and other significant economic damages arising from their treatment of Georgians with likely opioid abuse disorder.

¹ O.C.G.A. § 37-7-120.

² O.C.G.A. § 51-1-46.

³ O.C.G.A. § 51-1-46(b).

7. As further alleged below, the CSBs submit claims for the services they provide to Georgians with likely opioid abuse disorder to government payors such as the Georgia Department of Behavioral Health and Developmental Disabilities (“DBHDD”) and Medicaid, and to private insurance companies just like other healthcare providers. The CSBs also obtain funding from the counties they serve. Yet, the damages sought by the CSBs are unique to the CSBs themselves. They are not pass-through entities. The CSBs seek the damages they have specifically incurred as a result of Defendants’ conduct.

8. One Plaintiff CSB alone has calculated that its past costs related to treating clients with opioid abuse or likely opioid abuse disorder have exceeded the reimbursement it received from its funding sources by more than \$17.3 million dollars. The Plaintiff CSBs also project losses due to patients with opioid abuse disorder or likely opioid abuse disorder missing their appointments as costing the CSBs a combined \$100 million in the past and in the years ahead.

9. In fact, the Plaintiff CSBs have calculated the costs of treating clients with opioid abuse or likely opioid abuse disorder ranging from approximately \$700 - \$1,700 per year.

10. In total, the Plaintiff CSBs have spent over \$155 million treating patients with an opioid abuse or likely opioid abuse disorder in the past, and they

anticipate spending nearly \$250 million on these costs in the next fifteen years. Combined with the cost of missed appointments, the total impact of Defendants' illegal conduct on the Plaintiff CSBs is more than \$500 million.

11. These costs are only going to continue as the damages caused by Defendants' continue to mount.

12. The CSBs bring this action pursuant to their statutory and common law authority to redress the financial harm caused by Defendants' improper conduct and to recover damages and other relief to compensate the CSBs for the excessive and significant costs they have borne as a result of Defendants' tortious conduct.

13. In communities with ever-climbing opioid addiction and overdose death rates, the CSBs' role in providing a comprehensive system of care for substance abuse and mental health services has never been more critical. The CSBs have borne the costs, both in money and heartache, of Defendants' tortious actions, which proximately caused and continue to cause injury and damage to the CSBs. Accordingly, the CSBs bring this action to recover money and resources the CSBs have spent to combat and otherwise respond to the opioid epidemic throughout the State of Georgia. The CSBs seek all available: (a) damages for any and all of the CSBs' costs associated with Defendants' unlawful conduct as well as

losses sustained for uncompensated or undercompensated care provided to patients with likely opioid abuse disorders; (b) damages for, and abatement of, the public health epidemic which is a nuisance that Defendants have created, and as a result of which, the CSBs have suffered special injuries; (c) other damages sustained by the CSBs as a result of Defendants' conduct; (d) treble damages; (e) disgorgement of Defendants' unjust profits; (f) punitive damages; and (g) any other equitable relief within this Court's powers to redress and halt Defendants' unlawful practices.

14. Specifically, the CSBs seek economic damages from Defendants as reimbursement for the healthcare costs associated with past, present, and future efforts to permanently eliminate the hazards to public health and safety and abate this crisis and to make the CSBs whole from the harm caused by the Defendants. Categories of past and continuing sustained damages include but are not limited to: (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, rehabilitation, and other mental health or substance abuse services to patients suffering from likely opioid disorders or other related addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from likely opioid disorders or other related addiction or disease

and their families; (4) costs associated with providing care and counseling for children whose parents suffer from likely opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with likely opioid abuse disorders; and (6) lost revenue for writing off uncompensated or undercompensated care related to likely opioid abuse disorder.

PARTIES

PLAINTIFFS

15. CSBs are public corporations created by Georgia's General Assembly that provide substance abuse services.

16. The State of Georgia has recognized "its responsibility for its citizens who are mentally ill or developmentally disabled including individuals ... who abuse alcohol, narcotics, or other drugs: and its "obligation to such citizens to meet their needs through a coordinated system of community facilities, programs, and services." O.C.G.A. § 37-2-1(a). The State has further recognized the "policy of this state to provide adequate mental health, ..., addictive disease, and other disability services to all of its citizens" and "the policy of this state to provide such services through a unified system which encourages cooperation and sharing of resources among all providers of such services, both governmental and private." O.C.G.A. § 37-2-1(b).

17. CSBs are statutorily responsible for providing mental health, developmental disabilities, and addictive disease services to Georgia residents.⁴

18. As the State's safety net provider for these critical services, the CSBs ensure that mental health and addiction prevention, treatment, and recovery support services are available to individuals and families in Georgia, irrespective of their patients' ability to pay.

19. While they are subject to high-level oversight by Georgia's Department of Behavioral Health and Developmental Disabilities (DBHDD), daily operations and personnel matters are managed by the CSBs' boards and supporting staff.

20. Unlike a traditional "public agency," the CSBs obtain their funding through a variety of sources. In addition to state funding, federal funding, and county funding, they also obtain funding from private insurance companies and cash-paying patients based on the healthcare services they provide.

21. The statute creating CSBs specifically authorizes the CSBs to "enroll and contract with [DBHDD], the Department of Human Services, the Department of Public Health, or the Department of Community Health to become a provider of mental health, developmental disabilities, and addictive diseases services or health,

⁴ O.C.G.A. § 37-2-6(a).

recovery, housing, or other supportive services.” O.C.G.A. § 37-2-6(a). Thus, although considered “public agencies”, the CSBs are required to, on their own, become enrolled providers of these programs.

22. Much like other healthcare providers, such as public hospital systems, the CSBs then submit claims to the applicable program or insurance provider for the services they provide.

23. While not permitted to operate for a profit, Georgia law further expressly authorizes the CSBs to “fix fees, rents, rates, and charges that are reasonably expected to produce revenues, which, together with all other funds of the community service board, will be sufficient to administer, operate, and provide” their statutorily-mandated services. O.C.G.A. §37-2-6.1(f).

24. Despite being public bodies, CSBs have “the power to bring an action in [their] own name[s].” O.C.G.A. §37-2-6.3(b).

25. Even more, Georgia law states that the “debts, obligations, and liabilities of a community service board are not debts, obligations, or liabilities of the state or of the counties in which such board operates.” O.C.G.A. §37-2-6.3(d). Therefore, the losses suffered by the CSBs as a result of Defendants’ conduct are unique to the CSBs and not shared by the state or the counties in which the CSBs operate.

26. Thus, the CSBs have standing to recover damages incurred as a result of Defendants' acts and omissions and have standing to bring all claims pled herein.

27. There are 23 CSBs serving six regions designated by the Georgia Department of Behavioral Health and Developmental Disabilities ("DBHDD").

28. The statutory framework that created and empowers the CSBs also confers broad authority to take the necessary actions to carry out their mission and serve their respective communities.

29. CSBs provide a wide range of services to fulfill the needs of adults and children with complex behavioral and addictive disease disorders, including opioid addiction. CSBs manage local provider networks, develop educational programs, and administer state and federal grants.

30. CSBs also provide inpatient and outpatient services, including Crisis Stabilization Units offering psychiatric stabilization and detoxification services. CSBs operate multiple residential treatment centers for patients requiring intensive care to treat substance abuse disorders. Some CSBs operate specialized recovery facilities to treat pregnant or parenting women with substance abuse disorders, as well as residential and outpatient centers to treat adolescents with substance abuse disorders. CSBs also provide psychiatric evaluation, counseling in individual and

group settings, peer-to-peer support programs, medication management and court services. Patients who complete treatment at a CSB may qualify for transitional housing, vocational training, transportation, and other support services.

31. CSBs provide health services irrespective of financial circumstances under contracts with the DBHDD, the Department of Human Services, the Department of Public Health, and the Department of Community Health and other state and federal agencies. Some services are billed on a sliding fee schedule or reimbursed on a fee-for-service basis by Medicaid, Medicare, or commercial insurance.

32. The CSBs are on the front lines of the state-wide recognized opioid epidemic. The fiscal requirements and extraordinary costs created by the opioid crisis in Georgia continues to make unprecedented, excessive demands on, and stretch the CSBs budgets, resulting in economic losses directly tied to uncompensated and undercompensated care provided to patients with likely opioid abuse disorder.

33. Plaintiff Advantage Behavioral Health Systems is a CSB with a principal address of 250 North Avenue, Athens, Georgia 30601. Advantage Behavioral Health Systems provides addictive disease services, including

addressing and treating opioid addiction and related issues in the following counties:

- Barrow
- Clarke
- Elbert
- Greene
- Jackson
- Madison
- Morgan
- Oconee
- Oglethorpe
- Walton

34. Plaintiff Albany Area Community Service Board d/b/a Aspire Behavioral Health & Developmental Disability Services (hereinafter “Aspire”) is a CSB with a principal address of 601 11th Avenue, Albany, Georgia 31701. Aspire provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Baker
- Calhoun
- Dougherty
- Early
- Lee
- Miller
- Terrell
- Worth

35. Plaintiff Georgia Mountains Community Services d/b/a Avita Community Partners (hereinafter “Avita”) is a CSB with a principal address of 4331 Thurmond Tanner Parkway, Flowery Branch, Georgia 30542. Avita provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Banks
- Dawson
- Forsyth
- Franklin
- Habersham
- Hall
- Hart
- Lumpkin
- Rabun
- Stephens
- Towns
- Union
- White

36. Plaintiff Clayton Community MH/SA/DS Service Board is a CSB with a principal address of 157 Smith Street, Jonesboro, Georgia 30236. Clayton Community MH/SA/DS Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in Clayton County.

37. Plaintiff Cobb County Community Service Board is a CSB with a principal address of 3830 S. Cobb Drive, Suite 300, Smyrna, Georgia 30080. Cobb County Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in Cobb County.

38. Plaintiff Community Service Board of Middle Georgia is a CSB with a principal address of 2121-A Bellevue Road, Dublin, Georgia 31021. Community Service Board of Middle Georgia provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Bleckley
- Burke
- Dodge
- Emanuel
- Glascock
- Jefferson
- Jenkins
- Johnson
- Laurens
- Montgomery
- Pulaski
- Screven
- Telfair
- Treutlen
- Wheeler
- Wilcox

39. Plaintiff Gateway Community Service Board is a CSB with a principal address of 600 Coastal Village Drive, Brunswick, Georgia 31520. Gateway Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Bryan
- Camden
- Chatham
- Effingham
- Glynn
- Liberty
- Long
- McIntosh

40. Plaintiff Georgia Pines Community Service Board is a CSB with a principal address of 1102 Smith Avenue, Suite H, Thomasville, Georgia 31792. Georgia Pines Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Colquitt
- Decatur
- Grady
- Mitchell
- Seminole
- Thomas

41. Plaintiff Highland Rivers Community Service Board d/b/a Highland Rivers Health (hereinafter “Highland Rivers”) is a CSB with a principal address of 1503 N. Tibbs Road, Dalton, GA, 30720. Highland Rivers provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Bartow
- Cherokee
- Fannin
- Floyd
- Gilmer
- Gordon
- Haralson
- Murray
- Paulding
- Pickens
- Polk
- Whitfield

42. Plaintiff Lookout Mountain Community Service Board is a CSB with a principal address of 501 Mize Street, LaFayette, Georgia 30728. Lookout Mountain Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Catoosa
- Chattooga
- Dade

- Walker

43. Plaintiff Middle Flint Area Community Service Board d/b/a Middle Flint Behavioral HealthCare is a CSB with a principal address of 415 N. Jackson Street, P.O. Drawer 1348, Americus, GA 31709. Middle Flint Area Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Crawford
- Crisp
- Dooly
- Houston
- Macon
- Marion
- Peach
- Schley
- Sumter
- Taylor
- Webster

44. Plaintiff New Horizons Community Service Board is a CSB with a principal address of 2100 Comer Avenue, Columbus, Georgia 31904. New Horizons Community Service Board provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Chattahoochee

- Clay
- Harris
- Muscogee
- Quitman
- Randolph
- Stewart
- Talbot

45. Plaintiff Pineland Behavioral Health and Developmental Disabilities CSB (hereinafter “Pineland”) is a CSB with a principal address of 5 West Altman Street, Statesboro, Georgia 30458. Pineland provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Appling
- Bulloch
- Candler
- Evans
- Jeff Davis
- Tattnall
- Toombs
- Wayne

46. Plaintiff River Edge Behavioral Health is a CSB with a principal address of 175 Emery Highway, Macon, Georgia 31217. River Edge Behavioral Health provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Baldwin

- Bibb
- Fulton
- Jones
- Monroe
- Putnam
- Twiggs
- Wilkinson

47. Plaintiff Community Mental Health Center of East Central Georgia d/b/a Serenity Behavioral Health Systems (hereinafter “Serenity”) is a CSB with a principal address of 3421 Mike Padgett Highway, Augusta, Georgia 30906. Serenity provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Columbia
- Lincoln
- McDuffie
- Richmond
- Taliaferro
- Warren
- Wilkes

48. Plaintiff Satilla Community Services d/b/a Unison Behavioral Health (hereinafter “Unison”) is a CSB with a principal address of 1007 Mary Street, Waycross, Georgia 31503. Unison provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Atkinson
- Bacon
- Brantley
- Charlton
- Clinch
- Coffee
- Pierce
- Ware

49. Plaintiff View Point Health is a CSB with a principal address of 175 Gwinnett Drive, Suite 260, Lawrenceville, Georgia 30046. View Point Health provides addictive disease services, including addressing and treating opioid addiction and related issues in the following counties:

- Gwinnett
- Newton
- Rockdale

50. The CSBs bring this action pursuant to their statutory and common law authority, including the authority granted to them by O.C.G.A. § 37-2-6.3(b).

51. The CSBs have standing to recover damages incurred as a result of Defendants' actions and omissions. The CSBs have standing to bring all claims pled herein.

DEFENDANTS

Manufacturer Defendants

52. At all relevant times, the Manufacturer Defendants have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including the Northern District of Georgia.

Teva and Associated Companies

53. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Its registered agent is Corporations Creations Network, Inc. located at 3411 Silverside Road Tatnall Building, Suite 104, Wilmington, DE 19810.

54. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

55. Teva Pharmaceuticals USA, Inc. acquired Cephalon in October 2011.

56. Cephalon, Inc., Teva Pharmaceuticals USA, Inc., and their DEA registrant subsidiaries and affiliates (collectively “Cephalon/Teva”) are in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including in Georgia. These

opioids include, but are not limited to, Actiq and Fentora. Actiq and Fentora are both formulations of fentanyl citrate, a very potent opioid.

57. The Cephalon/Teva Defendants may be served with process through Teva Pharmaceuticals USA, Inc.'s registered agent at the following address: Corporate Creations Network Inc., 2985 Gordy Parkway, 1st Floor, Marietta, GA 30066.

Endo and Associated Companies

58. Defendant Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business located at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

59. Defendant Endo Pharmaceuticals Inc. is a Delaware corporation with its principal place of business located at 1400 Atwater Drive, Malvern, Pennsylvania 19355, and is a wholly owned subsidiary of Endo Health Solutions, Inc.

60. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York and is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par

Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively “Par Pharmaceuticals”) were acquired by Endo International PLC in September 2015 and serve as operating companies of Endo International PLC.

61. Defendant Qualitest Pharmaceuticals, Inc. is an Alabama corporation with its principal office located in Huntsville, Alabama. Qualitest Pharmaceuticals, Inc. was acquired by Endo International PLC in 2010 and merged with Par Pharmaceuticals in 2010.

62. Endo Health Solutions, Inc., Endo Pharmaceuticals Inc., Par Pharmaceuticals, Qualitest Pharmaceuticals, Inc., and their DEA registrant subsidiaries and affiliates (collectively, “Endo”) are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including in Georgia. These include generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products and the branded opioids Opana (oxymorphone hydrochloride); Opana ER (extended release Opana); Percodan (oxycodone and aspirin); Percocet (oxycodone and acetaminophen); and Zydone (hydrocodone and acetaminophen).

63. The Endo Defendants may be served with process through Endo Pharmaceuticals Inc.’s registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

Allergan and Associated Companies

64. Defendant Allergan PLC is an Irish public limited company with its principal place of business in Dublin, Ireland and administrative headquarters and all executive offices located in Madison, New Jersey.

65. Defendant Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of defendant Allergan PLC f/k/a Actavis plc. Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October, 2012. The combined company changed its name to Actavis PLC in October, 2013.

66. Actavis PLC acquired Allergan PLC in March 2015. The combined company changed its name to Allergan PLC in June 2015.

67. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC f/k/a Actavis PLC. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic business to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Between 2000 and 2015, Watson Laboratories Inc. held the Abbreviated New Drug Applications

(“ANDA”) for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

68. Defendant Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. was previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan PLC’s 2016 sale of its generics business to Teva.

69. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis LLC is an indirect subsidiary of Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. As part of Allergan PLC’s 2016 sale of its generic business to Teva.

70. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan PLC f/k/a Actavis PLC.

71. Allergan PLC f/k/a Actavis PLC, Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Allergan USA, Inc. (collectively, “Allergan”) are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including Georgia. These opioids include, but are not limited to, the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Allergan also manufactured promethazine with codeine, which, when mixed with citrus flavored soda, is a commonly abused opioid “cocktail,” until it stopped manufacture in 2014 due to negative associations of this drug.

72. The Allergan Defendants may be served with process through their registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805. Alternatively, they may be served at the following address of Actavis Pharma, Inc.’s registered agent: Corporate Creations Network, Inc., 2985 Gordy Parkway, 1st Floor, Marietta, GA 30006.

Mallinckrodt and Associated Companies

73. Defendant Mallinckrodt LLC, a wholly owned subsidiary of Mallinckrodt PLC, is a Delaware limited liability company with its principal place of business in St. Louis, Missouri.

74. Defendant SpecGx, LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri, and is a wholly owned subsidiary of Mallinckrodt PLC.

75. Mallinckrodt LLC, SpecGx LLC, and their DEA registrant subsidiaries and affiliates (collectively, “Mallinckrodt”) are or have been in the business of manufacturing, marketing, selling and distributing opioids throughout the United States, including the State of Georgia, including generic formulations of morphine sulfate, extended release, morphine sulfate, fentanyl transdermal, oral transmucosal fentanyl citrate, oxycodone with acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride, hydromorphone hydrochloride, extended release, naltrexone hydrochloride, oxymorphone hydrochloride, methadone hydrochloride, oxycodone hydrochloride, buprenorphine, and naloxone.

76. Mallinckrodt is the largest supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

77. The Mallinckrodt Defendants may be served with process through Mallinckrodt LLC's registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

Purdue and Associated Companies (Bankruptcy)

77a. Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Co. Inc. (collectively "Purdue") are similarly situated to the named Manufacturer Defendants, being, at all relevant times, in the business of manufacturing, selling, promoting, and/or distributing brand name opioids (*i.e.*, Oxycontin) throughout the U.S. and Georgia. Purdue, however, is not a named defendant here because of the bankruptcy filings of the Purdue entities and Judge Drain's Second Amended Order Pursuant to 11 U.S.C. §105(a) Granting Motion for a Preliminary Injunction, dated November 6, 2019. By omitting Purdue as a named defendant, the Plaintiff CSBs do not waive their rights and claims against Purdue, and, for the record, the Plaintiff CSBs have duly filed their claims as creditors of Purdue in accordance with the established bankruptcy process. Notwithstanding the foregoing, because of Purdue's central role in the opioid story in Georgia, the Plaintiff CSBs include

herein good faith allegations regarding Purdue's conduct in order to inform and explain the conduct of the named defendants who each and all acted similarly to and in concert with Purdue.

Distributor Defendants

78. At all relevant times, Distributor Defendants were engaged in “wholesale distribution” as defined under state and federal law. Distributor Defendants distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling their legal obligations to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders⁵, thereby leading to the foreseeable diversion of these dangerous drugs for illegitimate and/or non-medical purposes.

79. Distributor Defendants' failure to meet their obligations is the reason for the substantial volume of prescription opioids plaguing the United States, including in the Northern District of Georgia.

⁵ For purposes of this Complaint, this duty to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders, is referred to as "obligations." For purposes of this Complaint, the term "suspicious orders" shall mean any orders of prescription opioids that are required to be investigated and/or reported under Georgia and/or federal law.

McKesson Corporation

80. Defendant McKesson Corporation (“McKesson”) is a Delaware corporation with its principal place of business in San Francisco, California.

81. At all relevant times, McKesson operated as a licensed pharmacy wholesaler throughout the United States, including in Georgia, and delivered substantial amounts of opioid drugs to buyers throughout the United States, including Georgia.

82. Moreover, McKesson operates a distribution center located at 2975 Evergreen Drive, Duluth, Georgia.

83. McKesson is the largest pharmaceutical distributor in North America and delivers approximately one-third of all pharmaceuticals used there. According to McKesson's 2017 Annual Report, the company's “pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”

84. Defendant McKesson Corporation may be served with process through its registered agent at the following address: Corporation Service Company, 40 Technology Parkway South, Suite 300, Norcross, GA 30092.

Cardinal Health, Inc.

85. Defendant Cardinal Health, Inc. (“Cardinal Health”) is an Ohio corporation with its principal place of business in Dublin, Ohio.

86. At all relevant times, Cardinal Health operated as a licensed pharmacy wholesaler throughout the United States, including in Georgia, and distributed substantial amounts of opioid drugs to buyers in the State of Georgia. Cardinal Health is a global distributor of pharmaceutical drugs and medical products, and is one of the largest distributors of opioids in the United States. In December 2013, Cardinal Health entered a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. In 2016, Cardinal Health generated \$121 billion in revenue.

AmerisourceBergen Drug Corporation

87. Defendant AmerisourceBergen Drug Corporation (“AmerisourceBergen”) is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen is the second largest pharmaceutical distributor in North America.

88. According to its 2016 Annual Report, AmerisourceBergen is “one of the largest global pharmaceutical sourcing and distribution services companies,

helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care.”

89. At all relevant times, AmerisourceBergen operated as a licensed pharmacy wholesaler throughout the United States, including in Georgia, and delivered substantial amounts of opioid drugs to buyers in Georgia. AmerisourceBergen is registered with the Georgia Secretary of State as a Delaware corporation.

90. Defendant AmerisourceBergen may be served with process through its registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

J M Smith Corporation

91. J M Smith Corporation is a Delaware corporation with its principal place of business in Spartanburg, South Carolina. Smith Drug Company is a division of J M Smith Corporation responsible for operating J M Smith Corporation's pharmaceutical distribution business. J M Smith Corporation and Smith Drug Company are referred to as “Smith Drug” throughout this Complaint.

92. Smith Drug is a wholesale pharmaceutical distributor primarily serving the eastern United States. At all relevant times, Smith Drug operated as a licensed pharmacy wholesaler in Georgia and delivered substantial amounts of

opioid drugs to buyers in Georgia. Smith Drug operates a distribution center in Valdosta, Georgia.

93. Defendant Smith Drug may be served with process through its registered agent at the following address: CT Corporation System, 289 South Culver Street, Lawrenceville, GA 30046-4805.

John Doe Defendants 1 Through 80

94. John Doe Defendants 1 through 10, whether singular or plural, are those entities or persons who marketed and promoted the use of prescription opioid drugs through false, scientifically unsupported or misleading representations: (1) in advertising, medical education presentations, speaking engagements, medical literature, publications, websites, and/or statements to physicians and medical students; (2) through funding or employing “Key Opinion Leaders” as described more fully below; and/or (3) through funding or participating in “Front Groups” as described more fully below.

95. John Doe Defendants 11 through 20, whether singular or plural, are those entities or persons that are wholesale distributors of prescription opioid drugs who: (1) failed to implement an effective system to monitor the distribution of opioid drugs; (2) failed to identify and report suspicious orders of opioid drugs destined to pharmacies and individuals in Georgia to the DEA or Georgia Drugs

and Narcotics Agency; (3) failed to maintain effective controls against diversion of opioid drugs for other than legitimate uses in violation of the Georgia Controlled Substances Act and related laws concerning distribution of controlled substances; and/or (4) otherwise failed to comply with the Georgia Controlled Substances Act and related laws concerning distribution of controlled substances.

96. John Doe Defendants 21 through 30 whether singular or plural, are those officers, directors, executives, or agents who were directly and personally involved in developing and executing the marketing efforts of Manufacturer Defendants or of John Doe Defendants 1-10.

97. John Doe Defendants 31 through 40, whether singular or plural, are those entities or persons who had a responsibility to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders of controlled substance prescriptions and who failed in their duty to do so.

98. John Doe Defendants 41 through 50, whether singular or plural, are those officers, directors, executives, entities, or agents who participated in the “Opioid Promotion Enterprise” described in Count I of this Complaint or who, through proceeds derived from the “Opioid Promotion Enterprise,” including real property or personal property of any nature (including money), acquired or maintained, directly or indirectly, any interest in or control of the enterprise.

99. John Doe Defendants 51 through 60, whether singular or plural, are those officers, directors, executives, entities, or agents who participated in the “Opioid Diversion Enterprise” described in Count I of this Complaint or who, through proceeds derived from the “Opioid Diversion Enterprise,” including real property or personal property of any nature (including money), acquired or maintained, directly or indirectly, any interest in or control of the enterprise.

100. John Doe Defendants 61 through 70, whether singular or plural, are those officers, directors, executives, entities, or agents who participated in a RICO Enterprise which caused or contributed to this opioid crisis or who, through proceeds derived from a RICO Enterprise, including real property or personal property of any nature (including money), acquired or maintained, directly or indirectly, any interest in or control of the enterprise.

101. John Doe Defendants 71 through 80, whether singular or plural, are those officers, directors, executives, entities, or agents who, by virtue of their position and the legal duties vested in them, had an obligation to monitor, detect, investigate, refuse, and/or report suspicious orders of prescription opioids.

102. The John Doe Defendants are incorporated where any Defendant is referenced in this civil action.

Defendants' Agents

103. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives who were actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment and/or with Defendants' actual, apparent, and/or ostensible authority.

JURISDICTION AND VENUE

104. This Court has diversity subject matter jurisdiction over this action under 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000, and there exists complete diversity between the parties, *i.e.*, no defendant is a citizen of Plaintiffs' home state of Georgia.

105. Additionally, 28 U.S.C. § 1331 grants this Court federal question subject matter jurisdiction over Plaintiffs' RICO claims as they arise under the Racketeer Influenced and Corrupt Organizations Act ("RICO").⁶ This allows the Court to also exercise supplemental jurisdiction over Plaintiffs' other claims

⁶ 18 U.S.C. §§ 1961 *et seq.*

because they form part of the same case or controversy as the federal RICO claims.⁷

106. This Court has personal jurisdiction over Defendants because Georgia law grants jurisdiction over nonresidents who transact business within the state, commit a tortious act or omission within the state, or cause a tortious injury that occurs within the state if they derive a substantial source of revenue from goods consumed within the state or engage in persistent conduct within the state.⁸ Defendants, by and through their authorized agents, servants, and employees, regularly transacted business in Georgia; manufactured, supplied, and distributed opioids in Georgia from which they received substantial revenue; and further, through their acts and omissions, tortuously caused injuries in Georgia by engaged in a persistent course of conduct in Georgia which violated Georgia law. Because Defendants purposefully directed their actions toward Georgia, consented to be sued in Georgia by registering an agent for service of process, and submitted to the jurisdiction of Georgia when obtaining a manufacturer or distributor license, they have the requisite minimum contacts with Georgia for this Court to constitutionally assert personal jurisdiction over Defendants.

⁷ 28 U.S.C. §1367(a).

⁸ O.C.G.A. § 9-10-91.

107. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. § 1965(b). The Court may exercise nationwide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiffs demonstrate national contacts. Here, the interests of justice require that Plaintiffs be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial.⁹

108. Venue is proper in the Atlanta Division of this District under Northern District of Georgia Local Rule 3.1. Venue is further proper in this District pursuant to 28 U.S.C. §1391 and 18 U.S.C. §1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District.

FACTUAL ALLEGATIONS

I. THE OPIOID CRISIS IN GEORGIA

109. “It is accurate to describe the opioid epidemic as a man-made plague, twenty years in the making. The pain, death, and heartache it has wrought cannot

⁹ See, e.g., *Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle Nat. Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher’s Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

be overstated.”¹⁰ As the Director of the Centers for Disease Control and Prevention (“CDC”) has noted: “We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.”¹¹

110. Georgia finds itself in the midst of an unprecedented prescription drug crisis, with hundreds of deaths attributable to opioid prescription drug overdoses every year.¹²

111. The State of Georgia had the eleventh highest number of opioid overdoses in the United States between 1999 and 2014.¹³ Opioid-involved overdose deaths have not just increased - but exploded by an astonishing 1,000% - since 1999 when these drugs were first meaningfully introduced to the State of Georgia.¹⁴

¹⁰ *In re: National Prescription Opiate Lit.*, No. 1:17-MD-02804-DAH, Doc. 1203, at *38 (N.D. Ohio, Dec. 19, 2018).

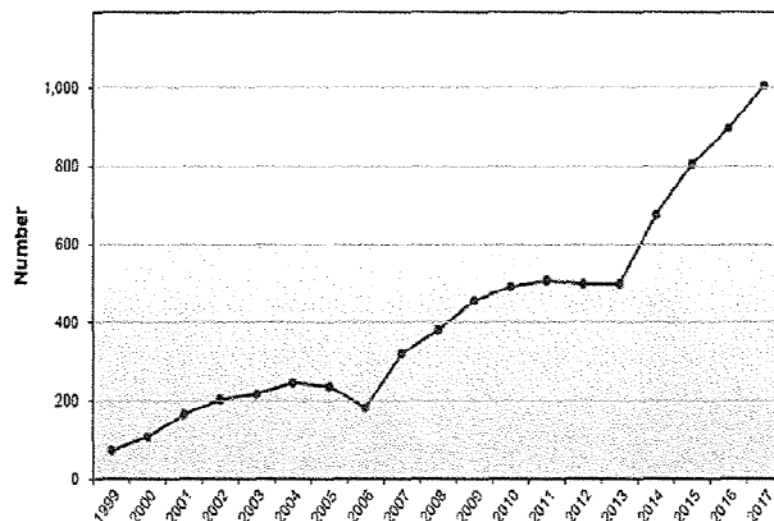
¹¹ Thomas R. Frieden & Debra Houry, *Reaching the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 372 NEW ENG. J. MED. 1501, 1503 (2016).

¹² The Henry J. Kaiser Family Foundation, *Opioid Overdose Deaths and Opioid Overdose Deaths as a Percent of All Drug Overdose Deaths* (2015), available at <https://www.kff.org/other/state-indicator/opioid-overdose-deaths/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last visited June 12, 2020).

¹³ Substance Abuse Research Alliance, *Prescription Opioids and Heroin Epidemic in Georgia*, (2017), available at <http://www.senate.ga.gov/sro/Documents/StudyCommRpts/OpioidsAppendix.pdf> (last visited June 12, 2020).

¹⁴ Online Analytical Statistical Information System (“OASIS”), Drug Overdoses/Opioids Web Query Tool, available at

Number of Deaths, All Opioids, Georgia, 1999-2017



MEASURE	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	1999-2017 TOTAL
Number of Deaths	73	108	164	203	217	246	237	181	321	380	456	491	508	499	499	675	806	897	1,007	7,968

112. Statistics in recent years show the ever-increasing momentum of this crisis: from 2010 to 2016, the total number of documented opioid-involved overdose deaths in Georgia increased by an astounding 117%, from 426 to 929 deaths, and the death rate increased by 111%, from 4.3 to 9.1 deaths/100,000 persons.¹⁵ In 2016, the State of Georgia experienced at least 897 opioid drug-

<https://oasis.state.ga.us/oasis/webquery/qryDrugOverdose.aspx> (last visited June 12, 2020).

¹⁵ Georgia Department of Public Health, *Opioid Overdose Surveillance, Georgia 2016 (Preliminary Report)* (2016), available at:

<https://dph.georgia.gov/sites/dph.georgia.gov/files/2016%20OPIOID%20PRELIMINARY%20REPORT.FINAL.PDF> (last visited June 12, 2020).

related deaths¹⁶ and 9,912 hospital admissions for drug-related disorders. Tellingly, the annual number of such hospital admissions tripled since 2000,¹⁷ with 2,435 documented emergency room visits and 1,709 hospitalizations due to opioid overdoses.¹⁸ In 2017, there were 1,529 deaths attributed to all drugs in the State of Georgia, but an overwhelming number of them (1,007) were the result of opioids.¹⁹ From 1999 to 2017, more people have died from opioid overdoses (7,968) in the State of Georgia than the 2010 total populations of sixteen (16) Georgia counties: Calhoun, Clay, Clinch, Echols, Glascock, Miller, Quitman, Randolph, Schley, Stewart, Talbot, Taliaferro, Treutlen, Warren, Webster, or Wheeler.²⁰

113. Haralson County, Georgia, with a population just under 21,000 people²¹ has lost almost 70 people to opioid overdoses since 1999.²²

¹⁶ It is anticipated this and other death estimates will increase as this litigation progresses.

¹⁷ Drug Overdoses/Opioids Web Query Tool, *supra* note 10.

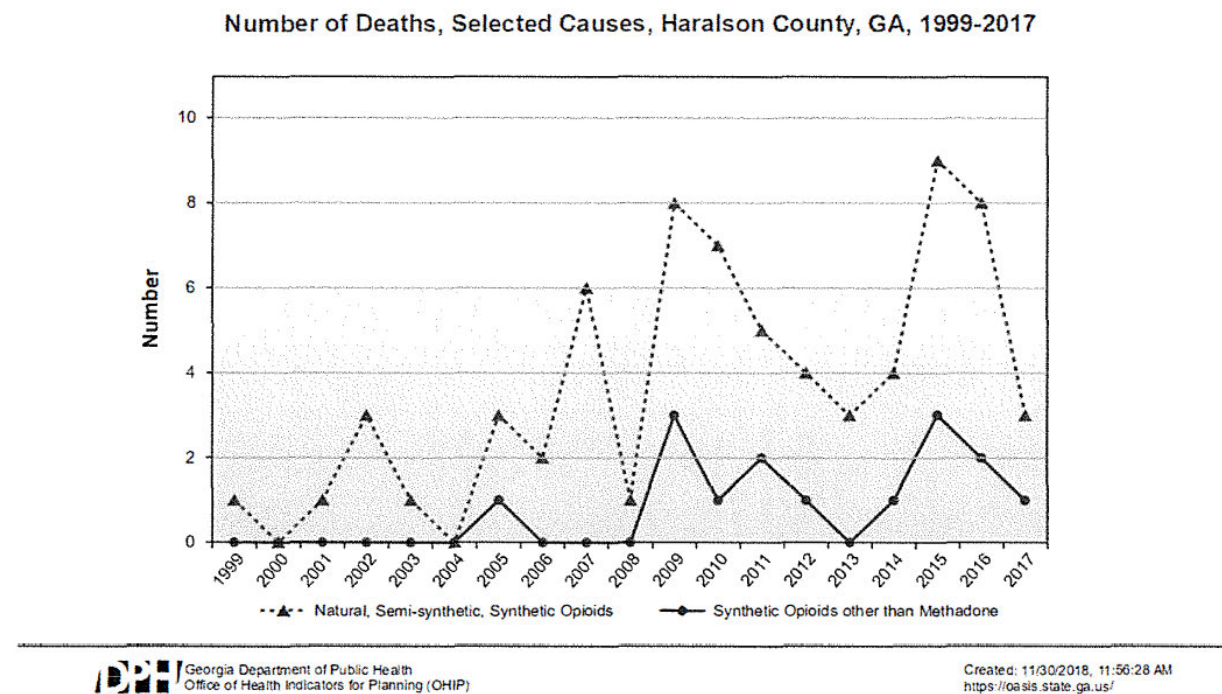
¹⁸ *Opioid Overdose Surveillance, Georgia 2016 (Preliminary Report)*, *supra* note 11.

¹⁹ Drug Overdoses/Opioids Web Query Tool, *supra* note 10.

²⁰ U.S. DEPT. OF COMMERCE, *Georgia: 2010 Population and Housing Unit Counts* (Aug. 2012) at 8, available at <https://www2.census.gov/library/publications/decennial/2010/cph-2/cph-2-12.pdf> (last visited June 12, 2020).

²¹ *Id.*

²² Drug Overdoses/Opioids Web Query Tool, *supra* note 10.



114. Emergency medical services administered the potentially life-saving opioid overdose reversal drug naloxone nearly 10,000 times in 2016 compared to 4,500 times in 2012.²³

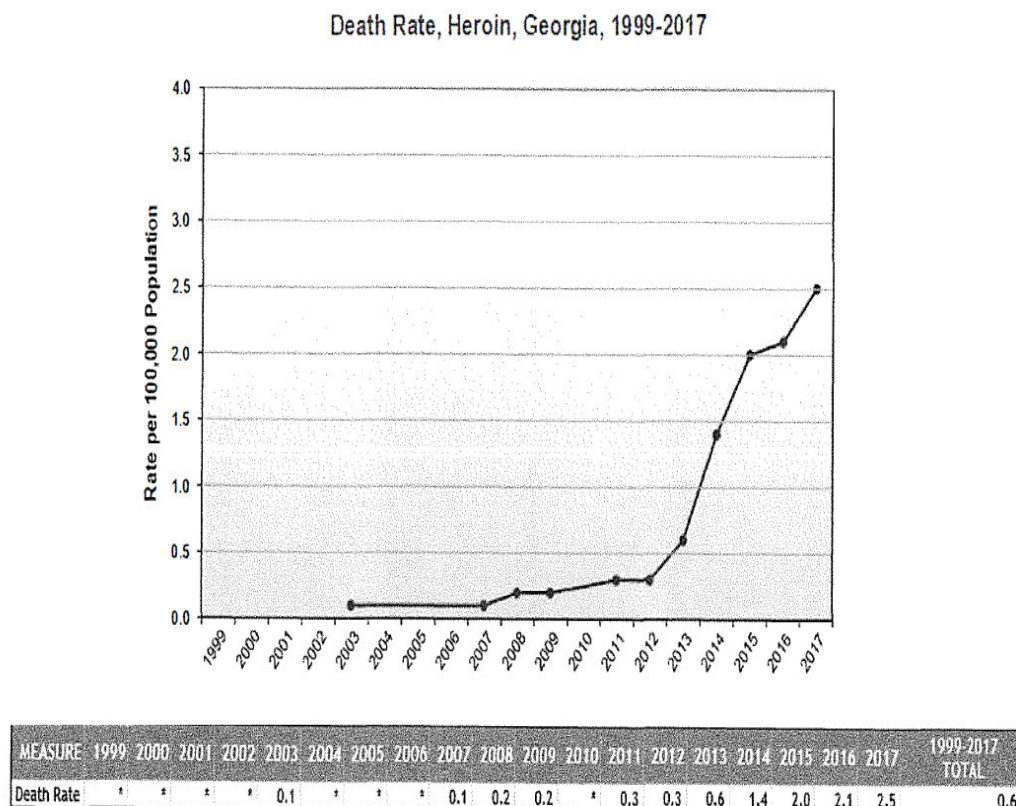
115. The health care costs associated with opioid misuse in Georgia were estimated at \$447 million in 2007.²⁴ Given the explosion in opioid-related deaths,

²³ GEORGIA DEPARTMENT OF AUDITS AND ACCOUNTS PERFORMANCE AUDIT DIVISION, Performance Audit Report No. 17-11, *Opioid Use Disorder—Access to Medication-Assisted Treatment* (Nov. 2017), available at www.open.georgia.gov/openga/report/downloadFile?rid=20499 (last visited June 12, 2020).

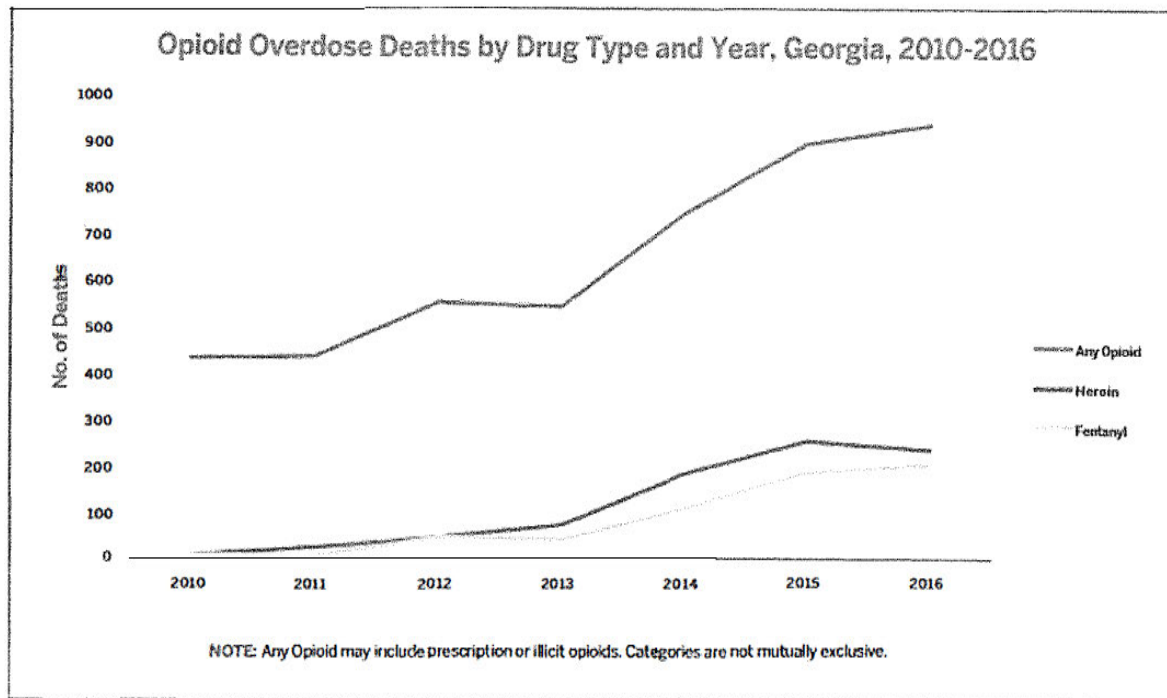
²⁴ *Prescription Opioids and Heroin Epidemic in Georgia*, *supra* note 9 at 7.

overdoses, and hospitalizations, some estimates indicate that health care costs associated with opioid misuse in Georgia have increased by at least 80%.²⁵

116. Heroin overdose deaths have skyrocketed too, as those addicted to prescription opioids often switch to a cheaper alternative to meet their addiction demands. Consequently, the heroin and fentanyl death rates correspond with the increase in opioid-related deaths.



²⁵ *Id.*

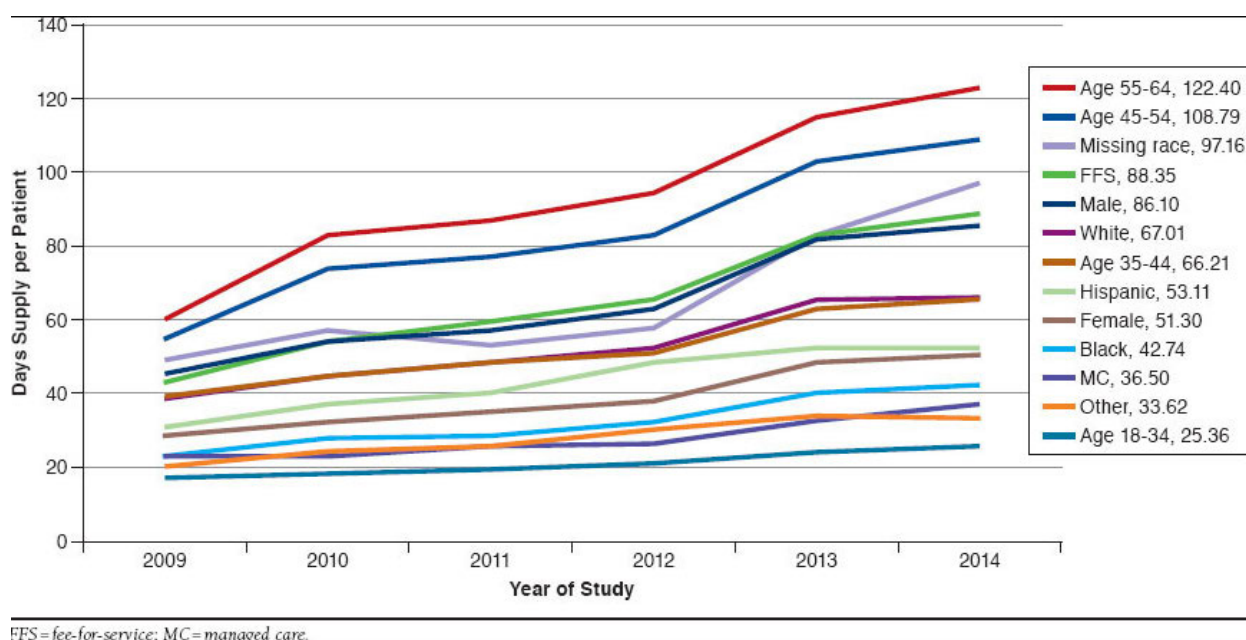


117. The death, addiction, and increased cost associated with prescription opioids is a direct consequence of Defendants' induced Georgia's opioid prescription rate increase over the same time period. By 2013, Georgia's average prescription rate for opioids (86.6% per 100 persons) was well over the national average (79.3).²⁶ In 2016, there were 0.778 opioid prescriptions per person in Georgia, according to the CDC. Some counties in Georgia had well over 1 prescription per person, including Bacon County (1.57), Catoosa (1.16), Coffee

²⁶ CDC, *U.S. State Prescribing Rates, Opioids* (2013), <https://www.cdc.gov/drugoverdose/maps/rxstate2013.html> (last visited June 12, 2020).

(1.73), and Decatur (1.22).²⁷ According to Georgia Medicaid, the average days' supply of opioids has increased for all age groups from 2009 to 2014:

Average Days Supply of Opioids per Patient by Insurance Type, Age, Gender, Race/Ethnicity, and Year²⁸



118. Not surprisingly, an estimated 180,000 Georgians have an opioid use disorder, which is more than the population of Macon, the fourth largest city in Georgia.²⁹

²⁷ CDC, *County Prescribing Rates, Opioids* (2016), <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html> (last visited June 12, 2020).

²⁸ Jayani Jayawardhana, Ph.D, Amanda J. Abraham, Ph.D, & Matthew Peri, Ph.D, *Opioid Analgesics in Georgia Medicaid: Trends in Potential Inappropriate Prescribing Practices by Demographic Characteristics, 2009-2014*, 24 JMCP 9 (Sept. 2018), available at <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2018.24.9.886> (last visited June 12, 2020).

119. As further alleged below, the CSBs have incurred substantial, increasing costs to address and combat this opioid epidemic. Because the opioid epidemic has so deeply and negatively impacted Georgia, the CSBs will continue to incur substantial costs in both combatting and responding to the crisis for years to come.

II. GEORGIA IS PART OF A NATIONAL CRISIS

120. The heartache and financial toll Defendants' have caused to Georgia is part of a larger, national opioid crisis. In 2016, the President of the United States declared that an opioid and heroin epidemic existed within the country.³⁰ Annual opioid prescriptions now roughly equal the number of adults living in the United States.³¹

121. The opioid crisis is America's deadliest overdose crisis ever. Today, opioids are responsible for the majority of drug overdoses,³² which have

²⁹ *Opioid Use Disorder—Access to Medication-Assisted Treatment*, *supra* note 19; U.S. CENSUS BUREAU, *Annual Estimates of the Resident Population for Incorporated Places of 50,000 or More, Ranked by July 1, 2017 Population: April 1, 2010 to July 1, 2017*, <https://www.census.gov/data/tables/time-series/demo/popest/2010s-total-cities-and-towns.html> (last visited June 12, 2020).

³⁰ See Proclamation No. 9499, 81 Fed. Reg. 65, 173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

³¹ See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. ENG. J. MED. 1480 (2016).

³² *Id.*

quadrupled nationally since 1999.³³ In just 2016, CDC data confirms at least 42,249 people died from opioid overdoses, which accounted for the majority (66.4%) of all drug overdose deaths in that year (63,632). From 1999 to 2016, more than 200,000 people have died in the United States from prescription opioid overdoses, and by 2016, people were dying at a rate five times greater than in 1999.³⁴

122. Moreover, this crisis has caused a significant spike in street drug use. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.³⁵ Heroin overdoses have climbed sharply during the opioid epidemic, more than tripling over a four-year period according to the CDC. This increase has been shown to be closely tied to opioid pain reliever misuse and dependence. People who are addicted to prescription opioid painkillers are forty times more likely to

³³ CDC, CENTERS FOR DISEASE CONTROL & PREVENTION: *Drug Overdose Deaths Data*, <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited June 12, 2020). Drug deaths take a long time to certify, so this is the most recent available data: U.S. DEPT. OF HEALTH & HUMAN SERVICES, NATIONAL VITAL STATISTICS SYSTEM, *Timeliness of Death Certificate Data for Mortality Surveillance and Provisional Estimates*, Report 001, Dec. 2016, <https://www.cdc.gov/nchs/data/vsrr/report001.pdf> (last visited June 12, 2020).

³⁴ CDC, CENTERS FOR DISEASE CONTROL & PREVENTION: *Prescription Opioid Data*, <https://www.cdc.gov/drugoverdose/data/prescribing.html> (last visited June 12, 2020).

³⁵ Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths-United States, 2010-2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 1445, 1450 (2016).

become addicted to heroin.³⁶ Heroin is pharmacologically similar to prescription opioids, and most current heroin users report prior non-medical use of prescription opioids before they initiated heroin use. In fact, non-medical use of prescription opioids has been identified to be one of, if not the, strongest serious risk factor for heroin use.³⁷

123. The CDC estimates that approximately three out of four new heroin addicts in the United States started by abusing prescription opioids.³⁸

124. Additionally, the youngest members of society have been affected by the opioid crisis. According to the CDC, 87 children died of opioid intoxication in 2015, an increase from 16 in 1999. Toddlers and young children are increasingly being found unconscious or dead after consuming an adult's drugs, and there has been a surge of opioid-dependent newborns.

125. Opioids also pose a grave risk to veterans who are twice as likely to die of an opioid overdose than the general population.³⁹

³⁶ See CDC, CENTERS FOR DISEASE CONTROL & PREVENTION: *Today's Heroin Epidemic*, <https://www.cdc.gov/vitalsigns/heroin/index.html> (last visited June 12, 2020).

³⁷ See Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. ENG. J. MED. 154 (2016).

³⁸ CDC, CENTERS FOR DISEASE CONTROL & PREVENTION, *Heroin Overdose Data* <https://www.cdc.gov/drugoverdose/data/heroin.html> (last visited June 12, 2020) (citing Cicero TJ, Ellis MS, Surratt, HL. *The Changing Face of Heroin Use in the United States. A Retrospective Analysis of the Past 50 Years*. JAMA PSYCHIATRY 2014; 71(7):821-826)).

126. Overall, the National Institute on Drug Abuse identifies misuse and addiction to opioids as a “serious national crisis that affects public health as well as social and economic welfare.”⁴⁰ The economic burden of prescription opioid use alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.⁴¹ Since 2001, some estimates have suggested that the opioid crisis has cost the United States more than a trillion dollars, and may exceed over \$500 billion over the next three years.⁴²

III. THE HISTORY OF OPIOIDS AND ADDICTION

127. Opioids are highly addictive synthetic drugs derived from opium and are otherwise chemically similar to opium alkaloids. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled

³⁹ Wilkie, Robert, Secretary for Veterans Affairs, *Fighting Pain and Addiction for Veterans*, The White House, available at <https://www.whitehouse.gov/articles/fighting-pain-addiction-veterans/> (last visited June 12, 2020).

⁴⁰ NATIONAL INSTITUTE ON DRUG ABUSE, *Opioid Overdose Crisis*, (Rev. Jan. 2019), <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> (last visited June 12, 2020).

⁴¹ *Id.*; Florence CS, Zhou C, Luo F, Xu L, *The Economic Burden of Prescription Opioid Overdose Abuse, and Dependence in the United States, 2013*, MED CARE 2016; 54(10):901-6, available at <https://www.ncbi.nlm.nih.gov/pubmed/27623005> (last visited June 12, 2020).

⁴² Allen, Greg, NPR, *Cost of U.S. Opioid Epidemic Since 2001 is \$1 Trillion and Climbing*, <https://www.npr.org/sections/health-shots/2018/02/13/585199746/cost-of-u-s-opioid-epidemic-since-2001-is-1-trillion-and-climbing> (last visited June 12, 2020).

substances by the DEA since 1970. The labels for scheduled opioids carry black box warnings of potential addiction and “[s]erious, life-threatening, or fatal respiratory depression” as a result of an excessive dose. The CDC has declared that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” (a diagnostic term for addiction).⁴³

128. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original and/or faxed copy of a manually signed prescription (which may not be refilled) from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829.

129. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Manufacturer Defendants, however, have manufactured, promoted, and marketed opioids for the management

⁴³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 MORBIDITY & MORTALITY WKLY REP 1 (March 18, 2016), available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last visited June 12, 2020).

of chronic pain by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of long-term opioid therapy.

130. Contrary to Manufacturer Defendants' representations, evidence shows that opioid drugs are not effective to treat chronic pain and may worsen a patient's health. One study found that opioids as a class do not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: “[O]ther analgesics were significantly more effective than were opioids.”⁴⁴

131. In 2013, in response to a petition to restrict the labels of extended-release opioid products, the FDA noted the “grave risks of opioids, the most well-known of which include addiction, overdose, and even death.”⁴⁵ The FDA further

⁴⁴ Andrea D. Furlan, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174 (11) CAN. MED. ASS'N J. 1589-1594 (2006), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/> (last visited June 12, 2020). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids.

⁴⁵ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing, Re: Docket No. FDA-2012-P-088 (Sept. 10, 2013), http://paindr.com/wp-content/uploads/2013/09/FDA_CDOR_Response_to_Physicians_for_Responsible

warned that “[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death.” The FDA required that, going forward, makers of extended-release opioid formulations clearly communicate these risks in their labels. Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain - that the adverse outcomes from opioid use include “addiction, unintentional overdose, and death” and that long-acting or extended release opioids “should be used ***only when alternative treatments are inadequate.***”⁴⁶

132. Notably, in reaching its conclusion, the FDA did not rely on new or otherwise previously unavailable scientific studies regarding the properties or effects of opioids.

133. The risks of opioid use disorder and overdose risk are present even when opioids are taken as prescribed.⁴⁷ Studies have shown that between 20% and 40% of long-term users of opioids experience problems with opioid use disorders. One study has shown that the duration of opioid therapy is a strong risk factor for opioid use disorder, even more important than daily dose - which itself is a strong predictor of continued opioid use.

[Opioid Prescribing Partial Petition Approval and Denial.pdf](#) (last visited June 12, 2020) [hereinafter Woodcock Sept. 10, 2013 letter].

⁴⁶ *Id.* (Emphasis added).

⁴⁷ *Id.*

134. Moreover, this crisis has caused a significant spike in street drug use. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.⁴⁸

135. As noted, opioids are extremely addictive. Studies have found diagnosed addiction⁴⁹ rates among opioid users in primary care settings as high as 26%.⁵⁰ Additionally, among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-abuse disorder.⁵¹

136. Once a patient begins opioid treatment, it is extraordinarily difficult to stop. A 2017 CDC study determined that the probability of long-term use escalates most sharply after five days and surges again when one month of opioids are

⁴⁸ Rudd et al., *supra* note 31.

⁴⁹ Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction. *Diagnostic and Statistical Manual of Mental Disorders* (5th ed. 20 I 3) ("DSM-V"). Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

⁵⁰ Deborah Dowell et al., *supra* note 39.

⁵¹ Joseph A. Boscario, Stuart N. Hoffman & John J. Han, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates*, 6 Substance Abuse and Rehabilitation 83 (2015); *see also* Joseph A. Boscario et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30 Journal of Addictive Diseases 185 (2011) (showing a 34.9% lifetime opioid use disorder).

prescribed.⁵² A patient initially prescribed one month of opioids has a 29.9% chance of still using at one year.⁵³ In one study, almost 60% of patients who used opioids for 90 days were still using them five years later.⁵⁴ When under the continuous influence of opioids over a period of time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient requires progressively higher doses to obtain the same levels of pain reduction he or she has become accustomed to – up to and including dosage amounts that are considered by many physicians to be “frighteningly high.”⁵⁵ And at higher doses, the effects of withdrawal are most substantial, leaving a patient at a much higher risk of addiction.

137. Tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids’ analgesic effects. Accordingly, the practice of continuously escalating dosages to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.⁵⁶ Patients receiving high

⁵² Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of long-Term Opioid Use - United States, 2006-2015*, 66 MORBIDITY & MORTALITY WKLY REP 265-269 (2017).

⁵³ *Id.*

⁵⁴ Bradley C. Martin et al., *long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26 J. GEN. INTERNAL. MED. 1450 (2011).

⁵⁵ Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer loses His Faith*, 170(16) ARCHIVES OF INTERNAL MED. 1422 (2010).

⁵⁶ See Thomas R. Frieden & Debra Houry, *supra* note 7.

doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses.

138. One in every 550 patients on opioid treatment will die within, on average, 2.6 years after their first opioid prescription. That number increases to 1 in 32 for patients receiving 200 morphine-milligram-equivalent per day (“MME/day”).

139. In short, there are no safe opioid doses, but the higher the dose and the longer the treatment, the more likely a patient will suffer serious health consequences.

140. While the risks and adverse effects of dependence, tolerance, and addiction are disclosed in the labels for Manufacturer Defendants' opioids, they are not disclosed and/or are minimized in Manufacturer Defendants' marketing.

IV. MANUFACTURER DEFENDANTS’ FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS

141. The opioid epidemic did not happen by accident.

142. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance

to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

143. In an effort to reverse this common medical understanding, each Manufacturer Defendant conducted, and continues to conduct, a marketing scheme designed to mislead doctors and patients about the safety and efficacy of opioids for the treatment of chronic pain. The result of this scheme has been the use of opioids by a far broader group of patients who are more likely to become addicted and suffer other adverse effects from the long-term use of opioids. Each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

144. Contrary to the language on their drugs' labels, Manufacturer Defendants have made false and misleading claims regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of “pseudoaddiction”; (3) exaggerated the effectiveness of screening tools and management techniques to prevent or mitigate addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; (6) asserted that other methods of pain relief

pose greater risks than opioids; (7) claimed that extended release opioids provided effective pain relief for 12 hours; and/or (8) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction. Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support Manufacturer Defendants’ claims.

145. Manufacturer Defendants disseminated these common messages directly, through their sales representatives and in speaker groups led by physicians Manufacturer Defendants recruited for the physicians’ support of Manufacturer Defendants’ marketing messages, and through unbranded marketing and industry-funded front groups. Through these efforts, Manufacturer Defendants sought to reverse the popular and medical understanding of opioids and their risks.

146. Manufacturer Defendants’ efforts have been wildly successful. In an open letter to the nation’s physicians in August 2016, the then-U.S. Surgeon General expressly connected this “urgent health crisis” to heavy marketing of

opioids to doctors ... [m]any of [whom] were even taught incorrectly that opioids are not addictive when prescribed for legitimate pain.”⁵⁷

147. Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating a crisis and causing the harms and damages alleged herein.

A. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids

148. Manufacturer Defendants employed the same marketing plans and strategies and deployed the same message in Georgia as they did nationwide. They spread their false and deceptive statements throughout the State, both by marketing their branded opioids directly to doctors and patients and through seemingly unbiased and independent third parties that they controlled.

149. Manufacturer Defendants' direct marketing of opioids proceeded on numerous tracks. First, each Manufacturer Defendant conducted advertising campaigns touting the purported benefits of their branded drugs, including through advertising in medical journals. Upon information and belief, Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids

⁵⁷ Letter from Yivek H. Murthy, M.D., U.S. Surgeon General (Aug. 2016), available at <http://i2.cdn.turner.com/cnn/2016/images/08/25/sg.opioid.letter.pdf> (last visited June 12, 2020).

in 2011, nearly triple what they spent in 2001. Many of these branded ads deceptively portrayed the benefits of opioids for chronic pain.

150. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through detailers - sales representatives who visited individual doctors and medical staff in their offices - and small-group speaker programs. Each Manufacturer Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, Manufacturer Defendants spent more than \$133 million⁵⁸ on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000. Sales representatives visited hundreds of thousands of doctors and disseminated Manufacturer Defendants' misleading marketing messages. In accordance with common industry practice, Manufacturer Defendants purchase and closely analyze prescription sales data from IMS Health Holdings, Inc. (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allows them to precisely track the rates of initial and renewal prescriptions by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

⁵⁸ The amount includes \$108 million spent by Purdue, \$13 million by Teva, \$10 million by Endo, and \$2 million by Allergan.

151. Third, Manufacturer Defendants marketed their opioids using unbranded advertising, paid speakers and key opinion leaders (“KOLs”), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”). By funding, directing, reviewing, editing, and distributing this unbranded advertising, Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to promote opioids falsely and misleadingly for the treatment of chronic pain through scientific publications, treatment guidelines, Continuing Medical Education (“CME”) programs, and medical conferences and seminars.

Key Opinion Leaders

152. Two of the most prominent KOLs were Dr. Russell Portenoy and Dr. Lynn Webster. Dr. Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, received research support, consulting fees, and honoraria from Cephalon/Teva, Endo, and Purdue (among others), and was a paid consultant to Cephalon/Teva and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) and American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which

endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), which issued education guides for patients, reporters, and policy makers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction.

153. Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”⁵⁹ Dr. Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did.”⁶⁰

154. Dr. Lynn Webster was the co-founder and Chief Medical Director of Lifetree Clinical Research, a pain clinic in Salt Lake City, Utah. Dr. Webster was

⁵⁹ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604> (last visited June 12, 2020).

⁶⁰ *Id.*

President of the AAPM in 2013. He is a Senior Editor of Pain Medicine, which published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon/Teva, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Manufacturer Defendants (including nearly \$2 million from Cephalon/Teva).

155. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to presort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening tools appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo and Purdue.

156. Dr. Webster also was a leading proponent of the concept of “pseudoaddiction,” the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain* - a book that is still available online - when faced with signs of aberrant behavior,

increasing the dose “in most cases ... should be the clinician's first response.”⁶¹ Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”⁶²

Front Groups

157. Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to misleadingly promote opioids for the treatment of chronic pain. Under the direction and control of Manufacturer Defendants, these Front Groups generated treatment guidelines, unbranded materials, and programs that touted the benefits of and minimized the risk associated with chronic opioid therapy. The Front Groups also assisted Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Manufacturer Defendants.

⁶¹ LYNN R. WEBSTER & BETH DOVE, AVOIDING OPIOID ABUSE WHILE MANAGING PAIN (Frederick W. Burgess, M.D. 2007).

⁶² John Fauber, *Painkiller Boom Fueled by Networking*, MILWAUKEE WISC. J. SENTINEL, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (last visited June 12, 2020).

158. These Front Groups depended on Manufacturer Defendants for funding and, in some cases, for survival. Manufacturer Defendants exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content. Manufacturer Defendants also funded their dissemination. In doing so, Manufacturer Defendants made sure that the Front Groups would generate only the messages that Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent entities serving the needs of their members - whether patients suffering from pain or doctors treating those patients.

159. Several of the most prominent of Manufacturer Defendants' Front Groups were the APF, APS, American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and Pain & Policy Studies Group (“PPSG”).⁶³

⁶³ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. On Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), available at [https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20\(5%20May%202017\).pdf](https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf) (last visited June 12, 2020).

160. The most well-known of these was the APF, which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed in May 2012. APF issued education guides for patients, reporters, and policy makers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes, including death, among returning soldiers. APF also engaged in a significant multimedia campaign, through radio, television and the internet, to educate patients about their “right” to pain treatment, namely opioids. All of APF's programs and materials were available nationally and were intended to reach citizens of Georgia.

161. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Manufacturer Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization “due to

irreparable economic circumstances.” APF “cease[d] to exist, effective immediately.”⁶⁴

162. Another Front Group for Manufacturer Defendants was the AAPM. With the assistance, prompting, involvement, and funding of Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

163. The AAPM and the APS issued a joint guideline in 2009 ("AAPM/APS Guidelines") which recommended the use of opioids to treat chronic pain while overstating the benefits and downplaying the risks.⁶⁵ Doctors, especially the general practitioners and family doctors targeted by Manufacturer Defendants, rely upon these treatment guidelines. Treatment guidelines not only directly inform doctors' prescribing practices but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should

⁶⁴ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, WASH. POST, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html?noredirect=on&utm_term=.6f519dd9210e (last visited June 12, 2020).

⁶⁵ Roger Chou *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 THE J. OF PAIN 113 (2009), available at [https://www.jpain.org/article/S1526-5900\(08\)00831-6/fulltext](https://www.jpain.org/article/S1526-5900(08)00831-6/fulltext) (last visited June 12, 2020).

cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Allergan, and Purdue discussed the AAPM/APS Guidelines with doctors during individual sales visits.

164. Manufacturer Defendants worked together, through these Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy.

B. Manufacturer Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids

i. Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair representations grossly understating and misstating the dangerous addiction risks of the opioid drugs.

165. To convince physicians and patients that opioids are safe, Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations, often aimed at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids, achieved their intended effect. Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. The

misrepresentations, described below, reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; (4) opioid dependence can be easily overcome via tapering or other methods; and (5) the use of abuse-deterrent opioids lowers the risk of addiction and overdose. Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

166. The first category of false, deceptive, and unfair claims utilized by Manufacturer Defendants to convince doctors that opioids were safe for the long term treatment of pain is that the risk of addiction was low. However these claims are contrary to the longstanding scientific evidence. The CDC explained in its opioid-prescription guideline (the “2016 CDC Guideline”) that there is “[e]xtensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose ...).”⁶⁶ The

⁶⁶ Deborah Dowell et al., *supra* note 39.

2016 CDC Guideline states that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”⁶⁷

167. The FDA further exposed the falsity of Manufacturer Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long acting (“ER/LA”) opioids in 2013 and for immediate release (“IR”) opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have proved inadequate.⁶⁸

⁶⁷ *Id.* at 2, 25.

⁶⁸ Woodcock Sept. 10, 2013 letter, *supra* note 41; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), *available at* <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last visited June 12, 2020) [hereinafter Woodcock Mar. 22, 2016 letter].

168. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, Manufacturer Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain and instructed doctors to increase the opioid prescription dose for patients who were already in danger. Dr. David Haddox, who became a vice president at Purdue, termed this supposed phenomenon as “pseudoaddiction.”

169. The CDC rejected the validity of pseudoaddiction, as it was a reason to push more opioid drugs onto already addicted patients.

170. A third category of false, deceptive, and unfair representations made by Manufacturer Defendants was that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow doctors to reliably identify and safely prescribe opioids to patients predisposed to addiction.

171. The 2016 CDC Guideline confirms the lack of support for these claims. In its guideline, the CDC explains that there are no studies assessing the effectiveness of risk mitigation strategies “or improving outcomes related to overdose, addiction, abuse or misuse.”⁶⁹

⁶⁹ Deborah Dowell et al., *supra* note 39 at 15.

172. A fourth category of deceptive messaging regarding dangerous opioids is Manufacturer Defendants' misrepresentations that opioid dependence could be easily eliminated. Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use.

173. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion, and premature labor in pregnant women.⁷⁰

174. A fifth category of false, deceptive, and unfair statements made by Manufacturer Defendants to sell more of their drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief.

⁷⁰ *Id.* at 26.

175. Once again, the 2016 CDC Guideline reveals that Manufacturer Defendants' representations were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."⁷¹ More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."⁷² The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."⁷³ That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.⁷⁴ Additionally, a CDC clinical evidence review found that higher opioid dosages were associated with increased risks of motor vehicle injury, opioid use disorder, and overdoses, and that the increased risk rises in a dose-dependent manner. Another study found that higher daily doses and possible opioid misuse were also strong predictors of continued use, and associated with increased risk of overdoses, fractures, dependence, and death.

176. Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example,

⁷¹ *Id.* at 22-23.

⁷² *Id.* at 23-24.

⁷³ *Id.* at 21.

⁷⁴ *Id.* at 16.

Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to ... forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."⁷⁵ Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

ii. Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair representations grossly overstating the benefits of the opioid drugs.

177. To convince doctors and patients that opioids should be used to treat chronic pain, Manufacturer Defendants also had to persuade them that there were significant benefits to long-term opioid therapy. Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that scientific evidence supported these benefits.

⁷⁵ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc., FDA-2012-P-095 (May 10, 2013), at 5, [hereinafter Woodcock May 10, 2013 letter].

178. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.⁷⁶

179. In 2010, the FDA warned Allergan, in response to its advertising of Kadian, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁷⁷ And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities ... has not been demonstrated by substantial evidence or substantial clinical experience."

⁷⁶ Deborah Dowell et al., *supra* note 39 at 15.

⁷⁷ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Comm., U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), *available at* <https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last visited June 12, 2020).

180. Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like nonsteroidal anti-inflammatory drugs ("NSAIDs"), so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.⁷⁸

181. Purdue and the APF misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours - a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half.

⁷⁸ Deborah Dowell et al., *supra* note 39.

182. Cephalon/Teva deceptively marketed and continues to market its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon/Teva from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse which are greatest in non-cancer patients.

iii. Each Manufacturer Defendant Made Materially Deceptive Statements and Concealed Material Facts in the Promotion of Their Opioid Products

Purdue

183. Purdue made and/or disseminated deceptive statements and concealed material facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of

chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioids, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

184. Illustrative examples of Purdue's false, deceptive and/or unfair claims include the following:

- a. Purdue published a pamphlet in 2011 entitled *Providing Relief: Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."
- b. Upon information and belief, Purdue ran a series of ads, called "pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.
- c. Upon information and belief: Purdue's "In the Face of Pain" website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- d. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.⁷⁹
- e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse." In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.
- f. Upon information and belief, Purdue sponsored a 2011 webinar, "Managing Patient's Opioid Use: Balancing the Need and Risk,"

⁷⁹ The College on Problems of Drug Dependence, *About the College*, <http://cpdd.org> (last visited June 12, 2020).

which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

- g. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients - and not opioids - are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.
- h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."⁸⁰ The guide further taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.⁸¹
- j. Purdue (along with Cephalon/Teva) sponsored APF's "Treatment Options: A Guide for People Living with Pain (2007)," which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. The guide further claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most

⁸⁰ Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], available at <http://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last visited June 12, 2020).

⁸¹ *Id.* at 32.

appropriate treatment for severe pain.⁸² The guide also counseled patients that opioids "give [pain patients] a quality of life we deserve."⁸³ This publication is still available online.⁸⁴

- k. Purdue (along with Endo and Cephalon/Teva) sponsored and/or distributed "Responsible Opioid Prescribing" (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction.⁸⁵ It also taught that relief of pain by opioids, by itself, improved patients' function.⁸⁶ The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.⁸⁷
- l. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants, including Purdue, argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.⁸⁸ The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.⁸⁹

⁸² Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*]
<http://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last visited June 12, 2020).

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ SCOTT M. FISHMAN, M.D., RESPONSIBLE OPIOID PRESCRIBING: A PHYSICIAN'S GUIDE (2007) at 62.

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

⁸⁹ *Id.*

185. Endo made and/or disseminated deceptive statements and concealed material facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations - including over \$5 million to the organization responsible for many of the most egregious misrepresentations— that made deceptive

statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

186. Illustrative examples of Endo's false, deceptive, and/or unfair claims include the following:

- a. Endo sponsored a website, "Pain Knowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted" and that opioid

dosages may be increased until "you are on the right dose of medication for your pain." Additionally, upon information and belief, the website claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated National Initiative on Pain Control's ("NIPC") intent to make misleading claims about function.

- b. Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.
- c. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled "Living with Someone with Chronic Pain," which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."
- d. Endo paid for a 2007 supplement in the Journal of Family entitled "Pain Management Dilemmas in Primary Care: Use of Opioids," which emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
- e. Endo distributed and made available on its website (opana.com) a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, such as construction workers, chefs, and teachers, implying that the drug would provide long-term pain-relief and functional improvement.

- f. Endo distributed a pamphlet edited by a KOL entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased ... You won't 'run out' of pain relief."⁹⁰
- g. Endo distributed "Responsible Opioid Prescribing" (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction.⁹¹ It also taught that relief of pain by opioids, by itself: improved patients' function.⁹² The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.⁹³
- h. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient." Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."
- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Endo), argued in an *amicus* brief to the United

⁹⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics*. (Russell K. Portenoy, M.D., ed., 2004).

⁹¹ Scott M. Fishman, M.D., *supra* note 81 at 62.

⁹² *Id.*

⁹³ *Id.*

States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.⁹⁴ The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.⁹⁵

Mallinckrodt

187. Mallinckrodt made and/or disseminated deceptive statements and concealed facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Mallinckrodt exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Mallinckrodt exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Mallinckrodt knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Mallinckrodt exercised final editorial control and approval, which presented an unbalanced

⁹⁴ Brief of APF, *supra* note 84 at 9.

⁹⁵ *Id.*

treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of

chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

188. Illustrative examples of Mallinckrodt's false, deceptive, and/or unfair claims include the following:

- a. Mallinckrodt, through an organization it controls called the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which ostensibly is devoted to responsible prescribing and reducing opioid pain medication abuse, published a book titled *Defeat Chronic Pain Now!* That made the following misrepresentations:
 - 1. "Only rarely does opioid medication cause a true addiction; It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
 - 2. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
 - 3. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
 - 4. "The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
 - 5. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't

have a prior history of 'any addiction and (2) he only takes the medication to treat pain.

6. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction. When prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- b. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."⁹⁶
- c. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Mallinckrodt), argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.⁹⁷ The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.⁹⁸

Cephalon/Teva

189. Cephalon/Teva made and/or disseminated deceptive statements and concealed material facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

⁹⁶ MALLINCKRODT PHARMACEUTICALS, <http://www.mallinckrodt.com/corporate-responsibility/responsible-use> (last visited June 12, 2020).

⁹⁷ Brief of APF, *supra* note 84 at 9.

⁹⁸ *Id.*

- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and break through chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon/Teva's potent rapid-onset opioids;
- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon/Teva's rapid-onset opioids;
- h. Directing its marketing of Cephalon/Teva's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon/Teva's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

- j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

190. Illustrative examples of Cephalon/Teva's false, deceptive and/or unfair claims include the following:

- a. Cephalon/Teva (along with Purdue) sponsored APF's "Treatment Options: A Guide for People Living with Pain" (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. The guide further claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.⁹⁹ The guide also counseled patients that opioids "give [pain patients] a quality of life we deserve."¹⁰⁰ This publication is still available online.¹⁰¹
- b. Cephalon/Teva (along with Endo and Purdue) sponsored and/or distributed "Responsible Opioid Prescribing" (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction.¹⁰² It also taught that relief of pain by opioids, by itself, improved patients' function.¹⁰³ The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.¹⁰⁴

⁹⁹ APF, *Treatment Options*, *supra* note 78, at 12.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² Scott M. Fishman, M.D., *supra* note 81 at 62.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

- c. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Cephalon/Teva), argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.¹⁰⁵ The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.¹⁰⁶

Allergan

191. Allergan made and/or disseminated deceptive statements and concealed material facts in marketing prescription opioids through multiple avenues, including but not limited to the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

192. Illustrative examples of Allergan's false, deceptive and/or unfair claims include the following:

¹⁰⁵ Brief of APF, *supra* note 84 at 9.

¹⁰⁶ *Id.*

- a. Allergan's predecessor caused a patient education brochure, "Managing Chronic Back Pain," to be distributed beginning in 2003 that admitted that opioid addiction is possible, but misleadingly claimed that it is "less likely if you have never had an addiction problem." Based on Allergan's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Allergan continued to use this brochure in 2009 and beyond.
- b. Upon information and belief Allergan distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- c. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and NFP, Front Groups for Manufacturer Defendants (including Allegran), argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.¹⁰⁷ The *amicus* brief also argued that "there is no 'ceiling dose'" for opioids.¹⁰⁸

iv. Manufacturer Defendants Have a History of Criminal and Civil Charges for their Unlawful Conduct.

193. In 2007, Purdue settled criminal and civil charges concerning its misbranding of OxyContin and entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. Purdue was forced to admit it illegally marketed and promoted OxyContin by claiming it was less addictive and less subject to abuse than other pain medications. Purdue agreed to pay nearly \$635 million in fines, and three of

¹⁰⁷ Brief of APF, *supra* note 84 at 9.

¹⁰⁸ *Id.*

its executives pled guilty to federal criminal charges for misleading regulators, doctors, and patients about OxyContin's risk of addiction and its potential to be abused. At the time, this was one of the largest settlements with a drug company for marketing misconduct.¹⁰⁹

194. In 2008, Cephalon/Teva pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.¹¹⁰

195. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in southeastern Indiana was linked to injection of the prescription painkiller Opana,¹¹¹ the first documented HIV outbreak in the United States associated with injection of a prescription painkiller. After the outbreak, the FDA required "that Endo Pharmaceuticals remove [Opana ER] from the market." The

¹⁰⁹ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), <https://www.nytimes.com/2007/05/10/business/11drug-web.html> (last visited June 12, 2020).

¹¹⁰ U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last visited June 12, 2020).

¹¹¹ State of Indiana Health Department, *HIV Outbreak in Southeastern Indiana* (Feb. 25, 2015), available at <https://calendar.in.gov/site/isdh/event/hiv-outbreak-in-southeastern-indiana/> (last visited June 12, 2020).

agency sought removal "based on its concern that the benefits of the drug may no longer outweigh its risks."¹¹²

196. In 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.¹¹³ Mallinckrodt was aware that it was fulfilling suspicious orders through chargeback data it collected to provide rebates or other discounts to the distributor or other third parties. Manufacturers of pharmaceuticals offer discounts, known as "chargebacks," based on sales to certain downstream customers. Distributors provide information on the downstream customer purchases to obtain the discount. The settlement requires a manufacturer to utilize chargeback and similar data to monitor and report to the DEA suspicious sales of its oxycodone at the next level in the supply chain, typically sales from distributors to independent and small chain pharmacy and pain clinic customers.

¹¹² CNN Wire, *FDA wants Opioid at Center of Scott County HIV Outbreak Pulled Off Market*, FOX59.COM (June 9, 2017) <https://fox59.com/2017/06/09/fda-wants-opioid-at-center-of-scott-county-hiv-outbreak-pulled-off-market/> (last visited June 12, 2020); FDA, *FDA Requests Removal of Opana ER for Risks Related to Abuse*, (June 8, 2017) <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm> (last visited June 12, 2020).

¹¹³ U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations*, <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders> (last visited June 12, 2020).

V. DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS

197. While Manufacturer Defendants created the demand for opioids, Distributor Defendants accelerated the opioid crisis which is arguably the worst drug crisis in Georgia and American history. Distributor Defendants serve as the critical choke point. They are obligated in Georgia, as well as to all states they do business in, to monitor, detect, report, investigate, or otherwise prevent the fulfillment of suspicious orders of prescription opioids destined for dispensing physicians and pharmacies in Georgia. If they fail in their duty, the foreseeable harm to the State of Georgia is the diversion of prescription opioids for illegitimate purposes.

198. Faced with this critically important duty, Distributor Defendants ignored it, and over time, flooded the market with opioid prescription drugs. These actions led to the widespread diversion of opioids for illegitimate purposes, which foreseeably devastated the communities the CSBs serve.

199. Distributor Defendants' unlawful conduct was actively concealed from the government authorities for years. One of the ways wholesale distributors are supposed to maintain controls against the diversion of prescription opiates is by inputting all distributions in the DEA Automation of Reports and Consolidated Orders Systems (ARCOS) database. This database contains monthly reports from

each wholesale distributor and documents the number of doses of each controlled substance sold to every pharmacy on a monthly basis. The information in the ARCOS database is confidential. The public has never seen the data related to the volume of prescription opiates distributed in each community. This data, when viewed in its total form will illustrate Distributor Defendants' indifference to their obligations. Additional discovery will reveal the full extent of Distributor Defendants' conduct.

A. Wholesale Drug Distributors are Obligated under Federal and State Law to Monitor, Detect, Report, Investigate, or Otherwise Prevent the Fulfillment of Suspicious Orders.

200. Opioids are a controlled substance and are categorized as having a "high potential for abuse" under Georgia law. *See* O.C.G.A. § 16-13-24; *see also* 21 U.S.C.A. §§ 812(b), 812(2)(A)-(C).

201. Distributor Defendants have numerous obligations under Georgia law related to the distribution of controlled substances. These obligations include the requirement that they operate in compliance with applicable Federal, State and local laws and regulations, including, among other things, the Georgia Controlled

Substances Act, O.C.G.A. § 16-13-1, *et seq.* ("GCSA"), and the federal Controlled Substances Act.¹¹⁴

202. Each Defendant is required, pursuant to the GCSA, to register with the Georgia State Board of Pharmacy. Registration as a distributor in Georgia is contingent upon Distributor Defendants' maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels. *See, e.g.*, O.C.G.A. § 16-13-36. The State of Georgia relies on each Distributor Defendant's representation that it meets its duties.

203. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substances Act. *See* GA. COMP. R. & REGS. 480-7-.03(10); 21 U.S.C. § 823(b), (e); and 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

¹¹⁴ *See* GA. COMP. R. & REGS. 480-7-.03(10) ("Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations" and "[w]holesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, Local, and DEA regulations").

204. Manufacturers and wholesale distributors have a duty to maintain adequate records of transactions involving a controlled substance. O.C.G.A. § 16-13-39.

205. Distributor Defendants are further obligated to “design and operate a system to disclose to the registrant [distributor] suspicious orders of controlled substances.” *See* 21 C.F.R. § 1307.74(b); *see also* GA. COMP. R. & REGS. 480-7-.03(10).¹¹⁵ Once discovered, Distributor Defendants have a duty to maintain records of suspicious orders of controlled substances received (GA. COMP. R. & REGS. 480-20-.02) and automatically submit reports of any suspicious orders of controlled substances to the Georgia Drugs and Narcotics Agency (O.C.G.A. § 26-4-115).

206. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. O.C.G.A. § 26-4-115; 21 C.F.R. § 1301.74(b).

¹¹⁵ *See also* HOMA and the National Association of Chain Drug Stores ("NACDS"), 2016 WL 1321983, at *4 ("[R]egulations ... in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).") [hereinafter Brief for HOMA and NACDS].

207. The suspicious order criteria are disjunctive and are not all inclusive.¹¹⁶ For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether an order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry. Distributor Defendants know all of this information in the course and scope of their operations.¹¹⁷

208. In addition to reporting all suspicious orders, distributors know they must also stop shipment on any order flagged as suspicious, and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the **distributor** can determine that the order is not likely to be diverted into illegal

¹¹⁶ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No.14-8 [hereinafter Rannazzisi Dec. 27, 2007 letter].

¹¹⁷ *Id.*

channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36487-01, 36501 (Drug Enf't Admin. July 3, 2007); *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

209. Fulfilling these obligations plays a critical role in protecting against the diversion of controlled substances. As the DEA advised all registrants, including each Defendant, in a letter dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”¹¹⁸ According to the DEA, “[t]his responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people” and “just one distributor that uses its DEA registration to facilitate diversion **can cause**

¹¹⁸ *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Sept. 27, 2006 letter] (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

enormous harm."¹¹⁹ Thus, all Defendants knew how critical their responsibility was to society, including to the State of Georgia.

210. In a second letter to all DEA registrants on December 27, 2007, the DEA again reminded Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and to "design and operate a system to disclose to the registrant suspicious orders of controlled substances."¹²⁰ The letter further explained:

- a. "Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders." Their responsibility "does not end merely with the filing of a suspicious order report ... [they] must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted."
- b. Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious."
- c. "Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a

¹¹⁹ *Id.* at 2. (emphasis added).

¹²⁰ See Rannazzisi Dec. 27, 2007 letter, *supra* note 112.

system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order."

- d. A drug distributor must, when reporting a suspicious order, "be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating 'excessive purchases' do not comply with the requirement to report suspicious orders, even if the registrant calls such reports 'suspicious order reports.'"
- e. Critically, drug distributors that "routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration."¹²¹

211. Distributor Defendants knew they were required to monitor, detect, investigate, report, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association ("HDMA"), the trade association of pharmaceutical distributors, explain that distributors are

¹²¹ *Id.*

"[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: if an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.¹²²

212. Distributor Defendants acknowledge that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs but ***undertake such efforts as responsible members of society.***"¹²³ Each Distributor Defendant owes a duty to satisfy its obligations under state and federal law to prevent the diversion into illicit markets in the state.

¹²² Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No.12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

¹²³ See Brief of Healthcare Distribution Management Association as *Amicus Curiae* for *Cardinal Health*, 2012 WL 1637016, at *2, filed in *Cardinal Health, Inc. v. Department of Justice*, No. 12-5061 (D.C. Cir. 2012). (emphasis added).

B. Distributor Defendants Breached their Duties

213. Distributor Defendants breached their duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opioids originating from pharmacies and dispensers in Georgia, and/or in areas from which Distributor Defendants knew opioids were likely to be diverted to Georgia residents.

214. Each Distributor Defendant sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Georgia and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to residents of the state.

215. The sheer volume of prescription opioids distributed to pharmacies in the State of Georgia, and/or to pharmacies and dispensing physicians from which Distributor Defendants knew the opioids were likely to be diverted into the state, is and was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no legitimate distributor of controlled substances can reasonably claim ignorance of them.¹²⁴

216. Distributor Defendants breached their duty to design and operate a system to disclose to the registrant suspicious orders of controlled substances.

¹²⁴ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55418-01, 55482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62316-01, 62322 (2012)).

217. Distributor Defendants failed to meet their reporting obligations related to suspicious orders originating from the state, and/or which Distributor Defendants knew were likely to be diverted to the state, to state and federal authorities, including the Georgia Drugs and Narcotics Agency ("GDNA") and the DEA.

218. Not only did they fail to report, but Distributor Defendants unlawfully filled suspicious orders in the State of Georgia and/or in areas from which Distributor Defendants knew opioids were likely to be diverted to Georgia.

219. The foreseeable harm resulting from Distributor Defendants breach of these duties was the diversion of prescription opioids for illegitimate purposes, harm to the public interest, and the resulting crisis plaguing Georgia today.

220. Because of Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. These actions include the following:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, FL distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn,

Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would pay a \$13.25 million civil fine and "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;"
- g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility, and Stafford Facility. The document also referenced allegations by the DEA that Cardinal Health failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, GA, Valencia, CA and Denver, CO;
- h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland

Facility for failure to maintain effective controls against diversion of oxycodone. Violations included exponentially increasing shipments of Oxycodone to several known pill mills in Florida subsequent to the MOA agreed upon to resolve the prior ISO in 2008 at the Lakeland Facility (shipments of Schedule II opioids to these four pharmacies increased 803% from 2008 to 2009, and 162% from 2009 to 2010);

- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against the Lakeland Facility, for failing to report suspicious orders of controlled substances; and
- j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO, Aurora, IL, Delran, NJ, LaCrosse, WI, Lakeland, FL, Landover, MD, La Vista, NE, Livonia, MI, Methuen, MA, Santa Fe Springs, CA, Washington Courthouse, OH and West Sacramento, CA.

221. The unlawful conduct by Distributor Defendants is purposeful and intentional and Distributor Defendants acted with actual malice in breaching their duties. Distributor Defendants refused, and continue to refuse, to abide by the duties imposed by state and federal law which are required to legally acquire and maintain a license to distribute prescription opiates. These repeated failures over an extended period demonstrate wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others, and Georgia CSBs in particular.

C. Distributor Defendants Used the Courts and the Legislative Process in an Effort to Exculpate their Wrongs and Misrepresented their Compliance with their Legal Duties

222. Distributor Defendants have used the courts and the legislative process in an effort to exculpate their wrongful conduct, and to further avoid their obligations to report and halt fulfillment of suspicious orders. Additionally, Distributor Defendants have repeatedly misrepresented their compliance with their legal duties and have wrongfully and repeatedly disavowed those duties to mislead regulators and the public regarding Distributor Defendants' compliance with their obligations.

223. In *Masters Pharmaceuticals*, the HDMA (a trade association controlled by Distributor Defendants), and the National Association for Chain Drug Stores ("NACDS") submitted *amicus* briefs stating that the legal duty of wholesale distributors was limited to reporting suspicious orders.¹²⁵ The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *See Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors

¹²⁵ Brief for HDMA and NACDS, *supra* note 111, 2016 WL 1321983, at *4-5.

must "decline to ship the order, or conduct some 'due diligence' and- if they are able to determine that the order is not likely to be diverted into illegal channels— ship the order." *Id.* at 212. A distributor's investigation must dispel all the red flags giving rise to the suspicious circumstance prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

224. Additionally, Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.¹²⁶

¹²⁶ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST, (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.81b689e74928 (last visited

225. In addition to taking actions to limit regulatory prosecutions and suspensions, Distributor Defendants undertook to fraudulently convince government regulators in states like Georgia, as well as the public, that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, Distributor Defendants attempted to assure the public that they were working to curb the opioid epidemic when they were not.

226. For example, a Cardinal Health executive claimed that Cardinal Health uses "advanced analytics" to monitor its supply chain and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."¹²⁷

June 12, 2020); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST, (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.de8b9282aa72 (last visited June 12, 2020); Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL, (Feb. 18, 2017) https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html (last visited June 12, 2020).

¹²⁷ Lenny Bernstein *et al.*, *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* WASH. POST, (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?noredirect=on&utm_term=.598e585aaf32 (last visited June 12, 2020).

227. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."¹²⁸

228. Given Cardinal Health's and McKesson's historical conduct, either these statements are false or misleading, or these companies ignored their monitoring programs.

229. By misleading government regulators and the public about the effectiveness of their controlled substance monitoring programs, Distributor Defendants successfully concealed facts which would have aroused suspicion of the claims that the CSBs now assert while at the same time allowing these Defendants to make billions in profits from this scheme at the expense of the CSBs. The State of Georgia and the CSBs did not know of the existence or scope of Distributor Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Distributor

¹²⁸ Scott Higham *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, WASH. POST, (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.b27455c29141 (last visited June 12, 2020).

Defendants, however, knew that government regulators and the public would rely on their statements.

230. The wrongful actions and omissions of Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in the CSBs' racketeering allegations below.

231. Distributor Defendants have ignored federal mandates and resisted, defied, and breached their duties under federal and state law, taken advantage of their superior knowledge and position over government entities, and abused the privilege of distributing controlled substances in the State of Georgia, causing enormous harm to the CSBs.

VI. MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS

232. Manufacturer Defendants had the same obligations to prevent diversion related to the fulfillment of suspicious prescription opioid orders as Distributor Defendants.

233. Under Georgia and federal law, Manufacturer Defendants are required to comply with substantially the same licensing and permitting requirements as

Distributor Defendants and the same rules regarding prevention of diversion and reporting suspicious orders, as set out above.

234. Manufacturer Defendants had access to and possession of the information necessary to meet their legal obligations to prevent diversion of prescription opioids. For example, Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors and built receipt of this information into the payment structure for opioids. Thus, Manufacturer Defendants knew just as Distributor Defendants knew the volume, frequency, and pattern of opioid orders being placed and filled.

235. Yet, the Manufacturer Defendants have failed to report suspicious orders of controlled substances, specifically including opioids, and violated recordkeeping mandates. For example, the Department of Justice has recently fined Mallinckrodt \$35 million for failing to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.¹²⁹ Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator,

¹²⁹ U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations*, <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders> (last visited June 12, 2020).

Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."

236. The same duties imposed by federal law on Mallinckrodt were imposed upon all Manufacturer Defendants. Indeed, the Report and Recommendation issued by the federal court overseeing the opioid Multi-District Litigation determined that Manufacturer Defendants, not just distributors, owed a duty to report, investigate, and halt suspicious orders.¹³⁰

237. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

238. Through, *inter alia*, the charge-back data, Manufacturer Defendants could monitor, detect, investigate, report, or otherwise prevent the fulfilment of suspicious orders of opioids yet intentionally and unlawfully failed to do so as required by Georgia and federal law.

¹³⁰ *In Re: National Prescription Opiate litigation*, No. 1:18-op-45090, 2018 WL 4895856, (N.D. Ohio Oct. 5, 2018) (Report and Recommendation of Magistrate Judge on Defendants' Motion to Dismiss); adopted by the District Court, *In Re: National Prescription Opiate Litigation*, No. 1:18-op-45090, ECF No. 1203, (N.D. Ohio Dec. 19, 2018) (Opinion and Order adopting in part and rejecting in part Magistrate Judge's Report and Recommendation).

239. Manufacturer Defendants have also misrepresented their compliance with Georgia and federal law.

240. Manufacturer Defendants enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

241. The wrongful actions and omissions of Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in the CSB's racketeering allegations below.

**VIII. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF
LEGAL DUTIES ARE THE DIRECT AND PROXIMATE CAUSE OF
AND/OR ARE A SUBSTANTIAL CONTRIBUTING FACTOR TO
THE HARMFUL CONDITIONS, INJURIES, AND DAMAGES
ALLEGED HEREIN**

242. As Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and sale of their products. Distributor Defendants' continued indifference to their legal duties led to the unlawful shipment of massive quantities of opioids into Georgia, fueling the epidemic to levels never seen before.

243. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."¹³¹

244. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.¹³²

245. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."¹³³

246. The increased abuse of prescription painkillers along with growing sales have contributed to many overdoses and deaths.¹³⁴

247. As shown above, the opioid epidemic has escalated in Georgia with devastating effects on the CSBs and people they serve. Substantial opiate-related substance abuse, hospitalization, and death correlates directly with Defendants' increased distribution of opiates.

¹³¹ Dart, Richard, M.D., Severtson G., et al. *Trends in Opioid Analgesic Abuse and Mortality in the United States*, NEW ENGL. J. OF MED. 2015; 372:241-248 (2015).

¹³² Elspeth Shipton et al., *Deaths From Opioid Overdosing: Implications of Coroners' Inquest Reports 2008-2012 and Annual Rise in Opioid Prescription Rates: A Population-Based Cohort Study*, PAIN & THERAPY (2012).

¹³³ *Id.*

¹³⁴ *Prescription Opioid Data*, *supra* note 30.

248. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids - like heroin and illicit (i.e., illegally manufactured) fentanyl - the massive distribution of opioids caused the opioid epidemic to become an opioid, heroin, and fentanyl crisis.

249. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for illegitimate purposes into the state.

250. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and mortality in the state. This diversion and the epidemic are direct causes of foreseeable harms and damages incurred by the CSBs.

251. The CSBs submit claims for the services they provide to Georgians with likely opioid abuse disorder to government payors such as the Georgia Department of Behavioral Health and Developmental Disabilities (“DBHDD”) and Medicaid. The CSBs also obtain funding from the counties they serve. Yet, the damages sought by the CSBs are unique to the CSBs themselves. They are not

pass-through entities. The CSBs seek the damages they have specifically incurred as a result of Defendants' conduct.

252. An analysis of the CSBs' claims data specifically related to services provided for likely opioid abuse disorder demonstrates how Defendants' conduct has impaired and continues to impair the CSBs' ability to fulfill their independent front-line healthcare duties and obligations and has caused the CSBs to suffer significant monetary losses.

253. By way of representative example, Gateway Community Service Board (hereinafter "Gateway") services Bryan, Camden, Chatham, Effingham, Glynn, Liberty, Long, and McIntosh counties, an area with an estimated population of 623,000 residents. Gateway provided substance abuse treatment to more than 6,400 unique clients between 2017-2019. The average annual cost of services received by opioid abuse or likely opioid abuse clients was almost \$700, which was more than other substance abuse clients.

254. By way of representative example, Lookout Mountain Community Service Board (hereinafter "Lookout Mountain") services Catoosa, Chattooga, Dade, and Walker counties, an area with an estimated population of 178,000 residents. Lookout Mountain provided substance abuse treatment to more than 4,000 unique clients between fiscal years 2012-2015. More than half of the billed

revenue for addiction services provided were for opioid abuse or likely opioid abuse clients. The average opioid abuse or likely opioid abuse clients also required 2 to 3.5 times more services than other substance abuse clients. Additionally, the average annual cost of services received by opioid abuse or likely opioid abuse clients was significantly more than other substance abuse clients. In 2015, the average annual value of services by opioid and likely opioid Lookout Mountain clients was \$1,750.53, compared to the average of \$502.27 for other substance abuse clients. The average annual cost of services per client was 187% greater for opioid or likely opioid abuse clients than other substance abuse clients.

255. By way of further representative example, Satilla Community Services d/b/a Unison Behavioral Health (hereinafter “Unison”) services Atkinson, Bacon, Brantley, Charlton, Clinch, Coffee, Pierce, and Ware counties, an area with an estimated population of 156,000 residents. Unison provided substance abuse treatment to more than 8,400 unique clients between 2012-April 2020. Almost half of Unison clients had an opioid abuse or likely opioid abuse disorder, and the services provided by Unison to these clients accounted for over 60% of Unison’s billed revenue. The average annual cost of services per client was over 80% greater for opioid or likely opioid abuse clients than other substance abuse clients.

256. By way of further representative example, View Point Health is a CSB that provides inpatient and outpatient mental health and addictive disease treatment for residents of Gwinnett, Newton, and Rockdale counties (approximately 1,127,000 residents) at more than a dozen locations. Between July 1, 2012 - June 30, 2019, View Point Health provided opioid abuse or likely opioid abuse services to almost 5,000 clients costing more than \$57.8 million in care. Additionally, View Point Health clients with an opioid abuse or likely opioid abuse diagnosis:

- a. Received 3.7 times more services than other substance abuse clients;
- a. Averaged 5.5 more days of detox services than clients with other substance abuse disorders;
- b. Were more than 8 times more likely to repeat detox services than patients with other substance abuse disorders;
- c. Received services with an average annual cost of more than \$1,490, which represents more than an 80% increase compared to other substance abuse clients.

257. View Point Health alone has had to write off more than \$17 million in losses for uncompensated or undercompensated care as a result of opioid abuse

services, which are direct losses to this CSB and losses not shared by the counties it serves or the State of Georgia.

258. The Georgia CSBs project their estimated damages for services they have historically provided to patients with likely opioid abuse disorder to be over \$150 million, and adding in the almost \$40 million in damages related to the cost of missed appointments, the Georgia CSBs project historical damages of nearly \$195 million.

259. Further, the Georgia CSBs estimate damages for the services they will have to provide to patients with likely abuse disorder diagnoses in the next fifteen years to be nearly \$250 million with more than an additional \$60 million related to the cost of missed appointments. The Georgia CSBs estimate total future damages of over \$305 million, which combined with the historical damages, is more than \$500 million in total damages related to Defendants' conduct.

260. The cost to the CSBs for treating clients with opioid abuse exceeds the reimbursement received from Medicaid, state contracted services through DBHDD, and other insurance payors, both private and public. The CSBs also face additional significant monetary losses for uninsured patients, for patients who do not show up for their appointments, for pharmacy services provided to these patients, and for services provided to family members of their patients who receive

opioid abuse related services. The CSBs have attempted to mitigate their losses from reserves and other funding sources to the great detriment of other programs and much needed capital development projects. Therefore, the opioid crisis has caused direct financial harm to the CSBs.

261. But for Defendants' tortious conduct, including intentional and negligent acts and omissions, the harmful conditions besetting the State of Georgia and the resulting injuries to the Georgia CSBs, as described herein, would not have occurred. Defendants' Defendants' tortious conduct, including intentional and negligent acts and omissions, resulted in direct and foreseeable past, present, and future economic damages for which the CSBs seek relief, as alleged herein. The CSBs also seek the means to abate the epidemic created by Defendants' tortious conduct.

262. The CSBs seek economic damages from Defendants as reimbursement for the costs associated with past, present, and future efforts to permanently eliminate the hazards to public health and safety and abate this crisis. Categories of past and continuing sustained damages include but are not limited to: (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering

from opioid disorders or other related addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and (6) lost revenue for writing off uncompensated or undercompensated care related to opioid abuse or likely opioid abuse disorders.

IX. STATUTES OF LIMITATION ARE TOLLED, AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES.

A. Continuing Conduct

263. The CSBs continue to suffer harm from Defendants' unlawful actions.

264. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once, but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The public nuisance remains unabated.

B. Equitable Estoppel

265. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the CSBs and the communities they serve, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Defendants affirmatively assured the public, that they were working to curb the opioid epidemic.

266. As explained above, Defendants misrepresented the effectiveness of their internal protocol and procedures to prevent diversion as well as their compliance with applicable state and federal laws governing the prevention of diversion.

267. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Distributor Defendants, through their trade associations HOMA and NACDS, filed an *amicus* brief in the *Masters Pharmaceuticals* case, which made the following statements:¹³⁵

¹³⁵ Brief for HOMA and NACDS, *supra* note 111, at *3-4, *25.

- a. "HOMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs but undertake such efforts as responsible members of society."
- b. "DEA regulations that have been in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."
- c. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process."
- d. "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."
- e. "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

268. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct complied with those obligations.

269. Distributor Defendants have also concealed and prevented discovery of critical information necessary to uncovering their wrongful conduct, including data from the ARCOS database, that would have confirmed their identities and the extent of their wrongful and illegal activities within the state. Moreover,

Defendants used their superior knowledge and position, as well as their ability to operate in darkness, to conceal material facts and to manipulate state entities, including the State of Georgia so they could continue their conduct unabated.

270. Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions that the studies did not support. Manufacturer Defendants promoted the concept of "pseudoaddiction" to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, and the State of Georgia, the CSBs, and the public were duped by Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs.

271. Defendants intended that their actions and omissions would be relied upon, including by the State and consumers in the state. Due to Defendants' actions and omissions, the State of Georgia and the CSBs and the residents in the

communities they serve did not know, and did not have the means to know, the truth.

272. The State of Georgia, the CSBs, and the residents in the communities they serve reasonably relied on Defendants' affirmative statements regarding compliance with their legal obligations and consent orders.

C. Fraudulent Conduct

273. The CSBs' claims are further subject to equitable tolling, stemming from Defendants' knowing and fraudulent concealment of the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from, among others, State and Federal regulators and the medical community, including the CSBs. Because of Defendants' active concealment of material information, State and Federal regulators and the medical community, including the CSBs, did not know, or could not have known through the exercise of reasonable diligence, of its causes of action.

274. Defendants' fraudulent misrepresentations, suppressions, and concealments of material facts also constitute a fraudulent concealment from the CSBs of the existence of causes of action by which the CSBs could have sought

recovery from Defendants for its injuries suffered because of Defendants' wrongful conduct.

275. As a proximate result of Defendants' fraudulent misrepresentations, suppressions, and concealments, the CSBs have been, and continue to be, injured and have incurred damages as stated herein.

276. As such, to the extent one would even apply, the limitations period has been tolled, and the CSBs have brought this action upon discovering the existence of the facts underlying the causes of action alleged herein, within the limitations period.

277. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the CSBs filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

278. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased because the public nuisance remains unabated.

279. The medical community, consumers, and the CSBs and the communities they serve were duped by Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the state.

280. The CSBs reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

281. The CSBs' claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts and their wrongful acts, and the material information pertinent to their discovery, which Defendants concealed from the CSBs. The CSBs did not know, or could not have known through the exercise of reasonable diligence, of its claims, as a result of Defendants' conduct.

282. As a result of Defendants' misrepresentations and deceptive statements about prescription opioids, the CSBs have suffered significant and ongoing damages in multiple ways, including but not limited to (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering from opioid disorders or other related addiction or disease; (3) costs associated with providing

residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and (6) lost revenue for writing off uncompensated or undercompensated care related to opioid abuse or likely opioid abuse disorders.

CLAIMS FOR RELIEF

Count I

RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS (RICO)
(18 U.S.C. § 1961, et. seq.)

(All Defendants)

283. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

284. The goal of Manufacturer and Distributor Defendants was the same: to create a large and excessive market for opioids, to bolster their revenue, to increase their profits, and to grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. Defendants utilized their superior knowledge and posture to accomplish this goal, taking advantage of limited governmental resources to mislead and manipulate

regulators in furtherance of their illegal scheme. Manufacturer Defendants unlawfully marketed their opioids to overturn years of medical concerns regarding the safety and efficacy of opioids for the treatment of chronic pain. And then all Defendants refused to comply with their obligations (and further concealed this refusal) to prevent the diversion of controlled substances so as to continuously expand the quantity of opioids they could manufacture and distribute. As discussed more fully below, Defendants acted in concert through a pattern of racketeering activity to achieve these unlawful goals.

The Enterprises

285. Defendants engaged in a pattern of racketeering activity through the following relevant enterprises in violation of 18 U.S.C. § 1962(c) and, as explained more fully below, in aid of the "Opioid Enterprise":

286. The definition of the term “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.”¹³⁶ This definition encompasses both legitimate and illegitimate enterprises.

¹³⁶ 18 U.S.C. § 1961(4).

287. Defendants engaged in two relevant illegal enterprises in violation of these statutes: the Opioid Promotion Enterprise and the Opioid Diversion Enterprise.

288. The Opioid Promotion Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Manufacturer Defendants, including their employees and agents; Front Groups, including their employees and agents; and KOL's; as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioid Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. §1961(3) and acted to enable Manufacturing Defendants to fraudulently market opioids as scientifically-proven to be safe and effective. The Opioid Promotion Enterprise functioned as an ongoing organization and continuing unit and was separate and distinct from 1) each of its component entities and 2) from the pattern of racketeering activity carried out by those entities. The Opioid Promotion Enterprise was created and organized to effectuate a pattern of racketeering activity and maintained systematic links through corporate ties, contractual relationships, interrelated financial interests, and continuing coordination of activities for a common purpose: to ensure the prescription of opioids for chronic pain. The Manufacturing Defendants participated in the operation and management of the

opioid marketing fraud enterprise by directing its affairs. Each member of the Opioid Promotion Enterprise shared in the bounty generated by the enterprise by sharing the benefit derived from increased sales of opioids and other revenue generated by the scheme to defraud prescribers and consumers in Plaintiffs' communities.

289. The Opioid Diversion Enterprise is an association-in-fact between Manufacturer Defendants and Distributor Defendants and executed by each of them. In particular, each Defendant was associated with, and conducted or participated in, the affairs of the enterprise, whose purpose was to engage in the unlawful sales of opioids and to deceive the public and regulators into believing that Defendants were faithfully fulfilling their statutory obligations.

290. Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while Plaintiffs suffered injuries caused by the reasonably foreseeable consequences of the opioid epidemic. As explained in detail below, Defendants' misconduct

violated Section 1962(c), and Plaintiffs are entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

291. Members of the Opioid Diversion Enterprise, finding it impossible to legally achieve their ever-increasing sales ambitions, systematically and fraudulently violated their statutory duties to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.¹³⁷ As discussed in detail below, through Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.¹³⁸ In doing so, Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate enormous profits.

292. Alternatively, Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which Defendants conducted their pattern of racketeering activity in Georgia and throughout the United States. Specifically, the Healthcare Distribution Alliance (HDA) is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit

¹³⁷ 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

¹³⁸ 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, the HDA qualifies as an “enterprise” within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

293. On information and belief, Defendants are members, participants, and/or sponsors of the HDA and utilized it to conduct the Opioid Diversion RICO Enterprise and to engage in the pattern of racketeering activity alleged herein.

294. Each Defendant is a legal entity separate and distinct from the HDA, and the HDA serves the interests of distributors and manufacturers beyond Defendants.

295. The HDA exists separately from the Opioid Diversion Enterprise, and each Defendant exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

296. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid Diversion Enterprise) and the legal enterprise (HDA) were each used by Defendants to conduct the RICO Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are pleaded in the alternative and are collectively referred to as the “RICO Enterprise.”

297. Each Defendant qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant.¹³⁴

298. Pursuant to the CSA and the Code of Federal Regulations, Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

299. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

300. At all relevant times, Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription

opioids from which to profit. Defendants conducted their pattern of racketeering activity in Georgia and throughout the United States through this enterprise.

301. At all relevant times, the RICO Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each Defendants; (d) characterized by interpersonal relationships among Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the RICO Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that Defendants would have a larger pool of prescription opioids from which to profit.

302. The RICO Enterprise also engaged in efforts to lobby against the DEA's authority to hold Defendants liable for disregarding their duty to prevent diversion.

303. Members of the Pain Care Forum (PCF) and HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The "Ensuring Patient Access and Effective Drug Enforcement Act" significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. The HDA and other members of the PCF contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. PCF and its members spent significant funds on lobbying efforts while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

304. The RICO Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But Defendants' profits were limited by the production quotas set by the DEA, so Defendants refused to identify, investigate, and/or report suspicious orders of their

prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

305. The RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout Georgia and the corresponding payment and/or receipt of money from the sale of the same.

306. Within the RICO Enterprise, there were interpersonal relationships and common communication by which Defendants shared information on a regular basis.

307. These interpersonal relationships also formed the organization of the RICO Enterprise. The RICO Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

308. Each Defendant had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. Defendants participated in

the operation and management of the RICO Enterprise by directing its affairs, as described herein.

309. While Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

310. Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the PCF and HDA, and through their contractual relationships.

311. The PCF has been described as a coalition of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

312. The Center for Public Integrity and the Associated Press obtained “internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.” Specifically, PCF participants spent over \$740 million lobbying in the nation’s

capital and in all 50 statehouses on an array of issues, including opioid-related measures.

313. Not surprisingly, each of Defendant who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in PCF. In 2012, membership and participating organizations included the HDA (of which all Defendants are members), Endo, Purdue, Allergan, and Teva. Each Manufacturer Defendant worked together through the PCF to advance the interests of the enterprise. But Manufacturer Defendants were not alone. Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.

314. The 2012 PCF Meeting Schedule indicates that meetings were generally held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis. Local members were encouraged to attend the monthly meetings in person, suggesting interpersonal relationships among the members and their representatives.

315. The 2012 PCF Meeting Schedule demonstrates that each Defendant participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug-makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic,

including the concerted lobbying efforts that the PCF undertook on behalf of its members.

316. The HDA also led to the formation of interpersonal relationships and an organization between Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each Distributor and Manufacturer Defendant is a member.

317. The HDA and each Distributor Defendant sought the active membership and participation of Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

318. The HDA touted the benefits of membership to Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”

319. Distributor Defendants and the HDA used membership in that organization as an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

320. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Defendants. The manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.

321. After becoming members, Distributor and Manufacturer Defendants were eligible to participate on councils, committees, task forces and working groups, which promoted the Opioid Diversion Enterprise efforts, including lobbying and even development of chargebacks, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems,

operational integration and the impact of e-commerce.” Participation in this committee includes distributors and manufacturer members.

- c. Health, Beauty and Wellness Committee: “This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain.” Participation in this committee includes distributors and manufacturer members.
- d. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributors and manufacturer members.
- e. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.
- f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.
- g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.
- h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.
- i. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined

through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation includes Distributor and Manufacturer Members.

322. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the RICO Enterprise’s organization.

323. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and Distributor Defendants advertise these conferences to Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.” The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.” HDA conferences and the organization as a whole functioned as significant opportunities for Manufacturer and Distributor Defendants to interact at a high-level of leadership. And it is clear that Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

324. Defendants also maintained their interpersonal relationships by working together and exchanging information with the purpose of driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs. Manufacturer Defendants engaged in an industry-wide practice of paying rebates and chargebacks to Distributor Defendants for sales of prescription opioids.¹³⁹ As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby Manufacturer Defendants paid the Distributor Defendants rebates and/or chargebacks on their prescription opioid sales.¹⁴⁰

325. On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, Distributor Defendants provided Manufacturer Defendants with detailed information regarding

¹³⁹ Lenny Bernstein & Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable*, WASH. POST, (April 2, 2017), <https://www.pharmacist.com/article/governments-struggle-to-hold-opioid-manufacturers-accountable> (last visited Jan. 10, 2020); *see also* Letter from Sen. Claire McCaskill, (July 26, 2017), <https://www.hsgac.senate.gov/imo/media/doc/2017-07-26%20CMC%20requests%20to%20Mallinckrodt,%20Teva,%20Endo,%20and%20Allergan.pdf> (last visited Jan. 10, 2020); <https://www.hsgac.senate.gov/imo/media/doc/2017-07-26%20CMC%20requests%20to%20McKesson,%20Cardinal%20Health,%20and%20AmerisourceBergen.pdf> (last visited Jan. 10, 2020).

¹⁴⁰ *Id.*

their prescription opioid sales, including purchase orders, ship notices, acknowledgements, and invoices.¹⁴¹ The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct Distributor Defendants on how to most effectively sell the prescription opioids.

326. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Manufacturer Defendants likely negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by Defendants as a tool to violate their reporting and anti-diversion duties.

327. Taken together, the interaction and length of the relationships between and among Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage

¹⁴¹ Webinars, Healthcare Distribution Alliance, (webinar held April 27, 2011), <https://www.healthcaredistribution.org/resources/webinar-leveraging-edl> (last visited Jan. 10, 2020).

in the unlawful sale of prescription opioids. The HDA and PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of all Defendants were in communication and cooperation.

328. As stated above, the PCF has been lobbying on behalf of Manufacturer and Distributor Defendants for more than a decade, who, from 2006 to 2016, collectively funneled over \$740 million through the organization into lobbying efforts across the country on various issues including opioid-related measures. Similarly, the HDA has continued its work on behalf of Defendants, without interruption, since at least 2000, if not longer.

329. As described above, Defendants began working together as early as 2006 through the PCF and HDA to promote the common purpose of their enterprise.

330. Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

Defendants' Conduct

331. The members of the Opioid Promotion Enterprise worked together to further the enterprise, by and among the following manner and means:

- a. Jointly planning to deceptively market and manufacture opioids that were purportedly non-addictive, safe and effective for the treatment of chronic, long-term pain;
- b. Concealing the addictive qualities of the opioids from prescribers and the public;
- c. Misleading the public about the addictive quality and safety and efficacy of opioids;
- d. Otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;
- e. Illegally marketing, selling and/or distributing opioids; and
- f. Collecting revenues and profits from the sale of such products for uses for which they are unapproved, unsafe or ineffective.

332. To achieve their common goals, Manufacturing Defendants hid from the general public the full extent of the unsafe and ineffective nature of opioids for chronic pain as described herein, and they actively published misleading information to change the minds of those who already thought opioids to be dangerous. The Manufacturing Defendants suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the addictive, unsafe and often ineffective nature of opioids. They did all of this knowingly and intentionally and accomplished it by working together through relationships formed as part of a common enterprise.

333. During the time period alleged in this Complaint, Defendants exerted control over, conducted, and/or participated in the RICO Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits.

334. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

335. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

336. Defendants paid nearly \$800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the PCF. Defendants were all members of the PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its members, included efforts to pass

legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

337. Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

338. Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids. Defendants lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."

339. Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

340. Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that Manufacturer Defendants knew included sales that were suspicious and involved

the diversion of opioids that had not been properly investigated or reported by Defendants.

341. Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help Defendants identify suspicious orders or customers who were likely to divert prescription opioids. The “know your customer” questionnaires informed Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and these questionnaires put the recipients on notice of suspicious orders.

342. Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of them despite their actual knowledge of drug diversion rings.

343. Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against Distributor Defendants in 178 registrant actions between 2008 and 2012, and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers

include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders—all for failure to report suspicious orders.

344. Defendants' scheme had a decision-making structure that was driven by Manufacturer Defendants and corroborated by Distributor Defendants. Manufacturer Defendants worked together to control the state and federal governments' response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify and report suspicious orders to the DEA.

345. Defendants worked together to control the flow of information and influence state and federal governments and politicians to pass legislation that benefitted Defendants. Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

346. Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, Defendants ensured that the DEA had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. Defendants influenced the DEA production quotas in the following ways:

- a. Distributor Defendants assisted the enterprise and Manufacturer Defendants in their lobbying efforts through the PCF;
- b. Distributor Defendants invited the participation, oversight and control of Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- c. Distributor Defendants provided sales information to Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;
- d. Manufacturer Defendants used a chargeback program to ensure delivery of Distributor Defendants' sales information;
- e. Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing [opioids]."
- f. Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- g. Manufacturer Defendants used Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- h. Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- i. Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of Distributor Defendants by the DEA for failure to report suspicious orders;
- j. Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the

“medical need” for and the net disposal of their drugs did not justify the production quotas set by the DEA; and

- k. The scheme devised and implemented by Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

347. Manufacturer Defendants worked together through Front Groups to intentionally distribute false and misleading information intended to deceive the public about the effects of opioids for the purpose of marketing their dangerous product in service of the Opioid Promotion Enterprise, which in turn served the overall opioid RICO Enterprise by driving up demand for opioids.

Pattern of Racketeering Activity

348. Defendants conducted and participated in the conduct of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. §1961(B), including mail fraud (18 U.S.C. §1341) and wire fraud (18 U.S.C. §1343); and 18 U.S.C. §1961(D) by the felonious manufacture, importation, receiving, concealment, buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

Mail and Wire Fraud

349. Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public, including Plaintiffs, by knowingly conducting or participating in the conduct of the RICO Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

350. Defendants committed, conspired to commit, and aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by Defendants’ regular use of the facilities, services, distribution channels, and employees of the RICO Enterprise. Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

351. Defendants used, directed the use of, and caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

352. In executing the illegal scheme, Defendants devised and knowingly carried out a material scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

353. Defendants' predicate acts of racketeering include, but are not limited to:¹⁴²

- a. Mail Fraud: Defendants violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

¹⁴² 18 U.S.C. §1961(1).

- b. Wire Fraud: Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

354. Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of Defendants' illegal scheme:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and facilitated Defendants' DEA registrations;
- e. Documents and communications that supported and facilitated Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. §827;
- g. Documents and communications related to Defendants' mandatory DEA reports pursuant to 21 U.S.C. §823 and 21 C.F.R. §1301.74;

- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;
- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- l. Payments to Defendants' lobbyists through the PCF;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

355. Manufacturer Defendants' specific acts of mail and wire fraud in furtherance of the Opioid Promotion Enterprise include but are not limited to,

- a. The Federation of State Medical Boards (FSMB)'s publication of opioid prescribing guidelines entitled "Responsible Opioid Prescribing," by Fishman;
- b. The FSMB's publication of "Revised and Expanded 2nd Edition [of] Responsible Opioid Prescribing[:] A Guide for Michigan Clinicians";
- c. The APF's publication of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families";
- d. The AAPM's "consensus statement" and educational programs featuring Fine;
- e. False or misleading communications to the public and to regulators;

- f. Sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;
- g. Documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- h. Documents to process and receive payment for opioids, including invoices and receipts;
- i. Payments to the foundations and physicians that deceptively marketed the Manufacturing Defendants' opioids;
- j. Deposits of proceeds; and
- k. Other documents and things, including electronic communications.

356. On information and belief, Defendants, for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

357. Manufacturer Defendants also used the Internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. Specifically, the Manufacturer Defendants made misrepresentations about opioids on their websites, YouTube and through online ads, all of which were intended to

mislead prescribers and the public about the safety, efficacy and non-addictiveness of opioids.

358. Manufacturer Defendants also communicated by U.S. Mail, by interstate facsimile and by interstate electronic mail with various other affiliates, regional offices, divisions, distributors and other third party entities in furtherance of the scheme. The mail and wire transmissions described herein were made in furtherance of the Manufacturer Defendants' scheme and common course of conduct to deceive prescribers and consumers and lure consumers into purchasing opioids, which Manufacturer Defendants knew or recklessly disregarded as being unsafe and ineffective for chronic long-term pain and addictive. The Manufacturer Defendants utilized mail and wire transmissions to create an extensive campaign that advertised the exact opposite message: that opioids were safe and effective and rarely if ever addictive.

359. Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

360. At the same time, Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

361. Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

362. Defendants communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

363. Several Defendants also entered into various Corporate Integrity Agreements with various entities, including the Office of Inspector General and the United States Department of Health and Human Services, that required the Defendants to annually certify in writing that they had implemented effective compliance programs and were otherwise in compliance with laws and regulations regarding, among other things, the manufacture and distribution of opioids. Defendants submitted through the mail and wires certifications that were false and misleading, in furtherance of the Opioid Diversion RICO Enterprise's operation

and goals, including false and misleading certifications required annually under the following:

- a. Section V of the Deferred Prosecution Agreement entered in *United States of America v. Endo Pharm., Inc.*, No. 1:14-CR-00066-MAD, ECF No. 2 (N.D.N.Y. Feb. 21, 2014);
- b. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Endo Pharmaceuticals, Inc. (fully executed on Feb. 21, 2014); and
- c. Section III of the Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Purdue Pharma, L.P. (fully executed on May 8, 2007).

364. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

365. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities and other criminal activity have been deliberately hidden and cannot be alleged without access to Defendants' books and records. But

Plaintiffs have described the types of, and in some instances, occasions on which numerous predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the items and documents described in the preceding paragraphs.

366. Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. §1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and/or minimize the losses for Defendants.

367. Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343 offenses.

Criminal Activity in Relation to Entities and Scheme

368. Defendants hid from the general public, and suppressed and ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that Defendants were filling on a daily basis—

leading to the diversion of tens of millions of doses of prescriptions opioids into the illicit market.

369. Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

370. Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

371. The predicate acts all had the purpose of generating significant revenue and profits for Defendants while Plaintiffs are left with substantial injuries to their interests through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by Defendants through their participation in the RICO Enterprise and in furtherance of its fraudulent scheme.

372. The pattern of racketeering activity and the RICO Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the RICO Enterprise.

373. The pattern of racketeering activity is continuing as of the date of this Complaint and will continue into the future unless enjoined by this Court.

374. Defendants conducted and participated in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

375. Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony.¹⁴³

¹⁴³ 21 U.S.C. § 483(d)(1).

Defendants' Knowledge

376. Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and omitted material information from reports, records, and other documents required to be filed with the DEA, including Manufacturer Defendants' applications for production quotas. Specifically, Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

377. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form 8K with the SEC announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.

378. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the *Los Angeles Times* reported that Purdue was aware of a pill mill operating out of Los

Angeles yet failed to alert the DEA. The *LA Times* uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking “Shouldn’t the DEA be contacted about this?” and adding that she felt “very certain this is an organized drug ring.” Despite knowledge of the staggering number of pills being issued in Los Angeles, and internal discussion of the problem, “Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals.”

379. Mallinckrodt also was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012. After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt’s response was that everyone knew what was going on in Florida, but they had no duty to report it.

380. These examples reflect the Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. §1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants. For example:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone;

- f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia, Valencia, California and Denver, Colorado;
- h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

381. These actions against them confirm that Distributor Defendants knew they had a duty to maintain effective controls against diversion, design and operate

a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate that Manufacturer Defendants were aware of the enforcement against their distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

Defendants' RICO Liability

382. The pattern of racketeering activity is continuing as of the date of this Complaint and will likely continue into the future unless enjoined by this Court.

383. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

384. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on Georgia or Plaintiffs. Defendants were aware that Plaintiffs rely on Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

385. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

386. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiffs by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

387. Defendants are liable to Plaintiffs under RICO.

RICO Damages

388. Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' injuries because Plaintiffs paid for costs associated with the opioid epidemic. These harms are on-going.

389. Plaintiffs' injuries, were, and are being, proximately caused by Defendants' racketeering activities. But for Defendants' conduct, Plaintiffs would not have paid the exorbitant costs and expenditures required as a result of the epidemic, including but not limited to (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering from opioid disorders or other related

addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and (6) lost revenue for writing off uncompensated care related to opioid abuse or likely opioid abuse disorders.

390. Plaintiffs have injuries that were directly caused by Defendants' racketeering activities.

391. Plaintiff seeks all legal and equitable relief as allowed by law, including but not limited to, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre and post-judgment interest.

COUNT II

RICO CONSPIRACY **(18 U.S.C. § 1962(d))**

(Against All Defendants)

392. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

393. At all relevant times, Defendants were associated with the RICO Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity. Under Section 1962(d) it is unlawful for “any person to conspire to violate” Section 1962(c), among other provisions.¹⁴⁴

394. Defendants conspired to violate Section 1962(c), as alleged more fully in Count I, by conducting the affairs of the RICO Enterprise through a pattern of racketeering activity, as incorporated by reference herein.

COUNT III

GEORGIA DRUG DEALER LIABILITY ACT (O.C.G.A. § 51-1-46, et. seq)

(Against All Defendants)

395. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

396. Georgia’s Drug Dealer Liability Act (DDLA),¹⁴⁵ provides a civil remedy against participants in “illegal marketing” of controlled substances for “damages to persons in a community as a result of illegal drug use.”¹⁴⁶

¹⁴⁴ 18 U.S.C. § 1962(d).

¹⁴⁵ O.C.G.A. §51-1-46, et seq.

397. The DDLA defines “participat[ion] in illegal marketing” as “[m]anufacturing, distributing, or delivering or attempting or conspiring to manufacture, distribute, or deliver, a controlled substance” in violation of federal or state law.

398. A controlled substance within the meaning of the DDLA is defined as a substance referenced under O.C.G.A. § 16-13-26(4), which, in turn, is defined as “a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of 21 C.F.R. Part 1308.”¹⁴⁷

399. Defendants distributed prescription opioids which are included within this list and are therefore controlled substances, including but not limited to, hydrocodone, oxycodone, oxymorphone, Roxicodone, OxyContin, Opana, and Lortab.

400. Defendants did so in violation of state and federal laws such as those which require registered distributors of controlled substances to report suspicious orders.

401. Among the persons to whom the DDLA provides a remedy is “a medical facility, insurer, governmental entity or other legal entity that financially

¹⁴⁶ O.C.G.A. § 51-1-46(d).

¹⁴⁷ O.C.G.A. § 51-1-46(c)(1).

supports a drug treatment or other assistance program for, or that otherwise expends money or provides unreimbursed service on behalf of, the individual abuser.”¹⁴⁸

402. The CSBs pay for drug treatments as contemplated by the DDLA and have expended significant sums of money as a result of the illegal distribution of opioids in Georgia.

403. One of the intents of the DDLA, among others, is “to shift, to the extent possible, the cost of the damage caused by the existence of the illegal drug market in a community to those who illegally profit from that market.”¹⁴⁹

404. The CSBs may bring an action and recover damages under the DDLA on behalf of a person injured by an individual drug abuser for injury resulting from an individual’s use of an illegal drug” from “a person who participated in illegal marketing of the controlled substance.”¹⁵⁰

405. The definition of a person injured by an individual drug abuser includes “a medical facility, insurer, governmental entity, or other legal entity that financially supports a drug treatment or other assistance program for, or that

¹⁴⁸ O.C.G.A. § 51-1-46(d)(2)(D).

¹⁴⁹ O.C.G.A. § 51-1-46.

¹⁵⁰ O.C.G.A. § 51-1-46(d)(1).

otherwise expends money or provides unreimbursed service on behalf of, the individual drug abuser.”¹⁵¹

406. An “individual drug abuser” is one who uses a controlled substance that is not obtained directly from or pursuant to a valid prescription or order of a practitioner who is acting in the course of the practitioner's professional practice or which use is not otherwise authorized by state law.¹⁵²

407. Upon information and belief, individuals acquired and used hydrocodone, oxycodone, oxymorphone, Roxicodone, OxyContin, and/or Opana in the communities the CSBs serve without a valid prescription and/or in a manner not authorized by state law.

408. Those who did so are “individual drug user[s]” under the DDLA.¹⁵³

409. The DDLA also imposes market liability on those who participate in the unlawful distribution of drugs in the area where illegal drugs cause damages.¹⁵⁴

410. Market share liability obtains if “(A) [t]he defendant was participating in the illegal marketing of the market area controlled substance at the time the individual abuser obtained or used that market area controlled substance; and (B)

¹⁵¹ O.C.G.A. § 51-1-46(d)(2)(D).

¹⁵² O.C.G.A. § 51-1-46(c)(2).

¹⁵³ O.C.G.A. § 51-1-46(c)(2).

¹⁵⁴ O.C.G.A. § 51-1-46(e).

[t]he individual abuser obtained or used the market area controlled substance, or caused the injury, within the defendant's market area.”¹⁵⁵

411. Defendants knowingly participated in the manufacture and/or distribution of prescription opioids that reached the communities and counties the CSBs serve during all times relevant to this complaint. For purposes of the DDLA, Defendants’ “market area for the controlled substance” is the entire state of Georgia, because Defendants participated in the illegal drug market by distributing 650 grams or more of a “specified controlled substance.”¹⁵⁶

412. As noted by the Georgia Attorney General’s Office, the Georgia market for opioid pills prescribed between June 2016 and May 2017 reached 541 individual doses, or 54 per Georgia Resident. Given that a single oxycodone tablet, on information and belief, weighs approximately 135 mg and contains at least 10 mg of opioid, there can be no question that each Manufacturer Defendant far exceeded the 650 grams level.

413. Manufacturer Defendants knowingly failed to implement effective controls and procedures in their supply chains to guard against theft, diversion, and abuse of prescription opioids, and failed to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

¹⁵⁵ O.C.G.A. § 51-1-46(e).

¹⁵⁶ O.C.G.A. §§ 51-1-46(c)(1)(6) & (e)(1)(D).

414. As a result, Manufacturer Defendants knowingly disseminated massive quantities of prescription opioids for distribution to Gwinnett County, including “pill mills,” and other drug dealers.

415. Defendants also knowingly enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including “pill mills” as well as and other drug dealers, knowing that such opioids would be illegally trafficked and abused.

416. The diversion of prescription opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health and financial resources of the CSBs.

417. Having knowingly participated in the illegal distribution of hydrocodone, oxycodone, oxymorphone, OxyContin, Roxicodone, and/or Opana, the drugs purchased or obtained by residents of Georgia in the “market area of controlled substance,” Defendants are liable to Plaintiffs under the DDLA for damages caused by opioids in Georgia including those that were acquired from distribution channels in which Defendants were only market participants.

COUNT IV**PUBLIC NUISANCE****(Against All Defendants)**

418. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

419. A nuisance is "anything that causes hurt, inconvenience, or damage to another and the fact that the act done may otherwise be lawful shall not keep it from being a nuisance."¹⁵⁷

420. Under Georgia law, a "public nuisance" is defined as one "which damages all persons who come within the sphere of its operation, though it may vary in its effects on individuals."¹⁵⁸

421. "Significant interference with 'the public health, the public safety, the public peace, the public comfort or the public convenience' may support a finding of public nuisance."¹⁵⁹ For example, the illegal dealing of drugs constitutes ample evidence of a public nuisance.¹⁶⁰

422. The public nuisance caused by Defendants includes the over-saturation, unlawful availability, and abuse of opioids in the state for non-medical

¹⁵⁷ O.C.G.A. § 41-1-1.

¹⁵⁸ O.C.G.A. § 41-1-2.

¹⁵⁹ *City of College Park v. 2600 Camp Creek, LLC*, 293 Ga. App. 207, 208 (2008).

¹⁶⁰ *Moreland v. Cheney*, 267 Ga. 469 (1997).

purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use. Manufacturer Defendants deceptively marketed their opioids to change the prescribing habits of doctors and increase their use for non-cancer chronic pain. Distributor Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including so-called “pill mills” and other dealers.

423. Defendants knew or should have known that their promotion of opioid use and failure to prevent the diversion of opioids for illicit use would create a public nuisance. As a Schedule II controlled substance, prescription opioids are as addictive and dangerous as heroin and, not surprisingly, addiction to prescription opioids has caused an increase in the prevalence of heroin within Georgia.

424. Defendants' actions were a substantial factor in opioids becoming widely available and widely used. Without Defendants' actions, opioid use would not have become so pervasive and widespread and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

425. The public nuisance created by Defendants has caused, and continues to cause, significant harm to, and the expenditure of taxpayer dollars by the CSBs, including, but not limited to:

- a. The staggering rate of opioid use among adults in Georgia has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths.
- b. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for illicit use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created a new secondary market for opioids - providing both the supply of narcotics to sell and the demand of addicts to buy them.
- c. The diversion of opioids into the secondary, illicit market and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, and financial resources of the CSBs.
- d. Adults and children in Georgia who have never taken opioids have also suffered the costs of Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids. All of these problems harm the CSBs by diminishing its revenues and forcing it to make increased expenditures on treating opioid abuse related services.
- e. The addictive nature of prescription opioids has also spawned a new crisis of heroin and fentanyl abuse and death. Use and overdoses from use of heroin and heroin contaminated with fentanyl have skyrocketed as users have switched from prescription opioids to illegal opioids.

426. The CSBs and the patients they serve have a right to be free from conduct that endangers their health and safety. Yet, Defendants have engaged in conduct which endangers or injures the health and safety of the CSBs and their

patients by their production, promotion, marketing of opioids for use by patients of the CSBs and their failure to monitor, report, and prevent such abuses.

427. The CSBs' resources are being overwhelmed in efforts to address the opioid epidemic.

428. Each Defendant has created or assisted in the creation of a condition that is injurious to the health and safety of the CSBs and their patients, and interferes with the comfortable enjoyment of life and property of entire communities and/or neighborhoods.

429. Defendants' conduct has caused deaths, serious injuries, and a severe disruption of the public peace, order, and safety, fueling the homeless and heroin crises facing the CSBs. Defendants' conduct is ongoing and continues to produce permanent and long-lasting damage.

430. The health and safety of the patients of the CSBs, including those who use, have used, or will use opioids, as well as those affected by the users of opioids, are matters of substantial public interest and of legitimate concern to the CSBs' patients.

431. Defendants' conduct has impacted and continues to impact a substantial number of people within the CSBs' communities and is likely to continue causing significant harm.

432. But for Defendants' actions, opioid use and ultimately its misuse and abuse are widespread, and the massive epidemic of opioid abuse that currently exists could have been avoided.

433. At all relevant times, Defendants possessed the right, ability, knowledge, opportunity, and position to control the nuisance-causing outflow of prescription opioids to pharmacy locations and other points of sale in Georgia. Defendants had the power to shut off the supply of illicit opioids into the state, or to control their flow so that widespread diversion did not occur. Defendants could have stopped providing false information to the market about the dangers of opioids and the highly addictive nature of their opioid products. Had Defendants adhered to their duties, as discussed in detail in this Complaint, there would be no opioid crisis.

434. The opioid crisis created by the Defendants is not a single accident/event or one-off emergency situation necessitating the normal provision of police, fire, and emergency services. Rather, it is a public harm of substantial magnitude that was caused by the Defendants' intentional, repetitive, and persistent course of deceptive conduct.

435. Defendants' intentional misconduct alleged in this case does not concern a discrete event or discrete emergency, and is not part of the normal and

expected costs of a local government's existence. The CSBs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

436. The Defendants designed and implemented materially deceptive marketing campaigns to mislead the public and prescribers about the risks and benefits of prescription opioids

437. The CSBs have incurred expenditures over and above their ordinary services and their effort to combat this unique crisis will continue for years to come.

438. Further, Defendants' conduct has not only impacted the CSBs' delivery of services supported by public funding, but also services supported by cash-paying patients or patients with private insurance.

439. The CSBs have suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than Georgia citizens at large. These are harms that can only be suffered by the CSBs.

440. The CSBs are asserting their own rights and interests and their claims are not based upon or derivative of the rights of others.

441. As detailed herein, the Defendants' conduct has interfered, and continues to interfere with rights common to the general public and has caused the

CSBs to sustain damages special and particular of a kind not sustained by the general public, including, but not limited to increased behavioral and other healthcare expenditures, increased substance abuse treatment expenditures, increased medical care services, lost economic opportunity, including but not limited to costs related to the provision of uncompensated or undercompensated care for patients with opioid abuse disorder.

442. As a direct and proximate result of the public nuisance, the CSBs have sustained harm by spending a substantial amount of money trying to respond, assess, and solve the societal harms caused by Defendants' nuisance-causing activity, including, but not limited to: (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering from opioid disorders or other related addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and (6) lost revenue for writing off

uncompensated or undercompensated care related to opioid abuse or likely opioid abuse disorders.

443. For all of these reasons, this public nuisance is extraordinary in its scope and severity. It is an unprecedented epidemic unseen in Georgia's history. This nuisance is man-made, and a consequence of Defendants' premeditated plan to profit by targeting multiple victims over a prolonged period of time using misconduct, corruption and deceit.

444. The nuisance created by Defendants' conduct is abatable.

445. Defendants should be required to pay the expenses the CSBs have incurred or will incur in the future to respond to this corporate-made crisis and further to fully abate the nuisance.

COUNT V

NEGLIGENCE

(All Defendants)

446. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

447. The elements of negligence under Georgia law are that a defendant has "a legal duty; breached that duty; a causal connection exists between the

defendant's conduct and the plaintiffs injury; and the plaintiff suffered damages."¹⁶¹

448. Each Defendant owed a duty of care to CSBs, their patients, and their communities to exercise reasonable care in the manufacturing, marketing, and distribution of highly dangerous opioid drugs in Georgia.

449. In violation of this duty, Defendants have failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids in the counties the CSBs serve by misrepresenting the risks and benefits associated with opioids.

450. The injuries and harms to the CSBs and their patients were foreseeable, and in fact were foreseen by each Defendant.

451. Defendants breached this duty by failing to take any action to prevent or reduce the improper and unlawful manufacture, marketing as well as distribution of the opioid drugs.

452. Reasonably prudent wholesale drug manufactures, marketers, and distributors would have anticipated the scourge of opioid addiction that would wreak havoc on communities, including the CBS in the counties they serve, when weighed against Defendants' conduct. Defendants were repeatedly warned by law enforcement. The escalating amounts of addictive drugs flowing through

¹⁶¹ *Seymour Elec. and Air Conditioning Service, Inc. v. Statom*, 309 Ga. App. 677 (2011).

Defendants' businesses and the sheer volume of these prescription opioids further alerted Defendants that addiction was fueling the increased consumption and that legitimate medical purposes were not being served.

453. Defendants knew or should have known that opioids were unreasonably dangerous and were likely to cause addiction.

454. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct. Defendants were negligent in failing to disclose suspicious orders for opioids to the State pursuant to the requirements of Georgia law and the federal Controlled Substances Act.

455. Defendants' acts and omissions combined and concurred to impose an unreasonable risk of harm to others and combined and concurred with the negligent and/or criminal acts of third parties to impose an unreasonable risk of harm to others.

456. Defendants are in a class of a limited number of parties that can legally manufacture and distribute opioids which places them in a position of great trust by the State.

457. The trust placed in Defendants by the State through the license to manufacture and distribute opioids in Georgia creates a duty on behalf of Defendants to prevent diversion of the medications they supply.

458. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their businesses.

459. Defendants are in exclusive control of the management of the opioids they manufacture, market, and distribute in Georgia.

460. The CSBs are without fault and the injuries to the CSBs and the residents they serve would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the manufacture and distribution of opioids.

461. Defendants' conduct described above created and was the primary cause of the conditions described above - Georgia's opioid crisis, and directly caused Plaintiffs' damages. The cause and conditions giving rise to Plaintiffs' damages resides with Defendants and not prescribing physicians, criminals, or other third parties.

462. Additionally, given the conduct of Defendants and conditions arising therefrom, as described above, the actions of prescribing physicians, criminals, and

other third parties related to excessive opioid use in Georgia was foreseeable, as was the consequence thereof, including excessive prescriptions and criminal drug activity.

463. The CSBs have incurred expenditures over and above their ordinary services and their effort to combat this unique crisis will continue for years to come.

464. Further, Defendants' conduct has not only impacted the CSBs' delivery of services supported by public funding, but also services supported by cash-paying patients or patients with private insurance. The CSBs have suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than Georgia citizens at large. These are harms that can only be suffered by the CSBs.

465. The CSBs are asserting their own rights and interests and their claims are not based upon or derivative of the rights of others.

466. As detailed herein, the Defendants' conduct has interfered, and continues to interfere with rights common to the general public and has caused the CSBs to sustain damages special and particular of a kind not sustained by the general public, including, but not limited to increased behavioral and other healthcare expenditures, increased substance abuse treatment expenditures,

increased medical care services, and lost economic opportunity, including but not limited to costs related to the provision of uncompensated or undercompensated care for patients with opioid abuse disorder.

467. As a direct and proximate cause of Defendants' negligence, the CSBs have suffered and will continue to suffer harm, and are entitled to damages in an amount determined at trial.

468. Specifically, the CSBs seek economic damages from Defendants as reimbursement for the costs associated with past, present, and future efforts to permanently eliminate the hazards to public health and safety and abate this crisis. Categories of past and continuing sustained damages include but are not limited to: (1) costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering from opioid disorders or other related addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and

(6) lost revenue for writing off uncompensated or undercompensated care related to opioid abuse or likely opioid abuse disorders.

COUNT VI

UNJUST ENRICHMENT

(All Defendants)

469. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

470. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the opioid epidemic.

471. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

472. For years, the CSBs conferred a benefit on Defendants by attempting to address all aspects of the opioid epidemic, including, but not limited to: supplying medical care and treatment to opioid users; education, counseling, rehabilitation, and therapy services to opioid users; abatement of nuisances; and other efforts and remedial measures designed to address and curb the increasing epidemic.

473. The CSBs have conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper marketing, promotion and distribution practices. Moreover, the CSBs have incurred expenditures for treatments and services over and above the CSB's ordinary services.

474. Defendants directly profited from the CSBs' remedial expenditures. Without such expenditures, there would not have been a profitable market for these dangerous and addictive drugs. These expenditures have helped to sustain Defendants' businesses.

475. The opioid crisis created by the Defendants is not a single accident/event or one-off emergency situation necessitating the normal provision of police, fire, and emergency services. Rather, it is a public harm of substantial magnitude that was caused by the Defendants' intentional, repetitive, and persistent course of deceptive conduct.

476. Defendants' intentional misconduct alleged in this case does not concern a discrete event or discrete emergency, and is not part of the normal and expected costs of a local government's existence. The CSBs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

477. The Defendants designed and implemented materially deceptive marketing campaigns to mislead the public and prescribers about the risks and benefits of prescription opioids

478. The CSBs have incurred expenditures over and above their ordinary services and their effort to combat this unique crisis will continue for years to come.

479. The CSBs have suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than Georgia citizens at large. These are harms that can only be suffered by the CSBs.

480. The CSBs are asserting their own rights and interests and their claims are not based upon or derivative of the rights of others.

481. As detailed herein, the Defendants' conduct has interfered, and continues to interfere with rights common to the general public and has caused the CSBs to sustain damages special and particular of a kind not sustained by the general public, including, but not limited to increased behavioral and other healthcare expenditures, increased substance abuse treatment expenditures, increased medical care services, and lost economic opportunity, including but not limited to costs related to the provision of uncompensated or undercompensated care for patients with opioid abuse disorder.

482. Defendants were, and are, aware of these obvious benefits, and their retention of these benefits is unjust. The misconduct alleged in this Complaint is ongoing and persistent.

483. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment that they would not otherwise have obtained. This enrichment was without justification.

484. Defendants have unjustly retained benefits to the detriment of the CSBs, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

485. Defendants, through the wrongful conduct described above, have been unjustly enriched at the expense of the CSBs.

486. In equity and good conscience, it would be unjust and inequitable to permit Defendants to enrich themselves at the expense of the CSBs.

487. The CSBs seek an order compelling Defendants to disgorge all unjust enrichment to the CSBs and awarding such other, further, and different relief as this Honorable Court may deem just.

COUNT VII**CIVIL CONSPIRACY****(All Defendants)**

488. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

489. Defendants engaged in (1) a common design between two or more persons, (2) to accomplish by concerted action an unlawful purpose, or a lawful purpose by unlawful means, (3) an overt act in furtherance of the conspiracy, and (4) resulting in injury to the CSBs.

490. Defendants engaged in one or more unlawful tortious activities to further the conspiracy. The objects of the conspiracy were racketeering, nuisance, negligence, fraud, misrepresentation and other unlawful tortious conduct as described above in this Complaint. Defendants knew that these objects were unlawful and would be accomplished by unlawful means such as fraud, misrepresentations, and omissions.

491. Defendants had a meeting of the minds on the object of or course of action for this conspiracy. Defendants knew and agreed upon the unlawful object of or course of action for this conspiracy. Defendants also knew that their wrongful

actions would inflict injury upon the targets of the conspiracy, including the CSBs and the communities they serve.

492. As described above, Defendants committed multiple unlawful and overt acts to further the object of or course of action for this conspiracy as described above.

493. These unlawful acts proximately caused the damages suffered by the CSBs. Accordingly, the CSBs are entitled to recover their actual damages.

494. Defendants conspired to create a public nuisance and to commit tortious conduct and are therefore liable for the damages flowing from the conspiracy.

COUNT VIII

FALSE ADVERTISING **(O.C.G.A. § 10-1-420, et seq.)**

(All Defendants)

495. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

496. Defendants, in marketing opioids, made numerous false statements about the nature of these drugs, including:

- a. that they are safe;
- b. that they are appropriate for the treatment of chronic, non-cancer pain;

- c. that they can improve bodily and mental function long-term or otherwise improve quality of life;
- d. that they are safe and effective for continued, long-term use;
- e. that they are not addictive;
- f. that pseudoaddiction is a legitimate medical concept;
- g. that patients who seem addicted are merely "pseudoaddicted," and should be treated with more opioids;
- h. that opioid addiction is the product of problem patients and doctors, not inherently of opioids; and
- i. that opioid abuse and addiction manifest themselves through snorting and injecting the drugs, and not oral or topical administration.

497. These false statements were made in order to induce residents of Georgia to purchase Defendants' opioids, and in turn, caused CSBs to expend extraordinary resources and funds to treat such residents.

498. These false statements were disseminated in public in the state through marketing brochures, websites, publications, advertising in periodicals, educational materials, speeches sponsored by Defendants, misleading scientific studies, statements to medical professionals, and endorsement of statements by others.

499. Defendants knew or should have known these statements were false.

COUNT IX**NEGLIGENCE PER SE****(All Defendants)**

500. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

501. Georgia law provides that "[w]hen the law requires a person to perform an act for the benefit of another or to refrain from doing an act which may injure another, although no cause of action is given in express terms, the injured party may recover for the breach of such legal duty if he suffers damage thereby."¹⁶²

502. Defendants were under an obligation to implement a system to monitor, identify, investigate, and halt suspicious orders and to stop and report confirmed suspicious orders. Furthermore, Georgia law incorporates federal requirements set out under the Controlled Substances Act and related controlled substance laws and regulations.

503. Each Defendant has an affirmative duty under Georgia and federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that distributors of Schedule II

¹⁶² O.C.G.A. § 51-1-6.

drugs, including opioids, maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."¹⁶³ Those requirements are adopted and incorporated into Georgia law, as set out above.

504. Defendants failed to implement an effective system for accomplishing this duty and continued to ship suspicious orders to pharmacies and other dispensers in Georgia, and they did not report such sales to the proper legal authorities of the State of Georgia.

505. As a result, opioid drugs have been diverted, illicitly used, and abused, resulting in thousands of overdoses, hospitalizations, and deaths.

506. That diversion proximately caused the opioid crisis which is the source of the injuries here complained of. Thousands of Georgia residents are now struggling with addiction. Criminal enterprises are increasing the supply of heroin and fentanyl to exploit the market for opioid addiction.

507. The purpose of the disclosure requirement for suspicious orders of opioids is to alert governing agencies and officials of the potential for abuse and harm resulting from large quantities of opioids within a community.

¹⁶³ 21 U.S.C. § 823(b)(1); 21 CFR 1301.74; . O.C.G.A. § 26-4-115.

508. The CSBs fall within the class of persons that O.C.G.A. § 26-4-115 and the Controlled Substances Act were intended to protect.

509. The expenses incurred by the CSBs in combating the opioid epidemic is the harm that the reporting requirements of O.C.G.A. § 26-4-115 and 21 U.S.C. § 823(b) were intended to prevent or mitigate.

510. The Defendants' illegal activity caused damages to the CSBs including but not limited to costs for providing medical care and detoxification services to patients suffering from opioid disorders or other related addiction or disease; (2) costs for providing treatment, counseling, and rehabilitation services to patients suffering from opioid disorders or other related addiction or disease; (3) costs associated with providing residential housing, vocational training, transportation and ongoing support services to patients suffering from opioid disorders or other related addiction or disease; (4) costs associated with providing care and counseling for children whose parents suffer from opioid related disabilities or incapacitation; (5) costs for treating pregnant or parenting women with opioid abuse disorders; and (6) lost revenue for writing off uncompensated or undercompensated care related to opioid abuse or likely opioid abuse disorders.

511. Defendants are liable for the costs of all of the CSBs' damages including those just listed, other past damages already incurred as a result of

Defendants' actions, and all future damages that will likely occur as a result of those actions.

512. The CSBs seek to recover the cost of all such damages resulting from Defendants' negligence per se.

513. The CSBs seek all legal and equitable relief as allowed by law.

COUNT X

BREACH OF STATUTORY DUTY
(O.C.G.A. § 51-1-6)

(All Defendants)

514. Plaintiffs reincorporate by reference and reallege the factual allegations stated in paragraphs 1-287 as if fully set forth herein.

515. Each Defendant had a duty under federal and state law to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids.¹⁶⁴

516. The purpose of the disclosure requirement for suspicious orders of opioids is to alert governing agencies and officials of the potential for abuse and harm resulting from large quantities of opioids within a community, so drug diversion does not occur.

¹⁶⁴ O.C.G.A. § 26-4-115.

517. These laws are intended to protect the health, safety, and welfare of individuals and communities, such as the CSBs from the deleterious effects of dangerous drugs by prevention their diversion.¹⁶⁵ Thus, they were enacted for the CSBs' benefit.

518. As explained in the facts section of this Complaint, Defendants' failure to monitor and report suspicious orders of opioids and shipment of suspicious orders resulted in injury to the CSBs and the communities they serve.

519. In violation of these laws, Defendants intentionally distributed and/or sold dangerous controlled substances without performing these required duties.

520. Defendants' violations of these laws breached a legal duty to Plaintiff created by the laws.

521. This breach resulted in the type of harm the laws seek to prevent, namely the diversion, illegal sale, and illegal use of dangerous drugs, which caused injury to the CSBs and the communities they serve.

522. Under O.C.G.A. § 51–1–6, Plaintiff is entitled to recover damages for caused by Defendants' breach of their legal duty to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids.

¹⁶⁵ 21 U.S.C.A. § 801; O.C.G.A. § 26-4-2.

523. The expenses incurred by the CSBs in combating the opioid epidemic is the harm that the reporting requirements of O.C.G.A. § 26-4-115 were intended to prevent or mitigate.

524. The CSBs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' tortious activity.

525. The CSBs seek all legal and equitable relief as allowed by law.

PUNITIVE DAMAGES

526. Plaintiffs re-incorporate by reference and re-allege the factual allegations stated in paragraphs 1-287 as though fully set forth herein.

527. The facts set forth above regarding Defendants' conduct, including but not limited to Defendants' fraudulent and intentionally deceptive acts, demonstrate that the Defendants' actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences.

528. Defendants' actions had a great probability of causing substantial harm.

529. When such harm materialized, Defendants acted with a prolonged indifference to the dire consequences of their wrongful conduct.

530. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels.

531. Because of the severe level of danger posed by, and indeed visited upon the CSBs the communities they serve, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes.

532. Defendants not only failed to live up this duty, but actively sought to undermine it in order to increase the volume of drugs they could sell.

533. Defendants chose profit over the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrent.

534. In light of Defendants' wrongful conduct, an award of punitive damages is necessary to deter future operations that harm the public.

535. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that gives rise to the presumption of a conscious indifference to consequences.

PRAYER FOR RELIEF

WHEREFORE, the CSBs pray for an Order that this Honorable Court:

- A. Enter judgment against Defendants jointly and severally and in favor of the CSBs;
- B. Award nominal, economic and/or consequential damages in an amount sufficient to fairly and completely compensate the CSBs for all compensable damages;
- C. Award actual and treble damages based on the amount of the CSBs' losses resulting from Defendants' violations of the Racketeer Influenced and Corrupt Organization ("RICO");
- D. Award pre-judgment and post-judgment interest as provided by law, and award such interest at the highest legal rate;
- E. Enter an Order requiring Defendants to fund an "abatement fund" for the purpose of abating the opioid nuisances, and further order Defendants to pay damages sufficient to fund an abatement plan;
- F. Award the CSBs the costs of suit, including reasonable attorneys' fees as provided by law;

- G. Require Defendants to disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and provide restitution to the CSBs; and
- H. Award such further and additional relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

The CSBs demand, and are entitled to, a trial by jury on all issues so triable.

Respectfully submitted, this 20th day of August, 2020.

/s/ Charles W. Byrd

Charles W. Byrd

Georgia Bar No. 100850

Jay F. Hirsch

Georgia Bar No. 357185

Michael J. Moore

Georgia Bar No. 520109

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Counsel for Plaintiff CSBs

EXHIBIT 4



IN THE DISTRICT COURT OF CANADIAN COUNTY
STATE OF OKLAHOMA

CITY OF EL RENO,

Plaintiff,

v.

Case No. *CJ 2020 382*

- (1) CEPHALON, INC.,
- (2) TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
- (3) TEVA PHARMACEUTICALS USA, INC.,
- (4) JANSSEN PHARMACEUTICALS, INC.,
- (5) JOHNSON & JOHNSON,
- (6) ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.,
- (7) JANSSEN PHARMACEUTICA, INC.,
- (8) ENDO HEALTH SOLUTIONS INC.,
- (9) ENDO PHARMACEUTICALS INC.,
- (10) PAR PHARMACEUTICAL, INC.
- (11) ALLERGAN PLC,
- (12) ACTAVIS PLC,
- (13) WATSON PHARMACEUTICALS, INC.,
- (14) WATSON LABORATORIES, INC.,
- (15) ACTAVIS PHARMA, INC.,
- (16) WATSON PHARMA, INC.,
- (17) ACTAVIS LLC,
- (18) MALLINCKRODT PLC,
- (19) MALLINCKRODT LLC,
- (20) SPECGX LLC,
- (21) MYLAN PHARMACEUTICALS INC.,
- (22) WEST-WARD PHARMACEUTICALS CORP. d/b/a HIKMA,
- (23) HIKMA PHARMACEUTICALS PLC,
- (24) INDIVIOR INC.,
- (25) INDIVIOR PLC,
- (26) SANDOZ INC.,
- (27) MCKESSON CORP.,
- (28) CARDINAL HEALTH, INC.,
- (29) AMERISOURCEBERGEN DRUG CORPORATION,
- (30) MORRIS & DICKSON CO., LLC
- (31) WALGREENS BOOTS ALLIANCE, INC. a/k/a WALGREEN CO.,
- (32) CVS HEALTH CORP.,
- (33) CVS PHARMACY, INC.,

PETITION



JUL 27 2020

BY *[Signature]*
DEPUTY

CASE ASSIGNED TO:

JACK D. MCCURDY II

JUDGE: _____

(34) OKLAHOMA CVS PHARMACY, LLC
(35) WAL-MART INC. f/k/a WAL-MART
STORES, INC.,
(36) SMITH DRUG COMPANY,
(37) SAJ DISTRIBUTORS,
Defendants.

INTRODUCTION

1. In 2017, the United States saw a record number of drug overdose deaths, totaling 72,000 people and an approximate ten percent increase from 2016. The 2017 drug overdose death toll is higher than the peak annual death totals for HIV, car wrecks, or gun deaths. Analysts pointed to the opioid epidemic ravaging communities across the country (with a growing number of opioid users) with deadlier prescription opioids becoming available. The opioid epidemic has been particularly devastating in Oklahoma and the City of El Reno as a result of corporate greed.

2. The City of El Reno employees dozens of people and is responsible for funding medical insurance plans for its employees.

3. City of El Reno brings this action in its own legal capacity to protect the health, safety, and welfare of all its residents.

4. Opioids are highly addictive and, historically, medical professionals have prescribed them in limited circumstances to patients with cancer, terminal illnesses, or acute short-term pain. Defendants manufacture and distribute opioids and, therefore, the limited uses for which medical professionals prescribed opioid prescriptions undermined Defendants' ability to maximize profits. Thus, Defendants sought to maximize their profits by selling more opioids. Defendants sought, and indeed accomplished this goal, by expanding the market beyond the limited circumstances of medically necessary opioid use and successfully convinced medical professionals to prescribe opioids to a broader range of patients for longer periods of time.

5. Defendants chose to falsely downplay the risk of opioid addiction and overstate the efficacy of opioids for more wide-ranging conditions, including chronic non-cancer pain, in a willful effort to maximize their profits at the expense of human life. Over several years, Defendants implemented unprecedented and large-scale deceptive marketing campaigns that misrepresented the risks of addiction from their opioids and pushed unsubstantiated benefits. Defendants were extremely successful in increasing the sales of opioids. For example, sales of OxyContin rose from roughly \$48 million in 1996 to roughly \$3 billion by 2009.

6. This epidemic has been building for years and the effects of this crisis have only been exacerbated by Defendants' efforts to conceal and minimize the risks of opioid addiction.

7. Upon information and belief, City of El Reno has been overwhelmed by the devastation from opioid addiction and its costs to provide a wide range of social services, including law enforcement, have substantially increased. The result has been that virtually every family in City of El Reno has personally experienced or knows someone who has been adversely impacted by the opioid epidemic.

8. These costs and adverse effects of the opioid epidemic could have been, and should have been, prevented by Defendants. The prescription drug industry is required by law to secure and monitor opioids at every step in the stream of commerce, thereby protecting opioids from theft, misuse, and diversion. The industry is required to implement and follow processes that stop suspicious or unusual orders by pharmacies, doctors, clinics, or patients.

9. Instead of acting with reasonable care and in compliance with their legal duties, Defendants intentionally and/or recklessly saturated communities with opioids and pocketed billions of dollars in the process.

10. Defendants also flooded the market with false declarations designed to convince doctors, patients, and government entities that prescription opioids posed a low risk of addiction. Those claims were false¹ and Defendants knew it.

11. As a direct result of Defendants' actions, criminal acts have been committed, not only by residents of the City of El Reno seeking to obtain opioids, but also by physicians themselves. Defendants created an environment where physicians sought to profit at the expense of their patients who would become addicted to opioids at the expense of the City of El Reno.

12. Defendants' actions directly and foreseeably caused damages to the City of El Reno, including but not limited to, actual costs, lost opportunity costs, healthcare and emergency care costs, costs for social services for those suffering from opioid addiction, overdose, or death; counseling, treatment and rehabilitation services; treatment of infants born with opioid-related medical conditions; welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation; and law enforcement and public safety relating to the opioid epidemic within the City. The City of El Reno has also suffered substantial damages due to the lost productivity of its residents, increased administrative costs, and the lost opportunity for growth and self-determination. These damages have been suffered and continue to be suffered directly by the City of El Reno.

13. City of El Reno also seeks the abatement of the continuing epidemic created by Defendants' wrongful and/or unlawful conduct.

¹ See Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at <http://turnthetiderx.org/>.

II. THE PARTIES

A. Plaintiff

14. City of El Reno is an organized municipality within the State of Oklahoma, a body corporate and politic, with the statutory authority and power to sue and be sued. City of El Reno provides a wide range of services on behalf of its residents, including but not limited to social services for families and children, public health, public assistance, law enforcement and emergency care. Plaintiff is referred to as “City of El Reno” or “City”.

B. Pharmaceutical Defendants

15. The Pharmaceutical Defendants are defined below. At all relevant times, the Pharmaceutical Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. The Pharmaceutical Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

16. CEPHALON, INC. is a Delaware corporation with its principal place in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. (“Teva USA”) is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011.

17. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the U.S., including in Oklahoma. The Federal Drug Administration (“FDA”)

approved Actiq and Fentora only for the management of breakthrough cancer pain in patients who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

18. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon- branded products through its “specialty medicines” division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly owned subsidiary of Teva Ltd. on prescription savings cards, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon’s promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon’s and Teva’s USA’s sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd. operates in Oklahoma and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the United States itself. Upon information

and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively as "Cephalon". Cephalon has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

19. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL- JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to collectively as "Janssen". Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical's products and corresponds with the FDA regarding Janssen's products.

20. Janssen manufactures, promotes, sells, and distributes drugs in the United States., including in Oklahoma, including the opioid Duragesic (fentanyl). Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Janssen has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

21. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly

owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. PAR PHARMACEUTICAL INC. is headquartered in Chestnut Ridge, NY and an operating company of ENDO INTERNATIONAL PLC. Endo Health Solutions Inc., Endo Pharmaceuticals Inc., and Par Pharmaceutical Inc. are referred to collectively as “Endo”.

22. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydane, in the United States, including in Oklahoma. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, including in Oklahoma, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

23. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015. Before that, WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of

these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to collectively as “Actavis”.

24. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States, including in Oklahoma. Actavis has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

25. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its United States headquarters in St. Louis, Missouri. MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc. SPECGX LLC is a subsidiary of Mallinckrodt, plc based in St. Louis, Missouri. Mallinckrodt, plc, Mallinckrodt, LLC, and SpecGx LLC are collectively referred to as “Mallinckrodt.”

26. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the United States Drug Enforcement Administration (“DEA”) of suspicious orders of controlled substances. Mallinckrodt has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

27. MYLAN PHARMACEUTICALS, INC. (“Mylan”) is headquartered in Canonsburg, Pennsylvania and is a subsidiary of Mylan N.V., a global pharmaceuticals company registered in the Netherlands with its principal executive offices in Hatfield, Hertfordshire, United Kingdom. Mylan manufactures, markets and/or distributes more than 387 drugs in the United States.

28. WEST-WARD PHARMACEUTICALS CORP. now doing business as HIKMA (“Hikma”) is a wholly owned U.S. subsidiary of HIKMA PHARMACEUTICALS PLC, based in Amman Jordan, and headquartered in London, England. Hikma’s U.S. headquarters are in Eatontown, New Jersey with manufacturing and research and development sites in Cherry Hill, New Jersey, Columbus, Ohio and Bedford Ohio. Hikma develops, manufactures, and markets branded and generic prescription drugs, including injectable prescription opioids such as hydromorphone. Hikma is one of the top 3 manufacturers of generic prescription drug injectables in the U.S.

29. INDIVIOR INC. (“Indivior”) formerly known as Reckitt Benckiser Pharmaceuticals Inc. has its principal headquarters in North Chesterfield in Richmond, Virginia and is a wholly-owned subsidiary of INDIVIOR PLC that is located in the United Kingdom. Indivior is a global pharmaceutical company that manufactures and markets medicines for the treatment of moderate to severe opioid use disorder, including Suboxone.

30. SANDOZ, INC. (“Sandoz”) is a Colorado corporation registered to do business in Pennsylvania with its principal headquarters in Princeton, New Jersey. Sandoz is a wholly owned subsidiary of Novartis International AG, which is based in Basel, Switzerland. Sandoz manufactures, markets, and/or distributes pharmaceutical drugs throughout the United States.

31. Sandoz manufactures, promotes, sells and distributes opioids such as fentanyl transdermal patch, methadone hydrochloride tablet, acetaminophen/hydrocodone bitrate tablet, acetaminophen/caffeine/dihydrocodeine bitrate tablet, acetaminophen/propoxyphene napsylate tablet, and oxycodone HCl USP tablet in the United States, including in Oklahoma.

32. Collectively, Cephalon, Janssen, Endo, Actavis, Mallinckrodt, Mylan, Hikma, Indivior, and Sandoz are the “Pharmaceutical Defendants”.

C. Distributor Defendants

33. MCKESSON CORPORATION (“McKesson”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California.

34. McKesson distributes prescription opioids to providers and retailers, including in Oklahoma. McKesson is registered to do business and receive service of process in Oklahoma. McKesson is also registered with the Oklahoma Department of Health as a wholesale prescription drug distributor in Oklahoma.

35. CARDINAL HEALTH, INC. (“Cardinal”) is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio. Cardinal distributes prescription opioids to providers and retailers, including in Oklahoma. Cardinal is registered to do business and receive service of process in Oklahoma. Cardinal is also registered with the Oklahoma Department of Health as a wholesale prescription drug distributor in Oklahoma.

36. AMERISOURCEBERGEN CORPORATION (“AmerisourceBergen”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania. AmerisourceBergen distributes prescription opioids to providers and

retailers, including in Oklahoma. AmerisourceBergen is registered to do business and receive service of process in Oklahoma. AmerisourceBergen is also registered with the Oklahoma Department of Health as a wholesale prescription drug distributor in Oklahoma.

37. MORRIS & DICKSON CO, LLC ("Morris") is a privately held company incorporated under the laws of Louisiana with its principal place of business in Louisiana.

38. Morris distributes prescription opioids to providers and retailers, including in Oklahoma. Morris is registered to do business and receive service of process in Oklahoma. Morris is also registered with the Oklahoma Department of Health as a wholesale prescription drug distributor in Oklahoma.

39. WALGREENS BOOTS ALLIANCE, INC. also known as WALGREEN CO. ("Walgreens") is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Walgreens has distributed and continues to distribute prescription opioids in and around City of El Reno.

40. CVS HEALTH CORPORATION is a Delaware corporation with its principal place of business in Rhode Island. CVS PHARMACY, INC. is a foreign for profit business corporation with its principal place of business in Rhode Island. OKLAHOMA CVS PHARMACY, LLC is a domestic limited liability company established under the laws of Oklahoma with its principal place of business in Oklahoma. CVS Health Corporation, CVS Pharmacy, Inc. and Oklahoma CVS Pharmacy, LLC are collectively known as "CVS". During all relevant times, CVS has sold and continues to sell prescription opioids in and around Oklahoma. CVS is also registered with the Oklahoma Department of Health as a wholesale prescription drug distributor in Oklahoma. At all relevant times, CVS has distributed and continues to distribute prescription opioids in and around the City of El Reno.

41. WAL-MART INC., formerly known as Wal-Mart Stores, Inc. (“Wal-Mart”), is a Delaware corporation with its principal place of business in Arkansas. At all relevant times, Wal-Mart has distributed and sold and continues to distribute and sell prescription opioids in Oklahoma, including in and around the City of El Reno.

42. Collectively, McKesson, Cardinal Health, AmerisourceBergen, Morris, Walgreens, CVS, Wal-Mart, are the “Distributor Defendants.”

III. JURISDICTION AND VENUE

43. This Court has jurisdiction over this action because Defendants conduct business in and around the City of El Reno and throughout Oklahoma and have deliberately engaged in significant acts and omissions within the City of El Reno that have injured its residents. Defendants purposefully directed their activities at the City of El Reno, including, but not limited to, marketing, distributing, or selling prescription opioids within the City of El Reno.

44. Venue is proper in Canadian County, State of Oklahoma.

45. This action is non-removable because there is incomplete diversity of residents, no substantial federal question presented, and a claim for the abatement of a public nuisance in the City of El Reno based on state law.

IV. ADDITIONAL FACTUAL BACKGROUND

A. Overview of National Opioid Epidemic

46. Historically, opioids were considered too addictive and debilitating to be part of a long-term pain management regimen for chronic pain. Prior to the 1990s, the medical profession adhered to the standard that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer and end-of-life care. Due to the lack of evidence that opioids improved patients’ ability to overcome pain and function, coupled with evidence of

greater pain complaints as patients developed tolerance to opioids over time as well as the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, medical professionals generally did not prescribe opioids for chronic pain.

47. Moreover, opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly over time no longer responds to the drug as strongly as before, thus requiring a higher dose to achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse for those addicted to opioids.

48. As described herein, Defendants engaged in conduct that directly caused medical professionals to unwittingly prescribe long-term and increased amounts of opioids to “aggressively” treat pain. Defendants did so to take advantage of a much larger and lucrative market for chronic pain patients.

49. As a result of Defendants’ wrongful conduct, prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.² From 1999 to 2013, the amount of prescription painkillers prescribed and sold in the United States nearly quadrupled. Yet, there had not been an overall change in the amount of pain reported by patients.

50. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention (“CDC”) declared prescription painkiller overdoses to be at epidemic levels. The press release noted:

² Katherine M. Keyes et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin) and oxymorphone (Opana).
- c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically, according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
- e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
- f. Almost 5,500 people start to misuse prescription painkillers every day.³

51. Many Americans, including residents of the City of El Reno, are now addicted to prescription opioids and the number of deaths due to prescription opioid overdose has reached epidemic levels. In 2016, drug overdoses killed roughly 64,000 people in the United States, an

³ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.⁴ The President of the United States has declared the opioid epidemic a public health emergency.

52. The National Institute on Drug Abuse identifies addiction to opioids as “a serious national crisis that affects public health as well as social and economic welfare.”⁵ The economic burden of prescription opioid misuse alone is hundreds of billions of dollars a year, including the costs of healthcare, lost productivity, addiction treatment and criminal justice expenditures.⁶

53. Deaths from prescription opioids have quadrupled in the past 20 years and treatment admission and emergency room visits related to the abuse of opioids for non-medical use have also dramatically increased.

54. According to the CDC,⁷ opioid deaths and treatment admissions are tied to opioid sales.

55. Defendants have continued their wrongful and unlawful conduct, despite their knowledge that such conduct is causing and continuing to cause the opioid epidemic.

⁴ See Ctrs. for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

⁵ Opioid Crisis, NIH, National Institute on Drug Abuse (available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis>, last visited Sept. 19, 2017) (“Opioid Crisis, NIH”) (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, *MMWR MORB MORTAL WKLY REP.* 2016;65, doi:10.15585/mmwr.mm655051e1).

⁶ *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

⁷ U.S. Dep’t of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf.

B. Overview of Opioid Epidemic in Oklahoma and City of El Reno

56. Communities have been devastated by the opioid epidemic as a result of Defendants' deceptive marketing and distribution/diversion of opioids. Oklahoma is one of the leading states in prescription painkiller sales per capita, with 128 painkiller prescriptions dispensed per 100 people in 2012. Drug overdose deaths in Oklahoma increased eightfold from 1999 to 2012, surpassing car crash deaths in 2009. In 2012, Oklahoma had the fifth-highest unintentional poisoning death rate and prescription opioids contributed to the majority of these deaths.

57. In 2014, Oklahoma's unintentional poisoning rate was 107% higher than the national rate. Oklahoma had the 10th highest drug overdose death rate in the nation in 2014. Opioids are the most common class of drug involved in unintentional overdose deaths in Oklahoma.

58. In 2015, 823 fatal drug overdoses occurred in Oklahoma, an almost 140% increase over 2001, with opioids contributing to the largest number of these deaths. As of 2015, there were more prescription drug overdose deaths each year in Oklahoma than overdose deaths from alcohol and all illegal drugs combined.

59. In Oklahoma, more overdose deaths involved hydrocodone or oxycodone than methamphetamines, heroin, and cocaine combined.

60. According to 2016 statistics, Oklahoma ranks number one in the nation in milligrams of opioids distributed per adult resident with approximately 877 milligrams of opioids distributed per adult resident.

61. A National Survey on Drug Use and Health revealed Oklahoma leads the nation in non-medical use of painkillers, with nearly 5% of the population aged 12 and older abusing or misusing painkillers.

62. From 2013-2017, there were 71 unintentional poisoning deaths in Canadian County, with thirty-five (35) of those deaths involving a prescription opioid. The most common substance involved in an overdose death during this time period in Canadian County was oxycodone. The City of El Reno is located on one of the largest and most-traveled interstates in Oklahoma (I-40) and is only 25 miles west of downtown Oklahoma City.

63. The City of El Reno's Police Department now carries Naloxone and/or Narcan, antidotes to opioid overdose, and uses them to save the lives of City of El Reno residents.

64. The Defendants' saturation of communities with prescription opioids has created accessibility and availability of prescription opioids, which is fueling illicit opioid addiction. According to the CDC, past misuse of prescription opioids is the strongest risk factor for a person starting and using heroin. Between 2000 and 2014, the number of overdose deaths from heroin nationwide quintupled.

65. Defendants' conduct is affecting even City of El Reno's youngest and most vulnerable citizens. The national rate of babies born with neonatal abstinence syndrome ("NAS"), a group of conditions newborns experience when withdrawing from exposure to drugs like opioids, increased fivefold from 2000 to 2012. In 2014, the number of newborns testing positive for prescription medications doubled the number reported in 2013.

C. Pharmaceutical Defendants False, Deceptive And Unfair Marketing Of Opioids

66. Each Pharmaceutical Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used for

treatment of chronic pain, resulting in opioid treatment for a much larger segment of the population, and for a longer time, of patients who are much more likely to become addicted. In connection with this scheme, each Pharmaceutical Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

67. The deceptive marketing schemes included, among others, (1) false or misleading direct, branded advertisements; (2) false or misleading direct-to-physician marketing, also known as “detailing;” (3) false or misleading materials speaker programs, webinars, and brochures; and (4) false or misleading unbranded advertisements or statements by purportedly neutral third parties that were really designed and distributed by the Pharmaceutical Defendants. In addition to using third parties to disguise the source of their misinformation campaign, the Pharmaceutical Defendants also retained the services of certain physicians, known as “key opinion leaders” (“KOLs”) to convince both doctors and patients that opioids were safe for the treatment of chronic pain.

68. The Pharmaceutical Defendants have made false and misleading claims, contrary to the language on their drugs’ labels, regarding the risks of using their drugs that: (1) downplayed the seriousness of addiction; (2) created and promoted the concept of “pseudo addiction” when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher dosages; and (6) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction. The Pharmaceutical Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of

opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Pharmaceutical Defendants' claims.

69. The Pharmaceutical Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Pharmaceutical Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups.

70. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that same evidence.

71. Upon information and belief, Defendants knew or should have known, that such dissemination of misinformation would include prescribers and impact their prescribing practices of opioids.

72. Pharmaceutical Defendants' efforts have been extremely successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."⁸ This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients

⁸ See Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at <http://turnthetidex.org/>.

physically and psychologically dependent on them (the demand). When those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

73. Pharmaceutical Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Each Pharmaceutical Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids

74. Pharmaceutical Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around City of El Reno. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout City of El Reno.

75. Pharmaceutical Defendants employed the same marketing plans and strategies and deployed the same messages in and around City of El Reno, as they did nationwide. Across the opioid pharmaceutical industry, corporate headquarters funded and oversaw “core message” development on a national basis. This comprehensive approach ensures that the Pharmaceutical Defendants’ messages are consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Pharmaceutical Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

76. The Pharmaceutical Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets

of visual aids, speaker slide decks and sales training materials; and nationally coordinated advertising. The Pharmaceutical Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to check on their performance and compliance.

i. Direct Marketing

77. The Pharmaceutical Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Pharmaceutical Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of opioids. For example, upon information and belief, the Pharmaceutical Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

78. Many of the Pharmaceutical Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction workers, chefs, and teachers, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

79. Each Pharmaceutical Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Pharmaceutical Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. The Pharmaceutical Defendants spent in excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

80. The Pharmaceutical Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Pharmaceutical Defendants purchase, manipulate, and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by an individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Pharmaceutical Defendants know their detailing to doctors is effective.

81. The Pharmaceutical Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."⁹

ii. Indirect Marketing

82. The Pharmaceutical Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and KOLs, and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

83. The Pharmaceutical Defendants deceptively marketed opioids in City of El Reno through unbranded advertising – e.g., advertising that promotes opioid use generally but does not

⁹ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.

name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Pharmaceutical Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their “core messages” via their own detailers and speaker programs, the Pharmaceutical Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education (“CME”) programs, and medical conferences and seminars. To this end, the Pharmaceutical Defendants used third-party public relations firms to help control those messages when they originated from third parties.

84. The Pharmaceutical Defendants marketed through third party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically not reviewed by the FDA. The Pharmaceutical Defendants also used third party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Pharmaceutical Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

85. Pharmaceutical Defendants also identified doctors to serve, for payment, on their speakers’ bureaus and to attend programs with speakers and meals paid for by Pharmaceutical Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are

providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. Upon information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Pharmaceutical Defendants' prior misrepresentations about the risks and benefits of opioids.

86. Borrowing a page from Big Tobacco's playbook, the Pharmaceutical Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging and directing doctors who served as KOLs and (b) funding, assisting, directing and encouraging seemingly neutral and credible Front Groups. The Pharmaceutical Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Pharmaceutical Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and that the "compassionate" treatment of pain required opioids.

87. Pro-opioid doctors are one of the most important avenues that the Pharmaceutical Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Pharmaceutical Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

88. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Pharmaceutical Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees and honoraria from Cephalon, Endo, and

Janssen (among others) and was a paid consultant to Cephalon. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) / American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by the Pharmaceutical Defendants.

89. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that “the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that the person is not going to become addicted.”¹⁰

90. Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that less than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids

¹⁰ Good Morning America (ABC television broadcast Aug. 30, 2010).

does not exist.”¹¹ Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”¹²

91. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of AAPM in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon and Endo. At the same time, Dr. Webster was receiving significant funding from the Pharmaceutical Defendants (including nearly \$2 million from Cephalon).

92. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the DEA, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than twenty (20) of Dr. Webster’s former patients at the Lifetree Clinic have died of opioid overdoses.

93. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster’s Opioid Risk Tool appear on, or are linked to, websites run by Endo and Janssen. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the

¹¹ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012,

<https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

¹² *Id.*

Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Pharmaceutical Defendants and those under their influence and control.

94. In 2011, Dr. Webster presented via webinar a program entitled “Managing Patient’s Opioid Use: Balancing the Need and the Risk.” Dr. Webster recommended use of risk screening tools, urine testing and patient agreements as a way to prevent “overuse of prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach doctors in Oklahoma and doctors treating residents of City of El Reno.¹³

95. Dr. Webster also was a leading proponent of the concept of “pseudo addiction,” the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster’s description, the only way to differentiate the two was to increase a patient’s dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of abnormal behavior, increasing the dose “in most cases . . . should be the clinician’s first response.”¹⁴ Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudo addiction] obviously became too much of an excuse to give patients more medication.”¹⁵

96. The Pharmaceutical Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the

¹³ See Emerging Solutions in Pain, *Managing Patient’s Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

¹⁴ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

¹⁵ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2m-139609053.html>.

treatment of chronic pain. Under the direction and control of the Pharmaceutical Defendants, these “Front Groups” generated treatment guidelines, unbranded materials and programs that favored chronic opioid therapy. They also assisted the Pharmaceutical Defendants by responding to negative articles, advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence and conducting outreach to vulnerable patient populations targeted by the Pharmaceutical Defendants.

97. These Front Groups depended on the Pharmaceutical Defendants for funding and, in some cases, for survival. The Pharmaceutical Defendants also exercised control over programs and materials created by these groups by collaborating on, editing and approving their content and by funding their dissemination. In doing so, the Pharmaceutical Defendants made sure that the Front Groups would generate only the messages that the Pharmaceutical Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

98. Pharmaceutical Defendants Cephalon, Endo and Janssen, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including APS, American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and the Pain & Policy Studies Group (“PPSG”).¹⁶

¹⁶ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015), <https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>.

99. The most prominent of the Pharmaceutical Defendants' Front Groups was APF, which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo. APF issued education guides for patients, reporters and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning veterans. APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach the residents of City of El Reno.

100. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of a total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from Pharmaceutical Defendants Cephalon, Endo and others to avoid using its line of credit.

101. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide “patient representatives” for the Pharmaceutical Defendants' promotional activities. APF functioned largely as an advocate for the interests of the Pharmaceutical Defendants, not patients.

102. Plaintiff is informed, and believes, that on several occasions representatives of Pharmaceutical Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

103. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Pharmaceutical Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."¹⁷

104. Another front group for the Pharmaceutical Defendants was AAPM. With the assistance, prompting, involvement, and funding of the Pharmaceutical Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Pharmaceutical Defendants' deceptive marketing of chronic opioid therapy.

105. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual

¹⁷ Charles Ornstein & Tracy Weber, Senate Panel Investigates Drug Companies' Ties to Pain Groups, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

event as an “exclusive venue” for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Pharmaceutical Defendants Endo and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

106. Upon information and belief, AAPM is viewed internally by Endo as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM’s presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

107. The Pharmaceutical Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

108. In 1996, AAPM and APS jointly issued a consensus statement, “The Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain and claimed that the risk of a patients’ addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011, and, upon information and belief, was taken down from AAPM’s website only after a doctor complained.¹⁸

¹⁸ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

109. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”) and continued to recommend the use of opioids to treat chronic pain.¹⁹ Doctors, especially the general practitioners and family doctors targeted by the Pharmaceutical Defendants, have relied upon treatment guidelines. Treatment guidelines not only directly inform doctors’ prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo and Actavis discussed treatment guidelines with doctors during individual sales visits.

110. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, received support from Pharmaceutical Defendants Janssen, Cephalon, and Endo. The 2009 Guidelines promote opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.²⁰ One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Pharmaceutical Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in City of El Reno during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The

¹⁹ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

²⁰ *Id.*

Pharmaceutical Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Pharmaceutical Defendants financial support to members of the panel.

111. The Pharmaceutical Defendants worked together through Front Groups to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, and Janssen) and various Front Groups, almost all of which received substantial funding from the Pharmaceutical Defendants. Among other projects, PCF worked to ensure that a FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Pharmaceutical Defendants determined would reduce prescribing.

D. Pharmaceutical Defendants' Marketing Scheme Misrepresented The Risks And Benefits of Opioids

1. The Pharmaceutical Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

112. To falsely assure physicians and patients that opioids are safe, the Pharmaceutical Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked. These misrepresentations, which are described below, reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher

opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Pharmaceutical Defendants have not only failed to correct these misrepresentations, they continue to make them today.

113. Opioid manufacturers, including Pharmaceutical Defendant Endo, has entered into settlement agreements with public entities that prohibit it from making many of the misrepresentations identified in this Petition. Yet even afterward, each Pharmaceutical Defendant continued to misrepresent the risks and benefits of long-term opioid use in City of El Reno and each continues to fail to correct its past misrepresentations.

114. Some illustrative examples of the Pharmaceutical Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

- a. Actavis' predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis' acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.
- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

- d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”
- f. Janssen currently runs a website, Prescriberresponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”
- g. Consistent with the Pharmaceutical Defendants’ published marketing materials, upon information and belief, detailers for Endo, Janssen, and Cephalon in Oklahoma and Plaintiff’s Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.
- h. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Pharmaceutical Defendants’ Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that “patients rarely become addicted to prescribed opioids,” citing research by their KOL, Dr. Portenoy.²¹

115. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the “2016 CDC Guideline”) explains that there is “[e]xtensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .).”²² The 2016 CDC Guideline further explains that “[o]pioid pain medication use presents serious risks, including overdose and opioid

²¹ Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

²² Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”²³

116. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting (“ER/LA”) opioids in 2013 and for immediate release (“IR”) opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed.²⁴

117. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.”²⁵ Endo had claimed on its www.opana.com

²³ *Id.* at 2, 25.

²⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf>; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf>.

²⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. Endo remains free, however, to make those statements in City of El Reno.

118. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, Pharmaceutical Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Pharmaceutical Defendants misrepresented, to both doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. “pseudo addiction”) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

119. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudo addiction fallacy as a reason to push more opioid drugs onto already addicted patients.

120. In addition to misstating the addiction risk and inventing the pseudo addiction falsehood, a third category of false, deceptive, and unfair practice is the Pharmaceutical Defendants’ false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Pharmaceutical Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Pharmaceutical Defendants’ misrepresentations made these doctors feel more comfortable

prescribing opioids to their patients and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

- a. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
- b. On information and belief, detailers for the Pharmaceutical Defendants have touted and continue to tout to doctors in Oklahoma the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

121. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by the Pharmaceutical Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – “for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, the Guideline recognizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”

122. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Pharmaceutical Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem and failed to disclose the increased difficulty of stopping opioids after long-term use.

123. For example, on information and belief, a 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

124. The Pharmaceutical Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, tremor, and tachycardia (rapid heartbeat) – and grossly understated the difficulty of tapering, particularly after long-term opioid use.

125. Contrary to the Pharmaceutical Defendants' representations, the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." (Emphasis added). The Guideline further states that "more than a few days of exposure to opioids significantly increases hazards" and "each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit."

126. The Pharmaceutical Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Pharmaceutical Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims are described below:

- a. On information and belief, Actavis' predecessor created a patient brochure for Kadian in 2007 that stated, "Over time,

your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.”

- b. Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. This guide is still available online.²⁶
- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that opioid dosages may be increased until “you are on the right dose of medication for your pain.”
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased. . . . You won’t ‘run out’ of pain relief.”²⁷
- e. Janssen, on information and belief, sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Front Group APF and others argued to the United States Fourth Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.

127. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.” More specifically, the CDC explains that “there is now an established

²⁶ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

²⁷ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC also states that there are “increased risks for opioid use disorder, respiratory depression, and death at higher dosages.”

128. The Pharmaceutical Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse.

129. These abuse deterrent formulations (AD opioids) purportedly are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids can be defeated – often quickly and easily – by those determined to do so. The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies—even when they work—do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the Director of the CDC, has further reported that his staff could not find “any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”²⁸

130. Despite this lack of evidence, the Pharmaceutical Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations.

²⁸ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public Integrity (Dec. 15, 2016), available at <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution>.

131. For example, Endo has marketed Opana ER²⁹ as tamper- or crush- resistant and less prone to misuse and abuse even though: (1) on information and belief, the FDA warned in a 2013 letter that there was no evidence that Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (2) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Nonetheless, Endo's advertisements for Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. And on information and belief, detailers for Endo have informed doctors that Opana ER is harder to abuse.

132. The development, marketing, and sale of AD opioids are a continuation of the Pharmaceutical Defendants' strategy to use misinformation to drive profit. The Pharmaceutical Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more expensive than other opioid products even though they provide little or no additional benefit.

2. The Pharmaceutical Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly overstating the benefits of the opioid drugs.

133. To convince doctors and patients that opioids should be used to treat chronic pain, the Pharmaceutical Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term

²⁹ Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, a FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market. Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.³⁰ The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

134. Some illustrative examples of the Pharmaceutical Defendants’ false claims are:

- a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) – which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.
- d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors’ offices, of presumed patients in active professions; the caption read, “Pain doesn’t fit into their schedules.”
- e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon and Endo, taught that relief of pain by opioids, by itself, improved patients’ function.
- f. Cephalon sponsored APF’s Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids

³⁰ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

“give [pain patients] a quality of life we deserve.”³¹

- g. Endo’s NIPC website “PainKnowledge” claimed in 2009, upon information and belief, that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make misleading claims about function, and Endo closely tracked visits to the site.
 - h. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled “Persistent Pain in the Older Patient.” Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.”
 - i. Janssen sponsored and funded a multimedia patient education campaign called “Let’s Talk Pain.” One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the “Let’s Talk Pain” campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to “continue to function.”
- 3. Cephalon’s, Endo’s, and Janssen’s sales representatives have conveyed, and continue to convey, the message that opioids will improve patient function.**

135. As the FDA and other agencies have made clear for years, these claims have no support in scientific literature.

136. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that “we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken

³¹ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life.”³² And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

137. The Pharmaceutical Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs (nonsteroidal anti-inflammatory drugs), so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Pharmaceutical Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain. The Pharmaceutical Defendants have overstated the number of deaths from NSAIDs and have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious risks of opioids.

138. Upon information and belief, research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which

³² Letter from Thomas Abrams to Doug Boothe, *supra* note 14.

release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial proportion” of chronic pain patients taking OxyContin experience it. This not only renders the promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

139. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl- based IR opioids. Neither is approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm.

140. Despite this, on information and belief, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe.³³ As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain.

³³ See Press Release, U.S. Dep’t of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million & Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

141. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses. For example:

- a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer- related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.
- b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

142. The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The Pharmaceutical Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have

issued pronouncements based on the medical evidence that conclusively expose the known falsity of the Pharmaceutical Defendants' misrepresentations.

143. On information and belief, the Pharmaceutical Defendants coordinated their messaging through national and regional sales and speaker trainings and coordinated advertisements and marketing materials.

144. Moreover, at all times relevant to this Petition, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Pharmaceutical Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Pharmaceutical Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

145. Finally, the Pharmaceutical Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Pharmaceutical Defendants distorted the meaning or significance of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the Pharmaceutical Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could City of El Reno have detected it.

146. The Pharmaceutical Defendants' efforts to artificially increase the number of opioid prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since

1999 and has increased in parallel with [opioid] overdoses.”³⁴ Many abusers start with legitimate prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “[t]o reverse the epidemic of opioid drug overdose deaths and prevent opioid- related morbidity.”³⁵ Accordingly, the Pharmaceutical Defendants’ false and misleading statements directly caused the current opioid epidemic.

E. Defendants’ Unlawful Distribution Of Opioids

147. In addition to common law duties to exercise reasonable care under the circumstances,³⁶ the Distributor Defendants owe a duty under state law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff’s Community as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff’s Community. *See* 63 O.S. Chapter 2 (Oklahoma Uniform Controlled Dangerous Substances Act, hereinafter “Oklahoma CSA”).

148. The Oklahoma CSA creates a legal framework for the distribution and dispensing of opioids in Oklahoma. It is a system of checks and balances throughout the entire supply chain of opioids and requires every person or entity that manufactures, distributes, or dispenses opioids to obtain “registration” with the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control. Registrants at every level of the supply chain must fulfill their obligations under the Oklahoma CSA; otherwise there is an overwhelming risk of harm to City of El Reno.

³⁴ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> .

³⁵ *Id.*

³⁶ This includes a duty not to create a foreseeable risk of harm to others, but also a duty to exercise reasonable care to prevent threatened harm after engaging in affirmative conduct and either realizing or should realize that such conduct has created an unreasonable risk of harm to another.

149. Pursuant to the Oklahoma CSA and the Oklahoma Administrative Code, all opioid distributors are required to maintain effective controls against opioid diversion. Defendant Distributors must create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders can include orders of unusual size, orders that deviate from usual ordering patterns, and/or unusual frequency of orders. Thus, at a minimum to comply with these requirements, Defendant Distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of potential diversion.

150. Oklahoma law also creates a distribution monitoring system for controlled substances and requires distributor and dispensers of controlled dangerous substances to keep records and maintain inventories.

151. Similarly, the Oklahoma administrative code requires anyone who distributes or dispenses prescription opioids to inform the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of suspicious orders when discovered. The code also requires reporting of theft or any significant loss of any controlled dangerous substances upon discovery of such theft or loss.

152. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

153. Each Distributor Defendant repeatedly and purposefully breached its duties under common law and state law. Such breaches are direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

154. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in City of El

Reno. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

155. The opioid epidemic in City of El Reno remains an immediate *hazard to public health and safety*.

156. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. The Distributor Defendants Negligently Failed to Control The Flow Of Opioids To City of El Reno Through Illicit Channels

157. The DEA has provided guidance to distributors to combat opioid diversion. On information and belief, since 2006 the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities. The DEA also provides distributors with data on controlled substance distribution patterns and trends, including data on the volume and frequency of orders and the percentage of controlled versus non-controlled purchases. On information and belief, the DEA has also hosted conferences for opioid distributors and has participated in numerous meetings and events with trade associations.

158. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring and the responsibilities and obligations of registrants to prevent diversion.

159. As part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of each and every order prior to filling. Circumstances that could be indicative of diversion include ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; ordering a disproportionate amount of controlled substances versus non-controlled prescription

drugs; ordering excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors.

160. Suspicious orders must be reported when discovered. Registrants must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted and filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.

161. On information and belief, the Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each member of the supply chain in distributing controlled substances. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

162. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

163. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

164. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.³⁷ The DEA has repeatedly taken action to attempt to

³⁷ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post, Oct. 15, 2017, available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3; Lenny Bernstein, David S. Fallis, and Scott

force compliance, including 178 registrant actions between 2008 and 2012, 76 orders to show cause issued by the Office of Administrative Law Judges, and 41 actions involving immediate suspension orders.³⁸ The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

- a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined \$150,000,000.³⁹
- b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer.
- c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion.
- d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in

Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post, Oct. 22, 2016, available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics_story&utm_term=.4f439ef106a8.

³⁸ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf>.

³⁹ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download>.

Lakeland, Florida, for failure to maintain effective controls against diversion.

- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion.
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion.
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States.⁴⁰
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states.
- j. In December 2016, the Department of Justice announced a multi-million-dollar settlement with Cardinal for violations of the Controlled Substances Act.⁴¹
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were

⁴⁰ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post, Jan. 11, 2017, available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66.

⁴¹ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act>.

receiving approximately 69,000 doses/year.

- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.
- n. In May of 2018, Morris was ordered by the Drug Enforcement Administration (DEA) to cease sales of opioids, alleging that the company failed to report unusually large narcotics shipments to drugstores. Morris had distributed excessive amounts of opioids to five of the top 10 pharmacies purchasing narcotics in Louisiana. In some cases, Morris allowed independent pharmacies to purchase six times the quantity of narcotics than they would normally order from the distributor. Despite receiving these excessively large orders, Morris never filed a suspicious activity report on any of the drugstores in question.
- o. In 2013, Walgreens agreed to pay \$80 million in civil penalties related to allegations of record-keeping and dispensing violations. The allegations accused Walgreens of endangering public safety in that it allowed millions of controlled substances, including oxycodone, to reach the black market. Walgreens was barred from shipping oxycodone and other controlled drugs from its Jupiter, Florida distribution center.
- p. In 2013, CVS agreed to pay \$11 million to the United States to settle civil penalty claims for record-keeping violations over a six-year period in the United States District Court for the Western District of Oklahoma. The violations included filling prescriptions for prescribers whose registration numbers were not current or valid, entering and maintaining CVS dispensing records in which non-prescribing practitioners were substituted for registration numbers of prescribing practitioners and creating, entering and maintaining invalid "dummy" registration numbers of prescribing practitioners that were provided to the Oklahoma prescription drug monitoring program.

165. Although law enforcement authorities have penalized distributors, these penalties have not changed their conduct. Distributor Defendants' pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

166. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid diversion created an enormous black market for prescription opioids, which extended to City of El Reno. Each Distributor Defendant knew or should have known that the opioids reaching City of El Reno were not being consumed for medical purposes and that the amount of opioids flowing to City of El Reno was far in excess of what could be consumed for medically necessary purposes.

167. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were inappropriately prescribing commonly-abused opioids; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around Plaintiff's Community; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

168. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing the areas around Plaintiff's Community to perform due diligence inspections to ensure that the controlled substances the Distributor Defendants had furnished were not being diverted to illegal uses.

169. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to

pharmacies and other facilities servicing the areas around Plaintiff's Community, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

170. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market in and around Plaintiff's Community with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

171. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death. It is also reasonably foreseeable that many of these injuries will be suffered by the residents of City of El Reno, and that the costs of these injuries will be borne by City of El Reno.

172. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic faced by City of El Reno, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

173. The Distributor Defendants were aware of widespread prescription opioid abuse in and around Plaintiff's Community, but, on information and belief, they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas in such quantities, and with such frequency that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

174. The use of opioids by residents of City of El Reno who were addicted or who did not have a medically necessary purpose could not occur without the knowing cooperation and

assistance of the Distributor Defendants. If the Distributor Defendants adhered to effective controls to guard against diversion, the residents of City of El Reno and City of El Reno would have avoided significant injury.

175. The Distributor Defendants made substantial profits over the years based on the diversion of opioids into City of El Reno. The Distributor Defendants knew that City of El Reno would be unjustly forced to bear the costs of these injuries and damages.

176. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids within City of El Reno showed an intentional or reckless disregard for the safety of City of El Reno and its residents. Their conduct poses a continuing threat to the health, safety, and welfare of City of El Reno.

177. The Distributor Defendants' violations constitute prima facie evidence of negligence.

2. The Pharmaceutical Defendants Negligently Failed to Control The Flow Of Opioids Within City of El Reno Through Illicit Channels

178. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants were also legally required of the Pharmaceutical Defendants under state law.

179. Like the Distributor Defendants, the Pharmaceutical Defendants are required to design and operate a system to detect suspicious orders, and to report such orders to law enforcement. *See* 63 O.S. Chapter 2 (Oklahoma CSA). The Pharmaceutical Defendants have not done so.

180. On information and belief, for over a decade the Pharmaceutical Defendants have been able to track the distribution and prescribing of their opioids down to the retail and prescriber level. Thus, the Pharmaceutical Defendants had actual knowledge of the prescribing

practices of doctors. The Pharmaceutical Defendants did not report those red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the Pharmaceutical Defendants breached their duties under common law and state law.

181. The Pharmaceutical Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Pharmaceutical Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Pharmaceutical Defendants knew the volume, frequency, and pattern of opioid orders being placed and filled. The Pharmaceutical Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

182. The Department of Justice recently fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.⁴² Among the allegations resolved by the settlement, the government alleged “Mallinckrodt failed to design and implement an effective system to detect and report suspicious orders for controlled substances – orders that are unusual in their frequency, size, or other patterns. . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills

⁴² See Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

without notifying DEA of these suspicious orders.”⁴³ Mallinckrodt agreed that its “system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.”⁴⁴

183. Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The New York Attorney General also found that, in certain cases where Endo’s sales representatives detailed prescribers who were convicted of illegal prescribing of opioids, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

184. On information and belief, the other Pharmaceutical Defendants have engaged in similar conduct in violation of their responsibilities to prevent diversion.

185. The Pharmaceutical Defendants’ actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into City of El Reno.

⁴³ *Id.*

⁴⁴ 2017 Mallinckrodt MOA at p. 2-3.

**F. Defendants' Unlawful Conduct And Breaches Of Legal Duties
Caused The Harm Alleged Herein And Substantial Damages**

186. As the Pharmaceutical Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products along with the rates of opioid-related substance abuse, hospitalization, and death among the people of City of El Reno. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like City of El Reno, while prescribers have helped fuel the epidemic.

187. As shown above, the opioid epidemic has escalated in Plaintiff's Community with devastating effects. Substantial opioid-related substance abuse, hospitalization and death that mirror Defendants' increased sales, distribution, and prescribing of opioids.

188. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids to City of El Reno and areas from which such opioids are being diverted into City of El Reno, has caused the opioid epidemic caused directly by Defendants to include heroin addiction, abuse, and death.

189. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety to the residents of City of El Reno.

190. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety to the residents of City of El Reno.

191. Defendants repeatedly and purposefully breached their duties under common and state law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into City of El Reno.

192. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in City of El Reno. This diversion and the epidemic are direct causes of foreseeable harms incurred by City of El Reno.

193. Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which City of El Reno seeks relief, as alleged herein. City of El Reno also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

194. City of El Reno seeks economic damages from the Defendants as reimbursement for the costs association with past efforts to eliminate the hazards to public health and safety.

195. City of El Reno seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the public nuisance.

196. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opioids, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon City of El Reno.

V. CAUSES OF ACTION

A. Public Nuisance, (Against all Defendants)

197. Plaintiff incorporates the allegations set forth above as if they were fully set forth herein.

198. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injury the property, health, safety and/or comfort of a considerable

number of persons in City of El Reno by their production, promotion, and marketing of opioids for use by residents of City of El Reno.

199. Defendants' misrepresentations and omissions regarding opioids, as set forth above, have created an opioid addiction epidemic in City of El Reno that constitutes a public nuisance. Defendants have created a condition that affects entire communities, neighborhoods, and considerable numbers of persons at the same time.

200. Defendants' misrepresentations and omissions regarding opioids constitute unlawful acts and/or omissions of duties, which annoy, injure, or endanger the comfort, repose, health, and/or safety of others, and offend decency to a considerable number of persons in City of El Reno. It has even caused deaths, serious injuries, and a severe disruption of public peace, order and safety.

201. Defendants have a duty to abate the nuisance caused by the prescription opioid epidemic.

202. Defendants have failed to abate the nuisance they created.

203. Defendants' conduct directly and proximately caused injury to Plaintiff and its residents.

204. As a direct result of Defendants' conduct, City of El Reno and its residents have suffered actual injury and economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, social services and other services, lost tax revenue, as well as injury and death of residents of City of El Reno.

205. Defendants are liable to City of El Reno for the costs borne by it as a result of the opioid epidemic and for the costs of abating the nuisance created by Defendants.

B. Fraud: Actual and Constructive (Against All Defendants)

206. Plaintiff incorporates the allegations set forth above as if they were fully set forth herein.

207. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and concealed facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

208. Defendants knew at the time that they made their misrepresentations that they were false, made recklessly without knowledge of the truth, and/or had no reasonable ground for believing such assertions. Namely, Defendants knowingly and/or recklessly:

- a. downplayed the substantial risks of addiction and other side-effects of their opioids, including affirmatively stating in sales calls and other marketing outlets that their drugs were not as addictive as they truly are, stating that classic signs of addiction were actually an indication of "pseudo addiction" requiring more opioid treatment, and omitting the high risk of addiction actually present;
- b. overstated the efficacy of their opioids, including making false statements regarding the effectiveness of the drugs for treating chronic non-cancer pain and their ability to improve function; and
- c. misrepresented the medical usefulness and necessity of their opioids, including affirmatively marketing their drugs for off label uses without solicitation and not in response to questions from healthcare providers.

209. Defendants intended that Plaintiff and its residents would rely on their misrepresentations regarding the risks, efficacy, and medical necessity of their opioids, to increase the number of opioid prescriptions and users within City of El Reno.

210. Plaintiff and its residents reasonably relied upon Defendants' misrepresentations, and that Defendants would not conceal material facts.

211. Defendants are liable to Plaintiff for their actual fraud.

212. Defendants had a legal and/or equitable duty to disclose the dangerous and addictive nature of opioids and prevent their diversion. Instead, Defendants mislead the medical community and the residents of City of El Reno and flooded the market with their dangerous drugs. Defendants had a duty to accurately disclose the dangers of opioids, and not mislead the public in order to make profits.

213. Defendant's conduct constitutes constructive fraud for which Defendants are liable to Plaintiff.

214. As a result of Defendants' actual and constructive fraud, City of El Reno has suffered actual damages, including but not limited to, significant costs related to healthcare, undermining of the economic productivity of its residents, and the harming of the long-term health and welfare of the people of City of El Reno.

215. Defendants' repeated and continuing conduct was willful, wanton, and malicious and was directed at the public generally. As a result, City of El Reno seeks to recover punitive damages against Defendants.

C. Negligence and Negligent Misrepresentation (Against All Defendants)

216. Plaintiff incorporates the allegations set forth above as if they were fully set forth herein.

217. Defendants had a legal duty to act with the exercise of ordinary care or skill to prevent injury to another.

218. Defendants breached this duty through their deceptive marketing campaign, distributions of opioids, and failure to divert opioids from illicit channels. Defendants knew of the highly addictive nature and dangers of prescription opioids. Yet, Defendants' negligently

misrepresented and omitted the danger of opioids to consumers, including in City of El Reno, in a coordinated effort to sell more opioids.

219. Defendants' repeated and continuing breach of their duty of care directly and proximately caused damage to City of El Reno.

D. Civil Conspiracy (Against All Defendants)

220. Plaintiff incorporates the allegations set forth above as if they were fully set forth herein.

221. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids and/or distribution of opioids into City of El Reno.

222. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein.

223. Defendants' conspiracy, and Defendants' repeated and continuing actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

E. Unjust Enrichment (Against All Defendants)

224. Plaintiff incorporates the allegations set forth above as if they were fully set forth herein.

225. Defendants received a benefit in the form of billions of dollars in revenue from the sale of prescription opioids to treat chronic pain.

226. Defendants were aware they were receiving that benefit. Defendants' repeated and continuing conduct was designed to bring about that benefit.

227. Defendants retained that benefit at the expense of City of El Reno, who has borne, and who continues to bear, the economic and social costs of Defendants' scheme.

228. It is inequitable for the Defendants to retain that benefit without paying for it.

229. City of El Reno is entitled to recover from Defendants' prescription opioid profits the amounts City of El Reno has spent and will have to spend in the future to address the effects of Defendants' actions.

F. Punitive Damages

230. Plaintiff incorporates the allegations set forth above as if they were fully set forth herein.

231. Defendants acted with malice, purposely, and intentionally. At a minimum, Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm.

232. Plaintiff is entitled to punitive damages in addition to actual damages from Defendants.

JURY TRIAL DEMAND

233. Plaintiff hereby requests a trial by jury.

RELIEF

WHEREFORE, Plaintiff respectfully prays that this Court grant the following relief:

1. Enter Judgment in favor of Plaintiff against each of Defendants awarding Plaintiff its actual damages for the damages caused by the opioid epidemic, including but not limited to: (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs for providing care for children whose parents suffer from opioid-related disability or

incapacitation; (5) costs associated with law enforcement and public safety relating to the opioid epidemic; and (6) costs associated with drug court and other resources expended through the judicial system.

2. Order that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

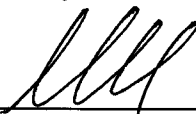
3. Order Defendants to fund an “abatement fund” for the purposes of abating the opioid nuisance;

4. Enter judgment against Defendants requiring Defendants to pay punitive damages;

5. Enter judgment against Defendants awarding Plaintiff its reasonable attorneys’ fees, all costs and expenses, pre-judgment and post-judgment interest; and,

6. All other such and further relief as this Court may deem just and proper.

Respectfully submitted,



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EXHIBIT 5

STATE OF SOUTH CAROLINA
COUNTY OF GREENVILLE

IN THE COURT OF COMMON PLEAS
THIRTEENTH JUDICIAL CIRCUIT

**IN RE: SOUTH CAROLINA OPIOID
LITIGATION**

This document relates to:

All cases.

Honorable Perry H. Gravely

C.A. 2018-CP-23-01294

**SECOND MASTER AMENDED
COMPLAINT**

COME NOW Plaintiffs in these consolidated actions, who collectively file this Second Master Amended Complaint and Jury Demand against Defendants. Plaintiffs in the above-captioned litigation, *In re: South Carolina Opioid Litigation*, bring and/or adopt this Second Master Amended Complaint, and complain and allege against Defendants as follows:

PRELIMINARY STATEMENT

1. Plaintiffs herein are local governmental entities in the State of South Carolina and are bringing actions seeking to abate the public nuisance caused by the opioid epidemic in their communities and to recoup damages they have suffered due to Defendants' false, deceptive, and/or unlawful marketing, distribution, and/or diversion of opioids. Plaintiffs allege that each of the named defendants have caused and/or contributed to the opioid epidemics in their communities.

2. The Defendants named herein are: Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Rhodes Technologies; Rhodes Technologies Inc.; Rhodes Pharmaceuticals L.P.; Rhodes Pharmaceuticals Inc.; P.F. Laboratories, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Depomed, Inc.; Endo Health Solutions, Inc.;

Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc.; Allergan plc f/k/a Actavis plc; Allergan Finance LLC f/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Insys Therapeutics, Inc.; Mallinckrodt plc; Mallinckrodt LLC; SpecGX LLC; Mylan Pharmaceuticals, Inc.; Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals, Inc.; Amneal Pharmaceuticals of New York, LLC; KVK-Tech, Inc.; Sandoz, Inc.; West-Ward Pharmaceutical Corp.; McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Drug Corporation; Smith Drug Company; Omnicare Distribution Center LLC; North Carolina Mutual Wholesale Drug Company Inc.; Miami-Luken; Rite Aid of South Carolina, Inc.; Walgreen Co.; Wal-Mart Stores East LP; Wal-Mart Stores, Inc.; CVS Pharmacy, Inc.; CVS Health Corporation; The Kroger Co.; Kroger Limited Partnership I; Kroger Limited Partnership II; Kroger Pharmacy; Leavis Sullivan; Leigh Varnadore; Paul Kitchin; Beth Taylor; Mark Waldrop; Michael Madden; Wendy Kay; Jeffrey Ward; Aathirayen Thiagarajah; Pain and Spine Consultants, PA.; Oaktree Medical Center, P.C.; Pain Management Associates of the Carolinas, LLC; Pain Management Associates of North Carolina, P.C.; Blake Leche; Amanda Leche; Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; Beverly Sackler; Theresa Sackler; David A. Sackler; Trust for the Benefit of Members of the Raymond Sackler Family; and Stuart D. Baker.

3. Pursuant to the Order of Chief Justice Beatty of the South Carolina Supreme Court dated August 9, 2018, and as amended on August 23, 2018 and August 29, 2018, all “opioid litigation currently pending and to be filed in the state court system” has been assigned to the Honorable Perry H. Gravely, who is “vested with exclusive jurisdiction to hear and dispose of all opioid litigation cases” and “to dispose of all pretrial matters arising out of the opioid litigation.”

The South Carolina coordinated opioid litigation is collectively referred to as the *In re: South Carolina Opioid Litigation* proceedings.

4. This Second Master Amended Complaint is intended to serve the administrative functions of efficiency and economy by presenting certain common claims and common questions of fact and law for consideration by this Court within the context of the *In re: South Carolina Opioid Litigation* proceedings. See Initial Status Conference Order, dated September 6, 2018.

5. This Second Master Amended Complaint is being filed in the Greenville County Court of Common Pleas under the case caption: *County of Greenville v. Rite Aid of South Carolina, Inc.*, C.A. No. 2018-CP-23-01294, which is serving as the court of original jurisdiction and the Master Docket for the filing of pleadings, motions, orders, and other documents common to South Carolina opioid coordinated proceedings under the style, *In re South Carolina Opioid Litigation*. This Second Master Amended Complaint shall be deemed part of the record with respect to each individual Plaintiff's case, which is subject to the consolidation orders of the South Carolina Supreme Court and is a part of the coordinated South Carolina opioid litigation.

6. Plaintiffs submit this Second Master Amended Complaint against Defendants. Plaintiffs make the allegations herein based on personal knowledge and on information and belief, as well as on investigative efforts regarding the opioid epidemic in Plaintiffs' communities and in South Carolina. Plaintiffs further make the allegations herein based on documents, summaries of documents, and filings appearing in the public record.

INTRODUCTION

7. The opioid crisis is one of the worst man-made epidemics in modern times.

8. In August 2016, the U.S. Surgeon General deemed the opioid epidemic “an urgent health crisis.” On October 2, 2017, the President declared the opioid epidemic a public health emergency.

9. From 1999 through 2016, opioid overdoses killed more than 350,000 Americans, and 200,000 of these deaths were from opioids prescribed by doctors to treat pain.

10. The number of opioid overdoses in the United States rose from 8,000 in 1999 to over 20,000 in 2009, and over 33,000 in 2015. In the twelve months that ended in September 2017, there were 45,000 deaths due to opioid overdoses.

11. The opioid crisis initially arose from the pharmaceutical manufacturers’ deliberate and deceptive marketing strategy to expand opioid use. Ultimately, the manufacturers, distributors, retail pharmacies, sales representatives, and dealers have responsibility for expanding the number of opioid users in South Carolina and failing to prevent diversion of prescription opioids.

12. The Manufacturer Defendants manufacture, market, and sell prescription opioid pain medications, including brand name drugs such as OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydane, Subsys, Wartemis XR, Exalgo, Nucynta/Nucynta ER, and Duragesic, and generic drugs such as oxycodone, hydrocodone, morphine, and codeine.

13. Prescription opioids are narcotics. They are derived from or possess properties similar to opium and heroin, and they are highly addictive and dangerous. They are, therefore, regulated as controlled substances at both the state and federal level.¹

¹ Opioids have been regulated since 1970 both nationally and in South Carolina under the federal Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* (the “FCSA”), and the South Carolina Controlled Poisons, Drugs, and Other Controlled Substances Act, S.C. Code Ann. §§ 44-53-10 *et seq.*

14. Most prescription opioids are categorized as Schedule II or Schedule III controlled substances. Schedule II drugs are considered to have “a high potential for abuse,” have “a currently accepted medical use,” and their “[a]buse may lead to severe psychological or physical dependence.” S.C. Code Ann. § 44-53-200. Schedule III drugs, which are considered to have less potential for abuse than Schedule II drugs, have “a currently accepted medical use,” and “[a]buse of the substance may lead to moderate or low physical dependence or high psychological dependence.” *Id.* § 44-53-220. Examples of Schedule II opioids include OxyContin, Hysingla ER, MS Contin, Dilaudid, Dilaudid HP, and Targiniq ER. Butrans is a Schedule III opioid.

15. Opioids can provide effective treatment for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care. Opioids are approved by the FDA for use in the management of moderate to severe pain, and their use is typically appropriate in the short-term.

16. Putting patients on opioids puts them at risk. Although opioids can dampen the perception of pain, they can also create an addictive, euphoric high. At higher doses, opioids can slow the user’s breathing and cause potentially fatal respiratory depression.

17. Most patients who receive more than a few weeks of opioid therapy will experience withdrawal symptoms such as severe anxiety, nausea, vomiting, headaches, tremors, delirium, blurry vision, rapid heartbeat, and pain if they discontinue or delay opioid use. Withdrawal can last so long and is so painful that it is difficult to stop taking opioids. Additionally, patients who use opioids continuously grow tolerant to their analgesic effects (relief of pain) and require progressively higher doses, thereby increasing the risks of withdrawal, addiction, and overdose.

18. Because of these dangers, the medical community traditionally used opioids sparingly and with caution, reserving them to treat severe short-term pain or for patients near the end of life. (For example, doctors prescribed opioids to treat acute pain for severe bodily trauma,

such as gunshot wounds and post-surgical pain, and to provide relief to cancer patients experiencing extreme levels of pain.) The market for prescription opioids was thus limited prior to the 1990s.

19. The tradition of limiting opioids to short-term treatment ended after Purdue introduced OxyContin in the mid-1990s and began marketing it and other opioids using deceptive claims.

20. OxyContin's sole active ingredient is oxycodone, a molecule nearly identical to heroin. Purdue later introduced another dangerous drug, Butrans, which releases opioids into the body from a skin patch. Purdue also later introduced Hysingla, which contains yet another opioid.

21. Almost all of Purdue's business has been in selling opioids. Purdue knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, knee pain, neck pain, migraines, and arthritis. (Unless otherwise indicated herein, "long-term" refers to a period of three months or longer.)

22. Purdue, joined by the other Manufacturer Defendants, began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions, despite knowing the dangers of opioids.

23. Purdue and the other Manufacturer Defendants cultivated a narrative that pain was being undertreated and that healthcare providers should make the treatment of pain a higher priority. Consistent with this narrative and as part of their marketing strategy, the Manufacturer Defendants promoted opioids as safe, effective, and appropriate for long-term use for routine pain conditions and misrepresented that the risk of addiction associated with opioid use was modest,

manageable, and outweighed by other benefits. This paved the way for increased prescribing of opioids for a larger number of pain conditions and expanded the market for prescription opioids.

24. From the time the Manufacturer Defendants began manufacturing opioids and throughout the time their opioids were marketed, prescribed, and used, Defendants knew that, barring exceptional circumstances, opioids are too addictive and too debilitating for long-term use for chronic, non-cancer pain lasting three months or longer. (As used herein, the term “chronic pain” refers to non-cancer pain lasting three months or longer.)

25. Defendants knew that, with prolonged use, the effectiveness of opioids wanes, requiring higher doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.

26. Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (i.e., not longer than three months) in managed settings such as hospitals where the risks of addiction and other adverse outcomes were significantly minimized.

27. To date, there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use. (Unless otherwise indicated herein, “long-term studies” refers to studies that include the period of 16 weeks or longer.)

28. Despite knowing the safety risks and lack of efficacy for long-term use, Defendants expanded the market for opioids in order to realize blockbuster profits. Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and for treatment of a wider range of problems. Defendants created that false perception through a coordinated, sophisticated, and highly deceptive marketing campaign that began in the late 1990s, became more aggressive in or around 2006, and continues to the present.

29. Defendants accomplished their marketing goals by peddling falsehoods to convince healthcare providers, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks and that most patients could safely use opioids.

30. Although Defendants knew that long-term opioid use causes addiction and presents serious risks, they individually and collectively misrepresented the dangers of long-term opioid use to physicians, pharmacists, patients, governmental entities, and others by engaging in a campaign to minimize the risks of and encourage long-term opioid use.

31. This campaign of misrepresentations began with the decision of Defendant Purdue Pharma, L.P. to promote opioids deceptively and illegally to significantly increase sales and generate billions of dollars in revenue for Purdue's private owners, the Sackler family. It was the Sackler family members who were the chief architects and beneficiaries of Purdue's deception.

32. The other Manufacturer Defendants followed Purdue's strategies, using misrepresentations regarding the risks and benefits of opioids to encourage widespread prescribing of opioids for common, chronic pain conditions.

33. The Manufacturer Defendants created a population of addicted patients, and their profits soared as more and more people became dependent on opioids.

34. On the supply side, the Distributor Defendants fueled the opioid crisis by failing to maintain effective controls over the distribution of prescription opioids. Defendants have contributed substantially to the opioid crisis by selling and distributing prescription opioids in quantities that vastly exceed amounts that they knew or should have known were appropriate for legitimate medical uses. Defendants failed to report and take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of opioid drugs and fueling an illegal secondary market.

35. The Retail Pharmacy Defendants were also responsible for the distribution of prescription opioids in South Carolina. The Retail Pharmacy Defendants were aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries, and, with this information, they continued to participate in and profit from the oversupply of opioids. These Defendants further ignored red flags and dispensed prescription opioids in the face of such flags when they knew or should have known that opioids were likely to be diverted.

36. Purdue and the other Manufacturer Defendants used sales representatives as a powerful tool of deception to promote opioids to South Carolina doctors, nurses, and pharmacists face-to-face. The named Sales Representative Defendants were responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in South Carolina, including to those who prescribed and/or consumed the drug across the State. During sales visits, the Sales Representative Defendants made false and misleading claims directly to the professionals who care for South Carolina patients and utilized deceptive sales tactics and marketing materials developed by Purdue. The Sales Representative Defendants promoted opioids to South Carolina doctors, nurses, and pharmacists while knowing that OxyContin was highly susceptible to addiction, misuse, abuse, and/or diversion, and knowing that the degree of risk bore a direct relationship to the amount and volume of opioids prescribed.

37. The Dealer Defendants facilitated the distributing and dispensing of opioids outside the usual course and scope of professional practice and not for a medical purpose. The Dealer Defendants caused and/or contributed to the illegal diversion of opioids for nonmedical purposes in South Carolina.

38. All Defendants could have and should have reported and stopped the illegal flow of prescription opioids into Plaintiffs' communities. Instead, Defendants intentionally, recklessly, and/or negligently failed to investigate, report, and halt suspicious orders. As a direct result of Defendants' misconduct, substantial and dangerous quantities of prescription opioids were overprescribed and illegally diverted to Plaintiffs' communities.

39. Defendants have been extremely successful in expanding opioid use in South Carolina and they have profited enormously from their wrongful conduct. The wrongful conduct complained of herein is responsible for increasing the number of opioid users and for causing the current epidemic of opioid addiction, injury, overdose, and death in Plaintiffs' communities.

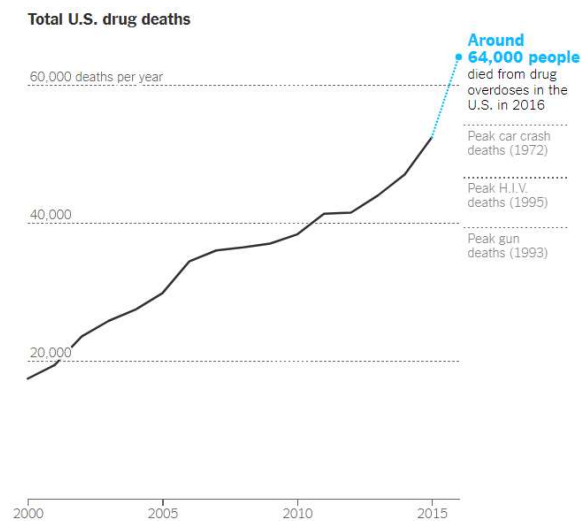
40. According to the Centers for Disease Control and Prevention ("CDC"), more than 115 Americans die every day from an opioid overdose, and, in 2017, more than 191 million opioid prescriptions were dispensed to Americans.

41. Nationwide, overdoses from prescription pain relievers have been a driving factor in the increase in opioid overdose deaths. From 1999 to 2016, more than 350,000 people died from an overdose involving any opioid, including prescription and illicit opioids. At least 197,000 of those deaths were from prescription opioids.

42. Opioid addiction and overdoses have reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."

43. Also, in 2016, approximately 64,000 people died from drug overdoses in the United States, which is 10,000 more than in 2015 and more than the peak yearly death tolls from car crashes, HIV deaths, or gun deaths. Sixty-six percent of the drug overdose deaths in 2016 involved opioids.

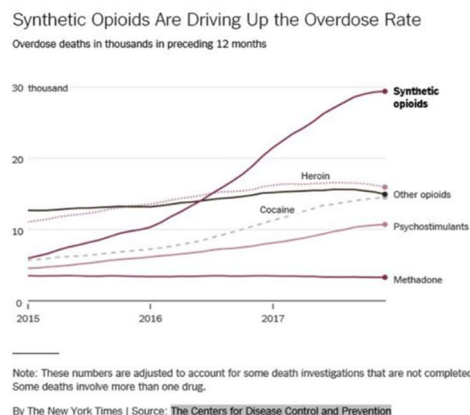
44. The below graph from *The New York Times* shows the trend relating to overdose deaths since 2000:



Available at: <https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html>

45. The number of overdose deaths in 2017 increased approximately 10% from 2016. In 2017, an estimated 72,000 Americans died from drug overdoses, a total which, again, is higher than the peak yearly death totals from HIV, car crashes, or gun deaths.

46. Strong synthetic opioids, particularly fentanyl, have contributed to the increasing overdose rate. The below graph from *The New York Times* shows the spike in synthetic opioid overdose deaths from 2015 to 2017:



Available at: <https://www.nytimes.com/2018/08/15/upshot/opioids-overdose-deaths-rising-fentanyl.html>

47. Defendants' campaign to increase opioid use has been extremely profitable to them. For example, in 2012 alone, opioids generated \$8 billion in revenue for drug companies. Of that amount, OxyContin sales generated \$3.1 billion in revenue for Purdue.

48. A recent study in JAMA Network Open reported that the pharmaceutical industry spent approximately \$40 million promoting opioid medications to nearly 68,000 doctors from 2013 to 2015, and for every three additional payments that companies made to doctors per 100,000 people in a county, prescription opioid overdose deaths in those counties a year later were 18 percent higher.²

49. Despite the increase in opioid use since 1999, there has been no overall change in the amount of pain that Americans report.

50. Within the State of South Carolina, opioid use and abuse has become widespread as a result of Defendants' wrongful conduct. For example, in 2016, 940 opioid prescriptions were dispensed for every 1,000 residents, and in 2017, 863 opioid prescriptions were dispensed per every 1,000 residents. South Carolina ranked ninth in the nation in opioid prescribing rates in 2016.

51. There are a significant number of South Carolinians who are addicted to opioids and have opioid use disorders. According to the South Carolina Department of Alcohol and Other Drug Abuse Services ("DAODAS"), 5,689 patients were diagnosed with an opioid use disorder in 2016 at public treatment provider locations. That number increased to 6,305 patients in 2017. Additionally, within the Medicaid population in South Carolina, 8,464 patients were identified

² Abby Goodnough, *Study Links Drug Maker Gifts for Opioids to More Overdose Deaths*, The New York Times (Jan. 20, 2019, <https://www.nytimes.com/2019/01/18/health/opioids-doctors-overdose-deaths.html>).

with an opioid use disorder in 2016 and 8,444 patients were identified with an opioid use disorder in 2017.

52. The number of overdose deaths involving opioids in South Carolina is increasing. In 2016, there were 876 total drug overdose deaths in South Carolina, and 616 of those deaths involved opioids. In 2017, the number of drug overdose deaths in South Carolina increased to 1,001, and 748 of those deaths involved opioids.

53. In the last five years, more than 3,000 South Carolinians died from prescription opioids. Heroin overdoses have also increased dramatically because individuals who cannot obtain prescription opioids turn to heroin. It is estimated that 80% of heroin users previously used prescription opioids. Another, more recent and deadly problem stemming from the prescription opioid epidemic involves fentanyl, a powerful opioid that is making its way into South Carolina communities through trafficking.

54. Addiction and misuse of opioids in South Carolina and in Plaintiffs' communities have resulted in increased emergency room visits, emergency responses, and administration of naloxone (or Narcan), the antidote to an opioid overdose. In South Carolina, naloxone was administered 4,610 times in 2015; that number increased to 6,427 in 2016.

55. Abuse of opioids has caused additional medical conditions that harm the residents of Plaintiffs' communities and necessitate care paid for by taxpayers. For example, the number of chronic Hepatitis C patients in South Carolina increased from 3,258 in 2011 to 4,668 in 2015. This increase is largely a result of intravenous drug use stemming from the opioid epidemic.

56. Abuse of opioids has also harmed infants and children in South Carolina and in Plaintiffs' communities. Neonatal abstinence syndrome ("NAS") is a condition where babies are born addicted to drugs because they were exposed to drugs in the womb before birth. NAS is most

often caused when a woman uses opioids during pregnancy. A baby born with NAS may experience withdrawal and other complications after birth. In 2016, the rate of newborns identified with NAS in South Carolina was 219 per 1,000 newborns. In 2017, the rate increased to 264 newborns identified with NAS per 1,000 newborns. The average hospital cost for a newborn with NAS is substantially higher than the average hospital cost for a healthy newborn.

57. Additionally, an increased number of children in South Carolina and in Plaintiffs' communities have parents or caregivers struggling with opioid addiction and, as a result, those children frequently end up in the foster care system and/or require the assistance and intervention of child welfare services.

58. The increase in the number of persons addicted to opioids has led to significantly increased costs and problems in Plaintiffs' communities, including, for example, increased healthcare costs, a dramatic increase in social problems, an increase in drug abuse and diversion, and an increase in criminal acts related to attempts to obtain opioids. These increases in costs and problems have occurred throughout the State of South Carolina and in Plaintiffs' communities, and Plaintiffs' resources have been diverted from other programs and uses in order to fight the opioid epidemic.

59. Additionally, opioid addiction and morbidity have negatively impacted productivity in the workforce across South Carolina and in Plaintiffs' communities and have resulted in an economic burden on Plaintiffs.

60. Public health and safety in the State of South Carolina and in Plaintiffs' communities has been negatively impacted due to Defendants' wrongful conduct complained of herein.

61. Defendants' wrongful conduct in creating, causing, and/or contributing to the opioid epidemic in each of Plaintiffs' communities has directly and foreseeably caused harm to Plaintiffs.

62. Plaintiffs have been required to spend millions of dollars to combat the public nuisance created by Defendants' wrongful conduct. Plaintiffs have incurred and continue to incur costs related to opioid addiction and abuse, including, but not limited to, healthcare costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations and omissions regarding the safety and efficacy of long-term opioid use and their violations of their legal duties have proximately caused injury to Plaintiffs.

63. The burdens imposed on Plaintiffs as a result of the opioid epidemics in their communities are not the normal or typical burdens of government programs and services. Instead, they are extraordinary costs and losses that are related directly to Defendants' illegal, intentional, reckless, and/or negligent wrongful conduct. Additionally, Defendants' conduct has created a public nuisance in each of Plaintiffs' communities.

JURISDICTION AND VENUE

64. This Court has subject matter jurisdiction pursuant to S.C. Const. art. V §11 and SC Code Ann. §§ 4-1-10; 4-9-25; and 14-1-80.

65. Additionally, this Court has jurisdiction over this consolidated action pursuant to the orders of Chief Justice Beatty of the South Carolina Supreme Court, dated August 9, 2018, and as amended on August 23, 2018 and August 29, 2018.

66. This Court has personal jurisdiction over all Defendants named herein, consistent with due process and the requirement of South Carolina's long-arm statute, S.C. Code Ann. § 36-2-803. Defendants, acting directly and/or through agents, manufactured, produced, distributed, and/or dispensed prescription opioids with the intention and reasonable expectation that those

drugs would be used and/or consumed in the State of South Carolina, and those drugs were so used and/or consumed.

67. Although these cases have been consolidated for purposes of pretrial matters and discovery, venue for trial is appropriate in each Plaintiff's county court.

68. None of the cases filed by Plaintiffs are removable to federal court because there is no basis for federal court jurisdiction. Diversity jurisdiction does not exist under 28 U.S.C. § 1332, nor is a federal question presented for purposes of 28 U.S.C. § 1331. Plaintiffs are not alleging any federal causes of action. *See Cty. of Greenville v. Rite Aid of S.C., Inc.*, C.A. No. 6:18-cv-01085-TMC, Doc. 66, at 13 (D.S.C. May 21, 2018) (remanding to the Court of Common Pleas of Greenville County, South Carolina); *Cty. of Spartanburg v. Rite Aid of S.C., Inc.*, C.A. No. 7:18-cv-01799-BHH, Doc. 32, at 15 (D.S.C. July 25, 2018) (remanding to the Court of Common Pleas of Spartanburg County, South Carolina); *Cty. of Anderson v. Rite Aid of S.C., Inc.*, C.A. No. 8:18-cv-01947-BHH, Doc. 44, at 21 (D.S.C. Aug. 20, 2018) (remanding to the Court of Common Pleas of Anderson County, South Carolina); *Cty. of Lexington v. Rite Aid of S.C., Inc.*, C.A. No. 3:18-cv-02357-BHH, Doc. 33, at 1 (D.S.C. Oct. 9, 2018) (remanding to the Court of Common Pleas of Lexington County, South Carolina).

PLAINTIFFS

69. Plaintiffs are counties and governmental entities in the State of South Carolina. Plaintiffs are body politics and possess broad home rule powers mandated by the South Carolina Constitution, including the power to bring suit and general police power. Plaintiffs are empowered to exercise their powers to preserve health, peace, and order for their citizens. S.C. Code Ann. § 4-9-25. Plaintiffs are collectively referred to herein as the "County Plaintiffs" or "Plaintiffs."

70. Plaintiffs have standing to bring these actions against Defendants to address the opioid epidemic in their communities and to protect and preserve the public health. Plaintiffs are

bringing suit to recover for infringement of their interests and because the opioid epidemic is a matter of overriding public concern for Plaintiffs. Plaintiffs further have standing to sue to abate the public nuisance and threat to the public health in their communities, which was created and/or exacerbated by the acts and/or omissions of the defendants.

71. While Defendants have profited from the alarming rate of opioids used in South Carolina, Plaintiffs' communities have suffered. Plaintiffs have been required to allocate substantial public monies and resources to combat the opioid crisis in their communities and to mitigate the repercussions of the opioid epidemic.

72. Plaintiffs have incurred and continue to incur substantial costs because of Defendants' conduct as described herein, including, but not limited to, costs of increased county services with respect to law enforcement, first responders such as emergency medical services, county health facilities (including hospitals and clinics), detention centers and jails, county courts, drug courts, diversion programs, prevention and treatment centers, community outreach programs, equipment and supplies, victim services support, inmate services (including housing, health, and support staff), and intervention programs, as well as general societal costs, public health cost, and lost productivity costs.

DEFENDANTS

1. Manufacturer Defendants

73. Defendant Purdue Pharma L.P. ("PPLP") is a limited partnership organized under the laws of the State of Delaware with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, in Stamford, Connecticut 06901.

74. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, in Stamford, Connecticut 06901.

75. Defendant The Purdue Frederick Company, Inc. (“PF Co.”) is a New York corporation with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, in Stamford, Connecticut 06901.

76. Defendant Rhodes Technologies (“Rhodes Tech”) is a Delaware general partnership formed on April 12, 2005 with its principal place of business in Coventry, Rhode Island. Rhodes Tech is an owner of the Improved API patents and is involved in the manufacture of the API used in the extended-release oxycodone pain medication sold under the brand name OxyContin.

77. Defendant Rhodes Technologies Inc. (“Rhodes Tech Inc.”) is a Delaware corporation formed January 29, 1999 with its principal place of business in Coventry, Rhode Island. Rhodes Tech Inc. is a general partner of Rhodes Tech.

78. Defendant Rhodes Pharmaceuticals L.P. (“Rhodes Pharma”) is a limited partnership organized under the laws of Delaware on November 9, 2007, with its principal place of business at 498 Washington Street, Coventry, Rhode Island 02816.

79. Defendant Rhodes Pharmaceuticals Inc. (“Rhodes Pharma Inc.”) is a New York corporation formed on November 9, 2007 with its principal place of business in Coventry, Rhode Island. Rhodes Pharma Inc. is a general partner of Rhodes Pharma.

80. Defendant The P.F. Laboratories, Inc. (“PF Labs”) is a New Jersey corporation with its principal place of business located in Totowa, New Jersey.

81. Defendants PPLP, PPI, PF Co., Rhodes Tech Rhodes Tech Inc., Rhodes Pharma, Rhodes Pharma Inc., and PF Labs are collectively referred to herein as “Purdue.” The Purdue Defendants acted collectively to carry out all of the misconduct alleged in this Complaint.

82. Purdue is engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in South Carolina. These opioids include OxyContin (oxycodone hydrochloride extended release), MS Contin (morphine sulfate extended release), Dilaudid (hydromorphone hydrochloride), Dilaudid-HP (hydromorphone hydrochloride), Butrans (buprenorphine), Hysingla ER (hydrocodone bitartrate), and Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride), all of which are Schedule II controlled substances except Butrans.

83. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing opioids. Purdue is subject to a Consent Judgment in South Carolina, dated May 15, 2007. Pursuant to the Consent Judgment, Purdue agreed to pay the United States \$635 million—at the time, one of the largest settlements with a drug company for marketing misconduct.

84. At the same time, Purdue executive officers Michael Friedman (the CEO), Howard Udell (Vice President and General Counsel), and Paul Goldenheim (Chief Medical Officer) pleaded guilty to criminal charges that they let Purdue deceive doctors and patients about its opioids. Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services, which required the company and its officers and directors, *inter alia*, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement.

85. None of this stopped Purdue. After 2007, even after being caught, Purdue continued to create the false perception that opioids were safe and effective for long term use by using unbranded marketing methods to circumvent the system. Purdue continued to engage in misleading marketing and continued to disseminate misrepresentations regarding prescription

opioids. Despite the criminal convictions, the fine, and the Corporate Integrity Agreement, Purdue continued to deceptively market and sell billions of dollars of opioids each year.

86. Purdue made thousands of payments to physicians nationwide, including in South Carolina, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance, and other services, which activities were not used to prevent diversion, but instead were used to deceptively promote and maximize the use of opioids.

87. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, a significant increase from 2006 sales of \$800 million. OxyContin sales constitutes roughly 30% of the entire market for analgesic drugs, or painkillers. OxyContin went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002.

88. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), which is an Israeli corporation with its U.S. headquarters located at 1090 Horsham Road, North Wales, Pennsylvania 19454.

89. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva Ltd. acquired Cephalon, Inc. in 2011.

90. Defendants Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute, and sell both brand name and generic versions of opioids nationally and in South Carolina. These opioids include Actiq (fentanyl citrate) and Fentora (fentanyl citrate tablet), which are both Schedule II drugs.

91. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in South Carolina, many of whom were not oncologists and did not treat cancer pain, ostensibly for activities including participating in speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, which activities were not used to prevent diversion, but instead were used to deceptively promote and maximize the use of opioids.

92. From 2005 to 2009, Teva USA was in the business of selling generic opioids, including a generic form of OxyContin, nationally and in South Carolina.

93. In 2008, Cephalon pleaded guilty to a criminal violation of the federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay a \$425 million fine.

94. Defendant Johnson & Johnson ("Johnson & Johnson" or "J&J") is a New Jersey corporation with its headquarters located at 1 Johnson & Johnson Plaza, New Brunswick New Jersey 08933.

95. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a New Jersey corporation with its headquarters at 1125 Bear Harbor Road, Titusville, New Jersey 08560. Janssen Pharmaceuticals is a wholly-owned subsidiary of J&J.

96. Janssen Pharmaceuticals was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

97. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho-McNeil-Janssen"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its headquarters at 1125 Bear Harbor Road, Titusville, New Jersey 08560.

98. Defendant Janssen Pharmaceutica, Inc. (“Janssen Pharmaceutica”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its headquarters at 1125 Bear Harbor Road, Titusville, New Jersey 08560.

99. Defendant Noramco, Inc. (“Noramco”) is a Delaware corporation headquartered in Wilmington, Delaware. Noramco was a wholly-owned subsidiary of Johnson & Johnson until July 2016 when it was sold. Noramco was responsible for processing and manufacturing the active ingredients in Johnson & Johnson’s opioid products and is a manufacturer of opioid products.

100. J&J is the only company that owns more than 10% of the stock in Janssen Pharmaceuticals. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs, J&J handles Janssen’s dealings with the FDA concerning Janssen’s drugs, and any profits of Janssen Pharmaceuticals inure to the benefit of J&J.

101. Defendants J&J, Janssen Pharmaceuticals, Ortho-McNeil-Janssen, Janssen Pharmaceutica, and Noramco (collectively, “Janssen”) are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in South Carolina. These opioids include Duragesic (fentanyl), Nucynta (tapentadol), and Nucynta ER (tapentadol extended release), all of which are Schedule II drugs.

102. Janssen made thousands of payments to physicians nationwide, including in South Carolina, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, which activities were not used to prevent diversion, but instead were used to deceptively promote and maximize the use of opioids.

103. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

104. Defendant Depomed, Inc. is a California corporation with its principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Depomed develops, markets and sells prescription drugs nationally and in South Carolina. Depomed acquired the rights to Nucynta and Nucynta ER for \$1.05 billion from Janssen pursuant to an Asset Purchase Agreement on January 15, 2015.

105. Defendant Endo Health Solutions Inc. is a Delaware corporation with its headquarters at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

106. Defendant Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Endo Health Solutions and is a Delaware corporation with its headquarters at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

107. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Defendant Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

108. Defendant Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York.

109. On information and belief, Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, “Par Pharmaceuticals”) were acquired by Endo Health Solutions Inc. in September 2015. Endo Health Solutions exercises control over the marketing and sales efforts of Par Pharmaceuticals and sales of Par Pharmaceutical products ultimately inure to its benefit.

110. Defendants Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceuticals, and their subsidiaries and affiliates (collectively, “Endo”) are and/or have been in the business of manufacturing, promoting, distributing, and selling both brand name and generic opioids nationally and in South Carolina. These opioids include branded opioids Opana ER (oxymorphone hydrochloride extended release), Opana (oxymorphone hydrochloride), Percodan (oxymorphone hydrochloride and aspirin), and Percocet (oxymorphone hydrochloride and acetaminophen), as well as generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

111. In 2012, opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion. From 2010 to 2013, Opana ER yielded revenue of \$1.15 billion and accounted for 10% of Endo’s total revenue in 2012.

112. Endo also manufactures and sells generic opioids, directly and through its subsidiary, Qualitest Pharmaceuticals, Inc. These generic opioids include generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

113. Defendant Allergan plc is a public limited liability company incorporated in Ireland with its principal place of business at Clonshaugh Business & Technology Park, Coolock, Dublin 17. Actavis plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc at that time.

114. Defendant Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. in January 2013. Actavis, Inc. is now known as Allergan Finance LLC.

115. Defendant Allergan Finance LLC is a Nevada corporation with its corporate headquarters located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

116. Defendant Watson Laboratories, Inc. is a Nevada corporation with its headquarters at 132 Business Center Drive, Corona, California; it is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.).

117. Defendant Actavis Pharma, Inc. f/k/a Actavis, Inc. is a Delaware corporation with its headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054; it was formerly known as Watson Pharma, Inc.

118. Defendant Actavis LLC is a Delaware limited liability company with its headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

119. Each of the defendants in ¶¶ 113–118 above is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, profits from the sale of Allergan and Actavis products, and ultimately benefits from them.

120. Defendants Allergan plc, Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are hereinafter collectively referred to as “Actavis.”

121. Actavis manufactures, promotes, distributes, and sells branded and generic opioids nationally and in South Carolina. These opioids include Kadian (morphine sulfate extended release) and Norco. Kadian is a Schedule II drug. Actavis also sells a generic version of Kadian, Duragesic, and Opana.

122. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

123. Defendant Insys Therapeutics, Inc. (“Insys”) is a Delaware corporation with its principal place of business in Chandler, Arizona.

124. Insys’s principal product and source of revenue is Subsys, a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under the tongue administration. Subsys is a Schedule II controlled substance, approved by the FDA solely for the treatment of breakthrough cancer pain. Insys has manufactured, promoted, distributed, and sold Subsys nationally and in South Carolina since 2012.

125. In its Form 10-K filing for 2015, Insys reported total revenues of \$331 million; of that amount, \$329.5 million was from sales of Subsys. Although Subsys was approved solely for treatment of breakthrough pain in cancer patients already receiving opioids for persistent cancer-related pain, Insys illegally and deceptively marketing Subsys for chronic pain conditions.

126. The founder and owner of Insys was recently arrested and charged (along with other Insys executives), with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. Other Insys executives and managers were previously indicted.

127. Defendant Mylan Pharmaceuticals Inc. (“Mylan”) is incorporated in West Virginia with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan is a wholly owned subsidiary of Mylan N.V., a Dutch corporation with its headquarters in Canonsburg, Pennsylvania. Mylan and Mylan N.V. are referred to collectively as “Mylan.”

128. Mylan manufactures generic versions of three of the top four most sold opioids in the United States: oxycodone, hydrocodone, and methadone. Mylan also manufactures fentanyl. As of 2015, Mylan's Fentanyl Trans Dermic System—which is a fentanyl skin patch and a generic product equivalent to the Johnson & Johnson product, Duragesic—was the number one selling fentanyl patch in the country.

129. Defendant Mallinckrodt, plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with U.S. headquarters in St. Louis, Missouri.

130. Defendant Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Since June 28, 2013, Mallinckrodt, LLC has been a wholly-owned subsidiary of Mallinckrodt, plc. Prior to that time, Mallinckrodt, LLC was a wholly-owned subsidiary of Covidien plc.

131. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri. SpecGX LLC is a wholly-owned subsidiary of Mallinckrodt, plc and currently manufactures and sells opioids which were previously manufactured by Mallinckrodt, LLC.

132. Defendants Mallinckrodt, plc, Mallinckrodt, LLC, and SpecGx LLC are referred to collectively herein as "Mallinckrodt."

133. Mallinckrodt is the largest supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States based on prescriptions. Mallinckrodt manufactures, markets, promotes, distributes, and sells prescription opioids, which include generic opioids and branded opioids.

134. Mallinckrodt manufactures, markets, promotes, distributes, and sells 4 branded opioids: Exalgo, is an extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths.

135. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals.

136. In addition, Mallinckrodt developed Methadose and developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued.

137. Mallinckrodt promoted its branded opioid products with its own direct sales force.

138. Mallinckrodt has been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

139. Mallinckrodt operates a vertically integrated business in the United States, importing raw opioid materials, manufacturing generic opioid products, and marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

140. Mallinckrodt manufactures opioids in the United States and promotes, distributes, and sells opioids nationally and in South Carolina. It is one of the largest U.S. suppliers of prescription opioid pain medications.

141. Mallinckrodt made thousands of payments to physicians nationwide, including in South Carolina, ostensibly for activities including participating on speaker bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, which activities were not used to prevent diversion, but instead were used to deceptively promote and maximize the use of opioids.

142. In 2017, Mallinckrodt paid a \$35 million fine to the Department of Justice for its failure to report suspicious orders of its opioids.

143. Defendant Amneal Pharmaceuticals LLC is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey.

144. Defendant Amneal Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in Bridgewater, New Jersey. On information and belief, Amneal Pharmaceuticals, Inc. was formed when Impax Laboratories, Inc. merged with and into Amneal Pharmaceuticals LLC in May 2018.

145. Defendant Amneal Pharmaceuticals of New York, LLC is a Delaware limited liability company with its principal place of business in Hauppauge, New York. On information and belief, Amneal Pharmaceuticals of New York, LLC is a subsidiary of Amneal Pharmaceuticals, Inc.

146. Defendants Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., and Amneal Pharmaceuticals of New York, LLC are referred to collectively herein as “Amneal.”

147. At all relevant times, Amneal is and/or has been in the business of manufacturing, promoting, distributing, and selling opioids nationally and in South Carolina, including, for example, oxycodone, oxymorphone, hydrocodone, tramadol, morphine, and codeine.

148. Defendant KVK-Tech, Inc. is a Pennsylvania corporation with its principal place of business in Newton, Pennsylvania. At all relevant times, KVK-Tech, Inc. is and/or has been in the business of manufacturing, promoting, distributing, and/or selling opioids nationally and in South Carolina, including, for example, oxymorphone and oxycodone.

149. Defendant Sandoz, Inc. is a corporation organized under the laws of the State of Colorado with its principal place of business in Princeton, New Jersey. At all relevant times, Sandoz, Inc. is and/or has been in the business of manufacturing, promoting, distributing, and/or selling branded and generic opioids nationally and in South Carolina.

150. Defendant West-Ward Pharmaceutical Corp. (“West-Ward”) is a corporation organized under the laws of the State of Delaware with its principal place of business in Eatontown, New Jersey. At all relevant times, West-War is and/or has been in the business of manufacturing, promoting, distributing, and/or selling branded and generic opioids nationally and in South Carolina.

151. The defendants listed in ¶¶ 73–150 above are at times referred to collectively herein as the “Manufacturer Defendants.”

2. Distributor Defendants

152. Defendant McKesson Corporation (“McKesson”) is a corporation organized and existing under laws of the State of Delaware. McKesson’s corporate headquarters and principal place of business is located at One Post Street, San Francisco, California 94104.

153. McKesson is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. McKesson distributes pharmaceuticals throughout the United States, including within South Carolina, through its network of distribution centers in various locations nationwide.

154. McKesson is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of \$191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including South Carolina.

155. In January 2017, McKesson paid a record \$150 million to resolve an investigation by the U.S. Department of Justice (“DOJ”) for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these “staged suspensions” as “among the most severe sanctions ever agreed to by a [DEA] registered distributor.”

156. Defendant Cardinal Health, Inc. (“Cardinal”) is an Ohio corporation with its headquarters at 7000 Cardinal Place, Dublin, Ohio 43017.

157. Cardinal distributes pharmaceuticals drugs, including opioids, throughout the United States, including within South Carolina.

158. Defendant AmerisourceBergen Drug Corporation (“AmerisourceBergen”) is a Delaware corporation with its headquarters at 1300 Morris Drive, Chesterbrook, Pennsylvania 19087.

159. AmerisourceBergen is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including within South Carolina. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of \$147 billion in 2016.

160. McKesson, Cardinal, and AmerisourceBergen have each been cited and fined by the DEA and/or the DOJ for failing to maintain effective controls against diversion. This unlawful conduct is a substantial cause of the volume of prescription opioids plaguing South Carolina and Plaintiffs’ communities.

161. Collectively, McKesson, Cardinal, and AmerisourceBergen are at times referred to as “the Big Three.”

162. Defendant Smith Drug Company (“Smith”) is a South Carolina corporation with its headquarters at 9098 Fairforest Road, Spartanburg, South Carolina 29301. Smith distributes wholesale pharmaceutical drugs, including opioids, throughout South Carolina and in Plaintiffs’ communities. Smith manages several large distribution centers in the United States and holds itself out as employing state-of-the-art technology in its distribution operations.

163. Smith distributed an excessive quantity of opioids to pharmacies in Plaintiffs’ communities and knew or should have known that such drugs were likely to be diverted.

164. Defendant Miami-Luken is an Ohio Corporation with its headquarters and principal place of business in Springboro, Ohio. At all relevant times, Miami-Luken distributed substantial amounts of prescription opioids throughout the United States, including in South Carolina and in Plaintiffs’ communities.

165. Defendant Omnicare Distribution Center LLC (“Omnicare”) is a Delaware limited liability company with its headquarters and principal place of business in Cincinnati, Ohio. At all relevant times, Omnicare distributed substantial amounts of prescription opioids throughout the United States, including in South Carolina and in Plaintiffs’ communities.

166. Defendant North Carolina Mutual Wholesale Drug Company Inc. (“NC Mutual”) is a North Carolina corporation. NC Mutual is registered to business in South Carolina. At all relevant times, NC Mutual distributed substantial amounts of prescription opioids in South Carolina and in Plaintiffs’ communities.

167. The defendants listed in ¶¶ 152–166 above are at times referred to collectively herein as the “Distributor Defendants.”

168. The Distributor Defendants failed to detect and report conduct by the Dealer Defendants and others, which caused and/or contributed to the opioid epidemic plaguing the County Plaintiffs.

169. The Distributor Defendants distributed, supplied, sold, and placed into the stream of commerce prescription opioids without fulfilling their fundamental duties under state and federal statutes and South Carolina common law to detect, report, and refuse to ship suspicious orders of opioids in order to prevent diversion of these drugs for non-medical purposes.

170. The Distributor Defendants' unlawful conduct is a substantial cause of the opioid epidemic in communities across the State of South Carolina.

3. *Retail Pharmacy Defendants*

171. Defendant Walgreens Boots Alliance d/b/a Walgreen Co ("Walgreens") supplies pharmaceutical drugs, including opioids, to Walgreens pharmacies in South Carolina and throughout the United States. Walgreens pharmacies dispense prescription opioids to users in South Carolina.

172. Walgreens is headquartered in Deerfield, Illinois and has distribution centers across the country. Walgreens distribution centers distribute medications, including opioids, to various states, including South Carolina.

173. Walgreens is registered to do business in South Carolina under the name Walgreen Pharmacy Services Midwest LLC and Walgreen Co.

174. Walgreens is the second largest pharmacy store chain in the United States, with annual revenue of more than \$188 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in 2017.

175. Walgreens distributes and dispenses prescription opioids within South Carolina and within Plaintiffs' communities.

176. Defendant CVS Pharmacy, Inc. was incorporated in Rhode Island, is registered to do business in South Carolina, and distributes opioids to consumers within South Carolina.

177. Defendant CVS Health Corporation is incorporated in Delaware and has its headquarters at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Health Corporation serves as the parent corporation for CVS Pharmacy, Inc., and these entities are collectively referred to herein as "CVS."

178. Defendant CVS supplies pharmaceutical drugs, including opioids, to CVS pharmacies in South Carolina and throughout the United States. CVS distributes and dispenses prescription opioids within South Carolina and within Plaintiffs' communities.

179. Defendant Rite Aid of South Carolina, Inc. ("Rite Aid") was incorporated in South Carolina, has various locations throughout the state, and is a subsidiary of Rite Aid Corporation.

180. Rite Aid distributes and dispenses prescription opioids within South Carolina and within Plaintiffs' communities.

181. Defendant Wal-Mart Stores East, LP was incorporated in Delaware, has its principal place of business in Bentonville, Arkansas, and does business as Wal-Mart Pharmacy Warehouse #46. Wal-Mart Stores East, LP is registered to do business in South Carolina.

182. Defendant Wal-Mart Stores, Inc. was incorporated in Delaware and has its headquarters at 702 SW 8th Street, Bentonville, Arkansas 72716. Wal-Mart Stores, Inc. is registered to do business in South Carolina.

183. Wal-Mart Stores, Inc. acts as the parent company of Wal-Mart Stores East, LP, and these entities are collectively referred to herein as "Wal-Mart."

184. Wal-Mart distributes and dispenses prescription opioids within South Carolina and within Plaintiffs' communities.

185. Defendant The Kroger Co. is an Ohio corporation with headquarters in Cincinnati, Ohio. On information and belief, Defendants Kroger Limited Partnership I, Kroger Limited Partnership II, and Kroger Pharmacy are affiliates and/or subsidiaries of The Kroger Co.

186. The Kroger Co., Kroger Limited Partnership I, Kroger Limited Partnership II, and Kroger Pharmacy are referred to collectively herein as "Kroger."

187. Kroger operates 2,268 pharmacies in the United States, including pharmacies in South Carolina. At all times relevant to this Complaint, Kroger, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids throughout the United States, including in South Carolina and in one or more of Plaintiffs' communities.

188. Walgreens, CVS, Rite Aid, Wal-Mart, and Kroger acted both as distributors and as retail pharmacies dispensing opioids. These defendants are at times referred to collectively herein as the "Retail Pharmacy Defendants."

189. The Retail Pharmacy Defendants failed to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiffs' communities, as well as those orders which the Retail Pharmacy Defendants knew or should have known were likely to be diverted into Plaintiffs' communities, which caused and/or contributed to the opioid epidemic plaguing the County Plaintiffs.

190. The Retail Pharmacy Defendants dispensed, sold, and/or placed into the stream of commerce prescription opioids without fulfilling their fundamental duties under state and federal statutes and South Carolina common law to monitor, detect, investigate, refuse to fill, and report

suspicious orders of opioids and their duty to prevent diversion of these dangerous drugs for non-medical purposes.

191. The Retail Pharmacy Defendants' unlawful conduct is a substantial cause of the opioid epidemic in communities across the State of South Carolina.

4. *Sales Representative Defendants*

192. Defendant LeAvis Sullivan is a citizen and resident of South Carolina. During the relevant time period, Defendant Sullivan was a District Manager for Defendant Purdue Pharma, L.P. in South Carolina.

193. Defendant Leigh Varnadore is a citizen and resident of South Carolina. During the relevant time period, Defendant Varnadore was a Sales Representative and served as a District Manager for Defendant Purdue Pharma, L.P. in South Carolina.

194. Defendant Paul Kitchin is a resident and citizen of South Carolina. During the relevant time period, Defendant Kitchin was a Sales Representative and served as a District Manager for Defendant Purdue Pharma, L.P. in South Carolina.

195. Defendant Beth Taylor is a citizen and resident of South Carolina. During the relevant time period, Defendant Taylor was a Sales Representative, Analgesia Specialist for the Southeast Region, and served as a District Field Sales Trainer for Defendant Purdue Pharma, L.P. in South Carolina.

196. Defendant Mark Waldrop is a citizen and resident of South Carolina. During the relevant time period, Defendant Waldrop was a Territory Business Manager for Defendant Purdue Pharma, L.P. in South Carolina.

197. Defendant Jeffrey Ward is a citizen and resident of South Carolina. During the relevant time period, Defendant Ward was a Sales Representative and/or Territory Business Manager for Defendant Purdue Pharma, L.P. in South Carolina.

198. Defendant Wendy Kay is a citizen and resident of South Carolina. During the relevant time period, Defendant Kay was a Sales Representative and/or Territory Business Manager for Defendant Purdue Pharma, L.P. in South Carolina.

199. Defendant Michael Madden is a citizen and resident of South Carolina. During the relevant time period, Defendant Madden was a Territory Business Manager for Defendant Purdue Pharma, L.P. in South Carolina.

200. The defendants listed in ¶¶ 192–199 above are at times referred to collectively herein as the “Sales Representative Defendants.”

201. The Sales Representative Defendants were responsible for the sale of opioid medications for Purdue across the entire State of South Carolina. They were also responsible for the training, management, and direction of any new members of Purdue’s sales force in South Carolina.

202. The unlawful conduct of the Sales Representatives is a substantial cause of the opioid epidemic in communities across the State of South Carolina.

5. Dealer Defendants

203. Defendant Aathirayen Thiagarajah (“Dr. Thiya”) is a citizen of South Carolina and is, ostensibly, a physician licensed to practice medicine in South Carolina. Dr. Thiya has his primary place of business in Greenville County, South Carolina, and he has distributed and dispensed opioids for illegitimate purposes.

204. On information and belief, Dr. Thiyaga's actions have led to opioids being sold illegally in South Carolina and have led to overdoses in South Carolina. Dr. Thiyaga contributed to the diversion of opioids across South Carolina and his actions have caused economic loss to the County Plaintiffs.

205. Defendant Pain and Spine Consultants, PA ("Pain and Spine Consultants") is a South Carolina legal entity that ostensibly operates as a medical provider in Greenville County and in Anderson County. This clinic defendant is owned, operated by, an employer of, and/or is affiliated with Dr. Thiyaga.

206. The acts and/or omissions of Pain and Spine Consultants contributed to the illegal diversion of opioids across South Carolina, and opioids distributed or dispensed by this clinic defendant resulted in overdoses and diversion of opioids within South Carolina, causing economic loss to the County Plaintiffs.

207. Defendant Oaktree Medical Center, P.C. ("Oaktree") is a professional corporation authorized and existing under the laws of the State of South Carolina with its principal place of business in Greenville, South Carolina. Oaktree consists of a group of pain management clinics located throughout South Carolina and employs a number of physicians, physician assistants, nurse practitioners, and others who staff the various clinics.

208. Defendant Pain Management Associates of the Carolinas, LLC ("PMA of the Carolinas") is a limited liability company authorized and existing under the laws of the State of South Carolina. Oaktree owns a majority share in PMA of the Carolinas.

209. Defendant Pain Management Associates of North Carolina, P.C. ("PMA of North Carolina") is a professional corporation authorized and existing under the laws of the State of

North Carolina. PMA of North Carolina operates clinics in North Carolina, and, at all times material to this Complaint, has conducted business with individuals and entities in South Carolina.

210. At all times relevant to this Complaint, numerous pain management clinics throughout the Carolinas collectively did business as Pain Management Associates. Defendants Oaktree, PMA of the Carolinas, and PMA of North Carolina are referred to collectively herein as “PMA.”

211. PMA has distributed and dispensed opioids for illegitimate purposes.

212. Defendant Blake Leche (“Dr. Leche”) is a citizen and resident of South Carolina and is, ostensibly, a physician licensed to practice medicine in South Carolina. At all times relevant to this Complaint, Dr. Leche was a physician at PMA at had his primary place of business in Spartanburg County, South Carolina. Dr. Leche has distributed and dispensed opioids for illegitimate purposes.

213. Defendant Amanda Leche (“Amanda Leche”) is a citizen and resident of South Carolina. At all times relevant to this Complaint, Amanda Leche worked as a physician assistant at PMA in Spartanburg County along with Dr. Leche. Amanda Leche has distributed and dispensed opioids for illegitimate purposes.

214. The acts and/or omissions of PMA, Dr. Leche, and Amanda Leche have led to opioids being sold illegally in South Carolina and have led to overdoses in South Carolina. These defendants contributed to the diversion of opioids across South Carolina and their actions have caused economic loss to the County Plaintiffs.

215. The defendants listed in ¶¶ 203–214 above are at times referred to herein as the “Dealer Defendants.”

216. The acts and/or omissions of the Dealer Defendants contributed to the illegal diversion of opioids across South Carolina, and opioids distributed and/or dispensed by these defendants resulted in overdoses and diversion of opioids within South Carolina, causing economic loss to the County Plaintiffs.

6. *Purdue-Related Additional Defendants*

217. At all relevant times, Purdue has been beneficially owned, managed, and controlled by the families of Mortimer Sackler and Raymond Sackler, both of whom are now deceased.

218. Defendant Richard S. Sackler is a natural person residing in Florida. He is a son of Raymond Sackler and, beginning in the 1990's, served as a member of the board of directors of Purdue and Purdue-related entities.

219. Defendant Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He is a son of Raymond Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

220. Defendant Mortimer D.A. Sackler is a natural person residing in New York County, New York. He is the son of Mortimer Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

221. Defendant Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

222. Defendant Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

223. Defendant Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Raymond Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

224. Defendant Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

225. Defendant David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler) and has served as a member of the board of directors of Purdue and Purdue-related entities since July 2012. When this Complaint refers to “the Sacklers” or “the Sackler family,” David Sackler is included only for events since July 2012.

226. Defendant Trust for the Benefit of Members of the Raymond Sackler Family (the “Raymond Sackler Trust”) is a trust of which Defendants Beverly Sackler, Richard S. Sackler, and/or Jonathan D. Sackler are trustees. It is the 50% direct or indirect beneficial owner of Purdue and the Purdue-related entities and the recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

227. Defendant Stuart D. Baker is a natural person residing in Suffolk County, New York. He has served as a senior executive of, and/or counsel to, Purdue, Purdue-related entities, and members of the Sackler families since the 1990s.

228. Defendants Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler, Raymond Sackler Trust, and Stuart D. Baker (collectively “Purdue-Related Additional Defendants”) each

knowingly directed, aided, abetted, participated in, and benefitted from the wrongdoing of Purdue alleged herein.

GENERAL FACTUAL ALLEGATIONS

A. THE PAIN-RELIEVING AND ADDICTIVE PROPERTIES OF OPIOIDS.

229. The pain-relieving properties of opium have been recognized for millennia. Likewise, the magnitude of opium's potential for abuse and addiction has been well-known for ages and has led to its strict regulation worldwide.

230. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was with a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

231. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, leaving many veterans with morphine addictions.

232. Pharmaceutical companies tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." As Heroin's addictive properties and nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914, and heroin was banned altogether a decade later.

233. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the

same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

234. Although known to relieve pain, up until the 1990s, opioids were rightly considered to be highly addictive and were typically used only sparingly and cautiously.

235. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration (“DEA”) since 1970.

236. Studies and articles from the 1970s and 1980s outlined a number of reasons to avoid opioids: scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids had a mixed record in actually reducing pain long-term and failed to improve patients’ functioning; most patients developed a tolerance to opioids; many patients on opioids experienced a diminished ability to perform basic tasks; side effects of opioids; and addiction. Leading authorities discouraged or even prohibited the use of opioid therapy for chronic pain.

237. In 1986, Russell Portenoy, MD published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”³ Dr. Portenoy later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for drug companies.

238. Later, in 1994, Dr. Portenoy wrote an article in which he described the prevailing attitudes regarding the dangers of long-term opioid use:

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction.

³ R.K. Portenoy & K.M Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25(2) Pain 171 (1986).

According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself return the patient to normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.⁴

According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”⁵

239. Because of all the problems and risks associated with long-term opioid use, and in the words of one researcher, “it did not enter [doctors’] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them.”⁶

240. Discontinuing opioids after more than just a few weeks will cause most patients to experience withdrawal symptoms, which include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms. These symptoms may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

241. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, patients typically required progressively higher

⁴ R. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

⁵ *Id.*

⁶ J. Loeser, *Five Crises in Pain Management*, Pain Clinical Updates, 2012;20 (1):1–4 (cited by I. Kissin, Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety? 6 J. Pain Research 513, 514 (2013)).

doses to obtain the same levels of pain reduction to which they have become accustomed, up to and including doses that are “frighteningly high.” At higher doses, the effects of withdrawal are more substantial, thus leaving patients at higher risks of addiction. Patients taking higher doses to match their tolerance are also at risk of overdosing.

242. The effects of prescription opioids vary by duration. Long-acting (or extended release) opioids—such as Purdue’s OxyContin and MS Contin, Janssen’s Nucynta ER and Duragesic, Endo’s Opana ER, and Actavis’s Kadian—are designed to be taken once or twice daily and purport to provide continuous opioid therapy for, generally, twelve hours at a time. Short-acting (or immediate release) opioids, such as Cephalon’s Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address “episodic pain” and provide fast-acting, supplemental pain relief for about four to six hours. Other short-term opioids, such as Insys’s Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer.

243. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic “breakthrough” pain.

244. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting prescription opioids, the FDA warned of the “grave risks” of opioids, including “addiction, overdose, and even death.” The FDA further warned that “[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death.” Because of these grave risks, the FDA stated that long-acting or extended release opioids “should only be used when alternative treatments are inadequate.” The FDA required that,

going forward, makers of long-acting prescription opioids clearly communicate those risks in their labels.

245. In 2016, the FDA also expanded the warnings for short-acting, immediate-release opioid medications, requiring changes similar to those it had required for long-acting opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products, including additional information regarding the risks of prescription opioids.

246. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants at all times material to this Complaint.

B. OPIOID THERAPY MAKES PATIENTS SICKER WITHOUT LONG-TERM BENEFITS.

247. There is no scientific evidence establishing opioids to be safe or effective for long-term use. Defendants are (and have been) well aware of the lack of such scientific evidence at all times material to this Complaint.

248. When promoting opioids to treat chronic pain, Defendants failed to disclose the lack of evidence to support long-term use and further failed to disclose the substantial scientific evidence demonstrating that chronic opioid therapy actually worsens patients' health.

249. There are no controlled studies of the use of opioids beyond sixteen weeks, and there is no evidence that opioids actually improve patients' pain and functioning on a long-term basis. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and the evidence did not allow judgments regarding long-term use.

250. Instead, there is evidence that opioids are ineffective to treat chronic pain and actually worsen patients' health. For example, a 2006 study-of-studies found that opioids as a

class did not demonstrate improvement in functional outcomes over other, non-addictive treatments.⁷

251. Increasing the duration of opioid use is strongly associated with an increase in mental health conditions (including depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater healthcare utilization.

252. Although opioids may work acceptably well to relieve pain during a limited, short period of time, long-term use results in marked declines in patients' abilities to function, their general health, their mental health, and their social functioning. Over time, even high doses of prescription opioids often fail to control pain and patients exposed to such doses are unable to function normally.

253. The foregoing is true both generally and for specific pain-related conditions. For example, studies of long-term opioid use for chronic lower back pain have failed to demonstrate an improvement in patients' functioning. Instead, research has consistently shown that long-term opioid therapy for patients with lower back injuries does not permit patients to return to work or physical activity. This failure is due, in part, to addiction and other side effects of prescription opioids.

254. Additionally, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches, yet patients on opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability

⁷ A. Furlan *et al.*, *Opioids for Chronic Noncancer pain: A Meta-analysis of Effectiveness and Side Effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. K. Seal, *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

Assessment, and had higher rates of depression than non-opioid users. A survey conducted by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches and reported a lower quality of life than patients on other, non-opioid therapies.

C. DEFENDANTS' SCHEME TO CHANGE PRESCRIBING HABITS AND PUBLIC PERCEPTION.

255. Prior to Defendants' marketing campaign and other wrongful conduct complained of herein, generally accepted standards of medical practice dictated that opioids should only be used on a short-term, temporary basis to treat acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those limited instances, the risks of addiction are considered low or of little significance.

256. By its very nature, the market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. Defendants recognized if they could sell their opioid products for both short-term pain relief and for the treatment of long-term chronic pain, they could achieve blockbuster sales and exponentially increase their profits.

257. Defendants also recognized that the increased risk of addiction associated with long-term use of their highly-addictive opioid products would virtually guarantee that their blockbuster profits would continue indefinitely.

258. Defendants knew that to increase their profits from the sale of opioids they would need to convince doctors and patients that long-term opioid therapy was safe and effective. To do so, Defendants would need to persuade physicians to abandon long-held apprehensions about prescribing opioids and instead prescribe opioids for durations previously understood to be unsafe.

259. Defendants enlisted consultants and public relations firms to help them develop and execute a common strategy to reverse the long-settled understanding of the relative risks and

benefits of chronic opioid therapy. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, Defendants instead distorted and perverted medical and public perception of scientific data.

260. Defendants collectively and individually poured vast sums of money into generating articles, continuing medical education sources (“CMEs”) and other “educational” materials, conducting sales visits to individual prescribers, and supporting a network of professional societies and advocacy groups, all of which was intended to, and which did, create a new but patently false “consensus” supporting long-term use of opioids.

261. The Manufacturer Defendants promoted and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The Manufacturer Defendants have access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths, all of which have made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses and death in alarming numbers.

D. DEFENDANTS USED UNBRANDED MARKETING TO PROMOTE THE WIDESPREAD USE OF PRESCRIPTION OPIOIDS.

262. Promotional activity of pharmaceutical companies can be branded or unbranded; the latter typically focuses on education regarding a particular disease state or treatment rather than promoting a specific drug product. By using unbranded marketing in their communications, drug companies can avoid the extensive regulatory framework governing branded communications.

263. A company’s branded marketing, which identifies and promotes a specific drug must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include any false or misleading statements or material omissions; and (c) fairly balance the drug’s benefits and risks. *See* 121 U.S.C. § 352(a); 21 C.F.R. § 202.1(e)(3); 21 C.F.R. § 1.21(a).

264. The regulatory framework that governs the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to know and understand the properties and effects of their products, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of those drugs.

265. Defendants generally avoided using branded advertisements to spread their deceptive messages and claims about opioids. Defendants intentionally avoided branded promotional materials for the express purpose of escaping regulatory review and oversight.

266. Instead, Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated and unbranded marketing materials. These materials promoted opioid use generally but did not name a specific opioid product when doing so. Through these unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.

267. Also, by acting through third parties, Defendants were able to give the false appearance that Defendants' messages reflected the views of independent third parties. Defendants would then cite to these sources as "independent" corroboration of their own statements.

268. And, as one physician adviser to Defendants noted, third-party documents not only appeared to have greater credibility, but they also had broader distribution. For example, doctors were less likely to "push back" at having such materials—for example, literature from the American Pain Foundation—on display in their offices than they would with literature that came directly from a drug company.

269. As part of their marketing scheme, Defendants spread and validated their deceptive messages through the following unbranded vehicles (the "Vehicles"):

- i. use of so-called “key opinion leaders” (“KOLs”), physicians who are able to influence their peers’ medical practice, including, but not limited to, prescribing behavior, and who wrote favorable journal articles and delivered pro-opioid CMEs;
- ii. a body of biased and unsupported scientific literature, ghostwritten by Manufacturer Defendants and published by KOLs;
- iii. treatment guidelines ghostwritten by Manufacturer Defendants and published as a direct result of KOLs’ reputations and relationships with publishing organizations;
- iv. pro-opioid CMEs delivered by KOLs, which were attended by South Carolina prescribers; and
- v. unbranded patient education materials.

270. Defendants disseminated and distributed many of their false, misleading, imbalanced and unsupported messages through the Vehicles because they appeared to uninformed observers to be independent. Through unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.

271. Some of Defendants’ false and misleading materials and messages were disseminated by Defendants directly, while others were disseminated by groups purporting to be patient advocacy groups and professional organizations (“Front Groups”). These Front Groups were deliberately influenced by Defendant-controlled KOLs, who exercised their influence directly and indirectly. These KOLs served in leadership roles in these Front Groups.

272. Even when unbranded materials and messages were disseminated through third-party Vehicles, including KOLs, Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials and messages. Defendants knew these materials and messages were false, misleading, unsubstantiated, unbalanced, and incomplete from the outset. Additionally, Defendants’ sales representatives distributed deceptive marketing materials to Defendants’ target audiences.

273. Defendants took an active role in writing, guiding, reviewing, and approving many of the misleading statements issued by third parties, including the KOLs' statements, thereby ensuring that Defendants had control over the content of such statements. By funding, directing, editing, and distributing these materials, Defendants exercised control over the deceptive messages and acted in concert with third parties to fraudulently and misleadingly promote opioids for treatment of chronic pain. The process described in this paragraph is also known as "ghostwriting."

274. The unbranded marketing materials that Defendants had a hand in creating and distributing did not disclose the risks of addiction, abuse, misuse, and overdose and/or affirmatively denied or minimized those risks. All of these unbranded marketing materials were falsely promoted by KOLs from the outset as independent statements. The KOLs' false promotion of independence provided credibility to Defendants' unbranded marketing materials, and Defendants were thereby able to fraudulently induce South Carolina prescribers and prescribers within Plaintiffs' communities to prescribe opioids for chronic pain.

275. Each Manufacturer Defendant's conduct, and each misrepresentation, contributed to an overall scheme to mislead doctors, patients, payors, and the public about the risks and benefits of opioids.

1. The Manufacturer Defendants' Misuse of Key Opinion Leaders

276. With the purpose of falsely promoting their opioids, the Manufacturer Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Manufacturer Defendants solely because they promoted the aggressive treatment of chronic pain with opioids in return for payment by the Manufacturer Defendants.

277. Pro-opioid KOLs have been at the hub of Defendants' promotional efforts, presenting a false and misleading appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid KOLs have written, consulted on, edited, and lent their names to books and articles, and they have given speeches and CMEs supportive of long-term opioid therapy for chronic pain.

278. Additionally, pro-opioid KOLs have served on committees that developed treatment guidelines that strongly encourage use of opioids to treat chronic pain. They have likewise served on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

279. Defendants were able to exert control over each of these modalities through the KOLs, who all accepted money from Defendants to promote their false and misleading messages about opioids.

280. In return for successful, pro-opioid advocacy, KOLs received money, prestige, recognition, research funding, and avenues to publish. The more successfully a KOL was in his or her promotion of opioids for chronic pain, the more he or she was rewarded by the Manufacturer Defendants.

281. Defendants cited and promoted the KOLs themselves and studies and articles written by KOLs to broaden the market for chronic opioid therapy. Defendants did not, however, support, acknowledge, or disseminate publications of truly independent doctors who criticized the use of chronic opioid therapy.

282. Defendants carefully vetted KOLs to ensure they would remain on-message and supportive of Defendants' pro-opioid agenda. Defendants also kept close tabs on the contents of

all material published by KOLs, and, in some instances, Defendants authored, edited, and/or revised such materials prior to publication.

283. In promoting opioids for treatment of chronic pain, the KOLs knew their statements were false and misleading, or they recklessly disregarded the truth in doing so. Nonetheless, the KOLs continued to publish their misstatements to benefit Defendants.

2. *Defendants' Corruption of Scientific Literature through KOLs*

284. Rather than actually test the safety and efficacy of opioids for long-term use, Defendants relied on KOLs to mislead healthcare providers, patients, and healthcare payors into believing that such tests had already been performed.

285. Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

286. To accomplish their goal, Defendants—sometimes through third-party consultants and/or front groups—commissioned, edited, and arranged for the placement of favorable articles authored by KOLs in academic journals.

287. Defendants' plans for these materials did not originate in the departments within their organizations that are responsible for research, development, or any other area that would have scientific knowledge about the drugs and their effects on patients. Instead, Defendants' plans originated in their marketing departments and with Defendants' marketing and public relations consultants. Such materials were then published and promoted by KOLs.

288. In these materials, Defendants and their KOL surrogates often claimed to rely on “data on file” or presented posters, which are not subject to peer review. Defendants presented such materials to the medical community as scientific articles or studies, notwithstanding the fact that Defendants’ materials were not based on reliable data and were not subject to the scrutiny of others who were experts in the field.

289. Defendants made sure that articles favorable to opioids were disseminated and cited widely in the medical literature and by KOLs, even when Defendants knew that the articles distorted the significance or meaning of the underlying data or conclusions.

290. Notably, Purdue and other Manufacturer Defendants frequently cited to a 1980 item published in the *New England Journal of Medicine* in a manner that made it appear that the item reported the result of a peer-reviewed study. This item was actually a letter-to-the-editor, known as the “Porter & Jick Letter,” not a study (much less a peer-reviewed study), in which the authors examined their files of hospitalized patients who had received opioids.

291. The entire Porter & Jick Letter, J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980), is reproduced below:

**ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS**

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.

2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

292. The Manufacturer Defendants misleadingly cited to the Porter & Jick Letter in literature and at CMEs in a manner that made it appear that the letter reported the results of a peer-reviewed study.

293. The Porter & Jick Letter had a number of serious limitations that Defendants and the KOLs acting on their behalf did not disclose when they cited to it in support of their pro-opioid message and as the sole scientific support for the proposition that opioids are rarely addictive.

294. For one, the patients referred to in the Porter & Jick Letter were treated prior to the letter's publication in 1980, and treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain. The data, therefore, was useless for any generalization regarding the safety or efficacy of opioids for treating chronic pain.

295. Additionally, the letter notes that, when the patients' records were reviewed, the authors found almost no references to signs of addiction. However, there is no indication that caregivers were even instructed to look for, assess, or document signs of addiction, nor is there

any indication of whether the patients were followed after they were discharged from the hospital and, if so, for how long.

296. Dr. Jick has complained that his letter has been distorted and misused, as indeed it has.

297. Nonetheless, Defendants repeatedly cited the letter in promotional and educational materials as “evidence” of the low risk of addiction, while failing to disclose that the source was a mere letter to the editor, not a peer-reviewed paper or study.

298. After Purdue introduced OxyContin, cites to the letter increased significantly. The Manufacturer Defendants used the letter to support their assertions that opioids were not addictive, even though Dr. Jick himself explained, “that’s not in any shape or form what we suggested in our letter.”

299. Other Defendants relied on and disseminated the same distorted message. The enormous impact of Defendants’ misleading amplification of the Porter & Jick Letter was well documented in another letter published in the *New England Journal of Medicine* on June 1, 2017, which described how the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” The authors of the 2017 letter to the editor explained:

The [opioid] crisis arose in part because physicians were told that the risk of addiction was low when opioids were prescribed for chronic pain. A one-paragraph letter that was published in the *Journal* in 1980 was widely invoked in support of this claim, even though no evidence was provided by the correspondents [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy⁸

⁸ Letter to the Editor from P.T.M. Leung, E.M. McDonald, I.A. Dhalla, and D.N. Juurlink, “A 1980 Letter on the Risk of Opioid Addiction,” *New England Journal of Medicine* (June 1, 2017), available at <https://www.nejm.org/doi/pdf/10.1056/NEJMc1700150> (internal footnote omitted).

300. “It’s difficult to overstate the role of this letter,” said Dr. David Juurlink of the University of Toronto, who led the 2017 analysis quoted above. “It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern.”

i. Dr. Portenoy

301. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for the drug companies, published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”

302. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.

(emphasis added). According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”

303. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Manufacturer Defendants, promoting the

use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”

304. As one organizer of CME seminars who worked with Dr. Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”

305. Dr. Portenoy was also a critical component of the Manufacturer Defendants’ control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the American Pain Foundation. He was also the President of the American Pain Society.

306. In recent years, some of the Manufacturer Defendants’ KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature. Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” He mused, “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did”

307. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Dr. Portenoy stated that his earlier work purposefully relied on evidence that was not “real” and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven,

maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*

308. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was even more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."

ii. **Dr. Webster**

309. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of the American Academy of Pain Medicine ("AAPM"), a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

310. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the*

Risk. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent “overuse of prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach doctors in Plaintiffs’ communities.

311. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Manufacturer Defendants’ promotional messages, Dr. Webster apparently believed the solution to patients’ tolerance or addictive behaviors was more opioids, and he prescribed staggering quantities of pills.

312. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Dr. Webster and others titled, “Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results.” The presentation’s agenda description states: “Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment.” The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the “[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP.” This CME effectively amounted to off-label promotion of Cephalon’s opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain.

313. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

iii. **Dr. Fine**

314. Dr. Perry G. Fine's ties to the Manufacturer Defendants have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he too has argued against legislation restricting high-dose opioid prescriptions for non-cancer patients.

315. Dr. Fine has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.

316. Multiple videos feature Dr. Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death of a drug overdose.

317. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah, telling the university that he had received under \$5,000 in 2010 from J&J for providing "educational" services. However, J&J's website states that the company paid him \$32,017 for consulting, promotional talks, meals, and travel that year.

318. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

At clinically appropriate doses . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for

acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.

319. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.” In that article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain.” The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”

320. The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” The article also concluded that the number of abuse-related events was “small.”

321. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic Opioid Therapy,” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but also for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain. He states the “goal is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance

of therapeutic good and adverse events *over the course of years.*” The entire program assumes that opioids are appropriate treatment over a “protracted period of time,” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”

iv. Dr. Fishman

322. Dr. Scott Fishman is a physician with prolific ties to the opioid drug industry. He has served as an APF board member and as president of the AAPM and has participated tirelessly in numerous annual CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Manufacturer Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled “Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion.”

323. In 2007, Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled “Responsible Opioid Prescribing,” which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

324. In 2012, Dr. Fishman updated the guide and continued to emphasize the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment purportedly created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription

opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.

325. The updated guide still assures that “[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins.”

326. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: “I believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a ‘chemical coper’ and an addict.” The guide also continues to present symptoms of addiction as symptoms of “pseudoaddiction.”

3. *Defendants’ Misuse of Continuing Medical Education (“CME”) Programs*

327. A Continuing Medical Education (“CME”) program is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year to maintain their licenses. These programs are delivered in person (often in connection with conferences held by professional organizations) and online, or through written publications.

328. Doctors rely on CMEs not only to satisfy licensing requirements, but also to obtain information on new developments in medicine and to deepen their knowledge in specific areas of practice.

329. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians’ medical expertise, they can be especially influential with doctors.

330. Once the Manufacturer Defendants had assembled a group of physician promoters and built a false body of “literature,” they needed to make sure their false marketing message was widely distributed. One way the Manufacturer Defendants did so was through CMEs.

331. The Manufacturer Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

332. For example, Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC (“Medscape”) and which disseminated false and misleading information to physicians across the country.

333. One Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who “previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis.” He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using “targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway.” The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

334. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or

noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain.

335. *Responsible Opioid Prescribing* was a CME publication sponsored by Purdue, Endo and Teva. The Federation of State Medical Boards (“FSMB”) website described it as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Fishman.

336. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

337. The American Medical Association (“AMA”) has recognized the impropriety that pharmaceutical company-funded CMEs creates, stating that support from drug companies with a financial interest in the content being promoted “creates conditions in which external interests could influence the availability and/or content” of the programs and urging that, “[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter.”

338. Purdue sponsored a 2011 CME program titled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. The presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.”

339. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks and Improving Outcomes*. The presentation deceptively instructed prescribers that, through the use of screening tools, more frequent refills,

and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

340. In 2009, Endo sponsored a National Initiative on Pain Control (“NIPC”) CME Program titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted the concept of pseudoaddiction and listed “[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction” as an element to be considered in awarding grants to CME providers.

341. Endo also sponsored, through NIPC, a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

342. South Carolina physicians attended and/or reviewed CMEs sponsored by the Manufacturer Defendants during the relevant time period and were misled by them.

343. By sponsoring CME programs put on by Front Groups such as APF, AAPM, and others, the Manufacturer Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Manufacturer Defendants for funding and other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Manufacturer Defendant-driven content in these CMEs had a direct and immediate effect on prescribers’ views on opioids. Producers of CMEs and the Manufacturer Defendants measured the effects of CMEs on prescribers’ views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

4. *Defendants’ Misuse of Treatment Guidelines*

344. Treatment guidelines authored with KOLs' influence but under the direction and control of the Manufacturer Defendants have been particularly important in securing acceptance for chronic opioid therapy. The guidelines are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are generally not experts and who generally have no special training in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

i. FSMB

345. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

346. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 edition of the guidelines, *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (the "1998 Guidelines"), was produced "in collaboration with pharmaceutical companies" and taught that opioids were "essential" for the treatment of chronic pain, including as a first prescription option, rather than that opioids could be appropriate in limited cases after other treatments had failed.

347. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted

online and were available to and intended to reach physicians nationwide, including physicians in South Carolina and in Plaintiffs' communities.

348. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers and was supported by the FSMB. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications."

349. Cephalon was one of the Manufacturer Defendants that sponsored *Responsible Opioid Prescribing*, and Cephalon distributed the publication through its sales representatives. KOL Dr. Fishman drafted *Responsible Opioid Prescribing*, which was a signature piece of his work. Dr. Fishman was frequently hired by a consulting firm, Conrad & Associates LLC, to write pro-opioid pieces disguised as science, and his work was reviewed and approved by drug company representatives. As such, he felt compelled to draft pieces that he has since admitted distorted the risks and benefits of opioid therapy in order to meet the demands of his drug company sponsors.

350. *Responsible Opioid Prescribing* was no exception, and it contained a number of deceptive statements regarding opioids. For example, the publication claimed that, because pain had a negative impact on a patient's ability to function, relieving pain by itself would "reverse that effect and improve function." In fact, the truth is far more complicated. Functional improvements made from increased pain relief can be offset by a number of other problems, including, for example, addiction.

351. Defendants relied on the FSMB's 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were

documented. The FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

ii. AAPM/APS Guidelines

352. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies that received substantial funding from Defendants from 2009 to 2013.

353. In 1997, the AAPM issued a "consensus" statement that endorsed the use of opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.⁹ The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was a KOL, Dr. Russel Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

354. The AAPM and the APS issued their own guidelines in 2009 (the "2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Fine, received support from Manufacturer Defendants Janssen, Cephalon, and Purdue.

355. The 2009 Guidelines promoted opioids as "safe and effective" for treating chronic pain and concluded that the risk of addiction is manageable for patients, regardless of past abuse histories. These Guidelines were a particularly effective channel of deception and have influenced treating physicians and the body of scientific literature with respect to opioids. They were

⁹ Haddox J., et al., The Use of Opioids for the Treatment of Chronic Pain – A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society, 6(1) Pain Forum 77–79 (1997).

reprinted in the *Journal of Pain*, have been cited hundreds of time in academic literature, were available on line, and were disseminated in Plaintiffs' communities during the relevant time period.

356. Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support the conclusions set forth therein.

iii. Guidelines that did not receive Defendants' support

357. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines authored by those who did not accept drug company funding reached very different conclusions.

358. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, which were issued by the American Society of Interventional Pain Physicians ("ASIPP") warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it."¹⁰

359. ASIPPs' Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain."¹¹

360. ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain," and only when coupled with "continuous adherence

¹⁰ Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

¹¹ *Id.*

monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects.”¹²

361. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Educational Medicine, recommend against the “routine use of opioids in the management of patients with chronic pain,” finding “at least moderate evidence that harms and costs exceed benefits based on limited evidence.”¹³

362. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, which were issued by the U.S. Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) in 2010, likewise note that their review revealed a lack of solid, evidence-based research on the efficacy of long-term opioid therapy.¹⁴

5. ***Defendants’ Misuse of Patient Education Materials and Front Groups***

363. The Manufacturer Defendants’ false marketing campaign targeted not only the medical community, but also specifically targeted patients who experienced chronic pain.

364. Patient advocacy groups and professional associations, or “Front Groups,” became vehicles to reach prescribers, patients and policymakers.

365. According to pharmaceutical industry marketing experts, patient-focused advertising (including direct-to-consumer marketing) is particularly valuable in “increase[ing] market share . . . by bringing awareness to a particular disease that the drug treats.”¹⁵

¹² *Id.*

¹³ *American College of Occupational and Environmental Medicine’s Guidelines for the Chronic Use of Opioids* (2011).

¹⁴ Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_fulltext.pdf (accessed September 19, 2017).

¹⁵ Kanika Johar, *An Insider’s Perspective: Defense of the Pharmaceutical Industry’s Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

366. Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to patient requests holds true even for opioids and for conditions for which they are not approved.¹⁶

367. Recognizing this phenomenon, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient "education" about opioid treatment for chronic pain.

368. The Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and (through the Front Groups) with each other to deceptively promote the use of opioids for the treatment of chronic pain.

i. American Pain Foundation

369. The most prominent of the Front Groups was the American Pain Foundation ("APF"). While the APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical device industry, including from Manufacturer Defendants Purdue, Endo, Janssen, and Cephalon. From 2007 until it closed its doors in May 2012, the APF received more than \$10 million in funding from opioid manufacturers, and, by 2011, the APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was the APF's largest donor; it provided more than half of its \$10 million in funding from 2007 to 2012.

¹⁶ Prescribers often acquiesce to patient requests. According to one study, nearly 20% of sciatica patients requesting oxycodone would receive a prescription for it, compared with 1% making no request, and more than half of patients requesting a strong opioid received one. J.B. McKinlay et al., Effects of Patient Medication Requests on Physician Prescribing Behavior, 52(2) Med. Care 294 (2014).

370. The APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain* and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contained multiple misrepresentations regarding opioid use.

371. The APF also developed the National Initiative on Pain Control (“NIPC”), which ran a facially unaffiliated website, *www.painknowledge.com*. The NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. The NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of “dinner dialogues.” But, Endo substantially controlled the NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo’s control of the NIPC was such that Endo listed it as one of its “professional education initiative[s]” in a plan Endo submitted to the FDA. Yet, Endo’s involvement in the NIPC was nowhere disclosed on the website pages describing the NIPC or at *www.painknowledge.org*. Endo estimated it would reach 60,000 prescribers through the NIPC.

372. The APF was often called on to provide “patient representatives” for the Manufacturer Defendants’ promotional activities, including for Purdue’s “Partners Against Pain” and Janssen’s “Let’s Talk Pain.” Although the APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. As Purdue told the APF in 2001, the basis of a grant to the organization was Purdue’s desire to strategically align its investments in nonprofit organizations that share its business interests.

373. In practice, the APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

374. This alignment of interests was expressed most forcefully in the fact that Purdue hired the APF to provide consulting services on its marketing initiatives. Purdue and the APF entered into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control the APF’s work related to a specific promotional project. Moreover, based on the assignment of particular Purdue “contacts” for each project and the APF’s periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations the APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not the APF—the right to end the project (and, thus, the APF’s funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates the APF’s lack of independence and willingness to harness itself to Purdue’s control and commercial interests, which would have carried across all of the APF’s work.

375. The APF’s Board of Directors was largely comprised of doctors who were on the Manufacturer Defendants’ payrolls, either as consultants or speakers at medical events. The close relationship between the APF and the Manufacturer Defendants demonstrates the APF’s clear lack of independence in its finances, management, and mission. Its willingness to allow the Manufacturer Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications, even when Defendants’ messages contradicted the APF’s internal conclusions.

376. For example, a roundtable convened by the APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. The APF's formal summary of the meeting notes concluded that: "[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence."

377. In May 2012, the U.S. Senate Finance Committee began looking into the APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, the APF's board voted to dissolve the organization "due to irreparable economic circumstances." The APF then "cease[d] to exist, effective immediately." Without support from the Manufacturer Defendants, to whom the APF could no longer be helpful, the APF was no longer financially viable.

ii. **American Academy of Pain Medicine and the American Pain Society**

378. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, the AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The Chair of the committee that issued the statement, Dr. Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

379. The AAPM's corporate council includes Purdue, Depomed, Teva, and other pharmaceutical companies. The AAPM's past presidents include Dr. Haddox (1998), Dr. Fishman (2005), Dr. Fine (2011), and Dr. Webster (2013), who all had well-documented connections to the opioid manufacturers.

380. Dr. Fishman, who also served as a KOL for Manufacturer Defendants, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”

381. The AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. The AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with the AAPM’s marquee event—its annual meeting held in Palm Springs, California, or other resort locations.

382. The AAPM describes the annual event as an “exclusive venue” for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by the AAPM heavily emphasized CME sessions on opioids (37 out of roughly 40 at one conference alone).

383. AAPM staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence the AAPM both through their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

384. The AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”). The AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Manufacturer Defendants Janssen, Cephalon,

Endo, and Purdue. Of these individuals, six received support from Purdue, eight received support from Teva, nine received support from Janssen, and nine received support from Endo.

385. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

386. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

387. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced treating physicians and the scientific literature on opioids. They were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were available online.

388. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Manufacturer Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."

389. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have little or no specific training in treating chronic pain.

390. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support the conclusions therein, their involvement in the development of the Guidelines, or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

iii. Federation of State Medical Boards

391. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

392. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

393. As set forth above, the FSMB developed treatment guidelines and publications recommending the use of opioids for the treatment of pain. These guidelines and publications, which were sponsored and backed by Defendants, conveyed Defendants’ false and misleading messages about opioids and were widely distributed.

iv. The Alliance for Patient Access

394. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care.” The APA is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006. As of June 2017, the APA listed 30 “Associate Members and Financial Supporters.” The

list includes J&J (parent of Janssen), Endo, Mallinckrodt, Purdue, and Cephalon. References herein to the APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

395. APA board members have directly received substantial funding from pharmaceutical companies.

396. For instance, APA board vice president Dr. Srinivas Nalamachu, who practices in Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from defendants Endo, Insys, Purdue, and Cephalon. Dr. Nalamachu’s clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.

397. Other board members include Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies, including payments by Defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including Defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including Defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

398. The APA issued a “white paper” titled “Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.” Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

. . . .

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.

399. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements [I]t is not even certain that the regulations are helping prevent abuses.

400. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications.

401. In conclusion, the APA white paper states that “[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”

402. The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients’ access to Medicare and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA’s agenda.

403. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the “suspicious orders” provision of the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* (“FCSA” or “federal Controlled Substances Act”). The AAPM is also a signatory to this letter. An internal U.S. Department of Justice (“DOJ”) memo stated that the proposed bill ““could actually result in increased diversion, abuse, and public health and safety consequences”” and, according to DEA chief administrative law judge John J. Mulrooney, the law would make it “all but logically impossible” to prosecute manufacturers and distributors, like the defendants here, in the federal courts. The law passed both houses of Congress and was signed into law in 2016.

v. The U.S. Pain Foundation

404. The U.S. Pain Foundation (“USPF”) was another Front Group with systematic connections and interpersonal relationships with the Manufacturer Defendants. The USPF was

one of the largest recipients of contributions from the Manufacturer Defendants, collecting nearly \$3 million in payments between 2012 and 2015 alone.

405. The USPF was also a critical component of the Manufacturer Defendants' lobbying efforts to reduce the limits on over-prescription.

406. The USPF advertises its ties to the Manufacturer Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e., Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members. Industry Front Groups such as the American Academy of Pain Management, the AAPM, the APS, and PhRMA are also members of varying levels in the USPF.

vi. American Geriatrics Society

407. The American Geriatrics Society ("AGS") was another Front Group with systematic connections and interpersonal relationships with the Manufacturer Defendants. The AGS was a large recipient of contributions from the Manufacturer Defendants, including Endo, Purdue and Janssen.

408. The AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons, hereinafter "2002 AGS Guidelines") and 2009 (Pharmacological Management of Persistent Pain in Older Persons, hereinafter the "2009 AGS Guidelines").

409. According to news reports, the AGS has received at least \$344,000 in funding from opioid manufacturers since 2009. The AGS's complicity in the common purpose with the Manufacturer Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

410. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. These Guidelines further recommended that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

411. Representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts, and publications for the AGS to pursue. The AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

412. Members of the AGS Board of Directors were doctors who were on the Manufacturer Defendants’ payrolls, either as consultants or speakers at medical events. Many of the KOLs also served in leadership positions within the AGS.

E. DEFENDANTS PROMOTED MULTIPLE FALSEHOODS AND MISREPRESENTATIONS ABOUT OPIOIDS.

413. Defendants—through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects—caused deceptive materials, information, and statements to be placed into the marketplace and disseminated to the public, including to prescribers, patients, payors, and the general public in South Carolina and in Plaintiffs’ communities. Defendants’ promotional messages were intended

to and did encourage patients to request, doctors to prescribe, and payors to pay for chronic opioid therapy.

414. Defendants' false statements and misrepresentations about the use of opioids fall into seven general categories: (1) misrepresentations about use of opioids and the risk of addiction; (2) misrepresentations that use of opioids improves patient functioning and quality of life; (3) misrepresentations that addiction risk can be effectively managed; (4) use of the term "pseudoaddiction"; (5) false claims that withdrawal can be simply managed; (6) misrepresentations that higher doses of opioids do not pose any significant additional risks; and (7) omissions regarding the adverse risks of opioids and overstatements regarding the risks of alternative forms of pain treatment.

1. Falsehood #1. Defendants, acting individually and collectively, misrepresented the truth about how use of opioids leads to addiction.

415. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. Through their well-funded, comprehensive, and aggressive marketing efforts, Defendants succeeded in changing the perceptions of many physicians, patients, and healthcare payors and persuaded them that opioid addiction rates are low and that addiction is unlikely to develop when a patient is prescribed opioids.

416. Each of the Manufacturer Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of the Manufacturer Defendants have acknowledged, retracted, or corrected their false statements.

417. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, even at the recommended dose, and the risk of addiction increases substantially with more than three months

of use. As the 2016 CDC Guideline states, “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder.”¹⁷ (Opioid use disorder is a diagnostic term for addiction.)

418. Additionally, after it became apparent that there was an opioid epidemic, the Manufacturer Defendants attempted to shift the blame by pointing the finger at addicts and “bad” patients. The suggestion that the opioid epidemic is primarily the result of “bad” patients who manipulated doctors to illicitly obtain opioids is consistent with the Manufacturer Defendants’ marketing scheme, but such a conclusion is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they represent a small minority. Patients who “doctor-shop” (i.e., visit multiple prescribers to obtain opioid prescriptions) are responsible for roughly 2% of the opioid prescriptions. Instead, the epidemic of opioid addiction and abuse is overwhelmingly a problem of false and misleading marketing and irresponsible distribution and supply.

i. Purdue’s misrepresentations regarding addiction risk

419. When Purdue launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use in order to expand opioid use and achieve the level of sales of OxyContin that it wanted to achieve. Purdue needed research to back up its messaging, but Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (“NEJM”) in 1980, the Porter & Jick Letter.

420. From 2008 to 2015, Purdue maintained a website, *In the Face of Pain* (www.inthefaceofpain.com), which was deactivated in October 2015 following an investigation

¹⁷ Centers for Disease Control and Prevention (“CDC”) 2016 *Guideline for Prescribing Opioids for Chronic Pain* (“CDC Guideline”) at 2, 21.

by the New York Attorney General. This website downplayed the risks of chronic opioid therapy.¹⁸ As an unbranded pain management advocacy website, the site failed to disclose any connections with Purdue, making it appear neutral. But, from 2008 to 2013, Purdue made payments totaling almost \$231,000 for speaker programs, advisory meetings, and travel costs to eleven “Advocates” whose faces and testimonials appeared on the website.

421. At a hearing before the House of Representatives’ Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized “legitimate” treatment, dismissing cases of overdose and death as something that would not befall “legitimate” patients: “Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional.”¹⁹

422. Purdue spun this baseless “legitimate use” distinction out even further in a patient brochure about OxyContin, called “A Guide to Your New Pain Medicine and How to Become a Partner Against Pain.” In response to the question “Aren’t opioid pain medications like OxyContin Tablets ‘addicting’?,” Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes:

Drug addiction means using a drug to get “high” rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.²⁰

¹⁸ Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.* Assurance No.: 15-151 (August 19, 2015). <http://www.ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf> (Accessed January 17, 2019).

¹⁹ OxyContin: Its Use and Abuse, Hearing before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce House of Representatives, August 28, 2001. <https://www.govinfo.gov/content/pkg/CHRG-107hhrg75754/pdf/CHRG-107hhrg75754.pdf> (last accessed January 17, 2019).

²⁰ *Id.*

423. In a pamphlet for doctors, *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substance Prescribing Practices*, Purdue wrote that addiction “is not caused by drugs.” Instead, Purdue assured doctors that addiction happens when the wrong patients get drugs and abuse them, stating that “it is triggered in a susceptible individual by exposure to drugs, most commonly through abuse.”

424. Another Purdue publication, the *Resource Guide for People with Pain*, falsely assured patients and doctors that opioid medications are not addictive:

Many people living with pain and even some healthcare providers believe that opioid medications are addictive. The truth is that when properly prescribed by a healthcare professional and taken as directed, these medications give relief – not a “high.”

Purdue falsely denied the risk of addiction, falsely implied that addiction requires patients to get “high,” and falsely promised that patients would not become addicted if they took opioids as prescribed.

425. Purdue funded and distributed many more publications that were similarly misleading. *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, a publication targeting veterans, misleadingly claimed: “Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medication.”

426. The Purdue publication, *Responsible Opioid Prescribing*, also told doctors that only “a small minority of people seeking treatment may not be reliable or trustworthy” and not suitable for addictive opioid drugs.

427. Purdue sales representatives marketed OxyContin as a product “to start with and to stay with.” The sales representatives also received training in overcoming doctors’ concerns about addiction by using talking points about the drug’s abuse potential, which they knew to be untrue.

One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!" According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."²¹

428. Through its unbranded website, *Partners Against Pain*, Purdue stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids." The website also stated that "[a]ddiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain."

429. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive." May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients and to represent that "legitimate" patients would not become addicted.

430. In addition, Purdue sales representatives were trained to say that the twelve-hour dosing made extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.²²

431. Over and over, Purdue pushed the myth that addiction is a character flaw and that "trustworthy" patients do not get addicted to drugs. Purdue knew better. Blaming victims for

²¹ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (Rodale 2003) at 102.

²² David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), *The New Yorker* (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-newyorker-radio-hour/how-oxycontin-was-sold-to-the-masses>. (last accessed January 17, 2019).

being “untrustworthy” was another way to lie about the dangerous and highly addictive properties of Purdue’s opioid drugs.

432. Upon information and belief, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

ii. Endo’s misrepresentations regarding addiction risk

433. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

434. For example, until April 2012, Endo’s website for Opana, *www.opana.com*, stated that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”

435. Endo also worked closely with the American Pain Foundation (“APF”), a Front Group, provided substantial assistance to the APF, and exercised editorial control over the deceptive and misleading messages that the APF conveyed through its National Initiative on Pain Control (“NIPC”) and through its website, *painknowledge.com*, which claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”

436. Endo was one of the APF’s biggest financial supporters, providing more than half of the \$10 million the APF received from opioid manufacturers during its lifespan. Additionally, Endo was the sole funder of the NIPC and selected the APF to manage the NIPC. Endo was responsible for NIPC curriculum development, web postings, and workshops, and also developed and reviewed NIPC content and took a substantial role in distributing NIPC and APF materials. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

437. Endo sponsored a website, *PainAction.com*, which claimed: “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”

438. Endo distributed a brochure available on *Painknowledge.com* entitled, “*Pain: Opioid Facts*,” which stated that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.” Endo repeated this deceptive message in numerous patient education pamphlets.

439. In a patient education pamphlet entitled, “*Understanding Your Pain: Taking Oral Opioid Analgesics*,” Endo answers the hypothetical patient question of “What should I know about opioids and addiction?” by focusing on explaining what addiction is (“a chronic brain disease”) and what it is not (“taking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.”

440. Endo distributed another pamphlet, *Living with Someone with Chronic Pain*, which stated, “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website, www.opana.com, until at least April 2012.

441. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *Painknowledge.com*, omitted addiction from the “common risks” of opioids, as shown below:

As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- ▶ Constipation
- ▶ Drowsiness
- ▶ Confusion
- ▶ Nausea
- ▶ Itching
- ▶ Dizziness
- ▶ Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

iii. Janssen's misrepresentations regarding addiction risk

442. Janssen likewise misrepresented the addiction risk of opioids. Janssen sponsored a website, *Let's Talk Pain*, which states that “the stigma of drug addiction and abuse” associated with the use of opioids stemmed from a “lack of understanding about addiction.” The website carried Janssen’s trademark and was copy approved and controlled by Janssen.

443. The *Let's Talk Pain* website also perpetuated the concept of *pseudoaddiction*, associating patient behaviors such as “drug seeking,” “clock watching,” and “even illicit drug use or deception” with undertreated pain which can be resolved with “effective pain management.”

444. Janssen’s unbranded website, *PrescribeResponsibly.com*, states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”

445. Janssen reviewed, edited, approved, and distributed a patient education guide entitled, *Finding Relief: Pain Management for Older Adults*, which, described the claim that opioids are addictive as a “myth,” and asserted as “fact” that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” This excerpt is reprinted below:

Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

iv. **Cephalon's misrepresentations regarding addiction risk**

446. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included claims that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.”

447. Cephalon also sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

448. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the noncancer patient population The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion

between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.²³

v. Actavis's misrepresentations regarding addiction risk.

449. Upon information and belief, Actavis claimed in promotional materials titled, "Learn More about customized pain control with Kadian," that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

450. Training for Actavis sales representatives deceptively minimized the risk of addiction by: (i) attributing addiction to "predisposing factors" such as a family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term "pseudoaddiction," which, as described herein, dismisses evidence of addiction as the under-treatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.

451. Upon information and belief, Actavis conducted a market study on takeaways from prescribers' interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives' discussion of the low-abuse potential. Actavis' sales representatives' misstatements on the low-abuse potential was considered an important factor to doctors and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives used during the visits, and Actavis noted that doctors associated Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about

²³ CME: Pharmacological Management of Breakthrough or Incident Pain. Authors: Michael J. Brennan, MD; Steven D. Passik, PhD; Kenneth L. Kirsh, PhD Writer: Brigid Kane <https://www.medscape.org/viewarticle/449803> (Accessed January 17, 2019).

Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.

452. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and is less addictive than other opioids. The guide includes the following statements: (i) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and (ii) KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state."

453. These statements falsely convey both that (i) Kadian does not cause euphoria and therefore is less addictive and that (ii) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent and Actavis had no studies to suggest that Kadian was, in fact, less prone to abuse.

vi. Mallinckrodt's misrepresentations regarding addiction risk

454. Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR and opioids generally through a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through C.A.R.E.S. Alliance.

455. In 2010, Mallinckrodt created the C.A.R.E.S. Alliance, an acronym for "Collaborating and Acting Responsibly to Ensure Safety." Mallinckrodt described the C.A.R.E.S. Alliance as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." "C.A.R.E.S. Alliance" is a service mark of Mallinckrodt LLC (and was previously a

service mark of Mallinckrodt, Inc.), and was copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

456. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book entitled, *Defeat Chronic Pain Now!* This book contains a number of false claims and misrepresentations, including the following:

- a. “Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- b. “It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.”
- c. “When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving.”
- d. “Only a minority of chronic pain patients who are taking long-term opioids develop tolerance.”
- e. “**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- f. “Here are the facts. It is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”
- g. “Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.”

457. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, Mallinckrodt stated that, “[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated.” The policy statement also cites to a report that concludes that “the majority of people with pain use their prescription

drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others.”

vii. Mylan’s misrepresentations regarding addiction risk

458. Mylan made payments to the APS to spread information and deceive the public into thinking that opioids were safe to use for treating chronic pain. Mylan has attempted to downplay its involvement with and payments to the APS and has criticized a Senate inquiry into its activities as politically motivated.

459. Mylan made its first donation of \$15,000 in March 2015 at the same time it launched intermediate dosage strengths for its fentanyl transdermal system. Mylan characterized its payment as “marketing efforts to educate doctors about the availability of the intermediate strengths.”

460. Much like the other Manufacturer Defendants, Mylan sought to promote prescription opioids, and thereby increase sales of its opioid products, by promoting opioids for chronic pain and downplaying the risk of addiction.

461. Mylan seized on the opportunity created by the APS and the other Defendants through their promotion of chronic opioid therapy and marketed its fentanyl patch for persistent moderate-to-severe chronic pain, even though Mylan knew or should have known that its fentanyl patch was being abused and misused.

462. According to reports, Mylan’s generic fentanyl patch had become popular among drug abusers because it does not show up on drug tests. The patch is designed to slowly release over 72 hours, but drug users have found that cutting the patch and placing it inside their lips (like chewing tobacco) or cutting the patch in half and adhering it to their cheeks releases the fentanyl

more quickly. One case report in published medical literature recounted a drug overdose that resulted from intravenous injection of fentanyl extracted by boiling a Mylan fentanyl patch.

463. Additionally, not only has Mylan profited from causing addiction, the company has profited from addiction itself by selling generic methadone and buprenorphine.

2. *Falsehood #2. Defendants, acting individually and collectively, misrepresented that opioids improve function.*

464. Defendants produced, sponsored, or controlled materials with the expectation that, by instructing patients and prescribers that opioids would improve patient functioning and quality of life, patients would demand opioids and doctors would prescribe them.

465. The claims that opioids would improve function and quality of life also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in quality of life could be alleviated by increasing doses or by prescribing supplemental short-acting opioids to take on an as-needed basis for “breakthrough pain.”

466. The claims that opioids would improve function and quality of life also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in quality of life could be alleviated by increasing doses or by prescribing supplemental short-acting opioids to take on an as-needed basis for “breakthrough pain.”

467. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Manufacturer Defendants consistently promoted opioids as capable of improving patients’ function and quality of life because they viewed those claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

468. For example, Janssen promoted Duragesic as improving patients’ functioning and work productivity through an ad campaign that included the following statements: “[w]ork,

uninterrupted,” “[l]ife, uninterrupted,” “[g]ame, uninterrupted,” “[c]hronic pain relief that supports functionality,” and “[i]mprove[s] ... physical and social functioning.”

469. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine We do not have such data to support OxyContin promotion In addition, Janssen has been using the “life uninterrupted” message in promotion of Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less about their pain.” This is a competitive advantage based on our inability to make any quality of life claims.

470. Despite its acknowledgment that “[w]e do not have such data to support OxyContin promotion,” Purdue ran a full-page advertisement for OxyContin in the *Journal of the American Medical Association*, proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help improve users’ functioning. This ad prompted a warning letter from the FDA, which admonished, “It is particularly disturbing that your November ad would tout ‘Life With Relief’ yet fail to warn that patients can die from taking OxyContin.”

471. Purdue also sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But, the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids.”

472. A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes,” case studies featuring patients with pain conditions persisting over several months,

which implied functional improvement. For example, one advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively.

473. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, such as those of a construction worker or chef, and misleadingly implying that the drug would provide long-term pain relief and functional improvement.

474. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, such as sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’”

475. Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain with opioids, by itself, improved patients’ function.

476. In addition, Janssen’s *Let’s Talk Pain* website featured a video interview, which was edited by Janssen personnel and claimed that opioids were what allowed a patient to “continue to function,” falsely implying that the patient’s experience would be representative.

477. The APF’s *Treatment Options: A Guide for People Living with Pain* (2007), sponsored by Purdue and Cephalon, likewise counseled patients that opioids “give [pain patients] a quality of life we deserve.” This guide was available online until the APF shut its doors in May 2012.

478. Endo's NIPC website, *Painknowledge.com*, claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement.

479. Endo was the sponsor, through NIPC, of a series of CMEs entitled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

480. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."

481. The Manufacturer Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life. Additionally, based on a review of the existing scientific evidence, the CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."

482. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and actually worsen patients' health.

For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had “consistently poor results,” and “several studies have showed that opioids for chronic pain may actually worsen pain and functioning” along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

483. The available evidence indicates opioids may worsen patients’ health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (e.g., depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

484. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.” According to the CDC, “for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”

485. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.”

486. In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers who were prescribed opioids long-term tended to suffer from addiction that made them more likely to be disabled and unable to work. Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the

injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.

487. The first randomized clinical trial designed to make head-to-head comparisons between opioids and other kinds of pain medications was published on March 6, 2018, in the *Journal of the American Medical Association*. The study reported that “[t]here was no significant difference in pain-related function between the 2 groups”; the two groups were comprised of individuals whose pain was treated with opioids and those whose pain was treated with non-opioids, including acetaminophen and other non-steroidal anti-inflammatory drugs (“NSAIDs”) like ibuprofen. Accordingly, the study concluded: “Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months.”

3. *Falsehood #3. Defendants, acting individually and collectively, misrepresented that addiction risk can be effectively managed.*

488. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Manufacturer Defendants also asserted, that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires.

489. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. Defendants claimed that these tools could identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors could then more closely monitor those patients.

490. For example, Purdue provided its *Partners Against Pain* “Pain Management Kit” to prescribers, which contains several screening tools and catalogues of Purdue materials, which included these tools.

491. On its website *PrescribeResponsibly.com*, Janssen states that the risk of opioid addiction “can usually be managed” through tools such as opioid agreements between patients and doctors. The website, which directly provides screening tools to prescribers for risk assessments, includes a “[f]our question screener” to purportedly help physicians identify and address possible opioid misuse.

492. Purdue and Cephalon sponsored the APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can “ensure that you take the opioid as prescribed.”

493. Purdue sponsored a 2011 webinar and CME program taught by KOL Dr. Webster entitled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.”

494. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. This presentation deceptively instructed prescribers that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could still be treated with opioids.

495. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice*, which was written by a doctor who later became a member of Endo’s speaker’s bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary*

Care: Use of Opioids: (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* (“ORT”) created by Dr. Webster and linked to Janssen or (b) the *Screening and Opioid Assessment for Patients with Pain*; and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts. The ORT was linked to Endo-supported websites.

496. There are three fundamental flaws in the Manufacturer Defendants’ representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence demonstrating that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence establishing that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence showing that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

4. *Falsehood #4. Defendants, acting individually and collectively, mislead physicians, patients, and payors through the use of the term “pseudoaddiction.”*

497. The Manufacturer Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. They used the term “pseudoaddiction” to describe this concept and to mislead physicians, patients, payors, and the general public.

498. In 1989, Dr. Haddox, who later became a Senior Medical Director for Purdue, coined the term “pseudoaddiction,” which he described as “the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management.” In plain English, the notion underlying “pseudoaddiction” is that people on prescription opioids who exhibit classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their

doses, or claiming to have lost prescriptions in order to get more opioids—are not actually “addicted,” but rather are simply suffering from under-treatment of their pain, which calls for more opioids.

499. In the materials and outreach they produced, sponsored, or controlled, Defendants made numerous misrepresentations and omissions and misleadingly used the term pseudoaddiction, and they have never acknowledged, retracted, or corrected them.

500. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards’ (“FSMB”) *Responsible Opioid Prescribing* (2007) written by KOL Dr. Fishman, which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, which are all signs of genuine addiction, are instead really signs of “pseudoaddiction.”

501. In 2005, Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its website, *PartnersAgainstPain.com*, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including “illicit drug use and deception,” which it claimed was not evidence of true addiction but was “pseudoaddiction” caused by untreated pain.

502. Purdue sales representatives were trained and tested on the meaning of pseudoaddiction, and they used the term in their communications with prescribers and healthcare providers in South Carolina and in Plaintiffs’ communities.

503. Purdue’s Pain Management Kit likewise endorsed the concept of pseudoaddiction by claiming that “pain-relief seeking behavior can be mistaken for drug-seeking behavior.” This kit was used from roughly 2011 through at least June 2016.

504. A Purdue pamphlet, *Providing Relief, Preventing Abuse: A Reference Guide To Controlled Substances Prescribing Practices*, admonished doctors that “[u]ndertreatment of pain is a serious problem” and “pain should be treated aggressively.” Purdue stated: “Facts About Addiction: ‘Misunderstanding of addiction and mislabeling of patients as addicts result in unnecessary withholding of opioid medication.’”

505. Purdue also urged doctors to prescribe higher doses of opioids in a Purdue-sponsored book, *Responsible Opioid Prescribing*, suggesting that patients who appear to be addicted were instead “receiving an inadequate dose” and needed more drugs.

506. Endo also trained its sales representatives to promote the concept of pseudoaddiction. A training module taught Endo sales representatives that addiction and pseudoaddiction were commonly confused. The module went on to state: “The physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient’s opioid dose to increase pain relief.”

507. In 2009, Endo sponsored a NIPC CME program in entitled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted the concept of pseudoaddiction and listed “[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction” as an element to be considered in awarding grants to CME providers.

508. The pseudoaddiction concept has never been empirically validated and, in fact, has been abandoned by some of its prior proponents.

509. In a 2016 settlement with Endo, the New York Attorney General reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged

the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’” Endo thereafter agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in the State of New York.

510. Janssen sponsored, funded, and edited a website called *Let’s Talk Pain*, which in 2009 stated that “pseudoaddiction . . . refers to patient behaviors that may occur when *pain is undertreated* Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.” This website was accessible online until at least May 2012.

511. Janssen also currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are “overestimated,” and describes pseudoaddiction as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases.”

512. The CDC Guideline nowhere recommends attempting to provide more opioids to patients who exhibit signs or symptoms of addiction.

513. Additionally, KOL Dr. Webster has even admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

5. *Falsehood #5. Defendants, acting individually and collectively, claimed withdrawal is simply managed.*

514. In an effort to downplay the risk and impact of addiction, the Manufacturer Defendants falsely claimed that, while patients can become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed if and when pain relief is no longer desired by gradually tapering patients’ dose to avoid the adverse effects of withdrawal.

515. In making such claims, Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids, adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

516. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids.

517. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. The painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

518. Purdue sponsored the American Pain Foundation's ("APF") *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

519. To this day, the Manufacturer Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

6. *Falsehood #6. Defendants, acting individually and collectively, misrepresented that increased doses posed no significant additional risks.*

520. Defendants claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were “frighteningly high,” suggesting that patients would eventually reach a stable, effective dose. Defendants’ claims were deceptive because they omitted warnings of increased adverse effects that occur at higher doses.

521. These misrepresentations were integral to the Manufacturer Defendants’ promotion of prescription opioids. Over time, patients develop a tolerance to opioids’ analgesic effects, such that achieving long-term pain relief requires constantly increasing the dose.

522. In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is “no[] upward limit” for dosing and to ask “if there are any reservations in using a dose of 240mg–320mg of OxyContin.”

523. Purdue sales representatives aggressively pushed doctors to prescribe stronger, higher doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

It went something like this. “Doctor, what is the highest dose of OxyContin you have ever prescribed?” “20mg Q12h.” “Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?” “Okay.” “Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?” “I don’t know, maybe.” “Doctor, but you do agree that you would at least Rx the 40mg dose, right?” “Yes.”

The next week, the sales representative would follow-up and see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin.

524. These misrepresentations were particularly dangerous; patients who are prescribed higher opioid dosages are at a higher risk of overdose death. Opioid doses at or above 50 morphine milligram equivalents (MME) per day double the risk of overdose compared to 20 MME/day, and

50 MME is equal to just 33 mg of oxycodone.²⁴ The recommendation of 320 mg every twelve hours is ten times that amount.

525. In its 2010 Risk Evaluation and Mitigation Strategy (“REMS”) for OxyContin, Purdue did not address the increased risk of respiratory depression and death associated with increasing dose, and instead advised prescribers that: “dose adjustments may be made every 1-2 days”; “it is most appropriate to increase the q12h dose”; the “total daily dose can usually be increased by 25% to 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration.”

526. Endo sponsored a website, *Painknowledge.com*, which claimed that opioids may be increased until “you are on the right dose of medication for your pain,” at which point further dose increases would not be required.

527. Endo also published a patient education pamphlet on its website entitled *Understanding Your Pain: Taking Oral Analgesics*. In Q&A format, it asked: “If I take the opioid now, will it work later when I really need it?” The response is: “The dose can be increased You won’t ‘run out’ of pain relief.”

528. Purdue and Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have “no ceiling dose” and, therefore, are safer than NSAIDs.

529. The Manufacturer Defendants were aware of the greater dangers that high-dose opioids posed but failed to communicate those risks while simultaneously encouraging healthcare providers to prescribe and patients to consumer higher doses.

²⁴ See *Calculating Total Daily Dose of Opioids for Safer Dosage*, U.S. Dep’t of Health & Human Servs. Ctrs. for Disease Control & Prevention, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

530. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events” and that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”

531. Additionally, a study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths to be directly related to maximum daily dose.

7. *Falsehood #7. Defendants, acting individually and collectively, deceptively omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.*

532. In materials they produced, sponsored, or controlled, the Manufacturer Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products and alternative therapies so that prescribers and patients would favor opioids over other therapies, such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

533. In addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Manufacturer Defendants routinely ignored the risks of hyperalgesia (a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time”); hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth); and potentially fatal interactions with alcohol or with benzodiazepines (which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain).

534. The APF’s *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if “taken for more than a period of

months,” with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is closer to 3,200.

535. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009), a publication that listed dose limitations as “disadvantages” of other pain medicines but omitted any discussion of the risks of increased doses from opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the “myths/facts” of opioids on the facing page. The disadvantages of NSAIDs are described as involving “stomach upset or bleeding,” “kidney or liver damage if taken at high doses or for a long time,” “adverse reactions in people with asthma,” and “can increase the risk of heart attack and stroke.” The only adverse effects of opioids listed are “upset stomach or sleepiness” (which the brochure claims will go away) and constipation.

536. Endo’s NIPC website, *Painknowledge.com*, contained a flyer called “*Pain: Opioid Therapy*.” This publication listed some adverse effects associated with opioids, but, significantly, omitted a number of serious adverse effects, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

537. The Endo-sponsored CME put on by the NIPC, *Persistent Pain in the Older Adult* counseled that acetaminophen should be used only short-term and included five slides on the FDA’s restrictions on acetaminophen and its adverse effects (including severe liver injury and anaphylaxis). In contrast, the CME downplayed the risk of opioids, claiming that opioids have “possibly less potential for abuse than in younger patients,” and did not list overdose among the adverse effects.

538. In April 2007, Endo sponsored an article aimed at prescribers, which was published in *Pain Medicine News*. The article, entitled “Case Challenges in Pain Management: Opioid Therapy for Chronic Pain” asserted:

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.

539. In an attempt to allay these prescriber concerns, Endo emphasized the risks of NSAIDs as an alternative pain therapy to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including an example of a subject who was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

540. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

541. Purdue made these deceptive claims about research to “highlight” the risks of non-opioid drugs. Purdue deceptively compared the risks of high doses of acetaminophen and NSAIDs with its claim that opioids have “no ceiling dose” to falsely contend that opioids were safer, even though high doses of opioids pose grave risk of addiction and death.

542. Purdue paid for deceptive propaganda by groups designed to appear independent from Purdue, promoting the message that NSAIDs and Tylenol have “life-threatening” side effects but opioids are “the gold standard of pain medication.”

543. Purdue also funded “switch research” to “understand what triggers prescribers to switch patients” from safer NSAIDs to more dangerous opioids. Purdue hired consultants to study how to make doctors “more comfortable” with opioids and “more cautious” about prescribing drugs such as ibuprofen.

544. As a result of the Manufacturer Defendants' deceptive promotion of opioids over safer and more effective pain therapies, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.

F. DEFENDANTS' PROMOTION OF THEIR BRANDED DRUGS WAS ALSO DECEPTIVE.

545. While Defendants worked in concert to expand the market for opioids generally, they also worked to maximize their individual shares within that market. The Manufacturer Defendants engaged in widespread advertising campaigns touting the benefits of their branded opioid products.

546. The Manufacturer Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. Collectively, the Manufacturer Defendants spent more than \$14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million spent by Purdue, \$4.9 million spent by Janssen, and \$1.1 million spent by Endo.

547. The Manufacturer Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it, and they also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.

548. For example, Endo's research found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations.

549. The Manufacturer Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's offices.

550. Each of the Manufacturer Defendants also promoted its opioid product(s) through sales representatives and small group speaker programs to reach out to individual prescribers across South Carolina and in Plaintiffs' communities. By establishing close relationships with doctors, Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings in which they could differentiate their opioid product(s) and allay prescribers' concerns about prescribing opioids for chronic pain.

551. As an example, Janssen employed an elaborate campaign of deceptive marketing, which included bogus statements about the risks and benefits of its branded opioid products, Nucynta and Nucynta ER, and which deceptively promoted the painkillers as unlike most opioids. Janssen promoted its Nucynta products as safer and milder than other prescription opioids (such as OxyContin) by claiming that Nucynta products were "unlike traditional opioids" and possessed "non-opioid" properties. In fact, Nucynta and Nucynta ER are not milder and are not less addictive than other Schedule II opioids.

552. Additionally, in 2010, Purdue developed and introduced a reformulated "abuse-deterrent" formulation ("ADF") of OxyContin, which was purportedly designed to reduce certain forms of abuse. At that time, Purdue launched a new campaign to promote its ADF OxyContin, which capitalized on growing concerns about the increasing numbers of opioid addiction,

overdose, and death. Purdue deceptively marketed its ADF OxyContin by: (a) claiming that ADF OxyContin could not be crushed or snorted, which is false; (b) claiming that ADF OxyContin reduced opioid abuse and diversion, which is false; (c) failing to inform healthcare providers and others that ADF opioids have no impact on oral abuse; and (d) claiming that ADF OxyContin was safer than other opioids, which is false. This false, misleading, and deceptive marketing was designed to (and did) reassure prescribers who were concerned about addiction that they could continue to prescribe opioids and should further switch to Purdue's opioids because they were safer than other prescription opioids on the market.

G. DEFENDANTS KNEW THAT THEIR MARKETING OF CHRONIC OPIOID THERAPY WAS FALSE, UNFOUNDED, AND DANGEROUS, AND WOULD HARM PLAINTIFFS AND THEIR RESIDENTS.

553. Defendants made, promoted, and profited from their misrepresentations, individually and collectively, knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading.

554. Cephalon and Purdue entered into settlements for hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct.

555. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths, all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.

556. Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to consume, and payors to pay for their opioids for chronic pain.

557. When they began their deceptive marketing practices, Defendants recklessly disregarded the harm that they knew or should have known their practices were likely to cause.

558. As their scheme was implemented, and as reasonably foreseeable harm began to

occur, Defendants were well aware that it was occurring. Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon—overall, in individual practices, and for specific indications. Defendants’ sales representatives, who visited doctors and attended CME programs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

559. To provide a particularly egregious example, Insys engaged in an extended campaign of blatant fraud and deception to market its sublingual fentanyl medication Subsys for chronic pain, even though Subsys is indicated “for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain.” The indication also specifies that “SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.”

560. Fentanyl products such as Subsys are among “the most potent and dangerous opioids on the market.”²⁵ Subsys has such a limited and specific indication—i.e., it is approved only for breakthrough pain (“BTP”) in cancer patients already receiving opioids for persistent cancer-related pain—because it is a highly potent and dangerous opioid.

²⁵ Dina Gusovsky, *The pain killer: A drug company putting profits above patients*, CNBC, available at <http://www.cnbc.com/2015/11/04/thedeadly-drug-appeal-of-insys-pharmaceuticals.html> (published Nov. 5, 2015, 10:13 AM).

561. Despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely, misleadingly, and fraudulently marketed Subsys to doctors as an effective treatment for back pain, neck pain, and other off-label pain conditions.²⁶

562. Insys promoted Subsys for a wide range of pain conditions and increased sales by, among other things, training and instructing its sales representatives to use a false definition of BTP, targeting and bribing prescribers who were not oncologists to write prescriptions for Subsys,²⁷ defrauding health insurance providers and lying to obtain prior authorizations for Subsys prescriptions, using a sham "speakers' bureau," and engaging in other wrongful, fraudulent, and unlawful conduct. This conduct has resulted in an indictment against Insys executives and officials, which details a coordinated, persistent scheme by Insys to illegally drive profits.

563. Insys engaged in this wrongful conduct and fraudulent behavior in South Carolina and targeted its efforts at prescribers in Plaintiffs' communities. One of the Dealer Defendants, Dr. Thiyaga, received payments from Insys and prescribed Subsys for non-medical purposes. Between 2014 and 2015, Dr. Thiyaga received over \$190,000 in payments for purportedly speaking, training, education, and consulting with Insys.

H. THE DEFENDANTS ACTIVELY AND FRAUDULENTLY CONCEALED THEIR MISREPRESENTATIONS.

564. Defendants took steps to avoid detection of, and to fraudulently conceal, their deceptive marketing and conspiratorial behavior.

²⁶ In the Matter of Insys Therapeutics, Inc., Notice of Unlawful Trade Practices and Proposed Resolution, <https://www.documentcloud.org/documents/2195731-insysdoj.html>, (dated July 10, 2015).

²⁷ According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others written by other specialists such as dentists and podiatrists. Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. times, available at http://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html?action=click&contentCollection=Business%20Day&region=Footer&module=MoreInSection&pgtype=Blogs&_r=2 (published May 13, 2014).

565. Defendants disguised their own roles in the deceptive marketing by funding and working through Front Groups purporting to be patient advocacy and professional organizations and through paid KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and KOLs and relied on them to vouch for the accuracy and integrity of Defendants' false and misleading statements about opioid use for chronic pain. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Defendants exerted their considerable influence on these purportedly "educational" or "scientific" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not public.

566. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear as though these items were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of materials they cited and offered them as evidence for propositions that the materials did not support.

567. The true lack of support for Defendants' deceptive messages was not apparent to the vast majority of the medical professionals who relied upon them in making treatment decisions or to others who relied on Defendants' misrepresentations about opioids. The false and misleading nature of Defendants' marketing was not known to, nor could it reasonably have been discovered by, Plaintiffs or Plaintiffs' residents.

568. Defendants also concealed their participation by extensively using the public relations companies they hired to work with Front Groups to produce and disseminate deceptive materials.

569. Defendants concealed from the medical community, patients, healthcare payors,

and the public facts sufficient to arouse suspicion of the existence of claims that Plaintiffs now assert. Plaintiffs did not discover the existence and scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

570. Through their public statements, marketing, and advertising, Defendants' deceptions deprived Plaintiffs of actual or implied knowledge of facts sufficient to put them on notice of any potential claims.

I. DEFENDANTS KEPT RECORDS OF PRESCRIBING DATA AND HAD KNOWLEDGE OF SUSPICIOUS ORDERS AND PRESCRIBERS.

571. The Manufacturer Defendants, Distributor Defendants, and Retail Pharmacy Defendants funneled far more opioids into communities across the United States than could have been expected to serve the legitimate medical needs of those communities, while they also intentionally ignored other red flags of suspicious orders.

572. At all times relevant to this Complaint, the Manufacturer Defendants, Distributor Defendants, and Retail Pharmacy Defendants were in possession of information that would have alerted them to potentially suspicious orders of opioids, as well as the emergence and/or existence of an opioid problem in Plaintiffs' communities.

573. For example:

- i. The Manufacturer Defendants, Distributor Defendants, and Retail Pharmacy Defendants have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy, and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;
- ii. The Manufacturer Defendants, Distributor Defendants, and Retail Pharmacy Defendants make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
- iii. The Manufacturer Defendants, Distributor Defendants, and Retail Pharmacy Defendants regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;

- iv. The Distributor Defendants and/or Retail Pharmacy Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and
- v. The Manufacturer Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

574. The conclusion that the Manufacturer Defendants, Distributor Defendants, and Retail Pharmacy Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids.

575. At all relevant times, the Manufacturer Defendants, Distributor Defendants, Retail and Pharmacy Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”).

576. The Distributor Defendants and/or Retail Pharmacy Defendants developed “know your customer” questionnaires and files. This information was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids. The “know your customer” questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, and the types of medical providers in the area, including

pain clinics, general practitioners, hospice facilities, and cancer treatment facilities, among others. These questionnaires put the recipients on notice of suspicious orders.

577. The Manufacturer Defendants, Distributor Defendants, Retail Pharmacy and Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, and identify pill mills. The information purchased by Defendants from the Data Vendors allowed Defendants to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.

578. For example, IMS Health provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.

579. Additionally, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs and analyzing the market share of those drugs.

580. This information allowed Defendants to track and identify instances of overprescribing. The Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.

581. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities and into Plaintiffs' communities.

582. Defendants refused to identify, investigate and report suspicious orders to the DEA or the appropriate South Carolina agencies when they became aware of suspicious orders, even though Defendants had actual knowledge of drug diversion.

583. For example, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012 and 117 recommended decisions in registrant actions from the Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders, all for failure to report suspicious orders.

584. The Sales Representative Defendants were also aware that the prescription opioids they promoted were being diverted, often with lethal consequences.

585. Defendants' sales incentives rewarded sales representatives who had "pill mills" within their territories, enticing those representatives to look the other way even when in-person sales visits to such clinics should have raised numerous red flags.

586. The Manufacturer Defendants failed to report South Carolina doctors they knew were engaged in suspicious prescribing to the South Carolina Board of Medical Examiners.

587. Instead, the Manufacturer Defendants and their employees either turned a blind eye, allowing certain clinics, including clinics within Plaintiffs' communities, to dispense staggering quantities of potent opioids, or actually targeted those prescribers for sales calls.

588. For example, one pain clinic in Horry County, South Carolina diverted massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away just to get opioid prescriptions for nonmedical uses. The DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But, Purdue's sales representative for that territory, Eric Wilson (who was a top-ranked sales representative) continued to promote OxyContin sales at the clinic despite being on notice of potential problems at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. In response to news stories about this clinic, Purdue issued a statement,

declaring that “if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not.”²⁸

589. This is consistent with how Purdue handled and responded to reports of suspicious prescribing elsewhere in the country. For example, in Los Angeles, California, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill, reporting when she visited the clinic with her sales representative, “it was packed with a line out the door, with people who looked like gang members,” and that she felt “very certain that this an organized drug ring[.]” She wrote emails to Purdue supervisors, stating, “This is clearly diversion. Shouldn’t the DEA be contacted about this?” But, her supervisor at Purdue responded that while they were “considering all angles,” it was “really up to [the wholesaler] to make the report.” This particular pill mill was the source of 1.1 million pills that were trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.²⁹

590. Defendants, as part of their marketing strategy, failed to adhere to their obligation to report suspicious prescribing and potential abuses. While Defendants did identify doctors who were the most prolific prescribers of opioids, instead of reporting them, they increased their marketing to those doctors and actually targeted them.

591. Upon information and belief, Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own sales and their competitors’ sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

²⁸ Barry Meier, Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death. P.300.

²⁹ “More than 1 million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew.” *Harriet Ryan, Lisa Girion and Scott Glover*, Los Angeles Times, July 10, 2016. <https://www.latimes.com/projects/la-me-oxycontin-part2/> (Accessed January 18, 2019).

592. For example, Actavis spent \$6.7 million in 2011 on Actavis's sales representatives, or "detailers," targeting physicians to deliver sales messages. Actavis tracked its detailers' progress, by having Actavis's sales and marketing department actively monitor the prescribing behavior of physicians. At a national sales meeting presentation in 2011, Actavis pressed its sales representatives to focus on its high prescribers and focus on how a "high volume physician" can impact sales performance.

593. This focus on marketing to the highest prescribers demonstrates that the Manufacturer Defendants were keenly aware of the doctors who were writing large quantities of opioid prescriptions, and, instead of investigating or reporting those doctors, Defendants focused on maintaining and increasing their sales.

594. Purdue and the other Manufacturer Defendants have consistently denied a role in or any responsibility for opioid diversion.

595. For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell was asked how Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by this "bad actor" doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."³⁰

596. But, given the closeness with which Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted

³⁰ <https://www.govinfo.gov/content/pkg/CHRG-107hrg75754/html/CHRG-107hrg75754.htm> (accessed January 21, 2019).

authorities. Purdue had the prescribing data from the clinic but alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

597. Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company's policies or duties to report suspicious activity. Instead, Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

J. THE DISTRIBUTOR DEFENDANTS FAILED TO REPORT SUSPICIOUS ORDERS AND FAILED TO OTHERWISE ACT TO PREVENT DIVERSION AND MISUSE.

598. The Distributor Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids into communities across America, including in South Carolina and in Plaintiffs' communities. Despite their obligations to control the supply, prevent diversion, report, and take steps to halt suspicious orders, the Distributor Defendants allowed Plaintiffs' communities to be flooded with opioids.

599. The Distributor Defendants played an integral role in the supply of opioids being distributed throughout Plaintiffs' communities.

600. All Defendants in the supply chain of prescription opioids have a duty to monitor and control the supply of opioids, prevent diversion, and take steps to halt suspicious orders. *See* S.C. Code Ann. § 44-53-300. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." S.C. Code Regs. 61-4.404(b).

601. The criteria listed in the definition of “suspicious orders” are disjunctive. For example, if an order deviates substantially from a normal pattern, even if the size of the order is not suspicious, the order must still be reported as suspicious. Additionally, the size of an order alone, regardless of whether it deviates from a normal pattern, can be enough to trigger a responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the customer base and patterns throughout the relevant segment of the industry.

602. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders. They have further admitted that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”

603. In addition to reporting all suspicious orders, the Distributor Defendants must stop shipment on any order which is flagged as suspicious and may only ship orders flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.

604. Each of the Distributor Defendants knew they were required to monitor, detect, report, and halt suspicious orders of controlled substances. Yet, the Distributor Defendants sold prescription opioids to retailers in Plaintiffs’ communities and/or to retailers from which Defendants knew or should have known prescription opioids were likely to be diverted.

605. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

606. For example, on January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for, *inter alia*, failing to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017), it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”

607. McKesson further admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the FCSA and the FCSA’s implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers” including the McKesson Distribution Center located in Washington Court House, Ohio. Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities some of which (including the one in Washington Courthouse, Ohio), investigators found “were supplying pharmacies that sold to criminal drug rings.”

608. Upon information and belief, McKesson engaged in similar wrongful conduct within the State of South Carolina. McKesson’s wrongful conduct caused and/or contributed to the opioid epidemic in Plaintiffs’ communities and violated South Carolina law.

609. Similarly, in 2017, the Department of Justice fined Mallinckrodt \$35 million for its failure to report suspicious orders of controlled substances, including opioids, and for violating

recordkeeping requirements. The government alleged that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”

610. Upon information and belief, Mallinckrodt engaged in similar wrongful activity within the State of South Carolina. Mallinckrodt’s wrongful conduct caused and/or contributed to the opioid epidemic in Plaintiffs’ communities and violated South Carolina law.

611. On December 23, 2016, Cardinal Health agreed to pay the United States \$44 million to resolve allegations that it violated the federal Controlled Substances Act (“FCSA”) in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the FCSA between January 1, 2009 and May 14, 2012 by failing to:

- i. “timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)”;
- ii. “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA’s regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)”;
- iii. “execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA ‘Form 222’ order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305.”

612. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the

FCSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities alone are sufficient to show that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for \$16 million to the state; Cardinal Health settled for \$20 million.

613. Upon information and belief, Cardinal Health and AmerisourceBergen engaged in similar wrongful activity within the State of South Carolina. The wrongful conduct of Cardinal Health and AmerisourceBergen caused and/or contributed to the opioid epidemic in Plaintiffs' communities and violated South Carolina law.

614. Each of the Distributor Defendants acted in disregard of their duties and pumped massive quantities of opioids in communities around the country and in South Carolina, despite their obligations to control the supply of opioids, prevent diversion, and report and take steps to halt suspicious orders.

615. The Distributor Defendants breached their duties by failing to report any suspicious orders of prescription opioids originating in Plaintiffs' communities at all times material to this Complaint. The Distributor Defendants' failures contributed to the excessive amount of opioid prescriptions filled for non-medical purposes in Plaintiffs' communities.

616. The Distributor Defendants, operating within South Carolina and in Plaintiffs' communities, knew or should have known they were neglecting their duties and should have detected and reported suspicious orders on numerous occasions. The Distributor Defendants'

failures are a direct and proximate cause of the diversion of prescription opioids in Plaintiffs' communities and across South Carolina, causing opioid abuse, addiction, and death in Plaintiffs' communities.

K. MEDICAL PROVIDERS, INCLUDING THE DEALER DEFENDANTS, CAUSED THE DIVERSION OF PRESCRIPTION OPIOIDS THROUGHOUT SOUTH CAROLINA.

617. The Dealer Defendants directly participated in the illegal diversion of opioids for nonmedical purposes in South Carolina and in Plaintiffs' communities.

618. The Dealer Defendants' conduct in this regard was negligent, deceptive, reckless, and/or willful and wanton.

619. Dealer Defendant Aathirayen Thiyagarajah, acting in concert with Dealer Defendant Spine and Pain Consultants, PA, prescribed Subsys and other opioids off-label within Greenville and Anderson Counties for nonmedical purposes not indicated by the FDA. These Defendants deliberately addicted patients, trapping them in a vicious cycle and ruining their lives, for the sake of profits while receiving kickbacks and expensive travel from Insys.³¹ They operated as *de facto* drug dealers in white coats, greatly contributing to the diversion of opioids and wave of addiction across South Carolina.

620. Defendants Thiyagarajah and Spine and Pain Consultants, PA knew that Subsys was approved by the FDA solely for use in cancer patients, already on opioids, experiencing BTP at the end of their life. Despite this knowledge, these Defendants knowingly and recklessly deceived chronic pain patients into believing Subsys was safe for long-term use.

621. As an example, one South Carolina woman reports that she was convinced by these

³¹ Kessler, Aaron, et al., *CNN Exclusive: The more opioids doctors prescribe, the more money they make*, <https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html>, (updated March 12, 2018, 8:45AM)

Defendants to take Subsys for chronic abdominal pain from Crohn's disease. She received the drug for years and experienced blackouts, uncontrolled diarrhea, and vomiting. Defendants Thiagarajah and Spine and Pain Consultants, PA consistently reassured her that it was not the Subsys causing these problems. The South Carolina woman became addicted and, she states, these Defendants ruined her life. At one point, she asked Defendant Thiagarajah to take her off Subsys, but he angrily insisted that it was Subsys or nothing.³² Defendants Thiagarajah and Spine and Pain Consultants, PA knew that if they stopped prescribing Subsys to this South Carolina woman and others, they would stop receiving the lavish kickbacks and trips from Insys.

622. Defendants Thiagarajah and Spine and Pain Consultants, PA received 50 times more payments from Insys than other similarly situated peers for speaking, training, education, and consulting on behalf of Insys.³³

623. Defendants Thiagarajah and Spine and Pain Consultants, PA issued opioid prescriptions for nonmedical purposes in addition to Subsys, issuing nearly double the amount of opioid prescriptions *per patient* than other similarly situated physicians. At one point in 2015, a DEA investigation concluded that these defendants were prescribing buprenorphine for nonmedical purposes as well, in violation of state and federal laws.³⁴

624. Defendants Thiagarajah and Spine and Pain Consultants, PA have victimized as many as 12,000 people from across South Carolina.³⁵

625. The actions of Defendants Thiagarajah and Spine and Pain Consultants, PA greatly contributed to the diversion of opioids and the wave of addiction across South Carolina

³² *Id.*

³³ Kessler, Aaron, *CNN Exclusive*, *Supra*.

³⁴ *Id.*

³⁵ Patient Fusion, <https://www.patientfusion.com/doctor/aathirayen-thiyagarajah-mbbs-md-59869> (accessed March 13, 2018).

and in Plaintiffs' communities.

626. Defendants Thiyagarajah and Spine and Pain Consultants, PA failed to exercise the nonmedical, administrative, ministerial, and routine duty owed to Plaintiffs and the public of preventing the diversion of opioids into the black market. Defendant Thiyagarajah wrote prescriptions for nonmedical purposes outside of a bona fide practitioner-patient relationship, in violation of S.C. Code Ann. §§ 44-53-360(c) and 44-53-360(h), and failed to conform with the record-keeping requirements of S.C. Code Ann. §§ 44-53-340 and 44-53-390(a)(4).

627. Defendants Thiyagarajah and Spine and Pain Consultants, PA failed to exercise the nonmedical, administrative, ministerial, and routine duty of determining whether patients obtained opioids from other physicians in violation of S.C. Code Ann. § 44-53-1645.

628. Defendants PMA, Dr. Leche, and Amanda Leche are also Dealer Defendants whose acts and/or omissions caused and/or contributed to the illegal diversion of opioids for nonmedical purposes throughout South Carolina and in Plaintiffs' communities.

629. From at least January 1, 2011 through December 31, 2018, PMA providers regularly wrote prescriptions for opioid medications for PMA patients that were not for a medically-accepted indication and, therefore, lacked a legitimate medical purpose and medical necessity.

630. In many instances, PMA providers issued opioid prescriptions to patients without actually seeing the patients and/or without properly assessing the patients' need for the drugs.

631. Additionally, PMA employees used pre-signed and forged opioid prescriptions with patients when the patient's provider was not present. For example, Dr. Leche and Amanda Leche provided PMA staff at the Spartanburg office with pre-signed prescription forms, enabling the staff members to simply write in the name of the opioid drug and the dosage when Dr. Leche

was not present in the office or was otherwise unavailable to see the patient. In other instances, PMA staff forged Dr. Leche's signature on opioid prescriptions. This conduct was done with the knowledge and approval of Dr. Leche.

632. For instance, one PMA patient obtained a prescription for Norco (hydrocodone / acetaminophen), a Schedule II controlled substance, from Dr. Leche on April 9, 2018, despite the fact that there was no indication that Dr. Leche was in the office or saw the patient on that date.

633. In 2018, Dr. Leche and Amanda Leche were arrested on charges that they worked together to use blank, pre-signed prescriptions in order to obtain opioids from several pharmacies.

634. Another former PMA physician often saw well over 70 PMA patients per day, and his interactions with these patients were often cursory in nature and did not involve a substantive examination. This PMA physician nevertheless proceeded to prescribe opioids for patients that were medically unnecessary and without a legitimate medical purpose. This physician's medical assistant was instructed to fill out prescriptions for him, including altering the dosage or type of opioid medication upon the patient's request. The physician would then sign the prescriptions without adequately assessing the patient.

635. PMA's owners, managers, and decisionmakers were aware of improper prescribing conduct at PMA clinics and the attendant risks, but nevertheless permitted and/or condoned employees to continue writing improper opioid prescriptions, including prescriptions that would be reimbursed by government payors.

636. In a discussion with a PMA nurse practitioner, one of the owners of PMA, David McCollum, referred to his PMA clinics in Easley and in Spartanburg as "pill mills," a term commonly understood to describe the practice of prescribing narcotics without a legitimate medical purpose.

637. As of December 2017, at least two PMA patients had died from an overdose.

638. PMA's owners, managers, and decisionmakers failed to take appropriate or sufficient steps to curb the prescription of medically unnecessary and illegitimate opioids at PMA and, instead, profited from those prescribing practices.

639. The actions of Defendants PMA, Dr. Leche, and Amanda Leche greatly contributed to the diversion of opioids and the wave of addiction across South Carolina and in Plaintiffs' communities.

640. Defendants PMA, Dr. Leche, and Amanda Leche failed to exercise the nonmedical, administrative, ministerial, and routine duty owed to Plaintiffs and the public of preventing the diversion of opioids into the black market. Dr. Leche and PMA providers wrote prescriptions for nonmedical purposes outside of a bona fide practitioner-patient relationship, in violation of S.C. Code Ann. §§ 44-53-360(c) and 44-53-36(h), and failed to conform with the record-keeping requirements of S.C. Code Ann. §§ 44-53-340 and 44-53-390(a)(4).

641. Defendants PMA, Dr. Leche, and Amanda Leche failed to exercise the nonmedical, administrative, ministerial, and routine duty of determining whether patients obtained opioids from other physicians in violation of S.C. Code ann. § 44-53-1645.

642. Upon information and belief, the Dealer Defendants financially benefited and continue to derive financial benefit from the acts described herein.

643. Other physicians in South Carolina also engaged in wrongful conduct with respect to opioids. For example, Dr. Hershline operated an office in Hilton Head, South Carolina that functioned as a "Pill Mill"; he vastly overprescribed opioid medications without a legitimate medical purpose.

644. Dr. Hershline wrote thousands of opioid prescriptions without the appropriate

physical examination or medical need to profit from this activity, causing diversion of opioid medications throughout South Carolina.³⁶

645. Dr. Hershline conspired with others to distribute and dispense outside the usual course and scope of professional practice and not for a legitimate medical purpose, oxycodone and methadone.

646. Additionally, Dr. D. Vincent Rhodes participated in a prescription drug ring, prescribing prescription opioids without the appropriate physical examination or medical need to profit from this activity, causing diversion of over ten thousand opioid medications across South Carolina.³⁷

647. Dr. Hershline and Dr. Rhodes had many patients that traveled from all over South Carolina and elsewhere for the primary purpose of obtaining prescription opioids.

648. Other healthcare providers in South Carolina wrote thousands of opioid prescriptions without the appropriate physical examination or medical need to profit from this activity, causing diversion of opioid medications throughout South Carolina.

649. Dr. Hershline, Dr. Rhodes, and the Dealer Defendant's practices resulted in the additional cost for, among other things, substance abuse treatment, toxicology assessment, emergency hospitalization care, lost tax revenue, economic loss, and foster care to Plaintiffs, costs which continue to be incurred to date.

L. THE SALES REPRESENTATIVE DEFENDANTS MISREPRESENTED THE SAFETY OF OPIOID THERAPY TO PHYSICIANS, HEALTHCARE PROVIDERS, AND OTHERS IN SOUTH CAROLINA AND IN PLAINTIFFS' COMMUNITIES.

³⁶ Davis, Kelly, *Doctor sentenced to 41 months in prison*, <http://www.thestate.com/news/local/crime/article14379230.html> (accessed December 21, 2017).

³⁷ Moody, Erin, *Beaufort doctor sentenced to 1 year for role in cocaine, prescription drug ring*, <http://www.islandpacket.com/news/local/community/beaufort-news/article33613854.html> (accessed December 21, 2017).

650. The Sales Representative Defendants were responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in South Carolina, including to those who prescribed and/or consumed the drug in South Carolina.

651. The Sales Representative Defendants and their agents disseminated Purdue's marketing materials and messages to prescribers and healthcare providers in South Carolina through targeted, in-person visits. Purdue sales representatives visited some South Carolina prescribers as often as every week or every other week.

652. At all relevant times, Defendant Sullivan was a Purdue sales detail person and/or district manager in South Carolina and was responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in South Carolina, including to those who prescribed and/or consumed the drug in Plaintiffs' communities and across the State.

653. From 1992 until 2017, Defendant Sullivan directed, ratified, trained, supervised, and managed Purdue sales personnel within the State of South Carolina, including within Plaintiffs' communities, to utilize all of the deceptive sales tactics and marketing materials developed by Purdue and described in this Complaint.

654. At all relevant times, Defendant Varnadore was a Purdue sales detail person and/or district manager in South Carolina and was responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in South Carolina, including to those who prescribed and/or consumed the drug in Plaintiffs' communities and across the State.

655. From 1998 until the present, Defendant Varnadore directed, ratified, trained, supervised, and managed Purdue sales personnel within the state of South Carolina to utilize all of the deceptive sales tactics and marketing materials developed by Purdue and described in this Complaint.

656. At all relevant times, Defendant Kitchin was a Purdue sales detail person and/or district manager in South Carolina and was responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in South Carolina, including to those who prescribed and/or consumed the drug in Plaintiffs' communities and across the State.

657. From 1990 until 2009, Defendant Kitchin directed, ratified, trained, supervised, and managed Purdue sales personnel within the State of South Carolina to utilize all of the deceptive sales tactics and marketing materials developed by Purdue and described in this Complaint.

658. At all relevant times, Defendant Taylor was a Purdue sales detail person, Analgesia Specialist for the Southeast Region, and/or district field trainer in South Carolina and was responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in South Carolina, including to those who prescribed and/or consumed the drug in Plaintiffs' communities and across the State.

659. From 1998 until 2015, Defendant Taylor directed, ratified, trained, supervised, and managed Purdue sales personnel within the State of South Carolina to utilize all of the deceptive sales tactics and marketing materials developed by Purdue and described in this Complaint.

660. At all relevant times, Defendant Waldrop was a Purdue sales representative who promoted, advertised, marketed, sold, and/or distributed OxyContin in South Carolina, including to prescribers and consumers in Plaintiffs' communities and across the State.

661. At all relevant times, Defendant Kay was a Purdue sales representative who promoted, advertised, marketed, sold, and/or distributed OxyContin in South Carolina, including to prescribers and consumers in Plaintiffs' communities and across the State.

662. At all relevant times, Defendant Madden was a Purdue sales representative who promoted, advertised, marketed, sold, and/or distributed OxyContin in South Carolina, including to prescribers and consumers in Plaintiffs' communities and across the State.

663. The Sales Representative Defendants owed a duty of care to Plaintiffs in the marketing, advertising, sale, and promotion of Purdue's highly dangerous, addictive and abuse-prone OxyContin.

664. The Sales Representative Defendants owed Plaintiffs a duty to use reasonable care because, *inter alia*, it was foreseeable, and in fact known to the Sales Representative Defendants that their conduct would result in injuries and damages to Plaintiffs and within Plaintiffs' communities.

665. The Sales Representative Defendants were aware that OxyContin posed an excessive risk of harm to South Carolina and to Plaintiffs, including its risks relating to addiction, abuse, and diversion, all of which were occurring and ongoing in Plaintiffs' communities and across the State.

666. The Sales Representative Defendants had actual knowledge that the safety, efficacy, addictiveness, abuse, and diversion potential of OxyContin were being negligently and recklessly misrepresenting in the marketing, advertising, promoting, and selling of OxyContin.

667. The Sales Representative Defendants knew that OxyContin was highly susceptible to addiction, misuse, abuse, and/or diversion, and the risk for each of these factors bore a direct relationship to the amount and volume of opioids being prescribed within South Carolina and in Plaintiffs' communities.

668. The Sales Representative Defendants further knew or should have known that OxyContin was being misused, abused, and diverted across the country, including within Plaintiffs' communities and across South Carolina. For example:

- i. The Sales Representative Defendants witnessed first-hand the devastating effects of OxyContin in and around South Carolina and in Plaintiffs' communities and knew or should have known that OxyContin was being regularly abused, misused, and diverted;
- ii. The Sales Representative Defendants were informed, alerted, questioned, and/or made aware by prescribers throughout South Carolina and in Plaintiffs' communities that OxyContin was being abused, misused, and diverted and, on at least one occasion, that a family member of a prescriber within South Carolina had overdosed on OxyContin in South Carolina;
- iii. Memos from sales representatives working within South Carolina and/or surrounding areas were distributed and/or discussed between Purdue employees and representatives, including the Sales Representative Defendants, which contained "red flags" about OxyContin and detailed reports from prescribers that their patients were misusing, abusing, and diverting OxyContin; and,
- iv. The Sales Representative Defendants were made aware of medical literature and studies that concluded OxyContin was more attractive to drug abusers compared to other prescription pain pills.

669. The Sales Representative Defendants knew or should have known that OxyContin was unreasonably dangerous and highly addictive and highly susceptible to abuse and diversion, yet they knowingly and/or negligently provided false and/or misleading information to prescribers within South Carolina, including prescribers in Plaintiffs' communities, concerning the risk of addiction, abuse, and diversion of OxyContin and information about its relative safety.

670. The Sales Representative Defendants also misrepresented to prescribers throughout South Carolina and in Plaintiffs' communities that OxyContin was safe for use in chronic pain patients.

671. Upon information and belief, the Sales Representative Defendants purposefully or negligently caused communities across South Carolina, including Plaintiffs' communities, to be flooded with highly dangerous and addictive opioids, even though they knew that these drugs were being misused, abused, and diverted.

672. The Sales Representative Defendants knew or should have known that opioid addiction, abuse, and/or diversion and their related consequences would injure and damage communities across the country, including Plaintiffs' communities. Applicable South Carolina laws and the industry standards applicable to the manufacture, advertising, labeling, distribution, and sale of opioid drugs exist to control addiction, abuse, and/or diversion associated with these dangerous drugs. Moreover, the Sales Representative Defendants were aware of their actions and the effects their actions were having in communities across the country, including in Plaintiffs' communities. The escalating amounts of highly addictive drugs being prescribed and distributed, and the sheer volume of these prescription opioids, further alerted the Sales Representative Defendants that addiction was fueling increased addiction, abuse, and diversion and that legitimate medical purposes were not being served.

673. Despite this knowledge, and in direct disregard of the known and foreseeable harms to Plaintiffs, the Sales Representative Defendants negligently and recklessly breached their duties to Plaintiffs by, for example:

- i. Negligently and recklessly marketing, advertising, and promoting OxyContin in Plaintiffs' communities and surrounding areas;
- ii. Misrepresenting and misstating the addiction, abuse, and/or diversion potential of OxyContin;
- iii. Overstating the benefits of chronic OxyContin therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;

- iv. Downplaying and/or obscuring OxyContin's serious risks and adverse outcomes, including the risk of addiction, abuse, diversion, overdose, and death;
- v. Overstating OxyContin's superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;
- vi. Mischaracterizing the difficulty of withdrawal from OxyContin and the prevalence of withdrawal symptoms;
- vii. Marketing OxyContin for indications and benefits that were not supported by substantial evidence; and,
- viii. Misrepresenting to healthcare providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of misuse or abuse.

674. At all times material herein, the Sales Representative Defendants willingly and knowingly participated in Defendant Purdue's deceptive and misleading marketing scheme, were aware of its existence, and did nothing about it. The Sales Representative Defendants promoted, perpetuated, and furthered Purdue's deceptive and misleading marketing campaign by knowingly and falsely promoting and marketing OxyContin as less addictive and less subject to abuse and diversion than other opioids.

675. The Sales Representative Defendants had a financial incentive to knowingly provide false information to prescribers within South Carolina and in Plaintiffs' communities, as their pay and continued employment depended on the volume of sales and prescriptions written within their District and surrounding areas. Upon information and belief, the Sales Representative Defendants received lucrative bonuses, trips, and other items of value as a result of their success in pushing OxyContin into the communities of South Carolina.

676. The Sales Representative Defendants further trained their sales representatives to employ various tactics to evade physicians' questions regarding OxyContin's addictiveness and likelihood of addiction, misuse, abuse, and/or diversion. The Sales Representative Defendants

also trained their sales force to misrepresent and conceal facts regarding OxyContin's safety. By way of example, one of the Sales Representative Defendants trained her sales representatives to be "Audible Ready" when questioned about opioid street-abuse and to misrepresent OxyContin's addictiveness and likelihood of abuse, diversion, and misuse.

677. Upon information and belief, after receiving reports from prescribers and medical professionals that OxyContin was being abused and diverted in and around Plaintiffs' communities, the Sales Representative Defendants instructed their sales team to ride out the controversy, ignore abuse reports, and "sell through it."³⁸

678. Upon information and belief, the Sales Representative Defendants would instruct their sales force to target doctors that data indicated were overprescribing opioid medications, instead of reporting those doctors to authorities.³⁹

679. The Sales Representative Defendants knew their marketing and the information they and their sales team provided was a substantial factor in physicians, patients, and others prescribing, purchasing, or using opioids in South Carolina and in Plaintiffs' communities.

680. At all times material herein, prescribers and consumers within South Carolina and in Plaintiffs' communities relied upon the representations made by the Sales Representative Defendants and their sales teams, and their reliance was justified.

681. The Sales Representative Defendants' breaches of their duties bear a causal connection with and/or proximately resulted in the harm and damages to Plaintiffs.

³⁸ Keefer, Patrick, *The New Yorker*, *The Family that Built and Empire of Pain: The Sackler Dynasty's Ruthless Marketing of Painkillers has Generated Billions of Dollars – and Millions of Addicts*, <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain> (published October 30, 2017).

³⁹ *Id.*

682. As a direct and proximate result of the Sales Representative Defendants' actions, Plaintiffs have suffered and continue to suffer injury and damages, including, but not limited to, incurring costs related to abuse and/or addiction or risk of addiction to opioids and costs related to having to provide necessary resources for care, treatment facilities, law enforcement, and other expenses associated with opioid addiction, abuse, and diversion.

M. THE RETAIL PHARMACY DEFENDANTS CONTRIBUTED TO THE DIVERSION OF PRESCRIPTION OPIOIDS THROUGHOUT SOUTH CAROLINA.

683. The Retail Pharmacy Defendants, as both distributors and dispensaries, violated both federal law, *see* 21 U.S.C. § 823, 21 CFR 1301.74, and South Carolina law, *see* S.C. Code Ann. § 40-43-86, by failing to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiffs' communities, as well as those orders which the Retail Pharmacy Defendants knew or should have known were likely to be diverted into Plaintiffs' communities.

684. The Retail Pharmacy Defendants profited significantly by distributing and dispensing prescription opioids in Plaintiffs' communities. They were aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained. Yet, instead of taking any meaningful action to stem the flow of opioids into Plaintiffs' communities, they continued to participate in and profit from the oversupply of prescription opioids.

685. Each of the Retail Pharmacy Defendants does substantial business throughout the United States and in South Carolina. This business includes the distribution and dispensing of prescription opioids in South Carolina and in Plaintiffs' communities.

686. The Retail Pharmacy Defendants distributed and dispensed substantial quantities of prescription opioids in South Carolina and in Plaintiffs' communities. In addition, they

distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to South Carolina. The Retail Pharmacy Defendants failed to take meaningful action to stop this diversion despite their knowledge of it and they contributed substantially to the diversion problem.

687. The Retail Pharmacy Defendants developed and maintained extensive data on opioids they distributed and dispensed. Through this data, the Retail Pharmacy Defendants had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Plaintiffs' communities. They used the data to evaluate their own sales activities and workforce.

688. On information and belief, the Retail Pharmacy Defendants also provided other Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The Retail Pharmacy Defendants' data is a valuable resource that they could have employed to stop diversion, but they did not.

1. *The Retail Pharmacy Defendants have a duty to prevent diversion.*

689. Each participant in the supply chain of opioid distribution, including each of the Retail Pharmacy Defendants, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

690. The Retail Pharmacy Defendants, like manufacturers and other distributors, are registrants under the FCSA, *see* 21 C.F.R. § 1301.11, and the South Carolina Poisons, Drugs, and Other Controlled Substances Act, S.C. Code Ann. §§ 44-53-10 *et seq.* (the "South Carolina CSA"). Each of the Retail Pharmacy Defendants is subject to the requirements of the South Carolina CSA and has a registration obligation under South Carolina law. *See id.* § 43-53-290(a) & (b); S.C. Code Regs. 61-4.102(x); S.C. Code Regs. 61-4.106.

691. The South Carolina CSA requires the Retail Pharmacy Defendants to, among other things, maintain “effective controls against diversion of controlled substances into other than legitimate medical scientific, or industrial channels” and to comply “with applicable state or federal law.” S.C. Code Ann. § 44-53-300(a)(1), (2). Additionally, South Carolina law requires the Retail Pharmacy Defendants to “provide effective controls and procedures to guard against theft and diversion of controlled substances,” S.C. Code Regs. 61-4.401(a), and to maintain “a complete and accurate record of all controlled substances” in their inventories for each registered location, S.C. Code Regs. 61-4.701(a), (b).

692. The Retail Pharmacy Defendants have duties with respect to the distribution and dispensing of controlled substances in South Carolina, including a duty to prevent diversion. They likewise have a responsibility to ensure that prescriptions are only issued, filled, and dispensed for a legitimate medical purpose.

693. The DEA and the South Carolina Board of Pharmacy have provided extensive guidance to pharmacies concerning their duties, including, for example, how to identify suspicious orders, red flags, and other evidence of diversion.

694. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration, among others. S.C. Code Regs. 61-4.404(b).

695. Some red flags of diversion that the Retail Pharmacy Defendants are responsible for detecting include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are

being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look “too good” or where the prescriber’s handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

696. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

697. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the Retail Pharmacy Defendants themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

698. If a South Carolina pharmacy finds evidence of prescription diversion, it must contact the South Carolina Board of Pharmacy and DEA.

699. Despite their legal obligations as registrants under the CSA and under South Carolina law, the Retail Pharmacy Defendants allowed widespread diversion to occur in Plaintiffs’ communities, and they did so knowingly.

700. Performance metrics and prescription quotas adopted by the Retail Pharmacy Defendants for their retail stores contributed to their failures. Under CVS’s Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely

predictable: opioids flowed out of Retail Pharmacy Defendants' pharmacies and into Plaintiffs' communities. The policies remained in place even as the opioid epidemic raged.

701. The performance metric systems rate the pharmacist employees at the stores operated by Retail Pharmacy Defendants based solely on productivity. These requirements place significant and unrealistic time pressures on the pharmacists.

702. The Retail Pharmacy Defendants measure how many and how quickly prescriptions are filled daily based on store volume. Many of the Retail Pharmacy Defendants' locations require pharmacists to fill one prescription every three minutes. The programs may also measure how many telephone calls are made to customers to refill and/or pick up prescriptions; how many flu shots are given; as well as other pharmacy tasks. All measurements focus on productivity with the end goal of maximizing the Retail Pharmacy Defendants' profits.

703. In addition to the pharmacist's other duties, Retail Pharmacy Defendants required their employee pharmacists to fill more than 600 prescriptions per work shift.

704. At the same time that Retail Pharmacy Defendants increased demands for productivity, they cut the hours of pharmacy technicians, leaving pharmacists severely understaffed and unable to provide all necessary services.

705. The Retail Pharmacy Defendants' high-volume and increased-profits business model led to a greater number of errors in dispensing prescriptions, which can result in substantial harm to pharmacy customers and to the public health.

706. A survey conducted by the Institute for Safe Medication Practices ("ISMP") of 673 pharmacists revealed that 83% believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, and that 49% felt specific time measurements were a significant contributing factor.

707. Further, the National Association of Boards of Pharmacy found that performance metrics, which measure the speed and efficiency of prescription work flow—using such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift—may distract pharmacists and impair professional judgment.

708. The practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions at a pharmacy.

709. The productivity policies of the Retail Pharmacy Defendants are directly at odds with their performance of the due diligence obligations required to be performed in conjunction with federal and state law, especially given the higher duty of care associated with the prescription of narcotic opioids.

710. The Retail Pharmacy Defendants were negligent in failing to ensure, or even permit, pharmacists in their stores to exercise the reasonable care necessary under the circumstances to detect and prevent diversion.

711. Upon information and belief, this problem was compounded by the failure of the Retail Pharmacy Defendants to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal,

or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

712. Upon information and belief, the Retail Pharmacy Defendants also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid epidemic in Plaintiffs' communities.

713. Upon information and belief, the Retail Pharmacy Defendants failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the communities in which their pharmacies are located; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

714. Upon information and belief, the Retail Pharmacy Defendants also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

715. Upon information and belief, the Retail Pharmacy Defendants also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

716. The Retail Pharmacy Defendants were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. *The Retail Pharmacy Defendants have repeatedly failed to adhere to their duties.*

717. The Retail Pharmacy Defendants have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids.

718. Indeed, several of the Retail Pharmacy Defendants have been repeatedly penalized for their illegal prescription opioid practices.

719. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Retail Pharmacy Defendants, employed by the Retail Pharmacy Defendants throughout South Carolina and in Plaintiffs' communities.

i. CVS

720. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

721. CVS is a repeat offender: the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as a cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating their recordkeeping and dispensing obligations.

722. For example, as recently as July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its

pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.

723. This fine was preceded by numerous others throughout the country.

724. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the FCSA by filling prescriptions with no legitimate medical purpose.

725. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the FCSA.

726. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein it agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

727. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that fifty of its stores violated the FCSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

728. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the FCSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

729. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida had dispensed prescription opioids “based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need.”

730. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations that it filled prescriptions written by a doctor whose controlled-substance registration had expired.

731. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

732. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the FCSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

ii. Walgreens

733. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

734. Walgreens has also been penalized for serious and flagrant violations of its duties with respect to prescription opioids. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the FCSA, including negligently allowing controlled

substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.

735. The settlement resolved investigations into and allegations of FCSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

736. In June 2014, Walgreens and the South Carolina State Pharmacy Board entered into a Consent Agreement, in which Walgreens admitted to violating S.C. Code Ann. § 40-43-140. Specifically, Walgreens admitted to failing to maintain effective controls against the diversion of controlled substances from its distribution centers into other than legitimate medical, scientific and industrial channels; failing to timely detect and report suspicious orders of controlled substances; distributing controlled substances from its distribution centers to pharmacies that the distribution centers knew or should have known were engaged in unlawful activity; failing to make complete and accurate ARCOS reports; failing to maintain or furnish accurate records; and engaging in conduct inconsistent with the Controlled Substances Act.

737. Walgreens' Florida operations highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011, which is more than ten times the average amount.

738. Walgreens increased orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet, Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,"

underscoring Walgreens' attitude that profit outweighed compliance with its duties or the health of communities.

739. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into a Walgreens distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter distribution center.

740. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).

741. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

742. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and failed to use sound professional judgment when dispensing opioids and other controlled substances, despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.

iii. Rite Aid

743. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States. Rite Aid has annual revenue of more than \$21 billion.

744. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the FCSA.

745. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had engaged in a pattern of non-compliance with the requirements of the FCSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of those Rite Aid pharmacies. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R 1301.76(b).

iv. Allegations applicable to all of the Retail Pharmacy Defendants

746. Numerous state and federal drug diversion prosecutions have occurred regarding the Retail Pharmacy Defendants' improper handling of prescription opioids. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

747. The litany of state and federal actions against the Retail Pharmacy Defendants demonstrate that they routinely, and as a matter of standard operating procedure, violated their legal obligations under the laws and regulations that govern the distribution and dispensing of prescription opioids.

748. Throughout the country and in South Carolina in particular, the Retail Pharmacy Defendants were aware or should have been aware of numerous red flags indicating potential suspicious activity and diversion of prescription opioids.

749. On information and belief, the Retail Pharmacy Defendants knew or reasonably should have known about the disproportionate flow of opioids into Plaintiffs' communities and knew or should have known about the operation of "pill mills" in Plaintiffs' communities that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

750. On information and belief, the Retail Pharmacy Defendants knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids in Plaintiffs' communities, including spiking opioid overdose rates and other harmful consequences.

751. The Retail Pharmacy Defendants knew or should have known that their distribution and dispensing activities fell short of the legal requirements.

752. The Retail Pharmacy Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

N. THE PURDUE-RELATED ADDITIONAL DEFENDANTS PARTICIPATED AND PROFITED FROM PURDUE'S WRONGDOING AND ARE, THEREFORE, PERSONALLY LIABLE.

753. At all relevant times, the Sackler Families—in particular, Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Kathe Sackler, Beverly Sackler, Theresa Sackler, Ilene Sackler Lefcourt, David Sackler, and Raymond Sackler Trust ("Sackler Defendants")—controlled Purdue and its associated companies.

754. Purdue is part of a complex web of entities which the Sackler Families own and control. PPI is the managing general partner of PPLP and of many of the various Purdue-related entities. Its status as managing general partner of the various entities ensures PPI's control of

those entities. In turn, at all relevant times, all the members of the board of PPI have been members of the Sackler Families or Sackler-family retainers.

755. Because the Sackler Families control of the board of PPI, the officers of PPI and PPLP reported to them. This ensured Sackler control of PPI and PPLP, even when the officers of those entities were not themselves members of the Sackler Families.

756. At relevant times, Rhodes Tech or its predecessor has manufactured and supplied PPLP with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations.

757. At relevant times, Rhodes Tech Inc. has manufactured and supplied PPLP with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations or has managed Rhodes Tech or its predecessor in doing so.

758. At all relevant times, Rhodes Pharma has marketed a generic form of OxyContin, which is manufactured by Purdue Pharmaceuticals L.P. ("PPNC"), a Delaware limited partnership, which is a subsidiary of PPLP and which owns and operates a pharmaceutical manufacturing facility in Wilson, North Carolina.

759. At all relevant times, Rhodes Pharma Inc. has marketed a generic form of OxyContin, which is manufactured by PPNC.

760. At relevant times, PF Labs engaged in the business of manufacturing OxyContin for PPLP.

761. The Sackler Defendants made the decision that the Sackler Families should enter the generic market for OxyContin in or about 2008 and that they should do so through Rhodes Pharma, a Sackler-owned entity created for that purpose.

762. The Sackler Defendants caused Purdue and other associated companies that they beneficially owned and controlled to distribute to the Sackler Families hundreds of millions of dollars of profits earned by Purdue and its associated companies from the sale of opioids.

763. Each of the Sackler Defendants named herein has served on the board of directors of, or as an officer of, Purdue and one or more Purdue-related entities. These Defendants were the chief architects and beneficiaries of Purdue's deception.

764. The Sackler Defendants beneficially own and control all of the entities owned by the Sackler Families, including PF Labs and the Rhodes Defendants, in substantially the same way as they control PPLP and its affiliates, although they may do so using different holding companies and trusts than those used to control PPLP. The Purdue-related entities that are not controlled by the Sackler Defendants through PPI are controlled by them through different entities unknown to Plaintiffs.

765. At all relevant times, Richard Sackler played an active and central role in the management of Purdue and the Purdue-related Defendants. He began working for Purdue as Assistant to the President (his father, Raymond) in the 1970s. He later served as Vice President of Marketing and Sales. In the early 1990s, he became Senior Vice President, which was the position he held at the time OxyContin was launched in 1996. In 1999, he became President, and he served in that position until 2003.

766. Richard Sackler resigned as President in 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve, with his uncle Mortimer, as Co-Chair of the Board of Purdue. In that way, among others, the family maintained control over their family-owned business, even though they were no longer officers, because the officers reported to them.

767. As a senior executive of Purdue, Richard Sackler was actively involved in the invention, development, marketing, promotion, and sale of Purdue's opioid products, including OxyContin. He worked tirelessly to make OxyContin a blockbuster drug for Purdue, telling colleagues how devoted he was to the drug's success. Along with his father Raymond and his uncle Mortimer, he launched OxyContin with one of the biggest pharmaceutical marketing campaigns in history, deploying many persuasive techniques pioneered by his uncle Arthur. Within five years of its introduction, OxyContin was generating a billion dollars a year. When OxyContin was met with resistance, Richard Sackler directly participated in Purdue's efforts to counter that resistance.

768. At all relevant times, Richard Sackler served as a trustee of one or more trusts that beneficially own and control Purdue.

769. Richard Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and its affiliates from the sale of opioids.

770. Jonathan Sackler was a Vice President of Purdue in 1991, and by 2000 he was a Senior Vice President. Like his brother Richard, he resigned that position in or after 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve on the Board of Purdue.

771. At all relevant times, Jonathan Sackler served as a trustee or one or more trusts that beneficially owns and controls Purdue.

772. Jonathan Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and its affiliates from the sale of opioids.

773. Mortimer D.A. Sackler served as a Vice President of Purdue during the period of the development, launch, and promotion of OxyContin. He resigned that position in or after

2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve on the Board of Purdue.

774. Mortimer D.A. Sackler is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and its affiliates from the sale of opioids.

775. Kathe A. Sackler was a Vice President of Purdue in 1991, and by 2000 she was a Senior Vice President. She resigned that position in or about 2003 due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, she continued to serve on the Board of Purdue.

776. Kathe A. Sackler is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and its affiliates from the sale of opioids.

777. Ilene Sackler Lefcourt served as Vice President of Purdue during the period of the development, launch, and promotion of OxyContin. She resigned that position in or after 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, she continued to serve on the Board of Purdue.

778. Ilene Sackler Lefcourt is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and its affiliates from the sale of opioids.

779. At all relevant times, Beverly Sackler served as a trustee of one or more trusts that beneficially own and control Purdue and to which 50% of the profits of Purdue and its affiliates from the sale of opioids has been conveyed. She has also served as a member of the Board of Directors of Purdue since the 1990s.

780. Beverly Sackler is the direct or indirect beneficiary of some portion of 50% of the profits earned by Purdue and its affiliates from the sale of opioids.

781. Theresa Sackler is the direct or indirect beneficiary of 50% of the profits earned by Purdue and its affiliates from the sale of opioids. She has also served as a member of the Board of Directors of Purdue since the 1990s.

782. David A. Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and its affiliates from the sale of opioids. He has also served as a member of the Board of Directors of Purdue since 2012.

783. Stuart Baker joined Purdue in 1994 as Executive Vice President of PPLP and as Vice President of PF Co. He served as legal counsel to the entire Purdue organization and the Sackler Families. He also served as an officer of other Sackler-owned, Purdue-related entities. He served as a trustee of one or more trusts that beneficially own and control Purdue and its affiliates. He served as Corporate Secretary for Purdue, and as such he gained direct knowledge of the wrongdoing alleged in this Complaint. In his capacity as an officer, director, and lawyer, he knowingly aided, abetted, participated in, and benefitted from the wrongdoing of Purdue as alleged in this Complaint, and further knowingly aided and abetted the Sackler Families and the Purdue-Related Additional Defendants in structuring their personal affairs and the personal and business organizations they beneficially owned and controlled in such a way as to attempt to evade personal liability for the wrongdoing in which he knew they had engaged and in which he knew they intended to continue to engage.

784. The Sackler Families are the sole beneficial owners of Purdue and its associated companies. All profits of Purdue and its associated companies go to Sackler-family trusts and entities.

785. Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, the Raymond Sackler Trust

(through its trustees), and Stuart D. Baker each knowingly aided, abetted, participated in, and benefitted from the wrongdoing of Purdue as alleged in this Complaint. These defendants owned and controlled Purdue as their own privately held drug company. They had the power to decide how addictive narcotics were sold. They got more patients on opioids, at higher doses, for longer. They paid themselves billions of dollars. They are responsible for addiction, overdose, and death that cost the victims' communities untold sums. They should be held accountable for their role in the opioid epidemic.

786. Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, the Raymond Sackler Trust (through its trustees), and Stuart D. Baker controlled the misconduct described below. They knew and intended that sales representatives in South Carolina would unfairly and deceptively promote opioid sales that are dangerous for patients by:

- a. falsely blaming the dangers of opioids on patients rather than the addictive drugs;
- b. pushing opioids for elderly patients without disclosing the higher risks;
- c. pushing opioids for patients who had never taken them before without disclosing the higher risks;
- d. pushing opioids as substitutes for safer medications with improper comparative claims;
- e. falsely assuring doctors and patients that reformulated OxyContin was safe;
- f. pushing doctors and patients to use higher doses of opioids without disclosing the higher risks;
- g. pushing doctors and patients to use opioids for longer periods of time without disclosing the higher risks; and
- h. pushing opioid prescriptions by doctors that Purdue knew were writing dangerous prescriptions.

1. *Purdue's Directors Knowingly Participated in Purdue's Wrongdoing.*

787. The members of the Board of Purdue were intimately involved in the activities of the entities that they managed, often on a weekly or even daily basis.

788. Purdue and the Sackler Families launched OxyContin with one of the biggest pharmaceutical marketing campaigns in history, deploying many persuasive techniques pioneered by Arthur Sackler. They trained and armed a force of approximately 1,000 sales representatives with charts showing OxyContin's purported benefits. A major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or for cancer pain, but also for less acute, longer-lasting pain, such as arthritis, back pain, sports injuries, and fibromyalgia. The number of conditions that OxyContin could treat seemed almost unlimited.

789. The training included "training in 'overcoming objections' from clinicians." "If a doctor inquired about addiction," Purdue representatives were instructed to respond as follows: "'The delivery system is believed to reduce the abuse liability of the drug.'" One sales representative has said that Purdue executives "told us to say things like it is 'virtually' non-addicting."

790. Purdue sales representatives were provided with studies and literature provided by other physicians. Purdue had a speakers' bureau through which it paid several thousand doctors to attend medical conferences and deliver presentations about OxyContin's merits. Doctors were offered all-expenses-paid trips to pain-management seminars in places such as Boca Raton, Florida. Doctors who attended these seminars wrote OxyContin prescriptions more than twice as often as those who did not.

791. Purdue also advertised in medical journals and produced promotional videos featuring satisfied patients and doctors' testimonials. The marketing of OxyContin relied on an

empirical circularity: the company convinced doctors of the drug's safety with literature that had been produced by doctors who were paid, or funded, by the company.

792. According to a former OxyContin sales representative, Richard Sackler was “‘the dude that made it happen.’” Richard Sackler himself was tireless in his dedication to OxyContin's success. When benefit plans began citing OxyContin abuse as an excuse not to pay, Richard Sackler sent an email to sales representatives stating that, for insurers, “‘addiction’ may be a convenient way to just say ‘NO.’”

793. Members of the Sackler family were on site at Purdue's headquarters on a daily basis, controlling the management of their family-owned business and all of its employees.

794. Richard Sackler is named as inventor on some 50 patents relating to oxycodone and other pain medications, including several patents apparently issued as late as 2016. Virtually all such patents invented by Richard Sackler were assigned to Purdue.

795. In 1997, both Richard and Kathe Sackler were part of a conspiracy to deceive physicians into believing that oxycodone was half as strong as morphine, when in fact the opposite was true. This deception was known by Purdue to ease the fears of well-meaning and careful physicians about prescribing OxyContin for non-cancer pain uses.

796. In the late 1990s Richard, Jonathan and Kathe Sackler participated in an unlawful attempt to deceive European drug regulators into classifying OxyContin as totally uncontrolled, i.e., capable of being obtained without a prescription, even though all of these family members were by then well aware of the abuse liability of the drug in the U.S.

797. In 2001, Kathe Sackler attended a talk given by the chief medical officer of Sikorsky Aircraft, in which the speaker expressed grave concern about the risks associated with OxyContin. Instead of acknowledging this fact to the medical officer, Kathe Sackler remained

silent and returned to the Purdue headquarters, where employees were directed to find ways to undercut and deflect the Sikorsky medical officer's concerns.

798. In the period around 1999-2003, Purdue developed a method to cause company emails to self-destruct at a pre-determined time; this was an attempt to create a system where potentially incriminating documents would automatically self-destruct, even after receipt by unrelated third-parties. Richard, Jonathan, and Kathe Sackler all were directly aware of and supportive of this project.

2. *Members of the Sackler Families were Aware of Risks Associated with OxyContin No Later than the Summer of 1999.*

799. That prescription opioids would lead to addiction, and specifically that OxyContin could be and was being abused, has been known to Purdue and to the members of the Sackler Families involved in running the family business since at least the summer of 1999.

800. In the summer of 1999, a Purdue sales representative wrote to the President of Purdue reporting widespread abuse of OxyContin. As a result of that memo, a secretary at Purdue, Maureen Sara, was tasked with doing research on the Internet to learn about the nature and scope of the abuse, specifically to learn about how recreational drug users were misusing OxyContin.

801. To carry out her assignment, Ms. Sara began visiting drug-user Internet "news groups" or "chat rooms" daily. Two groups in particular that Ms. Sara visited were alt.drugs and alt.drugs.hard. For a period, in the late summer and early fall of 1999, Ms. Sara would forward screen shots from these news groups daily to Howard Udell, then General Counsel of Purdue.

802. In October or November, 1999, Ms. Sara prepared a memo summarizing her research into misuse of OxyContin. The memo described how users would remove the coating on the OxyContin pills, crush them, cook them, and snort or shoot them. Ms. Sara sent the memo containing the details of OxyContin abuse by drug users not only to the President of Purdue and

to its General Counsel, but also to Purdue's then-medical director, and directly to members of the Sackler Families involved in the management of the company, including Richard Sackler, Jonathan Sackler, and Kathe Sackler.

803. Purdue, Richard Sackler, Jonathan Sackler, and Kathe Sackler were thus all aware of the risks and abuse potential and reality of OxyContin long before Purdue acknowledged the same to the government, the healthcare community, or the public.

804. In sworn testimony before the U.S. House of Representatives in 2001, Purdue President Michael Friedman, in the presence of Purdue General Counsel Howard R. Udell, swore that the first the companies knew of widespread abuse of OxyContin was in the year 2000. This was, of course, patently inconsistent with what the members of the Sackler Families knew from the Sara memo they had received in 1999. No member of the Sackler Families at any time tried to correct the false narrative promulgated far and wide about the abuse liability of OxyContin, nor did they correct the false statement about when Purdue became aware of this problem with the drug.

805. Richard Sackler, Kathe Sackler, Jonathan Sackler, Theresa Sackler, Mortimer D.A. Sackler, and Ilene Sackler have been aware since at least 1999 of potential liability for Purdue and those acting in concert with Purdue. With the intention of shielding from creditors the proceeds of their wrongdoing, they have stripped out of Purdue and the Purdue-related additional Defendants each and every year hundreds of millions of dollars of profits from the sales of OxyContin and other opioid-containing medications, including a generic form of OxyContin sold by Rhodes Pharma. All such transfers were and are fraudulent within the meaning of applicable fraudulent transfer statutes and case law; all such transfers unjustly enriched the recipients; and all

such transferred funds should be clawed back from the Sackler Defendants in order to satisfy the opioid-related liabilities of the companies from which they were transferred.

3. *The Purdue-Related Defendants Continued to Oversee Purdue's Wrongdoing Even after Purdue was Fined and Warned about its Conduct.*

806. From the 1990s until 2007, the Purdue-related Defendants directed misconduct which led to criminal convictions, an adverse judgment, and commitments that Purdue would not deceive doctors and patients again. Because the Purdue-related Defendants had already been given a second chance, their misconduct since 2007 against that backdrop was manifestly knowing and intentional.

807. From 2001 to 2007, Purdue was investigated by 26 states and the U.S. Department of Justice. Beginning in or about 2003, advised by Baker, who served as legal counsel to the entire Purdue organization and the Sackler Families, all of the Sacklers who served as executive officers of Purdue resigned out of concern that they might be held personally liable for conduct on behalf of Purdue in which they had previously engaged and in which they expected and intended to continue to engage after their respective resignations.

808. By 2006, prosecutors had found damning evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers voted that their first drug company, PF Co., should plead guilty to a felony for misbranding OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse events and side effects than other pain medications. The Sacklers also voted that three Purdue executives, Michael Friedman (the CEO), Paul Goldenheim (Chief Medical Officer), and Howard Udell (Vice President and General Counsel), but no member of the Sackler family, should plead guilty as individuals to criminal charges that they let Purdue deceive doctors and patients about Purdue's opioids.

809. In May 2007, the Sacklers again voted to have their company plead guilty and enter into a series of agreements that Purdue would never again deceive doctors and patients about opioids. PF Co. agreed to pay nearly \$700 million and pleaded guilty to a felony for misleading doctors and patients about opioids. Purdue admitted that its supervisors and employees, “with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.”

810. The Sacklers voted to admit in an Agreed Statement of Facts that, for more than six years, supervisors and employees intentionally deceived doctors about OxyContin: “Beginning on or about December 12, 1995, and continuing until on or about June 30, 2000, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.” To remove any doubt, the Sacklers voted to enter into a plea agreement that stated: “Purdue is pleading guilty as described above because Purdue is in fact guilty.”

811. As part of the plea agreement in 2007, Purdue signed a detailed Corporate Integrity Agreement with the U.S. government. The Agreement required Purdue to ensure that it did not deceive doctors and patients again. As a further requirement of the Corporate Integrity Agreement, Purdue was required to appoint a Compliance Officer who would “be a member of senior management of Purdue,” “make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors,” and “be authorized to report on such matters to the Board of Directors at any time.” The Corporate Integrity Agreement was built on the idea that the directors would ensure that Purdue never deceived doctors and patients again.

812. The Corporate Integrity Agreement included the directors as “Covered Persons” from 2007 through 2012. All Covered Persons, including the directors and CEO, were required to comply with rules that prohibit deception about Purdue opioids. The directors were required to undergo hours of training to ensure that they understood the rules. The directors were required to report all violations of the rules. The directors were warned that they could face consequences if they failed to comply with the rules. The directors certified that they had read and understood the rules and would comply with them. Accordingly, Purdue and the Sacklers promised to comply with rules that prohibited deception about Purdue opioids.

813. The directors were aware of their obligations under the Corporate Integrity Agreement because in 2009 Purdue had to report to the Inspector General of the U.S. Department of Health and Human Services that it had not immediately trained a new director on the Agreement. Purdue reported: “a new Director was appointed to Purdue’s Board of Directors, without timely notice to either Corporate Compliance or the Office of General Counsel, as otherwise required by policy, resulting in failure to timely launch the training assignment to this new Board member.” Purdue assured the U.S. government that it had trained the new director: “Relevant personnel were reminded of existing policy to notify Corporate Compliance and the Office of General Counsel of changes to the Board of Directors. In both instances, these individuals completed their training assignments within 1 day of Corporate Compliance learning of this issue.” Purdue promised the government that the director’s training had addressed “the proper methods of promoting, marketing, selling, and disseminating information about Purdue’s products,” so Purdue would never deceive doctors and patients again.

814. Also, in 2007, in conjunction with the guilty plea, the Sacklers voted to enter into a Consent Judgment (“2007 Judgment”). The 2007 Judgment ordered that Purdue “shall not make

any written or oral claim that is false, misleading, or deceptive” in the promotion or marketing of OxyContin. The Judgment further required that Purdue provide fair balance regarding the risks and benefits in all promotions of OxyContin. The Judgment required fair balance about the risks of taking higher doses for longer periods and the risks of addiction, overdose, and death.

815. Additionally, the 2007 Judgment required that Purdue establish and follow an abuse and diversion detection program to identify high-prescribing doctors who showed signs of inappropriate prescribing, stop promoting drugs to them, and report them to the authorities.

816. The 2007 Judgment and related agreements should have ended the misconduct of Purdue and the Sacklers. Instead, they continued to break the law, expanding their deceptive sales campaign to make more money from more patients on more dangerous doses of opioids.

4. *Purdue and the Sacklers continued to engage in misconduct from the 2007 Judgment until today.*

817. From the date of the 2007 Judgment to 2018, the Sacklers controlled Purdue’s deceptive sale campaign. They directed the company to hire hundreds more sales representatives to visit doctors thousands more times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so that staff had to create special reports just for them. Richard Sackler even went into the field to supervise sales representatives and to promote opioids to doctors face to face. The Sacklers’ micromanagement was so intrusive that the VP of Sales and Marketing wrote to the CEO: “Anything you can do to reduce the direct contact of Richard into the organization is appreciated.”

818. As detailed below, the misconduct of Purdue and the Sacklers continued from the 2007 Judgement and convictions through 2018.

i. 2007

819. In July 2007, staff told the Sacklers that more than 5,000 cases of adverse events had been reported to Purdue in just the first three months of 2007. Staff also told the Sacklers that Purdue received 572 Reports of Concern about abuse and diversion of Purdue opioids during Q2 2007. Staff reported to the Sacklers that they had completed only 21 field inquiries in response. Staff also told the Sacklers that they had received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase." Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities.

820. Purdue's failure to report abuse and diversion continued, quarter after quarter, even though the 2007 Judgment required Purdue to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or directing sales representatives to stop visiting them, the Sacklers chose to keep pushing opioids to whoever prescribed the most.

821. Staff also reported to the Sacklers that they continued to mail out thousands of deceptive marketing materials, including 12,528 publications in the first half of 2007. The single most-distributed material was volume #1 of Purdue's "*Focused and Customized Education Topic Selections in Pain Management*" (FACETS).

822. In FACETS, Purdue falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life" - just as Richard Sackler had been saying since the 1990s. In the same material, Purdue also falsely told doctors and patients that signs of addiction were actually "pseudoaddiction," and that doctors

should respond by prescribing more opioids. Staff told the Sacklers that another of the publications they had sent most often to doctors was “*Complexities in Caring for People in Pain*.” In it, Purdue repeated again its false claim that warning signs of addiction are really “pseudoaddiction” that should be treated with more opioids.

823. At the same time, staff also reported to the Sacklers that Purdue was making more money than expected. A few months earlier, they had projected a profit of \$407,000,000; now they expected more than \$600,000,000.

824. Staff reported to the Sacklers that “sales effort” was a key reason that profits were high. Purdue employed 301 sales representatives to promote opioids. In comparison, Purdue employed only 34 people in drug discovery.

825. From the 2007 convictions until today, the Sacklers ordered Purdue to hire hundreds of sales representatives to carry out their deceptive sales campaign.

826. In August, Mr. Udell was still serving as Purdue’s senior lawyer, even after his criminal conviction. He wrote to Richard, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler: “Over the last week there have been numerous news stories across the nation reporting on the Associated Press’s analysis of DEA data showing very large increases in the use of opioids analgesics (particularly OxyContin) between the years 1997 and 2005. Many of these articles have suggested that this increase is a negative development suggesting overpromotion and increasing abuse and diversion of these products.”

827. In October, the Sacklers learned that Purdue received 284 Reports of Concern about abuse and diversion of Purdue’s opioids in Q3 2007. They conducted only 46 field inquiries in response. Staff reported to the Sacklers that they received 39 tips to Purdue’s compliance hotline during the quarter, but Purdue did not report any of them to the authorities.

828. Purdue had by then hired more sales representatives and now employed 304. Staff reported to the Sacklers that Purdue was succeeding at promoting its highest doses of opioids: “OxyContin 80mg is at Rx levels not seen in over 2 years.”

829. In preparation for an upcoming Board meeting, Richard Sackler requested the spreadsheets underlying their sales analysis, so that he could do his own calculations. The spreadsheets showed that, in 2007, Purdue expected to collect more than half its total revenue from sales of 80mg OxyContin - its most powerful, most profitable, and most dangerous pill.

830. In November, the Sacklers voted to spend \$86,900,000 to employ sales representatives in 2008 and another \$1,000,000 to buy them laptops. The Sacklers also voted for a resolution regarding salary increases and bonus targets for the sales representatives.

ii. 2008

831. In January, staff told the Sacklers that Purdue they were succeeding at the goal of promoting higher doses of opioids: “OxyContin 80mg continues to grow.” The Sacklers were advised that, in 2007, Purdue’s net sales were just over \$1 billion, almost “DOUBLE” what the company had planned. OxyContin accounted for more than 90% of those sales.

832. The Sacklers wanted more details on tactics for pushing sales. Richard Sackler wrote to Russell Gasdia, Vice President of Sales and Marketing (hereinafter “Sales VP”), demanding information about Purdue’s opioid savings cards. Richard asked Gasdia how long the opioid savings cards lasted, how much savings they offered a patient, and whether there had been any changes since he had last been briefed on the opioid savings card scheme. Richard sent Gasdia a detailed hypothetical scenario to make sure he understood the sales tactic down to the smallest details. Staff followed up with a presentation about opioid savings cards to the Sacklers at the next Board meeting.

833. Staff also told the Sacklers that Purdue received 689 Reports of Concern about abuse and diversion of Purdue's opioids in Q4 2007, but had conducted only 21 field inquiries in response. The Sacklers learned that Purdue had received 83 tips to Purdue's compliance hotline during the quarter but did not report any of them to the authorities.

834. Meanwhile, when staff proposed a plan to get pharmacies to increase their inventory of OxyContin from 2 bottles to 3 bottles, Richard Sackler demanded to know why they couldn't get up to 4 bottles or more.

835. The Sacklers also made the decision to expand their sales force. At Purdue, hiring more sales representatives was not a matter for middle management. Selling opioids door-to-door, in visits to doctor's offices and hospitals, was the core business of the company. The Sacklers themselves made the decisions about how big the sales force would be and what it would do.

836. In February, the Sacklers used their power on the Board of Directors to order Purdue to "begin expanding the sales force by an additional 100 sales representatives beginning effective as of April 1, 2008."

837. The Sacklers knew and intended that, because of their direct orders, more sales reps would promote opioids to prescribers in South Carolina. In preparation for the Sacklers' vote, staff told them that adding 100 sales representatives would allow Purdue to make 12,000 more sales visits to prescribers every month.

838. The Sacklers also knew and intended that the sales representatives would push higher doses of Purdue's opioids. That same month, Richard Sackler directed Purdue management to "measure our performance by Rx's by strength, giving higher measures to higher strengths." He copied Jonathan and Mortimer Sackler on the instruction. The Sacklers knew higher doses put

patients at higher risk. As far back as the 1990s, Jonathan and Kathe Sackler knew that patients frequently suffer harm when “high doses of an opioid are used for long periods of time.”

839. On Valentine’s Day, the Sacklers voted to pay former CEO and criminal convict Michael Friedman \$3,000,000. It was one of several multi-million-dollar payments to the convicted executives to maintain their loyalty and to protect the Sackler family.

840. By 2008, Purdue was working on a crush-proof reformulation of OxyContin to extend Purdue’s patent monopoly. The Sacklers learned that another company was planning clinical research to test whether crush-proof opioids are safer for patients. Mortimer Sackler suggested that Purdue conduct similar studies to find out whether reformulated OxyContin was really safer *before* selling it to millions of patients. He wrote to Richard Sackler: “Purdue should be leading the charge on this type of research and should be generating the research to support our formulation. Why are we playing catch up ...? Shouldn’t we have studies like this ...?” The Sacklers decided not to do the research because they wanted the profits from a new product, regardless of whether the deaths continued. Richard didn’t want a paper trail, so he instructed Mortimer to call him, and CEO John Stewart met with his staff to plan how to phrase a carefully worded reply. Later that month, Stewart wrote to Richard that reformulating OxyContin “will not stop patients from the simple act of taking too many pills.”

841. Meanwhile, staff gave Jonathan, Kathe, Mortimer and Richard Sackler projections indicating that OxyContin sales could plateau. Mortimer demanded to know why sales would not grow. Richard, in an 8:30 p.m. communication, instructed the staff to find answers “before tomorrow.” Staff emailed among themselves about how unrealistic and harmful the Sacklers’ demands were and decided it was safer to discuss the problem by phone.

842. In March, Richard Sackler became immersed in Purdue's strategy for selling more OxyContin. He asked sales and marketing staff for thousands of pieces of data about sales trends, including data to distinguish the kilograms of active drug from the number of prescriptions, so he could analyze higher doses. Staff delivered the data early Sunday morning; Richard responded with detailed instructions for new data that he wanted that same day. An employee sent Richard the additional data only a few hours later, stating: "I have done as much as I can." The employee explained that he had family visiting from out of town to which Richard responded by calling him at home. Richard insisted that the sales forecast was too low and threatened that he would have the Board reject it. On Monday, staff emailed among themselves to prepare for a meeting with Richard, highlighting that Richard was looking for results that could only be achieved by hiring more sales representatives. Meanwhile, Richard met with John Stewart to discuss his analysis of the weekend's data and new graphs Richard had made.

843. Sales VP Russell Gasdia felt pressured. When Richard Sackler sent Gasdia a list of seven sales questions to answer on a Saturday (copied to Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler), Gasdia wrote to John Stewart: "John, I know it is tricky, but Dr. Richard has to back off somewhat. He is pulling people in all directions, creating a lot of extra work and increasing pressure and stress. I will draft a response but he is not realistic in his expectations and it is very difficult to get him to understand."

844. Richard Sackler did not back off but instead pushed staff to sell more of the highest doses of opioids and get more pills in each prescription. Richard sent Gasdia another set of instructions, directing him to identify tactics for "exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx)." The next day, Gasdia was writing

up plans for how adding sales representatives, opioid savings cards, and promoting more intermediate doses of OxyContin could help increase sales.

845. Richard Sackler followed through on his threat that he would have the Board reject the sales plan. Two days later, Richard circulated his own sales analysis to the Board, ordered the Secretary to “put this high in the Board agenda,” and proposed that he and Mortimer Sackler oversee a redo of the annual plan as well as the 5-year plan for Purdue’s opioids.

846. At the same time, Jonathan, Kathe, and Mortimer Sackler were also pushing staff about sales. Staff told those three Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007, “in spite of all the pressures.” Kathe demanded that staff identify the “pressures” and provide “quantification of their negative impact on projected sales.”

847. In April, staff reported to the Sacklers that the sales representatives had obtained data showing which pharmacies stocked higher strengths of OxyContin, which helped them convince area doctors to prescribe the highest doses. The Sacklers learned that Purdue received 853 Reports of Concern about abuse and diversion of Purdue opioids in Q1 2008, but had conducted only 17 field inquiries in response. Staff also reported to the Sacklers that they received 83 tips to Purdue’s compliance hotline during the quarter, but did not report any of them to the authorities.

848. On April 18, Richard Sackler sent Kathe, Ilene, David, Jonathan, and Mortimer Sackler a secret memo about how to keep money flowing to their family. Richard wrote that Purdue’s business posed a “dangerous concentration of risk.” After the criminal investigations that had almost reached the Sacklers, Richard wrote that it was crucial to install a CEO who would be loyal to the family: “People who will shift their loyalties rapidly under stress and temptation can

become a liability from the owners' viewpoint." Richard recommended John Stewart for CEO because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, pull the profits out of the business and "distribute more free cash flow" to themselves.

849. That month, the Sacklers voted to have Purdue pay their family \$50,000,000. From the 2007 convictions until 2018, the Sacklers voted dozens of times to pay out Purdue's opioid profits to their family, totaling *more than four billion dollars*.

850. On April 18, the Sacklers voted to increase the 2008 budget for Sales and Promotion to \$155,802,000. Richard Sackler then sent Sales VP Russell Gasdia a series of questions about Purdue's efforts to get patients to take higher doses and stay on opioids for longer times. Richard wanted to know: how many Purdue patients had insurance that would let them take unlimited quantities of Purdue opioids; how many patients were limited to 60 tablets per month; and how many patients had any limit on the number of tablets or dose or number of tablets per day. He demanded that sales staff be assigned to answer his questions "by tomorrow morning." When the sales staff asked for a few more hours to collect the data, Richard agreed to give them until the end of the day.

851. In May, staff sent the Sacklers more ideas about ways to promote Purdue's opioids. The proposal matched the Sacklers' own plan, which Richard had written out as CEO: deflect blame from Purdue's addictive drugs by stigmatizing people who become addicted. "KEY MESSAGES THAT WORK" included this lie: "It's not addiction, it's abuse. It's about personal responsibility."

852. In June, the Sacklers voted to appoint John Stewart as President and CEO of Purdue Pharma Inc. and Purdue Pharma L.P. The appointment followed through on Richard Sackler's

suggestion in his secret memo. On the same day, the Sacklers voted to pay their family \$250,000,000. The payment followed Richard Sackler's suggestion in the memo to "distribute more free cash flow" to themselves.

853. Meanwhile, Richard Sackler asked sales staff for more information about Purdue's opioid savings cards. Staff reported to Richard, Jonathan, Kathe, and Mortimer Sackler that 67,951 patients had used Purdue's opioid savings cards, and that the cards provided a discount on a patient's first five prescriptions.

854. After five prescriptions, many patients would face significant withdrawal symptoms if they tried to stop taking opioids. Staff told Richard, Jonathan, Kathe, and Mortimer Sackler that 27% of patients (more than 18,000 people) had used the cards for all five prescriptions.

855. In July, Purdue's Fleet Department reported to the Sacklers that Purdue had bought one hundred new Pontiac Vibes for the expanded sales force. The Sacklers were advised that Purdue received 890 Reports of Concern regarding abuse and diversion of Purdue's opioids in Q2 2008 and had conducted only 25 field inquiries in response. Staff reported to the Sacklers that they received 93 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.

856. In September, the Sacklers voted to pay their family \$199,012,182.

857. In October, staff told the Sacklers that surveillance data monitored by Purdue indicated a "wide geographic dispersion" of abuse and diversion of OxyContin "throughout the United States." Staff told the Sacklers that "availability of the product" and "prescribing practices" were key factors driving abuse and diversion of OxyContin." On the same day, staff told the Sacklers that Purdue had begun a new "Toppers Club sales contest" for sales representatives to win bonuses, based on how much a representative increased OxyContin use in his or her territory

and how much the representative increased the broader prescribing of opioids - the same “availability of product” and “prescribing practices” factors that increase the risk of diversion and abuse. In the same report, staff told the Sacklers that they received 163 tips to Purdue’s compliance hotline during Q3 2008, but did not report any of them to the authorities.

858. In November, the Sacklers expanded the sales force again. Purdue’s 2009 budget identified expanding the sales force as the #1 sales and marketing objective. The Sacklers voted to spend \$112,400,000 on sales representatives. Staff told the Sacklers that their decision would pay an average sales representative’s salary of \$89,708 and bonus of \$43,470, and the sales representatives would visit prescribers 518,359 times.

859. That same month, the Sacklers voted to pay their family \$325,000,000. They also voted to pay \$5,000,000 to Howard Udell, their lawyer and convicted criminal. Like their Valentine’s Day payment to Friedman, the Sacklers spent millions to maintain the loyalty of people who knew the truth about Purdue.

iii. 2009

860. In 2009, the American Journal of Public Health published an article about Purdue’s opioid marketing entitled, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy.” The article detailed Purdue’s use of sales representatives, targeting of high-prescribers, and deception about addiction. That same year, CDC reported that deaths from opioids had recently tripled.

861. In March 2009, the Sacklers voted to pay Purdue sales representatives and sales managers bonuses of 103 percent of Purdue’s target because they had sold so many opioids in 2008. The Sacklers also voted to increase the base pay of sales staff for 2009. On the same day, the Sacklers voted to pay their family \$200,000,000.

862. In April, staff told the Sacklers that Purdue employed 412 sales representatives and had made dramatic progress promoting higher doses of Purdue opioids: “for the first time since January 2008, OxyContin 80mg strength tablets exceeded the 40mg strength.” The Sacklers had a detailed conversation with Sales VP Russell Gasdia about the staffing of the sales force, how many sales representatives the company should employ, and how many prescribers each representative would visit each year. The Sacklers told sales executives to hire a new staff member who would contact prescribers electronically and promote Purdue opioids through the deceptive website *Partners Against Pain*.

863. Staff told the Sacklers that they received 122 tips to Purdue’s compliance hotline during Q1 2009 and had revealed one of them to an outside monitor. Staff reported to the Sacklers that compliance problems included improper use of OxyContin marketing materials and opioid savings cards.

864. In May, staff informed the Sacklers that Purdue had violated its Corporate Integrity Agreement with the U.S. government by failing to supervise its sales representatives. Because sales representatives lobbying doctors poses a high risk of misconduct (no witnesses, and the representative is paid to increase opioid sales), the United States required that Purdue managers supervise sales representatives in person at least 5 days each year. Purdue management had disregarded that obligation and had not even set up a system to track it. Even though Purdue executives had ignored the requirement and not monitored it, they responded to the violation by firing three employees in the field and letting all the executives at headquarters keep their jobs.

865. In June, Richard Sackler asked sales staff how a competing drug company had increased sales: “What is happening???”

866. A few days later, staff reported to the Sacklers that Purdue had expanded its sales force at the Board's direction: "As approved in the 2009 Budget, 50 New Sales Territories have been created." Staff told the Sacklers the expansion was focused on the most prolific opioid prescribers, because "there are a significant number of the top prescribers" that Purdue had not been able to visit with its smaller force of sales representatives. Later that month, the Sacklers voted to pay their family \$162,000,000.

867. In July, staff told the Sacklers that Purdue employed 429 sales representatives. Richard Sackler told staff that he was not satisfied with OxyContin sales and demanded a plan to "boost" them. He asked for the topic to be added to the agenda for the Board.

868. In August, Richard Sackler convened a meeting of Board members and staff about "all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market." He emphasized that \$200,000,000 in profit was at stake. At the meeting, staff told the Sacklers that the 80mg OxyContin pill was far-and-away Purdue's best performing drug. Purdue sold many more kilograms of active ingredient in the 80mg dose than any other dose.

869. Staff also reported to the Sacklers about their newest OxyContin sales campaign, with the slogan: *Options*. The *Options* campaign set the pattern that Purdue would follow for years: pushing doctors and patients up the ladder to higher doses. To make it easy for sales representatives to promote higher doses, the campaign materials emphasized the "range of tablet strengths," provided a picture of each dose, and said: "You can adjust your patient's dose every 1 to 2 days." Staff told the Sacklers that they would advertise the *Options* campaign in medical journals reaching 245,000 doctors.

870. Staff also reported to the Sacklers that more than 160,000 patients had used Purdue's opioid savings cards, more than doubling the number reported to the Sacklers the summer

before. Staff also told the Sacklers that they would advertise OxyContin using a special television network: thousands of doctors would be given free digital video recorders for their home televisions, in exchange for watching advertisements for drugs.

871. Immediately after meeting with sales staff, Richard Sackler asked for the raw data underlying their presentation. When staff had not responded within five minutes, he asked again.

872. In September, the Sacklers voted to pay their family \$173,000,000. But Mortimer Sackler was concerned that staff members were not selling Purdue's opioids aggressively enough. He asked why staff predicted a decline in OxyContin sales when he believed the market should grow.

873. That same month, the Sacklers and staff discussed federal sunshine legislation that would create a public database to disclose drug companies' payments to doctors. Purdue was paying many doctors to promote its opioids, but the payments could often be kept secret. Some of the Sacklers were concerned that doctors would be "much less willing" to work for Purdue if the payments were disclosed.

874. In November, the Sacklers voted to spend \$121,628,000 to employ sales representatives in 2010. Kathe and Richard Sackler were designated to review the sales projections. They also voted to pay Howard Udell up to another \$1,000,000, and to pay \$2,700,000 to settle personal injury claims by people harmed by Purdue's opioids.

875. At the Board meeting that month, Kathe and Richard Sackler asked staff to "identify specific programs that Sales and Marketing will implement to profitably grow the OER [extended-release oxycodone] market and OxyContin in light of competition; provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth; clarify the situation with respect to OxyContin being used by 35% of new patients, but

only retaining 30% of ongoing patients;” and give the Sacklers a copy of a report from McKinsey on tactics to increase OxyContin sales. The McKinsey report instructed sales representatives to maximize profits by “emphasizing [the] broad range of doses” – meaning the doses that were highest and most profitable.

876. At the same meeting, Richard Sackler also asked staff, “What are OxyContin’s clinical advantages vs. Opana ER, MS Contin, Kadian, Exalgo, Avinza, Nucynta and Duragesic? How are these differences communicated?” In response, staff reported to all the Sacklers a list of purported advantages of OxyContin over competing products, including that OxyContin purportedly reduces pain faster, has less variability in blood levels, and works for more pain conditions than competing drugs. These were all improper, unfair, and deceptive claims that Purdue had admitted were prohibited.

877. In December, Kathe and Richard Sackler met with sales staff to review plans for 2010. Staff warned the two Sacklers that, although OxyContin sales were at record-breaking levels (nearly \$3 billion per year), the decade-long rise in the total kilograms of oxycodone prescribed in America was beginning to flatten.

iv. 2010

878. In 2010, *Time* magazine published a story about Purdue’s opioids entitled, “The New Drug Crisis: Addiction by Prescription.” Overdoses were the leading cause of accidental death in 15 states.

879. In January 2010, Richard Sackler started the year by asking sales staff for new customized reports. Staff complained to each other until Sales VP Russell Gasdia asked CEO John Stewart to intervene: “Can you help with this? It seems like every week we get one off requests from Dr. Richard.” Neither Stewart nor anyone else could keep Richard out of sales. Days later,

Richard was writing to the sales employee on Saturday morning, stating that his need to review the sales plan was “urgent” and should be satisfied “this weekend.”

880. In February, Purdue’s Sales and Marketing Department told the Sacklers that a key objective for 2010 would be to “Meet or exceed total prescriber call targets of 545,000” visits to prescribers to promote Purdue opioids. For the next four years or more, a key objective for the sales employees was to meet a quota of sales visits, and the Sacklers tracked their performance. The target rose from 545,000 prescriber visits in 2010, to 712,000 visits in 2011, 752,417 visits in 2012, and 744,777 visits in 2013.

881. Staff also told the Sacklers that McKinsey estimated that new tactics by Purdue sales representatives would generate \$200,000,000 to \$400,000,000 more sales of OxyContin, and that sales representatives had been practicing the new tactics in front of management. McKinsey had reported to Purdue on opportunities to increase prescriptions by convincing doctors that opioids provide “freedom” and “peace of mind” and give patients “the best possible chance to live a full and active life.” McKinsey also suggested sales “drivers” based on the ideas that opioids reduce stress and make patients more optimistic and less isolated. In fact, becoming addicted to opioids makes patients more stressed, more isolated, and less likely to survive.

882. The Sacklers voted to spend \$226,000,000 on Sales and Promotion in 2010, and paid their family \$236,650,000.

883. In March, Richard Sackler instructed sales staff to send him monthly reports on sales of OxyContin and its competitors. They complied within ten minutes. The report showed that Purdue was selling more pills of its 80mg OxyContin (the highest dose) than any other dose, and that the highest dose pills were responsible for the greatest share of Purdue’s revenue by far.

884. Staff also told the Sacklers that a key selling point for OxyContin compared to a competitor's product was that OxyContin could be used by patients who had not taken opioids before. Deceptively promoting opioids for the opioid-naïve, patients who had not taken them before, was one of the ways Purdue put patients at risk.

885. In April, the Sacklers voted to pay their family another \$141,000,000.

886. Meanwhile, staff told the Sacklers that they were pushing back against the "threat" of public health rules that would limit high doses of opioids. They told the Sacklers that Purdue would oppose precautions that asked doctors to consult with specialists before prescribing the highest doses.

887. That same month (April 2010), staff gave the Sacklers one of many detailed reports on sales representatives' visits to prescribers. The Sacklers required each sales representative to visit an average of 7.5 prescribers per day. In April 2010, staff reported that they were falling short. During Q1 2010, representatives had averaged only 7.0 visits per day. Staff promised to try harder. The Sacklers continued to set a target for daily sales visits for every sales representative, and tracked the results, quarter by quarter, for at least the next four years. The results were always close to 7 visits per day.

888. The Sacklers also set targets for the total number of sales visits by the entire sales force per quarter - huge numbers that were always more than a hundred thousand visits. Meeting those targets was a top priority for the entire company. For Q1 2010, the target was to visit prescribers 127,376 times. Staff told the Sacklers that Purdue employed 489 sales representatives and that, during Q1 2010, they achieved the goal. As with the daily visits per sales representative, the Sacklers tracked the total number of sales visits per quarter, every quarter, for at least the next four years.

889. The Sacklers also tracked the cost of the sales visits. In April 2010, staff reported to the Sacklers that each visit to a prescriber cost Purdue \$219, and they were working to lower the cost to a target of \$201.

890. In June 2010, staff gave the Sacklers an updated 10-year plan for growing Purdue's opioid sales. According to the plan, the Sacklers expected Purdue to pay their family at least \$700,000,000 each year from 2010 through 2020. Beginning on page one, staff emphasized that selling as many opioids as the Sacklers wanted "will require significant salesforce support" so the plan detailed the "optimization" of sales visits and the number of representatives they would require. Sales VP Gasdia wrote to the Sacklers that they planned for each representative to visit prescribers 1,540 times per year, so that 500 representatives could make 770,000 visits at a cost of \$212 per visit. He proposed to grow the sales force to 1,050 sales representatives by 2015. To reach the Sacklers' expectations, Gasdia projected that Purdue would convince doctors to switch patients from Tylenol to Purdue's soon-to-be-released Butrans opioid, and Butrans would become a billion- dollar drug.

891. In July, Richard Sackler emailed staff just before the July 4th holiday weekend to demand more details about sales and marketing. Richard directed them to send to the Board plans for "the marketing program" and "the sales program," with instructions to "get this out before the weekend." Staff negotiated an extension and promised to provide full details about sales and marketing at the July Board meeting in Bermuda. To make sure the target date was met, Kathe Sackler ordered staff to circulate materials before the meeting.

892. By the Sacklers' choice, sitting on the Board of Purdue Pharma Inc. was a globe-trotting endeavor. The Sacklers held Board meetings for their U.S. drug company in a castle in Ireland, and in Bermuda, London, Portugal, Switzerland, New York, and Connecticut.

893. In Bermuda, the Sacklers focused on sales tactics again. Staff presented plans for selling Purdue's new Butrans opioid. Staff reported that sales representatives would try to switch patients to opioids from NSAIDs like ibuprofen and explained tactics for convincing doctors that patients needed the new drug. Staff told the Sacklers that they had identified 82,092 prescribers to target with the Butrans sales campaign. Staff reported that they planned to add 125 sales representatives and increase the number of prescriber visits by 30%.

894. Emails between staff and the Sacklers show that "the Board" (the Sacklers and at that point three other directors) responded with dozens of questions and orders about the sales campaign. The Board asked staff to determine whether sales would increase if they gave doctors free samples of opioids. The Board ordered staff to provide forecasts focused on higher doses of opioids. The Board demanded details about tactics Purdue sales staff used to influence doctors that Purdue viewed as "key opinion leaders," who could influence other doctors to prescribe more opioids: "Provide the Board with more information on the strategy/tactics with respect to KOL's, how they are identified, how do we plan to interact with them, how do we see them helping build appropriate utilization of Butrans - and any other relevant information that will/could influence the prescribing of the product."

895. The Board pushed staff about whether they were describing the benefits of opioids aggressively enough. Purdue was not legally allowed to say that Butrans was effective for 7 days, because the evidence did not show that, but the Board wanted to know why Purdue didn't claim 7 days of effectiveness in its marketing.

896. Purdue was not legally allowed to say that Butrans was effective for osteoarthritis ("OA"), because the clinical trials testing Butrans for patients with osteoarthritis had failed, but the Board wanted to know if sales representatives could sell more by remaining silent about the

failed trial: “What can be said in response to a prescriber who asks directly or indirectly, ‘can this product be prescribed for my patient with OA?’ In responding are we required to specifically mention the failed trials in OA?”

897. At the July 2010 Board meeting in Bermuda, the Sacklers and other Board members asked staff about opioid sales generated by doctors who were suspected of diversion and abuse, which Purdue had collected on a list code-named *Region Zero*. Staff assured the Board that Purdue tracked prescriptions by *Region Zero* doctors, including the exact prescriptions, units, and dollars from each prescriber. Staff then sent the data on those prescriptions to the Board. Staff gave the Board a list of the specific problem prescribers by name, along with the exact number of prescriptions and dollars of revenue each provided to Purdue.

898. At that same Board meeting in Bermuda, the Sacklers voted to expand the sales force by 125 more sales representatives. They ordered that the hiring begin in September 2010 and be completed before the National Sales Meeting in January 2011. They also directed Purdue to hire 18 more managers to supervise the representatives.

899. At the same meeting, the Sacklers voted to pay \$10,000,000 to settle lawsuits by people injured by OxyContin.

900. Later that month, staff told the Sacklers that during Q2 2010 sales representatives visited prescribers 135,824 times. Purdue paid their family \$389,000,000 in the first six months of 2010.

901. In August, the Sacklers continued to focus on the sales force. That month, they decided not to acquire a new insomnia drug because of the risk that promoting it could distract sales representatives from selling Purdue’s opioids. Richard Sackler concluded that “loss of focus”

in sales representatives' meetings with prescribers was too great a risk, and the Sacklers decided not to go through with the deal.

902. A few days later, the Sacklers discussed abuse of OxyContin. Staff told them that the most common way of abusing oxycodone, by far, was swallowing it - which a crush-proof coating on OxyContin did not affect. Staff also reported to the Sacklers that data from prescription monitoring programs showed far higher rates of "doctor-shopping" for OxyContin prescriptions than for any other opioid. The prescription monitoring program identifies "doctor-shopping" when a patient gets opioids from multiple prescribers - an indication that the patient is at risk of addiction, overdose, and death.

903. In September, staff reported to the Sacklers about the Board's July 2010 decision to hire more sales representatives. Staff said they were working to implement the decision, adding 125 sales territories. Staff also told the Sacklers that 82% of prescriptions for OxyContin were to patients who were already on the drug - a key ingredient in Purdue's plans to keep patients on opioids longer. The Sacklers voted to pay their family \$240,000,000.

904. In October, staff told the Sacklers that Purdue employed 506 sales representatives and, during Q3 2010, they visited prescribers 141,116 times.

905. Meanwhile, staff told the Sacklers that Purdue had paid their family \$629,000,000 in the first nine months of 2010. The Sacklers voted to pay another \$12,000,000 to settle claims of more patients injured by OxyContin.

906. In November, staff warned the Sacklers that doctors were not prescribing Purdue's highest dose and most profitable opioids as much as the company had expected, so it might be necessary to cut the family's quarter-end payout from \$320,000,000 to \$260,000,000 and distribute it in two parts: one in early December and one closer to the end of the month. Mortimer Sackler

objected to the decrease and the division into two payments: “Why are you BOTH reducing the amount of the distribution and delaying it and splitting it in two?” “Just a few weeks ago you agreed to distribute the full 320 [million dollars] in November.”

907. Staff also told the Sacklers that the expansion of the sales force that the Sacklers had ordered was being implemented, including 125 new sales territories. The Sacklers voted to spend \$158,086,000 to employ sales representatives in 2011.

908. Staff also reported to the Sacklers that drug company leaders can be punished for breaking the law and “owners, officers, and managers will especially face even more serious scrutiny in the future.”

909. In December, the Sacklers voted to pay their family \$260,000,000.

v. 2011

910. In 2011, the White House announced that prescription drug abuse was the nation’s fastest-growing drug problem and called for “educating healthcare providers about prescription drug abuse . . . so they will not over-prescribe[.]”The CDC announced that prescription opioid overdoses had reached epidemic levels and called out Purdue’s opioids by name. That same year, *Fortune* magazine interviewed Purdue executives, including Vice President Alan Must. *Fortune* published a story about Purdue, the Sackler Families, and evidence that they profited from opioid addiction. Mr. Must admitted that Purdue was “well aware” of concerns about its conduct, stating: “We are well aware of detractors. For those individuals who think we’re evil . . . I don’t think there’s anything we can do that is going to change their opinion.”

911. In January 2011, Richard Sackler met with sales representatives for several days at the Butrans Launch Meeting and discussed how they would promote Purdue’s newest opioid.

Richard quickly followed up with sales management to demand a briefing on how the sales visits were going in the field.

912. Richard's interventions into sales tactics made employees nervous. When Richard followed up to ask for information "tomorrow," two hours after sending his request, Richard ordered Sales VP Russell Gasdia to call him, on a Sunday morning, on his cell phone. Richard wanted to discuss "the resistance" and how Purdue's sales representatives were "overcoming" it right away.

913. Richard Sackler kept pushing for more sales. After one week of prescriptions doubled Purdue's forecast, Richard wrote to the sales staff: "I had hoped for better results." In a follow-up message, Richard asked staff to tell him the ratio of prescriptions per sales representative visit to a prescriber, divided out by the prescribers' specialties. He asked for a Board discussion of the barriers that sales representatives were encountering during promotion. After trying to answer Richard's questions and getting a dissatisfied response, sales staff wrote to the CEO to ask him to intervene. In a later message, Richard wrote to the staff again: "What do I have to do to get a weekly report on Butrans sales without having to ask for it?" The CEO announced that, from then on, staff would send a sales report to the Sacklers every week. When staff sent the first weekly report, Richard responded immediately: "What else more can we do to energize the sales and grow at a faster rate?" The next week, Richard wrote to the sales staff to ask about the performance of a specific sales representative.

914. Mortimer Sackler also asked staff for more information about sales. When two days passed without an answer, Mortimer insisted: "Any answer to this yet?" Staff rushed to prepare answers to share with all the Sacklers.

915. The people who worked for the Sacklers knew they sought ever increased sales. When the launch of Purdue's Butrans opioid was on track to beat every drug in its class, Richard Sackler asked sales staff: "Do you share my disappointment?" Sales VP Russell Gasdia replied privately to the CEO: "As far as his disappointment, I do not share that."

916. Throughout that spring of 2011, the Sacklers kept up the aggressive sales tactics, multi-million-dollar payouts, and disregard for the law. In January, the Sacklers voted to pay the legal expenses of specific individuals if they were defendants or witnesses in investigations of Purdue, including several sales executives and John Crowley, Executive Director of Controlled Substances Act Compliance. The Sacklers knew these employees were aware of misconduct because they had directed it. In September 2009, a Purdue sales manager had emailed Crowley that Purdue was promoting opioids to an illegal pill mill: "I feel very certain this is an organized drug ring," and "Shouldn't the DEA be contacted about this?" Purdue sat on the information and did not report it to the authorities for more than two years, until after the pill mill doctor had already been arrested and the Sacklers had arranged for lawyers in case Crowley was questioned.

917. In January 2011, staff reported to the Sacklers that a key initiative in Q4 2010 had been the expansion of the sales force. Staff told the Sacklers that Purdue employed 590 sales representatives and, during Q4 2010, they visited prescribers 125,712 times.

918. The Sacklers were paid \$889,000,000 in 2010 by Purdue. But staff reported that Purdue's revenue was still hundreds of millions of dollars less than expected because doctors were prescribing less of Purdue's highest dose opioids. Staff told the Sacklers that sales of the highest doses continued to fall below expectations, and the gap had cost the company \$120,000,000 in the month of December 2010 alone. The Sacklers faced the prospect that, if doctors did not prescribe more of the highest doses, their payouts would shrink.

919. In February, staff reported to the Sacklers that law enforcement was increasingly concerned about lawbreaking by drug companies and the resulting “danger to public safety.” Staff also told the Sacklers that Purdue was receiving a rising volume of hotline calls and other compliance issues were reaching an all-time high during Q4 2010. Staff reported to the Sacklers that sales representatives had engaged in improper promotion of Purdue opioids, but the company had decided not to report the violations to the government. Staff also reported to the Sacklers about the risks of OxyContin, including that 83% of patients in substance abuse treatment centers began abusing opioids by swallowing pills, and that it took, on average, 20 months for a patient to get treatment. Staff reported to the Sacklers that Purdue tracked to individual zip codes the correlation between poison control calls for OxyContin overdose, pharmacy thefts, and prescribers Purdue suspected of abuse and diversion in *Region Zero*.

920. In March, staff reported to the Sacklers on OxyContin sales and again focused on revenue from doctors in *Region Zero* -- prescribers that Purdue suspected of improper prescribing, but that Purdue had not reported to the authorities. Staff told the Sacklers that if *Region Zero* doctors stopped prescribing opioids, Purdue would lose almost 10% of its sales.

921. In April, the Sacklers met with Sales VP Russell Gasdia to talk about sales. He told them that OxyContin was the best-selling painkiller in America, with more than three billion dollars in annual sales -almost double the second-place drug. The Sacklers voted to pay their family \$189,700,000.

922. In May, in response to the Sacklers’ repeated requests, staff sent Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler a report on the sales tactics representatives were using to push Butrans. The first tactic reported to these Sacklers was focusing on a select “core” of

physicians that Purdue calculated would be most susceptible to sales representatives lobbying to prescribe more opioids.

923. The second tactic staff reported to Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler in the May 25, 2011 email was the “positioning of Butrans for specific patient types.” Promotion for “specific patient types” meant pushing opioids for elderly patients with arthritis.

924. A third tactic reported to these five Sacklers was getting prescribers to commit to put specific patients on opioids and asking prescribers to commit to prescribe opioids without disclosing significant risks.

925. Jonathan Sackler was not satisfied that these tactics would be enough to boost sales. He wrote to John Stewart: “this is starting to look ugly. Let’s talk.” Stewart and the sales team scrambled to put together a response and set up a meeting with Jonathan for the following week.

926. That same month, staff reported to the Sacklers that Purdue had hired 47 more sales representatives pursuant to the Sacklers’ orders. Purdue employed 639 sales representatives and, during Q1 2011, they visited prescribers 173,647 times.

927. Meanwhile, the Sacklers voted to pay \$10,000,000 to try to settle a lawsuit by the Attorney General of Kentucky regarding Purdue’s marketing of OxyContin. The Sacklers were on notice that Purdue’s unfair and deceptive marketing raised serious concerns. Staff also told the Sacklers that they had received another 88 calls to Purdue’s compliance hotline, but had not reported any of them to the authorities.

928. In June, staff reported to the Sacklers that Purdue’s opioid sales were hundreds of millions of dollars less than expected and that a prime reason was that doctors were not prescribing enough of the highest doses. The headline presented at the Board meeting read: “40 and 80mg tablet prescriptions have decreased significantly. The 10mg and 20mg tablet prescriptions initially

increased but given their lower value not enough to offset the higher strength decline.” Staff told the Sacklers: “As a result of the change in prescriptions by strength, OxyContin brand Kgs dispensed are below mid 2010 levels.” Staff reported to the Sacklers that Purdue would rely on sales representative visits and paid physician spokespersons to maintain demand. For a “Super Core” of “Very High Potential” opioid prescribers, Purdue would order its sales representatives to make sales visits every week.

929. The Sacklers immediately pushed to find ways to increase sales. Richard Sackler asked Sales VP Russell Gasdia to include him in a meeting with District Managers who were the day-to-day supervisors of the sales representatives. Then, having missed the meeting, he engaged Gasdia again by email. Gasdia told Richard that Purdue had hired 147 new sales representatives at the Board’s direction. Gasdia told Richard that Purdue instructed the sales representatives to focus on converting patients who had never been on opioids or patients taking “low dose Vicodin, Percocet, or tramadol” - all patients for whom Purdue’s opioids posed an increase in risk.

930. Gasdia told Richard Sackler again that Purdue instructed sales representatives to focus on the highest-prescribing doctors in their territory and visit them over and over. Gasdia also told Richard that staff had initiated performance enhancement plans for sales representatives who were not generating enough opioid prescriptions.

931. In response to Gasdia’s message about the sales representatives, Richard Sackler wrote back six minutes later and asked to meet with Gasdia without delay. Gasdia tried to schedule a meeting about sales tactics with Richard for first thing the next morning but Richard would not wait and instructed Gasdia to call him that same day.

932. Richard Sackler continued the correspondence that day, criticizing Purdue’s managers for allowing sales representatives to target “non-high potential prescribers.” “How can

our managers have allowed this to happen?” Richard insisted that sales representatives push the doctors who prescribed the most drugs.

933. To make sure his orders were followed, Richard Sackler insisted he be sent into the field with the sales representatives. Richard wanted a week shadowing Purdue sales representatives, two representatives per day. Gasdia appealed to Purdue’s Chief Compliance Officer, warning that Richard Sackler promoting opioids was “a potential compliance risk.” Compliance replied: “LOL.” To make sure the Sacklers’ involvement in marketing stayed secret, staff instructed: “Richard needs to be mum and be anonymous.”

934. A number of executives, including the CEO, got involved in planning Richard Sackler’s sales visits. All of them were concerned. One wrote: “About 5 last night, John [Stewart, the CEO] was walking by my office - I yelled out to stop him - and said that you had mentioned to me that Richard wanted to go into the field, and that you had raised concerns with me. John seemed angry and asked if I had concerns. I told him could be issues and Richard could be out on a limb if he spoke about product at all or got into conversations with HCPs, or identified himself, especially with FDA Bad Ad possibilities. John agreed Richard would have to be mum throughout, and not identify himself other than as a home office person.”

935. Richard Sackler did go into the field to promote opioids to doctors alongside a sales representative. When he returned, Richard argued to the Vice President of Sales that a legally-required warning about Purdue’s opioids wasn’t needed. He asserted that the warning “implies a danger of untoward reactions and hazards that simply aren’t there.” Richard insisted there should be “less threatening” ways to describe Purdue opioids.

936. Meanwhile, the Sacklers voted to pay their family \$200,000,000.

937. A few days later, sales and marketing staff again had to prepare responses to questions from the Sacklers. Mortimer Sackler asked about launching a generic version of OxyContin to “capture more cost sensitive patients.” Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert. Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

938. In July, staff assured the Sacklers that Purdue prohibited sales representatives from writing their sales pitches to prescribers in email.

939. In August, staff told the Sacklers that Purdue employed 640 sales representatives and, during Q2 2011, they visited prescribers 189,650 times.

940. Meanwhile, in the first seven months of 2011, Purdue paid the Sackler family \$411,000,000.

941. In September, Richard Sackler directed staff to study a savings card program for a widely-used cholesterol medication (not an addictive narcotic) to learn how Purdue could use it for opioids. That same month, the Sacklers voted to pay their family \$140,800,000 more.

942. In November, staff told the Sacklers that Purdue still employed 640 sales representatives and, during Q3 2011, they visited prescribers 189,698 times. Looking ahead, the Sacklers voted to spend \$162,682,000 to employ sales representatives in 2012.

943. Meanwhile, in the first nine months of 2011, Purdue paid the Sackler family \$551,000,000.

vi. 2012

944. In 2012, the U.S. Senate launched an investigation into whether Purdue was deceiving doctors and patients about opioids. In a letter to the CEO of Purdue, the Senators warned

of “an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers.” The Senate letter warned Purdue specifically of the danger of patients taking higher doses: “over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks while data suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses.” The Senate letter also warned about Purdue misleading doctors and patients: “There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs’ safety and effectiveness.” The Senate put the directors, the Sacklers, on notice that they were under scrutiny, demanding that Purdue produce to investigators a set of “presentations, reports, and communications to Purdue’s management team or board of directors from 2007 to the present.”

945. In January 2012, Jonathan Sackler started the year pressing Sales VP Russell Gasdia for weekly updates on sales. A few days later, Richard Sackler jumped in with the sales staff, this time about advertising. Richard noticed that online ads appeared indiscriminately on webpages with content associated with the ad - regardless of whether the association was positive or negative. Staff assured Richard that, when Purdue bought online advertising for opioids, it specified that the ads appear only on pages expressing positive views toward opioids and would not appear with articles “about how useless or damaging or dangerous is our product that we are trying to promote.”

946. That same month, staff told the Sacklers that Purdue employed 632 sales representatives and, during Q4 2011, they visited prescribers 165,994 times.

947. The Sacklers were not satisfied with the sales effort. In February, staff reported to the Sacklers that prescriptions had dropped, and that a decrease in sales representative visits to prescribers was a major driver of the decline. Staff asked the Sacklers to be patient, because representatives had missed work for December holidays and the company's mandatory National Sales Meeting in January. Mortimer Sackler suggested that, "in future years we should not plan the national sales meeting so close following the winter break as it extends the period of time since the doctor last saw our rep." Mortimer wrote: "Wouldn't it be better to have the reps get back to work for January and back in front of doctors." Mortimer was concerned that doctors were going too many days without a sales representative visiting to promote Purdue opioids. If Purdue rescheduled its meeting, "At least then the doctors will have gotten at least one reminder visit from our reps in the last month whereas now they might go two months without seeing one of our reps??" Staff replied to Mortimer, arguing for "balance." Richard Sackler replied within minutes that, since the National Sales Meeting prevented sales representatives from visiting doctors, "Maybe the thing to have done was not have the meeting at all." Purdue's compliance officer forwarded the exchange to his staff, commenting: "Oh dear."

948. Meanwhile, Richard Sackler interrupted sales staff many times a day, often in a hurry: "I had hoped you would have updated this," "Will I have it by noon?" "get to this ASAP." Staff advised each other: "avoid as much e mail with dr. r as you can." Sales VP Gasdia wrote to the CEO in exasperation: "I'm not sure what we can do about Dr. Richard."

949. Throughout the spring, the Sacklers pressed staff to promote Purdue's opioids more aggressively. In February, Gasdia wrote to sales staff that the Board of Directors ("BOD") was not satisfied with the money coming in: "Things are not good at the BOD level." When sales dropped for one week on account of the Presidents' Day holiday, Richard Sackler wrote to sales

management: “This is bad.” Gasdia forwarded Richard’s message to his colleagues, asking how they could “create a greater sense of urgency at the regional management and district management level.”

950. Gasdia pleaded with the CEO to defend him against Richard Sackler’s micromanagement of sales: “Anything you can do to reduce the direct contact of Richard into the organization is appreciated.” A week later, Richard wrote to sales management again to criticize them for U.S. sales being “among the worst” in the world.

951. In March, staff sent the Sacklers a revised 2012 budget that cut the proposed payout to their family from \$472,500,000 to \$418,200,000.

952. On one Saturday morning, Richard Sackler wrote to marketing staff, asking for monthly data for all extended release pain medications for the past twelve years and an immediate meeting that Monday night. Later that month, staff created for Richard a historical summary of key events determining OxyContin sales. Eleven of the key events in sales history were changes in the size of the Purdue sales force - all known to Richard because the Sacklers had ordered them.

953. A few days later, staff sent Richard Sackler an assessment of recently-improved opioid sales. Staff told Richard that the increase in prescriptions was caused by tactics that Purdue taught sales representatives: pushing opioids for elderly patients with arthritis (“proper patient selection”) and encouraging doctors to use higher doses of opioids (“quick titration”).

954. Richard Sackler wrote that he was not satisfied with the report on sales and instructed Gasdia to discuss it with him within a day. Then Richard asked Gasdia to address both Butrans sales tactics and a decline in OxyContin sales and propose corrective actions. John Stewart suggested that Richard’s frustrations could be linked to dosing: he encouraged Gasdia to tell Richard that patients on lower doses seemed to stop taking opioids sooner, and that much of

the profit that Purdue had lost had been from doctors backing off the highest dose of OxyContin (80mg).

955. Richard Sackler was not satisfied. Days later, after sales did not increase, staff told him that they were starting quantitative research to determine why patients stay on opioids, so they could find ways to sell more opioids at higher doses for longer.

956. In April, staff told the Sacklers that Purdue employed 630 sales representatives and, during Q1 2012, they visited prescribers 179,554 times.

957. Meanwhile, Richard Sackler kept pushing the staff to increase sales. When the mandatory weekly report to the Sacklers showed that sales representatives achieved 9,021 prescriptions in a week, Richard asked Sales VP Russell Gasdia for a commitment that the representatives would get weekly prescriptions to 10,000: “Are you committed to breaking 10K/wk Rx’s this month?” A colleague replied to Gasdia: “Is there any question of your commitment?” Gasdia tried to assure Richard Sackler that they were selling opioids aggressively: “Windell and the sales force, as well as Mike and the marketing team (initiatives being implemented) are focused and committed to accelerating the growth trend ... everyone in the commercial organization is focused on exceeding the annual forecast.” Richard wanted more. Richard wanted to know what tactics sales staff would use to get more prescriptions, and he wanted to talk about it right away. First he wrote: “give me the table of weekly Rx plan and the actual. Then show how you plan to make up the current shortfall.” He asked for a meeting within 24 hours. Then Richard didn’t want to wait that long: “Can we meet in person today?” On Friday the 13th, sales and marketing staff met with Richard to review how they would sell more opioids.

958. In June, the Sacklers discussed sales and marketing again. Staff reported to the Sacklers that they had added 120,000 sales visits to drive sales of OxyContin.

959. Staff also told the Sacklers that they expanded the opioid savings cards, because Purdue's latest data showed opioid savings cards led to 60% more patients remaining on OxyContin longer than 90 days. The Sacklers reviewed the results of Purdue's confidential studies showing that opioid savings cards kept more patients on opioids for 90 day, 120 days, 150 days, 180 days, 210 days, 240 days - even an entire year. Keeping patients on opioids for these lengths of time was especially dangerous for the patients and especially profitable for Purdue.

960. In July, David Sackler (Richard Sackler's son) took a seat on the Board. For events after July 2012, this Complaint includes David in "the Sacklers."

961. Staff also told the Sacklers that Purdue employed 633 sales representatives and, during Q2 2012, they visited prescribers 183,636 times.

962. In November, staff told the Sacklers the confidential results of a study of 57,000 patients that Purdue performed explicitly to determine how opioid dose "influences patient length of therapy." The results showed that patients on the highest doses "are the most persistent." The "Recommended Actions" presented to the Sacklers included "additional workshops for the sales force" and "specific direction" to the sales representatives about using higher doses to keep patients on drugs longer. Staff told the Sacklers that encouraging higher doses "is a focal point of our promotion," and that sales representatives would "emphasize the importance" of increasing patients' opioid doses, as soon as 3 days after starting treatment.

963. That same month, the Sacklers voted to set Purdue's budget for Sales and Promotion for 2013 at \$312,563,000. Staff told the Sacklers that Purdue employed 622 sales representatives and, during Q3 2012, they visited prescriber 180,723 times.

vii. 2013

964. In 2013, the *Los Angeles Times* revealed that Purdue had been compiling a list for the past decade of 1,800 doctors suspected of recklessly prescribing its opioids, but Purdue had reported only 8% of them to authorities. Purdue attorney Robin Abrams gave multiple interviews to the newspaper. Abrams was a Vice President of Purdue, and she had signed Purdue's 2007 settlement agreement. In 2013, she admitted that Purdue had the list, and said Purdue would not agree to disclose it to authorities because, "I don't really want to open up an opportunity for folks to come in here and start looking and second-guessing." Abrams and Purdue's directors, the Sackler family, knew they had reason to fear scrutiny. The Commonwealth of Kentucky was prosecuting a lawsuit against Purdue for deceiving doctors and patients about opioids. Purdue's lawyers surveyed residents who could be on the jury. One-third knew someone who overdosed or was seriously hurt taking a Purdue opioid, and 29 percent knew someone who died. Purdue itself filed those statistics in court.

965. In January 2013, in what was becoming a yearly ritual, Richard Sackler questioned staff about the drop in opioid prescriptions caused by Purdue sales representatives taking time off for the holidays. Richard wasn't satisfied: "Really don't understand why this happens. What about refills last week? Was our share up or down?" Staff assured Richard that doctors were "sensitive" to sales representative visits and, as soon as the representatives got back into action, they would "boost" opioid prescriptions again.

966. Staff told the Sacklers that they continued to reinforce the *Individualize The Dose* campaign, which the Sacklers knew and intended would promote higher doses. Staff also told the Sacklers that sales representatives would place greater emphasis on the opioid savings cards, which the Sacklers knew and intended would keep patients on opioids longer. Staff reported to the Sacklers that Purdue had conducted a sensitivity analysis on the opioid savings cards to maximize

their impact and, as a result, had increased the dollar value and set the program period to be 15 months long. Staff also reported to the Sacklers that Purdue had created promotional materials to support these tactics and had distributed them to the sales force. Staff also told the Sacklers that Purdue showed an opioid promotional video to 5,250 physicians on the Physician's Television Network. The video urged doctors to give patients Purdue's opioid savings cards.

967. That same month, staff told the Sacklers that Purdue employed 609 sales representatives and, during Q4 2012, they visited prescribers 153,890 times.

968. In February, the Sacklers met with staff about tactics for promoting Purdue's opioids. They discussed research on what influences prescriptions, how doctors had responded to Purdue's increased promotion, and sales force promotion themes. On the same day, the Sacklers voted to award bonuses and salary increases to executives, including those involved in marketing Purdue's opioids.

969. In March, staff reported to the Sacklers on the devastation caused by prescription opioids. Staff told the Sacklers that drug overdose deaths had more than tripled since 1990 - the period during which Purdue had made OxyContin the best-selling painkiller. Staff told the Sacklers that tens of thousands of deaths were only the "tip of the iceberg." Staff reported that, for every death, there were more than a hundred people suffering from prescription opioid dependence or abuse.

970. In May, staff reported to the Sacklers again that they were successfully using opioid savings cards to get patients to "remain on therapy longer." Staff told the Sacklers that they were using direct mail and email, as well as sales visits, to push the opioid savings cards.

971. Staff reported to the Sacklers that, despite these sales efforts, they were not achieving the goals of getting enough patients on higher doses of opioids and getting doctors to

prescribe more pills in each prescription. Staff told them that “there is an ‘unfavorable’ mix of prescriptions across strengths,” and Purdue was losing tens of millions of dollars in revenue because sales of the highest doses (60mg and 80mg) were too low. Staff told the Sacklers that there was also a second problem: “lower average tablet counts per prescription.” Because doctors were not prescribing enough pills during each patient visit, Purdue was losing tens of millions of dollars in revenue. Staff promised the Sacklers: “A deeper analysis is underway to determine the cause of the decline in the 30mg, 60mg, and 80mg tablet strengths, as well as the lower than budgeted average tablets per prescription. Once the analysis is complete, we will have a better sense of what tactics to implement to address both issues.”

972. The Sacklers met with Sales VP Russell Gasdia about the strategy for selling high doses. Gasdia told the Sacklers that “Titration up to higher strengths, especially the 40mg and 80mg strengths is declining.” He analyzed the “Causes of OxyContin’s Decline in Higher Strengths,” and how Purdue would reverse that decline. He told the Sacklers that Purdue’s #1 tactic to sell higher doses was sending sales representatives to visit prescribers. The #2 tactic was a marketing campaign designed to promote high doses – Purdue’s *Individualize The Dose* campaign. After that, Gasdia told the Sacklers, came opioid savings cards and finally, putting a special focus on the most prolific opioid prescribers.

973. Gasdia told the Sacklers that the staff would develop even more tactics to sell higher doses. They were using Purdue’s data on thousands of doctors and patients to learn what made people willing to use high doses of opioids. They had started a study of physician characteristics and a “patient level analysis to determine what patient characteristics” were associated with “higher dose volume.”

974. That same month, staff told the Sacklers that Purdue employed 637 sales representatives and, during Q1 2013, they visited prescribers 155,354 times.

975. In July, the Sacklers discussed “threats” to their business from data on long-term opioid use, as public health authorities reacted to the danger of keeping patients on opioids for longer periods of time. Meanwhile, staff sent the Sacklers a “Flash Report” that OxyContin sales had dropped \$96,400,000 from the year before. Staff explained to the Sacklers that insufficient volume of sales representative visits to promote OxyContin to prescribers was an important reason for the dropping sales. Staff told the Sacklers that they would increase the number of sales visits and had hired McKinsey to study how to get doctors to prescribe more OxyContin.

976. Staff also reported to the Sacklers that key priorities were to reverse “the decline in higher strengths” of Purdue opioids, and the decline in “tablets per Rx,” which were reducing Purdue’s profits. They told the Sacklers that Purdue staff was studying ways to fight these trends, and McKinsey would analyze the data down to the level of individual physicians.

977. Mortimer Sackler asked for more detail on what was being done to increase sales. Staff told the Sacklers that McKinsey would analyze whether sales representatives were targeting the prescribers who were most susceptible to increasing opioid use. Staff told the Sacklers that McKinsey would study whether Purdue could use incentive compensation to push representatives to generate more prescriptions. Making the sales representatives’ income depend on increasing prescriptions could be a powerful lever. Staff told the Sacklers that McKinsey would study using “patient pushback” to get doctors to prescribe more opioids: when doctors hesitated to prescribe Purdue opioids, Purdue could get patients to lobby for the drugs. Staff told the Sacklers that McKinsey would also study techniques for keeping patients on opioids longer, including the need

for sales representatives “to make a lot of calls on physicians with a high number of continuing patients.”

978. Staff also reported to the Sacklers that they had trained Purdue’s sales representatives to use new sales materials designed to get patients on higher doses of opioids for longer periods. Staff told the Sacklers that Purdue employed 634 sales representatives and, during Q2 2013, they visited prescribers 177,773 times. Staff assured the Sacklers that they were trying to achieve even more sales visits by monitoring the representatives.

979. Before the month ended, the Sacklers met to discuss a report on sales tactics that McKinsey had prepared for them: Identifying Granular Growth Opportunities for OxyContin: First Board Update. McKinsey confirmed that Purdue’s sales visits generated opioid prescriptions. They urged the Sacklers to demand more sales visits from sales representatives, increasing each representative’ annual quota from 1,400 towards 1,700. McKinsey also advised the Sacklers to control the sales representatives’ target lists more strictly, to make representatives visit doctors who give the biggest payoff. Based on a review of data, McKinsey also suggested that the Sacklers should have staff emphasize opioid savings cards in neighborhoods with high concentration of Walgreens pharmacies. To allow even more targeted promotion of high doses, McKinsey asked the Sacklers to obtain “prescriber level milligram dosing data” so they could analyze the doses prescribed by individual doctors.

980. Days later, Purdue paid the Sackler family \$42,000,000.

981. In August, the Sacklers met to discuss a new McKinsey report on sales tactics: Identifying Granular Growth Opportunities for OxyContin: Addendum to July 18th and August 5th Updates. McKinsey recommended that the Sacklers immediately order a series of actions to increase sales. McKinsey urged the Sacklers to direct sales representatives to the most prolific

opioid prescribers. The consultants told the Sacklers that prescribers in the more prolific group write “25 times as many OxyContin scripts” as less prolific prescribers. They also reported to the Sacklers that sales representative visits to these prolific prescribers caused them to prescribe even more opioids: if Purdue ordered representatives to focus on the most prolific prescribers, it could increase sales.

982. Second, McKinsey recommended that the Sacklers fight back against steps that the DEA, the U.S. Department of Justice, and others were taking to stop illegal drug sales. Two months earlier, the Walgreens pharmacy company admitted that it broke the law by filling illegitimate prescriptions, and it agreed to new safeguards to stop illegal prescribing. McKinsey told the Sacklers that “deep examination of Purdue’s available pharmacy purchasing data shows that Walgreens has reduced its units by 18%.” Even worse for the Sacklers, the new safeguards were hurting sales of the highest doses: “the Walgreens data also shows a significant impact on higher OxyContin dosages” - specifically the 80mg dose. McKinsey urged the Sacklers to lobby Walgreens’ leaders to loosen up. For the longer term, McKinsey advised the Sacklers to develop a “direct-to-patient mail order” business for Purdue opioids, so they could sell the high doses without pharmacies getting in the way.

983. Third, McKinsey advised the Sacklers that they should use their power on the Board to insist on increasing sales, with monthly accountability: “Establish a revenue growth goal (e.g., \$150M incremental stretch goal by July 2014) and set monthly progress reviews with CEO and Board.” McKinsey knew what the Sacklers were looking for: they reported that “the value at stake is significant - hundreds of millions, not tens of millions.” The consultants urged the Sacklers to make “a clear go-no go decision to ‘Turbocharge the Sales Engine.’”

984. In September and October, the Sacklers met again to discuss implementation of the sales tactics McKinsey had recommended. The Sacklers discussed DEA efforts to stop illegal dispensing of opioids at CVS and Walgreens and how Purdue could get around the new safeguards by shifting to mail-order pharmacies, specialty pharmacies, or by Purdue distributing opioids to patients directly.

985. Meanwhile, McKinsey continued reporting to Purdue on tactics to get more patients on higher doses of opioids. McKinsey found that Purdue could drive opioid prescriptions higher by targeting the highest-prescribing doctors and sending sales representatives to visit each prolific prescriber dozens of times per year.

986. In October, Mortimer Sackler pressed for more information on dosing and “the breakdown of OxyContin market share by strength.” Staff told the Sacklers that “the high dose prescriptions are declining,” and “there are fewer patients titrating to the higher strengths from the lower ones.” In response to the Sacklers’ questions, staff explained that sales of the highest doses were not keeping up with the Sacklers’ expectations because some pharmacies had implemented “good faith dispensing” policies to double-check prescriptions that looked illegal and some prescribers were under pressure from the DEA. Staff promised to increase the budget for promoting OxyContin by \$50,000,000 and get sales representatives to generate more prescriptions with a new initiative to be presented to the Sacklers the following week.

987. At the end of the month, the Sacklers met to discuss Purdue’s budget for sales and marketing for 2014. Staff told the Sacklers (again) that Purdue’s opioid savings cards kept patients on opioids longer. Looking ahead at 2014, staff reported to the Sacklers that doctors shifting away from high doses and towards fewer pills per prescription could cost Purdue hundreds of millions of dollars in lost sales. To fight against that threat, staff told the Sacklers that they would increase

the sales visits by each representative to 7.3 visits per day and visit prescribers 758,164 times in the year.

988. In November, Richard Sackler complained that he was getting too much information about the dangers of Purdue opioids. Richard had set up a Google alert to send him news about OxyContin, and he objected to a Purdue Vice President: “Why are all the alerts about negatives and not one about the positives of OxyContin tablets?” Staff immediately offered to replace Richard’s alert with a service that provided more flattering stories.

989. Staff reported to the Sacklers that a key initiative during Q3 2013 was for sales representatives to encourage doctors to prescribe OxyContin to elderly patients on Medicare.

990. Staff also reported to the Sacklers that another key initiative during Q3 2013 was for sales representatives to promote OxyContin for patients who had never taken opioids before.

991. Staff also told the Sacklers that analysis conducted in July 2013 showed that opioid savings cards earned the Sacklers more money by keeping patients on opioids longer; specifically, more patients stayed on OxyContin longer than 60 days. Staff reported to the Sacklers that Purdue was pushing opioid savings cards in sales representative visits, through email to tens of thousands of health care providers, and online.

992. Purdue had paid the Sackler family \$399,920,000 during January-September 2013. But staff told the Sacklers that, from January to September 2013, Purdue lost hundreds of millions of dollars in profits because some prescribers were shifting away from higher doses of Purdue opioids. Staff told the Sacklers that, in Q4 2013, sales representatives would increase the number of visits to prescribers.

993. Staff also reported to the Sacklers that a key initiative in 2013 was to train sales representatives to keep patients on Butrans opioids longer. They told the Sacklers that, at the same

time as the initiative to keep patients on opioids longer, Purdue launched a new high dose of its Butrans opioid. Sales representatives had begun promoting the new high dose to physicians using new sales materials, and initial orders were double the company's forecasts. Staff reported to the Sacklers that marketing and sales activities had generated 266,842 additional prescriptions and highlighted that opioid savings cards generate especially "high returns" by keeping patients on opioids longer.

994. Staff reported to the Sacklers that Purdue had sent more than 880,000 emails to health care professionals to promote its Butrans opioid and that online advertising was seen more than 5 million times for Butrans and nearly 4 million times for OxyContin. They told the Sacklers that hundreds of thousands of communications to prescribers nationwide presented the same "key selling messages" designed to get more patients on OxyContin at higher doses for longer periods of time, and specifically promoted Purdue's opioid savings cards.

995. Staff reported to the Sacklers that they were working with McKinsey to study ways to sell more OxyContin. Staff also reported that they had direct access to physician level data to analyze prescriptions by individual doctors. Staff gave the Sacklers the latest results regarding how opioid savings cards led to patients staying on OxyContin longer.

996. Staff also reported results from Purdue's marketing through the "OxyContin Physicians Television Network." Staff told the Sacklers that it increased opioid prescriptions.

997. Staff also told the Sacklers that they would begin reviews of sales representatives according to their sales ranking, with a focus on the bottom ten percent. Staff reported to the Sacklers that Purdue employed 637 sales representatives and, during Q3 2013, they visited prescribers 179,640 times.

998. In December, staff told Richard Sackler that Butrans sales were increasing, and they suspected the increase was caused by Purdue's improved targeting, in which sales representatives visited the most susceptible, prolific prescribers.

999. Meanwhile, staff contacted Richard Sackler because they were concerned that the company's "internal documents" could cause problems if investigations of the opioid crisis expanded. Early the next year, staff told Jonathan Sackler about the same concern. Jonathan studied collections of news reports and asked staff to assure him that journalists covering the opioid epidemic were not focused on the Sacklers.

viii. 2014

1000. In 2014, Edward Mahony, the Executive Vice President, CFO, and Treasurer of Purdue stated that the Kentucky lawsuit was so significant that it could "jeopardize Purdue's long-term viability."

1001. In January 2014, staff reported to the Sacklers on how Purdue's program for complying with state and federal law compared to recent agreements between other drug companies and the government. Other companies had agreed that sales representatives should not be paid bonuses based on increasing doctors' prescriptions, but Purdue still paid sales representatives for generating sales. Other companies disclosed to the public the money they spent to influence continuing medical education, but Purdue did not. Other companies had adopted "claw-back" policies so that executives would forfeit bonuses they earned from misconduct; but Purdue had not. The Boards of other companies passed resolutions each quarter certifying their oversight of the companies' compliance with the law; but the Sacklers did not.

1002. In February, staff sent the Sacklers the final results from 2013. Staff told the Sacklers that net sales were hundreds of millions of dollars below budget because doctors were

not prescribing enough of the highest doses of opioids and were including too few pills with each prescription, and sales representatives were not visiting doctors enough. Sales VP Russell Gasdia wrote privately friend: “Our myopic focus on extended release opioids with abuse deterrent properties has not yielded the results people thought it would in the market. It’s been hard to convince colleagues and the board that our success in this market is over.”

1003. To get higher sales, staff told the Sacklers that they had tightened the requirements for sales representatives’ pay: from now on, sales representatives would lose bonus pay if they did not visit “high value” prescribers often enough.

1004. A few days later, staff told the Sacklers that Purdue’s marketing had an immense effect in driving opioid prescriptions: according to Purdue’s analysis, its sales and marketing tactics generated an additional 560,036 prescriptions of OxyContin in 2012 and 2013. Nevertheless, staff reported to the Sacklers that net sales for 2013 had been \$377,000,000 less than budgeted. Staff again reported that Purdue was losing hundreds of millions of dollars in expected profits because prescribers were shifting away from higher doses of Purdue opioids and including fewer pills per prescription. Staff told the Sacklers that a “Key Initiative” was to get patients to “stay on therapy longer.”

1005. Staff also told the Sacklers that key sales priorities were again to encourage doctors to prescribe Purdue opioids for elderly patients and patients who had not taken opioids before. Staff reported to Sacklers again that sales representatives were continuing the *Individualize The Dose* campaign. As the Sacklers knew, Purdue designed that campaign to encourage higher doses. Staff also told the Sacklers that Purdue’s eMarketing campaign for OxyContin reached 84,250 health care providers during Q4 2013. Staff told the Sacklers that they found increasing

compliance concerns with Purdue's speaker programs, in which the company paid doctors to promote Purdue opioids to other doctors.

1006. Staff told the Sacklers that Purdue employed 632 sales representatives and, during Q4 2013, they visited prescribers 176,227 times.

1007. That February report was the last of its kind. After Q4 2013, Purdue abolished the detailed Quarterly Reports that had created a paper trail of targets for sales visits and been emailed among the Board and staff. In 2013, the City of Chicago served Purdue with a subpoena seeking internal documents about Purdue's marketing of opioids. That provoked a flurry of activity, including discussion among the Sacklers. Purdue fought the subpoena, and it was withdrawn. For 2014, Purdue decided to limit many of its official Board reports to numbers and graphs, and relay other information orally. But, the Sacklers continued to demand information about sales tactics, and their control of Purdue's deceptive marketing did not change.

1008. In March and April, staff told the Sacklers that Purdue was achieving its goals of selling higher doses of OxyContin and more pills of OxyContin per prescription, but weekly prescriptions of Purdue's Butrans opioid were below expectations because of a reduced number of sales representative visits promoting that opioid. The Sacklers had assumed prescriptions would fall, but staff was concerned that the effect could be greater than anticipated.

1009. In May, Richard and Jonathan's father, Raymond Sackler, sent David, Jonathan, and Richard Sackler a confidential memo about Purdue's strategy, including specifically putting patients on high doses of opioids for long periods of time. The memo recounted that some physicians had argued that patients should not be given high doses of Purdue opioids, or kept on Purdue opioids for long periods of time, but Purdue had defeated efforts to impose a maximum

dose limit or a maximum duration of use. Raymond asked David, Jonathan, and Richard to talk with him about the report.

1010. In June, the Sacklers removed Russell Gasdia as Vice President of Sales and Marketing and began pushing his replacement to sell more opioids faster. Gasdia warned his replacement that Richard managed the sales operation intensely—“there are times this becomes a tennis match with Dr. Richard.” Richard told Gasdia’s replacement that he would be given little time to show that he could increase opioid sales: “it is very late in the day to rescue the failed launch” of Butrans, which was not making as much money as Richard desired. CEO Mark Timney tried to caution Richard that it was “a little early” to be attacking the new sales leader, since he’d been at Purdue only two weeks.

1011. That same month, staff sent the Sacklers an “Update on L.A. Times mitigation effort” with tactics to discourage scrutiny of Purdue’s misconduct. Staff wrote to the Sacklers: “As you may recall, one of our efforts to mitigate the impact of a potential negative *Los Angeles Times* (LAT) story involved assisting a competing outlet in marginalizing the LAT’s unbalanced coverage by reporting the facts before the LAT story ran. The following *Orange County Register* story, developed in close coordination with Purdue, achieved this goal. This fact-based narrative robs the LAT account of its newsworthiness and contradicts many of the claims we expected that paper to make.”

1012. In 2012, the *Los Angeles Times* had studied coroners’ records and revealed that overdoses killed thousands of patients who were taking opioids prescribed by their doctors, refuting the Sacklers’ lie that patients who are prescribed opioids don’t get addicted and die. The next year, the *Los Angeles Times* revealed that Purdue tracked illegal sales of OxyContin with a secret list of 1,800 doctors, code-named *Region Zero*, but did not report them to the authorities.

The “mitigation effort” that the Sacklers ordered was not designed to protect patients from overdoses or from illegal prescribers, but instead to protect the Sacklers from reporters revealing the truth.

1013. In July, Richard Sackler called staff to complain about studies that the FDA required for opioids and how they might undermine Purdue’s sales. He emphasized that Purdue Board members felt the requirements to conduct studies were unfair. Staff tried to reassure Richard that the studies would take “several years to complete, thereby keeping our critics somewhat at-bay during this time.”

1014. In July and again in August, September, and October, staff warned the Sacklers that two of the greatest risks to Purdue’s business were “continued pressure against higher doses of opioids,” and “continued pressure against long term use of opioids.”

1015. Staff told the Sacklers that Purdue’s #1 opportunity to resist that pressure was by sending sales representatives to visit prescribers; and, specifically, by targeting the most susceptible doctors, who could be convinced to be prolific prescribers, and visiting them many times.

1016. In September 2014, Kathe Sackler dialed in to a confidential call about *Project Tango*. *Project Tango* was a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, Kathe and staff wrote down what Purdue publicly denied for decades: that addictive opioids and opioid addiction are “naturally linked.” They determined that Purdue should expand across “the pain and addiction spectrum,” to become “an end-to-end pain provider.” Purdue illustrated the end-to-end business model with a picture of a dark hole labeled “Pain Treatment” that a patient could fall into, and “Opioid Addiction Treatment” waiting at the bottom.

1017. Kathe Sackler and the *Project Tango* team reviewed their findings that the “market” of people addicted to opioids, measured coldly in billions of dollars, had doubled from 2009 to 2014. Kathe and the staff found that the catastrophe provided an excellent compound annual growth rate (“CAGR”): “Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010.”

1018. Kathe and the staff concluded that millions of people who became addicted to opioids were the Sacklers’ next business opportunity. Staff wrote: “It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction.” The team identified eight ways that Purdue’s experience getting patients on opioids could now be used to sell treatment for opioid addiction.

1019. Kathe Sackler instructed staff that *Project Tango* required their “immediate attention.” She pressed staff to look into reports of children requiring hospitalization after swallowing buprenorphine—the active ingredient in both Purdue’s Butrans opioid and the opioid addiction treatment that the Sacklers wanted to sell—through *Project Tango*, in a film form that melted in the mouth. Staff assured Kathe that children were overdosing on pills, not films, “which is a positive for Tango.”

1020. In February 2015, staff presented Kathe Sackler’s work on *Project Tango* to the Board. The plan was for a Joint Venture controlled by the Sacklers to sell the addiction medication suboxone.

1021. The *Tango* team mapped how patients could get addicted to opioids through prescription opioid analgesics such as Purdue’s OxyContin or heroin, and then become consumers of the new company’s suboxone. The team noted the opportunity to capture customers: even after patients were done buying suboxone the first time, 40-60% would relapse and need it again.

1022. The next month, *Project Tango* came to an end. Kathe, David, Jonathan, and Mortimer Sackler discussed the discontinuation of the project at their Business Development Committee meeting. But the Sackler's efforts to sell addictive opioids continued.

1023. In October 2014, staff sent the Sacklers a Proposed Operating Plan and Budget to be approved by the Board for 2015. Staff told the Sacklers that a key tactic for 2015 would be to convert patients from short-acting opioids to OxyContin. Staff warned the Sacklers that prescribers were shifting away from the highest doses of Purdue's opioids, and toward fewer pills per prescription, and those shifts would cost Purdue \$99,000,000 a year. Staff told the Sacklers that a key tactic to increase Butrans sales in 2015 would be for Purdue sales representatives to push doctors to "titrate up" to higher doses. Staff likewise told the Sacklers that visits to doctors by sales representatives would be a key tactic to launch Purdue's new Hysingla opioid: the company would: "Leverage Purdue's existing, experienced sales force to drive uptake with target HCPs" and "Add additional contract sales force capacity at launch to drive uptake." Staff proposed that Purdue employ 519 sales representatives, paid an average salary of \$81,300 plus a bonus of up to an additional \$124,600 based on sales.

1024. Meanwhile, sales staff exchanged news reports of the lawsuit in Kentucky accusing Purdue of deceptive marketing. They quoted Purdue's own attorney and Chief Financial Officer stating that the company faced claims of more than a billion dollars that "would have a crippling effect on Purdue's operations and jeopardize Purdue's long-term viability." Purdue's communications staff was delighted by the article because it did not reveal the Sacklers' role in the misconduct. "I'm quite pleased with where we ended up. There's almost nothing on the Sacklers and what is there is minimal and buried in the back."

1025. In November, staff reported to the Sacklers that their sales tactics were working, and the shift away from higher doses of OxyContin had slowed.

1026. In December, staff told the Sacklers that Purdue would pay their family \$163,000,000 in 2014 and projected \$350,000,000 in 2015.

1027. On New Year's Eve, Richard Sackler told staff that he was starting a confidential sales and marketing project on opioid prices, and he instructed them to meet with him about it on January 2.

ix. 2015

1028. Early in the morning of January 2, staff began collecting sales data for Richard Sackler. They didn't move quickly enough. Days later, Richard demanded a meeting with sales staff to go over plans for selling the highest doses. Richard asked for an exhaustive examination to be completed within 5 days, including: "unit projections by strength, mg by strength ... pricing expectations by strength ... individual strength's market totals and our share going backward to 2011 or 12 and then forward to 2019 or 2020 ... the same information for Hysingla ... [and] the history of OxyContin tablets from launch to the present."

1029. The CEO stepped in to say the work would take 3 weeks. Richard let him know that wasn't the correct response — "That's longer than I had hoped for" — and directed marketing staff to start sending him materials immediately.

1030. That same month, the Sacklers voted to evaluate employees' 2014 performance on a scorecard that assigned the greatest value to the volume of Purdue opioid sales. Employees were expected to generate more than one-and-a-half billion dollars. The Sacklers also voted to establish the company's scorecard for 2015: once again, the biggest factor determining employees' payout would be total Purdue opioid sales.

1031. In April, staff told the Sacklers that sales of Purdue's highest dose 80mg OxyContin were down 20% and that the average prescription had declined by eight pills since 2011.

1032. The Sacklers voted to expand the sales force by adding another 122 representatives. Staff told the Sacklers the additional representatives would increase net sales of opioids by \$59,000,000.

1033. In October, Purdue executives identified avoiding investigations of Purdue's opioid marketing as a "Key Activity" in the company's Operational Plan.

1034. In November, the Sacklers voted on the budget for Purdue for 2016. Staff warned the Sacklers that public concern about opioids could get in the way of Purdue's plans. Staff again told the Sacklers that two of the most significant challenges to Purdue's plans were doctors not prescribing enough of the highest strength opioids and including too few pills in each prescription. Staff told the Sacklers that declining prescriptions of the highest doses and fewer pills per prescription would cost Purdue \$77,000,000.

1035. Staff proposed to the Sacklers that, for 2016, Purdue would plan for prescribers to average 60 pills of Purdue opioids per prescription. They told the Sacklers that they would aim to make enough of those pills be high doses to make the average per pill 33 milligrams of oxycodone. That way, Purdue could hit its target for the total kilograms of oxycodone it wanted to sell.

1036. To make sure Purdue hit the targets, staff told the Sacklers that sales representatives were visiting prescribers 21% more often than before. Staff told the Sacklers that they had aggressively reviewed and terminated representatives who failed to generate prescriptions. Staff reported to the Sacklers that, in 2015 alone, Purdue replaced 14% of its sales representatives and 20% of its District Managers for failing to create enough opioid sales.

1037. Looking ahead, staff told the Sacklers that “the 2016 investment strategy focuses on expanding the Sales Force.” They reported that the proposed budget for sales and promotion was \$11,600,000 higher than 2015, “primarily due to the Sales Force expansion.” The top priority for the sales representatives would be to visit the highest-prescribing doctors again and again. Staff proposed to the Sacklers that the #1 overall priority for 2016 would be to sell OxyContin through “disproportionate focus on key customers.” They told the Sacklers that sales representatives would also target prescribers with the lowest levels of training, physician’s assistants and nurse practitioners, because they were “the only growing segment” in the opioid market. Purdue executives expected that, each quarter, the sales representatives would visit prescribers more than 200,000 times and would get 40,000 new patients onto Purdue opioids.

1038. In December, staff prepared to address wide-ranging concerns raised by the Sacklers. Kathe and Mortimer Sackler wanted staff to break out productivity data by indication versus prescriber specialty for each drug. Richard Sackler sought details on how staff was calculating 2016 mg/tablet trends. Jonathan Sackler sought a follow-up briefing on how public health efforts to prevent opioid addiction would affect OxyContin sales.

1039. Before the year ended, the Sacklers were invited to a “Beneficiaries Meeting” where Purdue staff reported to Sackler family members about the company’s efforts to sell opioids.

x. 2016

1040. In 2016, the CDC published the CDC *Guideline for Prescribing Opioids for Chronic Pain* to try to stop dangerous opioid prescribing.

1041. The Sacklers met with the Board in January, March, April, June, August, October, November, and December of 2016.

1042. In April, the Sacklers considered exactly how much money was riding on their strategy of pushing higher doses of opioids. The month before, the CDC announced guidelines to try to slow the epidemic of opioid overdose and death. The new CDC guidelines urged prescribers to avoid doses higher than 30mg of Purdue's OxyContin twice per day. The CDC discouraged twice-a-day prescriptions of all three of Purdue's most profitable strengths: 40mg, 60mg, and 80mg.

1043. In May, Richard Sackler told staff to circulate a *New York Times* story reporting that opioid prescriptions were dropping for the first time since Purdue launched OxyContin twenty years earlier. *The Times* wrote: "Experts say the drop is an important early signal that the long-running prescription opioid epidemic may be peaking, that doctors have begun heeding a drumbeat of warnings about the highly addictive nature of the drugs."

1044. In June, the Sacklers met to discuss a revised version of *Project Tango*, another attempt at profiting from the opioid crisis. This time, they considered a scheme to sell the overdose antidote Narcan. The need for Narcan to reverse overdoses was rising so fast that the Sacklers calculated it could provide a growing source of revenue, tripling from 2016 to 2018.

1045. Like *Tango*, Purdue's analysis of the market for Narcan confirmed that they saw the opioid epidemic as a money-making opportunity and that the Sacklers understood (in private, when no one was watching) how Purdue's opioids put patients at risk. The Sacklers identified a "strategic fit" because Narcan is a "complementary" product to Purdue opioids. They specifically identified patients on Purdue's prescription opioids as the target market for Narcan. Their plan called for studying "long-term script users" to "better understand target end-patients" for Narcan. Likewise, they identified the same doctors who prescribed the most Purdue opioids as the best

market for selling the overdose antidote; they planned to “leverage the current Purdue sales force” to “drive direct promotion to targeted opioid prescribers.”

1046. That same month, staff presented the 2016 Mid-Year Update. They warned the Sacklers that shifts in the national discussion of opioids threatened their plans and that the deception that Purdue had used to conceal the risks of opioids was at risk of being exposed.

1047. *First*, to convince doctors to prescribe dangerous opioids, Purdue had promoted its drugs as the solution to “undertreatment of pain.” Richard Sackler had made sure that Purdue bought the internet address *5thvitalsign.com* so it could promote pain as the “fifth vital sign” (along with temperature, blood pressure, pulse, and breathing rate) to expand the market for opioids. But now, staff reported to the Sacklers, doctors and patients were starting to worry more about the epidemic of opioid addiction and death.

1048. *Second*, to conceal the danger of addiction, Purdue had falsely blamed the terrible consequences of opioids on drug abuse. One of Purdue’s key messages argued: “It’s not addiction, it’s abuse.” But now, staff reported to the Sacklers, doctors and patients were realizing that addiction was a true danger.

1049. *Third*, to avoid responsibility for Purdue’s dangerous drugs, the Sacklers had chosen to stigmatize people who were hurt by opioids, calling them “junkies” and “criminals.” Richard Sackler wrote that Purdue should “hammer” them in every way possible. But now, staff reported to the Sacklers, Americans were seeing through the stigma and recognizing that millions of families were victims of addictive drugs. Staff told the Sacklers that nearly half of Americans reported that they knew someone who had been addicted to prescription opioids.

1050. *Fourth*, the Sacklers had long sought to hide behind the approval of Purdue’s drugs by the FDA. But FDA approval could not protect the Sacklers when their deceptive marketing led

thousands of patients to become addicted and die. The CDC reported that opioids were, indeed, killing people. The CDC Director said: “We know of no other medication that’s routinely used for a nonfatal condition that kills patients so frequently.” The 2016 Mid-Year Update warned that the truth was threatening Purdue. In the face of this pressure, staff told the Sacklers that the sales team was focusing on the doctors who prescribed the most opioids.

1051. In November, staff prepared statements to the press denying the Sacklers’ involvement in Purdue. Their draft claimed: “Sackler family members hold no leadership roles in the companies owned by the family trust.” That was a lie. Sackler family members held the controlling majority of seats on the Board and, in fact, controlled the company. A staff member reviewing the draft knew what was up and commented with apparent sarcasm: “Love the ... statement.” Staff eventually told the press: “Sackler family members hold no management positions.”

1052. Some employees worried about the deception. When journalists asked follow-up questions about the Sacklers, communications staff deliberated about whether to repeat the “no management positions” claim. They double-checked that Purdue’s top lawyers had ordered the statement. Then, they arranged for one of the Sacklers’ foreign companies to issue it, so U.S. employees would not be blamed: “The statement will come out of Singapore.”

1053. In December, Richard, Jonathan, and Mortimer Sackler had a call with staff about another revised version of *Project Tango*. The new idea was to buy a company that treated opioid addiction with implantable drug pumps. The business was a “strategic fit” because Purdue sold opioids and the new business treated the “strategically adjacent indication of opioid dependence.” The Sacklers kept searching for a way to expand their business by selling both addictive opioids and treatment for opioid addiction.

xi. 2017

1054. In 2017, the President of the United States declared the opioid crisis a national public health emergency.

1055. The Sacklers met with the Board in February, March, April, June, July, August, October, November, and December in 2017.

1056. In May 2017, staff told the Sacklers that an independent nonprofit had concluded that Purdue's reformulation of OxyContin was not a cost-effective way to prevent opioid abuse. Theresa Sackler asked staff what they were doing to fight back to convince doctors and patients to keep using the drug.

1057. That same month, the Sacklers were looking for a new CEO. Long-time employee Craig Landau wanted the job and prepared a business plan titled "SACKLER PHARMA ENTERPRISE." Landau was careful to acknowledge their power: he acknowledged that Purdue operated with "the Board of Directors serving as the 'de facto' CEO." He proposed that Purdue should take advantage of other companies' concerns about the opioid epidemic through an "opioid consolidation strategy" and become an even more dominant opioid seller "as other companies abandon the space." The Sacklers made him CEO a few weeks later.

1058. In June, staff told the Sacklers that getting doctors to prescribe high doses of opioids and many pills per prescription were still key "drivers" of Purdue's profit. Purdue's management was concerned that the CDC's efforts to save lives by reducing doses and pill counts would force the company "to adjust down our revenue expectations."

1059. Staff told the Sacklers that Purdue's opioid sales were being hurt by cultural trends such as the HBO documentary, "Warning: This Drug May Kill You." HBO's film was a problem

for Purdue because it showed actual footage from Purdue's misleading advertisements next to video of people who overdosed and died.

1060. Staff felt the pressure of the opioid epidemic, even if the billionaire Sacklers did not. In one presentation, staff came close to insubordination and told the Sacklers: "Purdue Needs a New Approach." Their suggestion for a new direction was: "A New Narrative: Appropriate Use."

1061. Employees proposed "appropriate use" of drugs to reinvent the company. Staff also suggested that the Sacklers create a family foundation to help solve the opioid crisis.

1062. The Sacklers did not redirect the company toward appropriate use or create the suggested family foundation. Instead, they decided to sell harder. For 2018, the Sacklers approved a target for sales reps to visit prescribers 1,050,000 times - almost double the number of sales visits they had ordered during the heyday of OxyContin in 2010.

1063. In October, Richard Sackler learned that insurance company Cigna had cut OxyContin from its list of covered drugs and replaced it with a drug from Purdue's competitor, Collegium. Richard read that Collegium had agreed to encourage doctors to prescribe lower doses of opioids, and Collegium's contract with Cigna was designed so Collegium would earn less money if doctors prescribed high doses. Cigna announced that opioid companies influence dosing: "While drug companies don't control prescriptions, they can help influence patient and doctor conversations by educating people about their medications." Richard's first thought was revenge. He immediately suggested that Purdue drop Cigna as the insurance provider for the company health plan.

1064. On October 17, Beverly Sackler served her last day on the Board. It was the beginning of the end for the Sackler family. A week later, the *New Yorker* published an article

entitled “The Family That Built an Empire of Pain.” The story quoted a former FDA Commissioner: “the goal should have been to sell the least dose of the drug to the smallest number of patients.” The reporter concluded: “Purdue set out to do exactly the opposite.”

1065. In November, Jonathan Sackler suggested that Purdue launch yet another opioid. Staff promised to present a plan for additional opioids at the next meeting of the Board. At the Board meeting that month, the remaining Sackler Board members (Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa) voted to cut the sales force from 582 reps to 302 reps. They knew sales reps would continue to promote opioids in South Carolina and would continue to visit prescribers in South Carolina.

xii. 2018

1066. In January 2018, Richard Sackler received a patent for a drug to treat opioid addiction—his own version of *Project Tango*. Richard had applied for the patent in 2007. He assigned it to a different company controlled by the Sackler family (rather than Purdue). Richard’s patent application says opioids are addictive, and the application calls the people who become addicted to opioids “junkies” and asks for a monopoly on a method of treating addiction.

1067. In January, Richard Sackler met with Purdue staff about the sales force again. They discussed plans to cut the force to 275 representatives. In February, Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler decided to lay off 300 sales representatives.

1068. By April, Richard Sackler was again asking questions about sales. Staff prepared a presentation for the Board of Directors (“BoD”). One employee suggested that they add more information about the company’s problems. Another cautioned against that: “I think we need to find a balance between being clear about what reality looks like - which I certainly support in [this]

situation - and just giving so much bad news about the future that it just makes things look hopeless. Let's not give the BoD a reason to just walk away."

1069. On May 3 and again on June 6 and 8, all seven remaining Sacklers attended meetings of the Board: Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa.

1070. On June 12, 2018, the Massachusetts Attorney General filed a suit to hold the Sacklers as well as Purdue accountable. Richard Sackler resigned from the Board in July. David Sackler quit in August Theresa Sackler served her last day in September. Ilene, Jonathan, Kathe, and Mortimer remain.

5. *The Purdue-related Defendants directed and controlled Purdue's false and deceptive marketing at all relevant times.*

1071. At all times the Purdue board of directors knew about, allowed, and directed Purdue's deception. They oversaw Purdue's scheme to send sales representatives to visit doctors thousands of times. They oversaw Purdue's scheme to hire top prescribers to promote its opioids. They oversaw Purdue's effort to get more patients on higher doses of opioids for longer periods. They were aware of, allowed and directed the content of the messages conveyed in Purdue's marketing.

1072. The directors of PPI controlled PPLP. The quarterly reports distributed to the directors of PPI demonstrate that the directors in fact controlled both PPI and PPLP. The reports and minutes make clear that the directors of PPI were kept fully informed of the activities of Purdue in the areas of "Finance," "Sales & Marketing," "Manufacturing & Supply Chain," "Quality," "Research & Development," "Discovery Research," "Licensing & Business Development," "Corporate Compliance," "External Affairs," "Health Policy," "Human Resources," and "Information Technology," all of which were overseen by the directors.

1073. The directors oversaw Purdue's sales representatives. Richard Sackler testified that the sales representatives were the main way that Purdue promoted its opioids. He testified that the key to getting doctors to prescribe and keep prescribing Purdue opioids was regular visits from the sales force. The board tracked the exact number of sales representatives and the exact number of visits they made to urge doctors to prescribe Purdue opioids. The board knew which drugs were promoted, how many visits sales representatives averaged per workday, how much each visit cost Purdue, and the company's plan for sales visits in each upcoming quarter. The Board approved specific plans to hire new sales representatives, hire and promote new District and Regional managers, and create sales "territories" in which representatives would target doctors.

1074. The directors oversaw the tactics that sales representatives used to push opioids. A board report analyzed a Purdue initiative to use iPads during sales visits, which increased the average length of the sales meeting with the doctor to "16.7 minutes in front of the customer."

1075. The directors oversaw promotional claims that representatives presented to doctors during sales visits. They received reports, for example, that a "review of call notes" recorded by Purdue sales representatives "suggested potential comparative claims of superiority of Purdue products relative to competitors," and deceptive promotion of opioids as treatment for "minor pain," including hundreds of examples of deceptive marketing that required "extensive remedial actions."

1076. The directors oversaw Purdue's research, including research that contradicted its marketing. The board received reports about studies of Purdue opioids in "opioid-naïve" patients and patients with osteoarthritis, down to the details of the strategy behind the studies and the enrollment of the first patients.

1077. The directors oversaw Purdue's improper response to signs of "abuse and diversion" by high-prescribing doctors. The board was told exactly how many "Reports Of Concern" Purdue sales representatives submitted to the company about doctors they visited to promote opioids and how many "field inquiries" Purdue had decided to conduct in response to the reports.

1078. The directors even monitored sales representatives' emails. Purdue held thousands of face-to-face sales meetings with doctors, but the company prohibited its sales representatives from writing emails to doctors, which could create evidence of Purdue's misconduct. When Purdue found that some sales representatives had emailed doctors, the company conducted an "investigation" and reported to the board that sales representatives had been disciplined and that their emails would be discussed at the board meeting.

1079. The directors also oversaw Purdue's strategy to pay high prescribers to promote Purdue opioid products. A report for the board listed the exact number of conferences and dinner meetings, with attendance figures, and assured the directors: "We are tracking the prescribing trends of these attendees following the programs and will report the results in future reports." The board was told the amounts paid to certain doctors, and they received detailed reports on the Return on Investment that Purdue gained from paying doctors to promote its drugs. The board was told that Purdue would allow a "spending limit for gifts" of \$750 per doctor per year, and that the directors should personally report when they gave money, meals, or gifts to doctors to promote Purdue drugs. The board was told explicitly that paying doctors to promote opioids was "a high risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities." When Congress required disclosure of drug company payments to doctors, the board was told there were "significant compliance implications" for Purdue.

1080. The directors also oversaw Purdue's strategy to push patients to higher doses of opioids, which are more dangerous, more addictive, and more profitable. The board routinely received reports on Purdue's efforts to push patients to higher doses. A report alerted the board that "Net sales of the 40 and 80 mg strengths of OxyContin" had fallen below Purdue's targets in the fall of 2010 and were \$85 million below budget. By summer, the board learned that income was \$500 million below budget "mainly due to declining sales in 40 mg and 80 mg strengths. By fall, the board reviewed an assessment that Purdue had lost more than \$800 million in revenue because patients weren't taking enough 40 mg and 80 mg doses. The board dug into the issue. Multiple reports to the board identified as a "threat" an initiative by public health authorities to save lives by requiring doctors to consult with pain specialists before prescribing opioid doses higher than 80mg/day. The CEO and directors oversaw Purdue's effort to push back against that public health initiative. Executives were pleased to report to the directors in 2013 that "initiatives to validate increased total daily doses are having impact in the field."

1081. The directors also oversaw Purdue's scheme to use higher doses of opioids to keep patients on drugs for longer periods of time. The board received detailed reports of how many patients stayed on Purdue's opioids for long periods (for example, longer than 35 days), along with Purdue's internal research showing that getting patients on higher doses keeps them on the drugs longer, all of which puts patients at greater risk of addiction and death. The board received the confidential results of a study of 57,000 patients that Purdue performed explicitly to determine how opioid dose "influences patient length of therapy." The results showed that patients on the highest doses "are the most persistent." The "Recommended Actions" presented to the board included "additional workshops for the sales force" and "specific direction" to the sales representatives about using higher doses to keep patients on drugs longer.

1082. The board was told in writing that encouraging higher doses “is a focal point of our promotion,” and that sales representatives would “emphasize the importance” of increasing patients’ opioid doses, as soon as 3 days after starting treatment. The board even tracked specific sales materials, such as “two new patient profiles designed to improve patient identification and titration,” to get more opioid-naïve and elderly patients on higher doses of opioids for longer periods of time. The board was told the exact research behind the sales strategy: higher doses would keep patients on drugs longer because Purdue had found that “83% of patients who discontinued were never titrated to higher doses.” The directors knew or should have known that Purdue’s sales strategy was deceptive and that putting patients on opioids at higher doses and for longer periods increased the risk of addiction, overdose, and death.

1083. The directors also oversaw Purdue’s strategy of using “savings cards” to get patients on Purdue opioids for longer periods. The board knew how many thousands of cards were used each quarter, how the company calculated the Return On Investment, and that the explicit goal of the program was to hook patients to “remain on therapy longer.”

1084. The directors also oversaw Purdue’s strategy to target prescribers who did not have special training in opioids (e.g., primary care doctors, nurse practitioners, and physician assistants) because they “show the highest responsiveness” to Purdue’s sales push. Purdue continued that strategy even though the DEA had expressed concern that Purdue was promoting opioids to clinicians who were not adequately trained in pain management. The directors also oversaw Purdue’s strategy to target elderly patients by promotion “targeted to HCPs that practice in the long-term care setting,” even down to the details of advertising that “leverages images of older patients.” The directors knew or should have known that Purdue’s sales strategy was deceptive

and that targeting primary care doctors and elderly patients increased the risk of addiction, overdose, and death.

1085. The directors also oversaw Purdue's push to steer patients away from safer alternative pain therapies. They tracked the company's effort to emphasize "the true risk and cost consequence of acetaminophen-related liver toxicity." The board even oversaw Purdue's deceptive websites and received reports about the specific section that was found to be deceptive by the New York Attorney General.

1086. The directors also oversaw Purdue's response to signs that patients were being harmed. Reports of harm came in by the hundreds and even thousands. One board report explained that "in excess of 5,000 cases with alleged adverse events have already been received and processed by Drug Safety and the Litigation Support group" during a single quarter.

1087. Each of the reports described above was sent to every Sackler Defendant on the board at the time the reports were prepared. Stuart Baker also received all of the reports described above.

FIRST CAUSE OF ACTION

South Carolina Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5-10 *et seq.*

(All Defendants)

1088. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1089. At all times relevant to this Complaint, Defendants were engaged in the trade or commerce of manufacturing, marketing, selling, distributing, and/or dispensing prescription opioid pain medications in South Carolina. For over twenty years, Defendants have been the leading force in the prescription opioid market, both nationwide and in South Carolina.

1090. By engaging in the acts and practices alleged herein, Defendants made or caused to be made to South Carolina consumers and to Plaintiffs, directly or indirectly, explicitly or by implication, misrepresentations that, reasonably interpreted, are material, false, and likely to mislead or deceive.

1091. Defendants violated the South Carolina Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5-10 *et seq.* (“SCUTPA”), because they engaged in deceptive acts or practices in the conduct of business, trade, or commerce within South Carolina, including, for example:

- i. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not;
- ii. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ creating, sponsoring, and/or assisting in the distribution of patient and prescriber education materials that contained false, misleading, and/or deceptive statements about prescription opioids;
- iii. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants’ own publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- iv. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ distributing brochures to doctors, patients, and the public that included deceptive statements concerning the indicators of possible opioid abuse, indicating that screening tools effectively prevent addiction, and representing that so-called “abuse-deterrent” opioids reduce tampering and abuse;
- v. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- vi. The Manufacturer Defendants’ and the Purdue-Related Defendants’ providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of

opioids to treat chronic pain while maintaining a more credible, “independent third party” appearance;

- vii. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
 - viii. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
 - ix. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
 - x. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
 - xi. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
 - xii. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
 - xiii. The Distributor Defendants’ and the Retail Pharmacy Defendants’ falsely holding themselves out as law-abiding distributors and participants in the supply chain but instead withholding information from the public and from law enforcement about diversion and over-prescribing of prescription opioids, and failing to take any action to prevent diversion; and
 - xiv. The Dealer Defendants’ falsely representing to patients and the public that they lawfully prescribed opioids for medical treatment when their practice of prescribing was for nonmedical purposes, violated laws, and was done for the sole purpose of making profit.
1092. Defendants knew at the time that they made their misrepresentations and omissions

that (1) they were false and (2) they had the tendency to influence the consumer choices of Plaintiffs and Plaintiffs' residents.

1093. Defendants designed their misrepresentations and omissions for the purpose of influencing Plaintiffs and Plaintiffs' residents into relying on them.

1094. Defendants' acts and practices as alleged in this Complaint had a capacity or tendency to deceive. When considered from the perspective of a reasonable consumer, these acts or practices were likely to mislead Plaintiffs and South Carolina consumers in Plaintiffs' communities.

1095. The Manufacturer Defendants', the Purdue-Related Defendants', and the Sales Representative Defendants' consistent, repeated, deceptive representations that their opioids had properties unsupported by medical literature did in fact deceive Plaintiffs and Plaintiffs' residents, causing them to both prescribe and consume opioids for the treatment of chronic pain conditions and suffer from addiction when they otherwise would not.

1096. The Distributor Defendants', the Retail Pharmacy Defendants', and the Dealer Defendants' consistent, repeated, deceptive representations that they kept records as required by law and were prescribing, distributing, dispensing, and approving opioids for legitimate medical purposes did in fact deceive Plaintiffs and Plaintiffs' residents, resulting in widespread addiction that otherwise would not have occurred.

1097. Given the incredible resources the Manufacturer Defendants, the Purdue-Related Defendants, and the Sales Representative Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiffs and Plaintiffs' residents reasonably relied upon Defendants' misrepresentations and omissions.

1098. Given the infinitely better-resourced and highly sophisticated nature of the

Distributor Defendants', the Retail Pharmacy Defendants', and the Dealer Defendants' practices and their intimate knowledge of state and federal legal requirements, Plaintiffs and Plaintiffs' residents reasonably relied on these Defendants to uphold their legal requirements and not commit intentional, material omissions to law enforcement for the sake of profits.

1099. Given the efforts taken by the Dealer Defendants to obtain medical licenses, operate businesses, and present the outward appearance of legitimate medical practitioners, Plaintiffs and Plaintiffs' residents reasonably relied on the Dealer Defendants' representations that they were providing medical treatment and not engaging in unlawful, nonmedical dissemination of opioids to addicts for the sole purpose of profit.

1100. Plaintiffs are "persons" with standing to sue under SCUPTA. *See* S.C. Code Ann. § 39-5-10(a). Plaintiffs and Plaintiffs' residents have been injured by reason of Defendants' violations of SCUTPA. Plaintiffs' injuries were directly caused by Defendants' deceptive behavior, resulting in lost productivity and tax revenue, as well as increased expenditures on public healthcare services, law enforcement, the justice system, and child and family services. The health and wellbeing of Plaintiffs' communities are matters of vital and legitimate concern to Plaintiffs and their residents.

1101. Defendants' conduct was willful or knowing under S.C. Code § 39-5-140.

1102. Defendants' acts or practices alleged herein constitute unfair or deceptive acts or practices in violation of SCUTPA and have proximately caused and continue to cause an ascertainable loss of money and property to Plaintiffs.

1103. Every deceptive, unfair, and/or misrepresentative act by Defendants constitutes a separate and distinct violation of S.C. Code § 39-5-20, capable of repetition and affecting and having an impact on the public interest. Defendants' acts in violation of SCUTPA are patently

offensive to public policy, unethical, immoral, and oppressive.

1104. Plaintiffs are informed and believe that they are entitled to actual damages in an amount to be determined by the jury, an award of treble damages under SCUTPA, and an award of reasonable attorney's fees.

SECOND CAUSE OF ACTION

Fraud (All Defendants)

1105. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1106. Defendants knowingly and intentionally made false, material statements to Plaintiffs and intentionally and unlawfully omitted or concealed information to Plaintiffs and the medical community in order to induce increased prescriptions of and increased use and consumption of opioids.

1107. Defendants made false statements about their compliance and/or omitted information about and concealed their non-compliance with applicable laws and regulations regarding their duties to monitor, detect, report, and halt suspicious prescriptions and prevent diversion. Defendants further made false statements regarding their due diligence with respect to prescription opioids.

1108. Defendants knew at the time that they made their misrepresentations and omissions that they were false or had a reckless disregard for the truth or falsity of such statements.

1109. Defendants intended to deceive Plaintiffs and did in fact deceive Plaintiffs and intended that their misrepresentations be acted on by Plaintiffs.

1110. Plaintiffs reasonably relied on the misrepresentations and omissions of Defendants.

1111. Defendants knew or should have known that Plaintiffs would be negatively impacted by their misrepresentations or omissions.

1112. Specifically, during the relevant period, Defendants' misrepresentations and omissions include, but are not limited to, the following:

- i. Defendants' misrepresentations overstating the benefits of and evidence supporting the use of opioids for chronic pain;
- ii. Defendants' misrepresentations that the risks of long-term opioid use, especially the risk of addiction, were overblown;
- iii. Defendants' misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;
- iv. Defendants' misrepresentations that signs of addiction were "pseudoaddiction" and thus reflected undertreated pain, which should be responded to with more opioids;
- v. Defendants' misrepresentations that screening tools effectively prevent addiction;
- vi. Defendants' misrepresentations concerning the comparative risks of NSAIDs and opioids;
- vii. Defendants' misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;
- viii. Defendants' misrepresentations that evidence supports the long-term use of opioids for chronic pain;
- ix. Defendants' misrepresentations that chronic opioid therapy would improve patients' function and quality of life;
- x. Defendants' false portrayal of their efforts and/or commitment to rein in the diversion and abuse of opioids;
- xi. Defendants' misrepresentations regarding their internal compliance programs;
- xii. Defendants' misrepresentations about their commitments to public health;
- xiii. Defendants' misrepresentations that withdrawal is easily managed;
- xiv. Purdue's, the Purdue-Related Defendants', and Endo's misrepresentations that alleged "abuse-deterrent" opioids reduce tampering and abuse;

- xv. Purdue's, the Purdue-Related Defendants', and the Sales Representative Defendants' misrepresentations that OxyContin provides a full 12 hours of pain relief;
- xvi. Purdue's, the Purdue-Related Defendants', and the Sales Representative Defendants' misrepresentations that Purdue cooperates with and supports efforts to prevent opioid abuse and diversion;
- xvii. Purdue's, the Purdue-Related Defendants', and the Sales Representative Defendants' misrepresentations that Purdue's alleged "abuse-deterrent" opioids could not be abused, reduce opioid abuse and diversion, and are safer than other prescription opioids;
- xviii. Janssen's misrepresentations that its Nucynta products were safer and milder than other prescription opioids (such as OxyContin) and Janssen's misrepresentations that its Nucynta products were "unlike traditional opioids" and possessed "non-opioid" properties;
- xix. Mallinckrodt's misrepresentations that it meets or exceeds legal requirements for controlling against diversion of controlled substances it has been entrusted to handle;
- xx. Insys's misrepresentations that Subsys was appropriate for treatment of non-cancer pain and its failure to disclose that Subsys was not approved for such use;
- xxi. Insys's misrepresentations to third-party payors to secure approval for coverage;
- xxii. Insys's use of speaker bureaus to disguise kickbacks to prescribers;
- xxiii. Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use; and
- xxiv. Cephalon's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain.

1113. Defendants used front groups to misrepresent that the deceptive statements from the sources described in this Complaint came from objective, independent sources.

1114. Defendants created a body of deceptive, misleading, and unsupported medical and popular literature, advertisements, training materials, and speaker presentations about opioids that:

(i) understated the risks and overstated the benefits of long-term opioid use; (ii) appeared to be the

result of independent, objective research; and (iii) was likely to be relied on by physicians, patients, payors, and others.

1115. Defendants engaged in the acts and practices alleged herein during the relevant time period with the intent that Plaintiffs and others rely on their omissions and misstatements.

1116. In their representations regarding opioids, Defendants omitted the following material facts, which Defendants had a duty to disclose:

- i. opioids are highly addictive and may result in overdose or death;
- ii. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;
- iii. high dose opioids subject the user to greater risks of addiction, other injury, and/or death;
- iv. opioids present the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines (these omissions occurred while Defendants exaggerated the risks of competing products such as NSAIDs);
- v. claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;
- vi. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;
- vii. Purdue's and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the common route of abuse (oral abuse), can be defeated with relative ease, and may increase overall abuse;
- viii. Defendants failed to report suspicious prescribers and/or orders;
- ix. Insys's use of kickback and insurance fraud schemes;
- x. Insys's failure to disclose that Subsys was not approved for non-cancer pain;
- xi. Cephalon's failure to disclose that Actiq and Fentora were not approved for non-cancer pain; and
- xii. Manufacturer Defendants' failure to disclose their financial ties to and role in connection with KOLs, front groups, and deceptive literature and materials.

1117. Defendants knew that their failures to disclose material facts about prescription opioids rendered their representations untrue and/or misleading.

1118. Defendants had a duty not to deceive Plaintiffs.

1119. Additionally, Defendants had a duty not to deceive Plaintiffs because Defendants had in their possession unique material knowledge that was unknown, and not knowable, to Plaintiffs, Plaintiffs' agents and decision-makers, Plaintiffs' communities, physicians, and the public.

1120. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations. Defendants' false representations and concealed facts were material to the conduct and actions at issue.

1121. Under the circumstances, Defendants intended and had reason to expect that Plaintiffs, Plaintiffs' agents and decision-makers, Plaintiffs' communities, physicians, and the public, and persons on whom Plaintiffs and agents relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable and justifiable reliance thereon.

1122. Defendants intended that Plaintiffs, Plaintiffs' agents and decision-makers, Plaintiffs' communities, physicians, the public, and persons on whom Plaintiffs and agents relied would rely on these Defendants' misrepresentations and omissions. Defendants intended and knew that this reasonable and rightful reliance would be induced by Defendants' misrepresentations and omissions, and Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

1123. Plaintiffs, Plaintiffs' agents and decision-makers, Plaintiffs' communities, the public, physicians and persons on whom Plaintiffs and agents relied, did in fact rightfully,

reasonably, and justifiably rely on Defendants' representations and/or concealments, both directly and indirectly. As Defendants knew or should have known, Plaintiffs were directly and proximately injured as a result of this reliance, and Plaintiffs' injuries were directly and proximately caused by this reliance.

1124. As a result of these representations and/or omissions, Plaintiffs proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants. As a consequence, Defendants prevented Plaintiffs from initiating a more timely and effective response to the opioid crisis in their communities.

1125. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiffs suffered injuries that were directly and proximately caused by this reliance.

1126. Defendants' misconduct as alleged in this case is ongoing and persistent.

1127. Defendants' misconduct as alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's operations.

1128. Plaintiffs have incurred costs for special programs and extraordinary expenses over and above Plaintiffs' ordinary public services.

1129. Defendants' conduct was accompanied by wanton and willful disregard of persons and/or entities who foreseeably could and would be harmed by their acts and omissions.

1130. Defendants' actions demonstrated both malice and aggravated, egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of others, even though that conduct had a great probability of causing substantial harm. Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

THIRD CAUSE OF ACTION
Unjust Enrichment

(All Defendants)

1131. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1132. Plaintiffs are entitled to recover those amounts by which Defendants have been unjustly enriched at the expense of Plaintiffs under the equitable doctrine of unjust enrichment.

1133. Defendants have knowingly and unjustly retained a benefit to Plaintiffs' detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

1134. By illegally and deceptively promoting opioids to treat chronic pain, directly, through their control of third parties, and by acting in concert with third parties, Defendants have unjustly enriched themselves at Plaintiffs' expense. Plaintiffs have made payments for opioid prescriptions and Defendants benefited from those payments. Because of their deceptive promotion of opioids and other wrongful conduct, Defendants have obtained enrichment they would not otherwise have obtained.

1135. In addition, Plaintiffs were injured and continue to be injured by Defendants' ongoing concerted actions in illegally and deceptively marketing opioids and causing doctors and other healthcare providers to prescribe and Plaintiffs to pay for long-term opioid treatment. Defendants caused and are responsible for those costs and claims. Plaintiffs have suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

1136. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Plaintiffs' communities, including from opioids foreseeably and deliberately diverted within and into Plaintiffs' communities.

1137. Plaintiffs have expended substantial amounts of money in an effort to remedy or mitigate the harms caused by Defendants' wrongful conduct.

1138. These expenditures include, for example, the provision of healthcare services and treatment services to people who use opioids and/or have become addicted to opioids.

1139. These expenditures have helped sustain Defendants' businesses.

1140. Plaintiffs have conferred a benefit upon Defendants by paying for Defendants' externalities (i.e., the cost of the harms caused by Defendants' improper distribution practices and other wrongful conduct described herein).

1141. Defendants were aware of these benefits, and their retention of those benefits would be unjust under the circumstances.

1142. Plaintiffs have paid for the cost of Defendants' externalities and Defendants have benefited from those payments and continued providing a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Manufacturer Defendants and the Purdue-Related Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, the other Defendants obtained enrichment they would not otherwise have obtained.

1143. Defendants' misconduct alleged in this case is ongoing and persistent.

1144. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's operations.

1145. Plaintiffs have incurred costs for special programs and extraordinary expenses over and above Plaintiffs' ordinary public services

FOURTH CAUSE OF ACTION
Negligence

(All Defendants)

1146. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1147. All Defendants have common law and statutory duties with respect to the handling, manufacturing, promoting, marketing, selling, distribution, dispensing, and/or administering of prescription opioids in South Carolina. All Defendants had a role in the availability of prescription opioids in South Carolina and in Plaintiffs' communities.

1148. Defendants owed Plaintiffs a duty, including a preexisting duty, to not expose Plaintiffs to an unreasonable risk of harm.

1149. Defendants had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in handling, manufacturing, promotion, marketing, selling, distribution, dispensing, and/or administering of prescription opioids in South Carolina.

1150. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in handling, manufacturing, promoting, marketing, selling, distribution, dispensing, and/or administering of prescription opioids, which are dangerously addictive drugs, requires a high degree of care and places them in a position of great trust and responsibility *vis-a-vis* Plaintiffs. Their duty cannot be delegated.

1151. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in handling, manufacturing, promoting, marketing, selling, distribution, dispensing, and/or administering of dangerous controlled substances.

1152. The Manufacturer Defendants, the Purdue-Related Defendants, and the Sales Representative Defendants breached duties owed to Plaintiffs by, among other things, engaging in

the deceptive marketing and promotion of opioids in South Carolina and in Plaintiffs' communities. These Defendants minimized the risks of addiction and overdose, exaggerated the purported benefits of long-term use of opioids for treatment of chronic pain, and made numerous other misrepresentations.

1153. The Distributor Defendants, Retail Pharmacy Defendants, and Dealer Defendants breached duties owed to Plaintiffs by, *inter alia*:

- i. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- ii. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;
- iii. Choosing not to effectively monitor for suspicious orders;
- iv. Choosing not to investigate suspicious orders;
- v. Choosing not to report suspicious orders;
- vi. Choosing not to stop or suspend shipments of suspicious orders;
- vii. Failing to address or prevent the abuse and misuse of prescription opioids; and
- viii. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

1154. The Manufacturer Defendants and the Purdue-Related Defendants also breached duties owed to Plaintiffs with respect to their failures to monitor, investigate, or report suspicious orders or otherwise prevent diversion of their prescription opioid products.

1155. Defendants' negligent conduct and breaches of their duties created and/or contributed to an illegal, secondary market for opioids, which resulted in a foreseeable and unreasonable risk of harm to Plaintiffs.

1156. Reasonably prudent participants in the supply chain for prescription opioids should have anticipated injury to Plaintiffs as a probable result of the negligent handling, manufacturing, promoting, marketing, selling, distribution, dispensing, and/or administering of opioids.

1157. It was reasonably foreseeable that Defendants' actions and omissions would result in the harm to Plaintiffs as described herein.

1158. Defendants had control over their conduct and the conduct of their agents operating in Plaintiffs' communities.

1159. The Manufacturer Defendants and the Purdue-Related Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint.

1160. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, including the criteria and processes they used to identify suspicious orders, whether and to what extent they trained their employees to report and halt suspicious orders, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

1161. Because of the Manufacturer Defendants' and the Purdue-Related Defendants' deceptive marketing of opioids and each of the Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

1162. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and as actively working to combat the opioid epidemic when, in reality, Defendants failed to take even minimal action to report suspicious orders or otherwise prevent diversion. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

1163. Defendants are in the business of handling, manufacturing, promoting, marketing, selling, distribution, dispensing, and/or administering prescription opioids, which are specifically known to Defendants to be dangerous because, *inter alia*, these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction. *See* S.C. Code Ann. § 44-53-200.

1164. Reasonably prudent manufacturers, distributors, retail pharmacies, sales representatives, and prescribers would have anticipated that the scourge of opioid addiction would wreak havoc on communities and would have reasonably foreseen the significant costs which would be imposed on the governmental entities associated with those communities. Indeed, it is a violation of state and federal law for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution, whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

1165. Manufacturer Defendants and the Purdue-Related Defendants knew or should have known that their affirmative misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing narcotic drugs created an unreasonable risk of harm. Defendants' sales data, reports from sales representatives, and internal documents, should have put them on notice

that such harm was not only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively withhold information about the dangers of opioids from Plaintiffs, physicians, patients, and the public.

1166. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, Plaintiffs have suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

1167. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, Plaintiffs have suffered and will continue to suffer stigma damage, non-physical property damage, and damage to their proprietary interests.

1168. As a direct and proximate result of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, there is now a national opioid epidemic that has caused enormous harm and injury to the public and to Plaintiffs' communities.

1169. Defendants' misconduct alleged in this case is ongoing and persistent.

1170. Defendants' misconduct alleged in this case does not concern a discrete event or a discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's operations.

1171. Plaintiffs have incurred expenditures for special programs over and above Plaintiffs' ordinary public services.

1172. Plaintiffs have suffered an indivisible injury as a result of the tortious conduct of Defendants.

1173. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiffs.

1174. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

FIFTH CAUSE OF ACTION
Negligent Misrepresentation
(All Defendants)

1175. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1176. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiffs and Plaintiffs' residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:

- i. The Manufacturer Defendants', the Purdue-Related Defendants', and the Sales Representative Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not;
- ii. The Manufacturer Defendants', the Purdue-Related Defendants', and the Sales Representative Defendants' creating, sponsoring, and/or assisting in the distribution of patient and prescriber education materials that contained false, misleading, and/or deceptive statements about prescription opioids;
- iii. The Manufacturer Defendants', the Purdue-Related Defendants', and the Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- iv. The Manufacturer Defendants', the Purdue-Related Defendants', and the Sales Representative Defendants' distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse, indicating that screening tools effectively prevent addiction, and representing that so-called "abuse-

deterrent” opioids reduce tampering and abuse;

- v. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- vi. The Manufacturer Defendants’ and the Purdue-Related Defendants’ providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, “independent third party” appearance;
- vii. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- viii. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- ix. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- x. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- xi. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- xii. The Manufacturer Defendants’, the Purdue-Related Defendants’, and the Sales Representative Defendants’ making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- xiii. The Distributor Defendants’ and Retail Pharmacy Defendants’ falsely

holding themselves out as law-abiding distributors and participants in the supply chain but instead withholding information from the public and from law enforcement about diversion and over-prescribing of prescription opioids, and failing to take any action to prevent diversion; and

- xiv. The Dealer Defendants' falsely representing to patients and the public that they lawfully prescribed opioids for medical treatment when their practice of prescribing was for nonmedical purposes, violated laws, and was done for the sole purpose of making profit.

1177. Defendants owed a duty of care to see that they communicated truthful information to Plaintiffs, yet Defendants breached that duty by failing to exercise due care.

1178. Defendants should have known at the time that they made their misrepresentations and omissions that they were false.

1179. Defendants should have, at the least, investigated the truth or falsity of their representations to Plaintiffs.

1180. Defendants intended that Plaintiffs and residents would rely on their misrepresentations and omissions.

1181. Given the incredible resources the Manufacturer Defendants, the Purdue-Related Defendants, and the Sales Representative Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiffs and Plaintiffs' residents reasonably relied upon Defendants' misrepresentations and omissions.

1182. Given the infinitely better-resourced and highly sophisticated nature of the Defendants' practices and their intimate knowledge of state and federal legal requirements, Plaintiffs and Plaintiffs' residents reasonably relied on Defendants to uphold their legal requirements and not commit intentional, material omissions to law enforcement for the sake of profits.

1183. Given the efforts taken by the Dealer Defendants to obtain medical licenses, operate businesses, and present the outward appearance of legitimate medical practitioners, Plaintiffs and

Plaintiffs' residents reasonably relied on the Dealer Defendants' representations that they were providing medical treatment and not engaging in unlawful, nonmedical dissemination of opioids to addicts for the sole purpose of profit.

1184. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiffs and Plaintiffs' residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services, as well as lost productivity and lost tax revenue.

1185. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally and at Plaintiffs. In addition to actual damages, Plaintiffs are entitled to punitive damages in an amount to be determined by the jury at the trial of the matter.

SIXTH CAUSE OF ACTION

Public Nuisance (All Defendants)

1186. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1187. Defendants' wrongful conduct described herein constituted an unreasonable and substantial interference with public health, public safety, and public order in Plaintiffs' communities and has injured the health of Plaintiffs' citizens. Defendants' conduct created and contributed to the opioid epidemic in each of Plaintiffs' communities. The opioid epidemic (or opioid crisis) constitutes a public nuisance.

1188. Defendants, individually and acting through their employees and agents, and in concert with each other, have knowingly, intentionally, recklessly, or negligently engaged in conduct or omissions which unreasonably interferes with the public health, safety, peace, comfort, convenience, or quality of life.

1189. The significant adverse impact of Defendants' conduct on Plaintiffs' communities has caused tremendous harm to Plaintiffs, including increased costs related to police, fire, and first responder services required to respond to opioid overdoses or suspected overdoses.

1190. Defendants, individually and acting through their employees and agents, have created and continue to perpetuate and maintain a public nuisance in each of Plaintiffs' communities through the flooding of those communities with addictive, commonly-abused prescription opioids.

1191. Defendants' wrongful conduct in expanding the market for prescription opioids and failing to prevent abuse and diversion foreseeably created a public nuisance in Plaintiffs' communities.

1192. Defendants failed to put in place effective controls and procedures to prevent or reduce theft and diversion of prescription opioids and failed to adequately monitor and report suspicious orders and other red flags. Defendants' failures have created a public nuisance in Plaintiffs' communities.

1193. Defendants enabled and/or failed to take any measures to prevent or reduce the illegal diversion of opioids into the black market, including through drug rings, pill mills, and other dealers in Plaintiffs' communities. Defendants knew or should have known about the illegal, secondary market for prescription opioids and were further on notice of the existence of an opioid crisis in Plaintiffs' communities.

1194. Defendants knew or should have known their conduct would cause harm and inconvenience to Plaintiffs in a number of ways. Defendants' conduct has caused deaths, serious injuries, and a severe disruption of public health, safety, peace, comfort, convenience, and quality of life; it is ongoing, and it is producing permanent and long-lasting damage.

1195. As a direct and foreseeable consequence of Defendants' conduct, Plaintiffs have paid, and continue to pay, for health care costs that stem from prescription opioid dependency created by Defendants' conduct and other costs. These costs include unnecessary and excessive opioid prescriptions, substance abuse treatment services, ambulatory services, emergency department services, and inpatient hospital services, among others. Defendants' conduct has also caused Plaintiffs to incur substantial economic, administrative, and social costs relating to opioid addiction and abuse, including criminal justice costs, victimization costs, lost productivity costs, and education and prevention program costs among others.

1196. Stemming the flow of illegally distributed prescription opioids and abating the public nuisance caused by the illegal flow of opioids will help alleviate the opioid crisis in Plaintiffs' communities, save lives, prevent injuries, and make Plaintiffs' communities safer places to live. Plaintiffs have a right to abatement of the conduct that perpetuates this continuing public nuisance caused by Defendants.

1197. The opioid epidemic can be abated in each of Plaintiffs' communities by, among other things: (a) educating prescribers (especially primary care physicians and prolific prescribers of opioids), patients, and the general public regarding the true risks and benefits of opioids, including the risk of addiction, to prevent future addiction, overdose, and death; (b) providing addiction treatment to individuals who are already suffering from opioid addiction; (c) making naloxone widely available; and (d) researching and implementing other community measures and initiatives aimed at targeting opioid addiction and morbidity. Plaintiffs are entitled to all reasonable costs of abating the public nuisance created by Defendants.

1198. Defendants are jointly and severally liable to Plaintiffs for all damages resulting from this public nuisance in an amount to be determined at trial, as well as punitive damages in an amount to be determined at trial, plus costs and attorneys' fees.

SEVENTH CAUSE OF ACTION

**Constructive Fraud
(All Defendants)**

1199. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1200. Defendants knew or should have known at the time that they made their misrepresentations and omissions that they were false.

1201. Defendants should have, at the least, investigated the truth or falsity of their representations to Plaintiffs.

1202. Defendants intended that Plaintiffs and residents would rely on their misrepresentations and omissions.

1203. Given the incredible resources the Manufacturer Defendants and the Purdue-Related Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiffs and Plaintiffs' residents reasonably relied upon (and had the right to rely on) Defendants' misrepresentations and omissions, as stated above.

1204. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' and Retail Pharmacy Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiffs and Plaintiffs' residents reasonably relied on (and had the right to rely on) the Distributor Defendants and Retail Pharmacy Defendants to uphold their legal requirements and not commit intentional, material omissions to law enforcement for the sake of profits.

1205. Given the efforts taken by the Dealer Defendants to obtain medical licenses, operate

businesses, and present the outward appearance of legitimate medical practitioners, Plaintiffs and Plaintiffs' residents reasonably relied on (and had a right to rely on) the Dealer Defendants' representations that they were providing medical treatment and not engaging in unlawful, nonmedical dissemination of opioids to addicts for the sole purpose of profit.

1206. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiffs had no knowledge of the Defendants' falsehoods and Plaintiffs and Plaintiffs' residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior, resulting in increased expenditures on public healthcare services, law enforcement, the justice system, and child and family services, and other governmental services to care for their citizens, as well as lost productivity and lost tax revenue.

1207. Defendants' wrongful conduct described herein had a tendency to deceive others, violated public confidence, and injured public interests.

1208. Defendants' intentional misconduct does not involve a discrete event or discrete emergency of the sort a political subdivision reasonably expects to occur and is not part of the normal and expected costs of a local government's existence.

1209. Defendants' conduct was willful, wanton, and malicious and was directed at Plaintiffs and the public generally. In addition to actual damages, Plaintiffs are entitled to punitive damages in an amount to be determined by the jury at the trial of the matter.

EIGHTH CAUSE OF ACTION

Negligence *Per Se* (All Defendants)

1210. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1211. All of the defendants named herein had duties arising from statutes and/or regulations, which fixed certain standards of conduct required of Defendants and which Defendants violated. Defendants' violations of those duties constituted negligence *per se*.

1212. The South Carolina Drug Act, S.C. Code Ann. §§ 39-23-10 *et seq.*, the South Carolina Poisons, Drugs, and Other Controlled Substances Act, S.C. Code Ann. §§ 44-53-10 *et seq.*, and its implementing regulations, and the FCSA impose a non-delegable duty upon the Manufacturer Defendants and Sales Representative Defendants with respect to the manufacturing and sale of prescription opioids. Defendants must, among other things, convey complete and accurate information about potential risks in drug advertising, *see* S.C. Code Ann. §§ 39-23-40, 39-23-80, “[m]aint[ain] effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels,” and “[comply] with applicable state or federal law,” *id.* § 44-53-300(a).

1213. The Manufacturer Defendants, the Purdue-Related Defendants, and the Sales Representative Defendants breached their duties within Plaintiffs' communities and in South Carolina by:

- i. Marketing opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;
- ii. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- iii. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- iv. Distributing brochures to doctors, patients, and the public that included deceptive statements concerning the indicators of possible opioid abuse, indicating that screening tools effectively prevent

addiction, and representing that so-called “abuse-deterrent” opioids reduce tampering and abuse;

- v. Sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- vi. Providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, “independent third party” appearance and allowing them to side-step labeling regulations in violation of South Carolina and Federal law;
- vii. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- viii. Developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- ix. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- x. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- xi. Disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- xii. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- xiii. Failing to monitor, detect, investigate, or report suspicious orders of prescription opioids; and
- xiv. Failing to take any action to prevent diversion of prescription opioids.

1214. The South Carolina Poisons, Drugs, and Other Controlled Substances Act, S.C.

Code Ann. §§ 44-53-10 *et seq.*, its implementing regulations, and the FCSA impose a non-delegable duty upon the Distributor Defendants to design and operate a system to disclose suspicious orders of controlled substances and to report suspicious orders when discovered. “Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” *See* S.C. Code Regs. 61-4.404(b); 21 C.F.R. § 1301.74(b).

1215. The purpose of the statutory scheme is to reduce the widespread diversion of controlled substances, like opioids, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. *See* S.C. Code Ann. § 44-53-300(a).

1216. The Distributor Defendants breached their duties within Plaintiffs’ communities and in South Carolina, as provided by state and federal law (and in many cases have admitted such breaches), by:

- i. Failing to design and operate a system to disclose suspicious orders of opioids;
- ii. Once compelled to design and operate a system to disclose suspicious orders of opioids, failing to report suspicious orders as required; and
- iii. Failing to avoid filling suspicious orders that were ultimately diverted.

1217. The South Carolina Poisons, Drugs, and Other Controlled Substances Act requires medical practitioners to keep adequate records that are accurate and verify the prescription history of patients receiving opioids. S.C. Code Ann. §§ 44-53-340; 44-53-390(a)(4); 44-53-1645. Furthermore, the Act makes it illegal for medical practitioners to distribute opioids for nonmedical purposes outside a *bona-fide* practitioner-patient relationship. *Id.* § 44-53-360(c); 44-53-260(h).

1218. The Dealer Defendants breached their duties under the relevant statutory and

regulatory provisions by:

- i. Distributing opioids for nonmedical purposes;
- ii. Distributing opioids for nonmedical purposes outside a *bona-fide* practitioner-patient relationship;
- iii. Failing to keep adequate records on patients being prescribed opioids;
- iv. Failing to keep accurate records on patients being prescribed opioids; and
- v. Failing to verify the prescription history of those to whom they prescribed opioids.

1219. The South Carolina Pharmacy Practices Act, the South Carolina Poisons, Drugs, and Other Controlled Substances Act, and the FCSA impose a duty on the Retail Pharmacy Defendants to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids. *See* 21 U.S.C. § 823; 21 C.F.R. 1301.74; S.C. Code Ann. § 40-43-86.

1220. The Retail Pharmacy Defendants breached their duties under the relevant statutory and regulatory provisions by:

- i. Failing to monitor dispensed prescription opioids;
- ii. Failing to detect suspicious dispensed prescription opioids;
- iii. Failing to investigate suspicious dispensed prescription opioids;
- iv. Failing to refuse to fill prescription opioids prescribed for nonmedical purpose; and
- v. Failing to report suspicious orders of prescription opioids.

1221. All of the aforementioned statutory provisions are designed to protect both individuals and the community-at-large, like Plaintiffs, from the addictive properties of opioids and the damages caused by opioid addiction, which includes the current opioid epidemic caused by Defendants that Plaintiffs are forced to cope with and ameliorate by use of public funds.

1222. As a direct and a proximate result of Defendants' acts and omissions that violated

the relevant statutory and regulatory provisions, Defendants and their agents have caused Plaintiffs to suffer damages by (among other things) incurring costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids. Plaintiffs have borne the massive costs of opioid-related illnesses and conditions by having to provide necessary resources for care, treatment facilities, law enforcement services, first responder services, child and family services, and other municipal services that Plaintiffs otherwise would not have incurred due to the need to use County resources to address opioid use and abuse. Additionally, Plaintiffs have suffered lost productivity from its workforce, thereby losing tax revenue.

1223. Defendants' intentional, willful, reckless, and/or negligent misconduct does not involve a discrete event or discrete emergency of the sort a political subdivision reasonably expects to occur and is not part of the normal and expected costs of a local government's existence.

1224. Defendants' acts are willful and wanton. In addition to actual damages, Plaintiffs are entitled to punitive damages in an amount to be determined by the jury at the trial of the matter.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs pray for relief and judgment against all Defendants as follows:

- a. For compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages;
- b. For treble damages under SCUTPA;
- c. For reasonable attorneys' fees under SCUTPA;
- d. For a reasonable amount of punitive damages to be determined by the jury at the trial of these cases;
- e. For interest, costs, and disbursements;

- f. For an injunction requiring Defendants to abate the opioid epidemic in South Carolina and in the Counties and enjoining Defendants from engaging in the wrongful conduct complained of herein; and
- g. For such other and further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and as to all issues.

Signature Page Follows

Respectfully submitted:

Plaintiffs' Liaison Counsel

/s/ John B. White, Jr.

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June 14, 2019

EXHIBIT 6

THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ALABAMA
NORTHERN DIVISION

CITY OF DEMOPOLIS, ALABAMA, a
municipal corporation,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION; CARDINAL HEALTH,
INC.; McKESSON CORPORATION;
PURDUE PHARMA L.P.; PURDUE
PHARMA, INC.; THE PURDUE FREDERICK
COMPANY, INC.; TEVA
PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; NORAMCO,
INC.; ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLS;
WATSON PHARMACEUTICALS, INC. n/k/a
ACTAVIS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS LLC;
ACTAVIS PHARMA, INC. f/k/a WATSON
PHARMA, INC.;
MALLINCKRODT PLC and
MALLINCKRODT LLC.

Defendants.

CASE NO.:

COMPLAINT

Complaint for Public Nuisance, Drug
Related Nuisance, Violations of Racketeer
Influenced and Corrupt Organizations Act
(RICO) 18 U.S.C. § 1961 *et seq.*,
Violations of 18 U.S.C. § 1962 *et seq.*,
Negligence and Negligent
Misrepresentation, Civil Conspiracy,
Fraud and Fraudulent Misrepresentation.

**JURY TRIAL DEMANDED AND
ENDORSED HEREON**

JM_0047140

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Plaintiff, CITY OF DEMOPOLIS, ALABAMA, brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively “Defendants”) and alleges as follows:

I. INTRODUCTION

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby and to recoup monies spent because of Defendants’ false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids.¹ Such economic damages were foreseeable to Defendants and were sustained because of Defendants’ intentional and/or unlawful actions and omissions.

2. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.²

3. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”³

¹ As used herein, the term “opioid” refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

² See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

³ See Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

4. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, which turned patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

5. Plaintiff also brings this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse, and report suspicious orders of prescription opioids.

II. PARTIES

A. PLAINTIFF.

6. Plaintiff CITY OF DEMOPOLIS, ALABAMA (“The City” or “Plaintiff”) is a municipal corporation organized under the laws of the State of Alabama and is authorized to bring the causes of action brought herein. ALA. CODE § 11-40-1 (“All municipal organizations now existing in the State of Alabama . . . shall sue and be sued Such municipal corporations shall be invested with the full powers, duties, and authority granted in this title.”). Plaintiff is responsible for the public health, safety and welfare of its citizens.

7. Plaintiff is specifically authorized to seek common law public nuisance remedies available under Alabama law. *See* ALA. CODE §§ 6-5-122 (“All municipalities in the State of Alabama may commence an action in the name of the city to abate or enjoin any public nuisance injurious to the health, morals, comfort, or welfare of the community or any portion thereof.”); 11-47-118; (“Municipalities may maintain a civil action to enjoin and abate any public nuisance, injurious to the health, morals, comfort or welfare of the community or any portion thereof.”);

11-47-117 (“All cities and towns of this state shall have the power to prevent injury or annoyances from anything dangerous or offensive or unwholesome and to cause all nuisances to be abated and assess the cost of abating the same against the person creating or maintaining the same.”).

8. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity, and mortality have created a serious public health and safety crisis and are a public nuisance and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

9. The distribution and diversion of opioids into Alabama (the “State”), and into the City and its surrounding areas (collectively, “Plaintiff’s Community”), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

10. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants’ conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; and (5) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. The Plaintiff has suffered and continues to suffer these damages directly.

11. Plaintiff also seeks the means to abate the epidemic Defendants’ wrongful and/or unlawful conduct has created.

12. Plaintiff has standing to bring an action for the opioid epidemic nuisance created by Defendants. *See, e.g.*, ALA. CODE § 6-5-155.2. (“Wherever there is reason to believe that a drug-related nuisance exists, ... the attorney for the county or municipality, ... may file an action ... to abate, enjoin, and prevent the drug-related nuisance.”).

13. Plaintiff also has standing to see relief as a “person” under Alabama law.

14. Plaintiff has standing to recover damages incurred as a result of Defendants’ actions and omissions. Plaintiff has standing to bring all claims pled herein, including, *inter alia*, to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) (“persons” include entities which can hold legal title to property) and 18 U.S.C. § 1964 (“persons” have standing).

B. DEFENDANTS.

1. Manufacturer Defendants.

15. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

16. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA, INC. is a New York corporation with its principal place of business in Stamford, Connecticut and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, “Purdue”).

17. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

18. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

19. Cephalon, Inc. manufactures, promotes, sells and distributes opioids, such as Actiq and Fentora, in the United States. The FDA has approved Actiq only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."⁴ The FDA has approved Fentora only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."⁵ In 2008, Cephalon

⁴ *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge*, CII (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s0301bl.pdf.

⁵ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet*, CII (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s0151bl.pdf.

pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.⁶

20. Teva Ltd., Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon-branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that Teva USA submitted the guide and directs physicians to contact Teva USA to report adverse events.

21. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.⁷ Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including, *inter alia*, sales of Fentora®.⁸ Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries, Cephalon and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and

⁶ Press Release, U.S. Dep’t of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

⁷ *E.g.*, ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (last visited Aug. 21, 2017).

⁸ Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; and Cephalon, Inc. are referred to as “Cephalon.”

22. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals’ drugs and Janssen’s profits inure to J&J’s benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco and J&J are referred to as “Janssen.”

23. Janssen manufactures, promotes, sells and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

24. ENDO HEALTH SOLUTIONS, INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS, INC. is a wholly owned subsidiary of Endo Health Solutions, Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. are referred to as “Endo.”

25. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet and Zydene, in the United States. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013 and accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids, such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products, in the United States, by itself and through its subsidiary, QUALITEST PHARMACEUTICALS, INC.

26. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Allergan PLC

owns each of these defendants and uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan PLC; Actavis PLC; Actavis, Inc.; Actavis LLC; Actavis Pharma, Inc.; Watson Pharmaceuticals, Inc.; Watson Pharma, Inc.; and Watson Laboratories, Inc. are referred to as “Actavis.”

27. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

28. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its United States headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc. Mallinckrodt, plc and Mallinckrodt, LLC are referred to as “Mallinckrodt.”

29. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.⁹

⁹ Press Release, U.S. Dep’t of Justice, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations*, July 11, 2017, <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>, last visited October 26, 2017.

2. Distributor Defendants.

30. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in “wholesale distribution,” as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Plaintiff’s Community.

31. McKESSON CORPORATION (“McKesson”) at all relevant times operated as a licensed pharmacy wholesaler in Alabama. McKesson is a Delaware corporation. McKesson has its principal place of business located in San Francisco, California. McKesson operates distribution centers in Alabama, including in McCalla, Alabama.

32. CARDINAL HEALTH, INC. (“Cardinal”) at all relevant times operated as a licensed pharmacy wholesaler in Alabama. Cardinal’s principal office is located in Dublin, Ohio. Cardinal operates distribution centers in Alabama, including in Birmingham, Alabama.

33. AMERISOURCEBERGEN DRUG CORPORATION (“AmerisourceBergen”) at all relevant times operated as a licensed pharmacy wholesaler in Alabama. AmerisourceBergen’s principal place of business is located in Chesterbrook, Pennsylvania. AmerisourceBergen operates distribution centers in Alabama, including in Pelham, Alabama.

34. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA’s confidential ARCOS database. *See Madel v.*

USDOJ, 784 F.3d 448 (8th Cir. 2015). Neither the DEA¹⁰ nor the wholesale distributors¹¹ will voluntarily disclose the data necessary to identify with specificity the transactions that will form the evidentiary basis for the claims asserted herein.

35. Consequently, Plaintiff has named the three (3) wholesale distributors (*i.e.*, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation) that dominate 85% of the market share for the distribution of prescription opioids. These “Big 3” are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Drug Corporation predecessors). The DEA has investigated and/or fined each for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct that resulted in the diversion of prescription opioids into Plaintiff’s Community, and that discovery likely will reveal others who likewise engaged in unlawful conduct. Plaintiff names each of the “Big 3” herein as defendants and places the industry on notice that the Plaintiff is acting to abate the public nuisance plaguing the community. Plaintiff will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

¹⁰ See Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit (“SARF”), FOI, Records Management Section (“SAR”), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is “kept confidential by the DEA”).

¹¹ See Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) (“Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.”).

III. JURISDICTION & VENUE

36. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* (“RICO”). This Court has supplemental jurisdiction over Plaintiff’s state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff’s federal claims that they form part of the same case or controversy.

37. This Court also has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a) because the Plaintiff is a “citizen” of this State, the named Defendants are citizens of different states and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

38. This Court has personal jurisdiction over Defendants because they conduct business in the State, they purposefully direct or directed their actions toward the State, some or all consented to be sued in the State by registering an agent for service of process, they consensually submitted to the jurisdiction of the State when obtaining a manufacturer or distributor license and they have the requisite minimum contacts with the State necessary to constitutionally permit the Court to exercise jurisdiction.

39. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle National Bank v.*

Arroyo Office Plaza, Ltd., 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

40. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965 because a substantial part of the events or omissions giving rise to the claims stated herein occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claims for relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. §1965(a).

IV. FACTUAL BACKGROUND

A. THE OPIOID EPIDEMIC.

1. The National Opioid Epidemic.

41. Increasing abuse and diversion of prescription drugs, including opioid medications, have characterized the past two decades in the United States.¹²

42. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.¹³

43. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention declared prescription painkiller overdoses to be at epidemic levels. The news release noted:

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

¹² See Richard C. Dart *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

¹³ Katherine M. Keyes, *et al.*, *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

- b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
- c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
- e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
- f. Almost 5,500 people start to misuse prescription painkillers every day.¹⁴

44. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.¹⁵

45. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed

¹⁴ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Prescription Painkiller Overdoses at Epidemic Levels* (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

¹⁵ See Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

roughly 64,000 people in the United States, an increase of more than twenty-two percent (22%) over the 52,404 drug deaths recorded the previous year.¹⁶

46. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.¹⁷

47. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.¹⁸

48. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in four (4) years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. ***Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use***, specifically among persons who report past-year dependence or abuse. The increased availability of heroin combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.¹⁹

¹⁶ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Provisional Counts of Drug Overdose Deaths*, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

¹⁷ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, <https://www.cdc.gov/vitalsigns/heroin/index.html> (last updated July 7, 2015).

¹⁸ See Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

¹⁹ See Rose A. Rudd *et al.*, *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

49. The societal costs of prescription drug abuse are “huge.”²⁰

50. Across the nation, local governments are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day, more than ninety (90) Americans lose their lives after overdosing on opioids.²¹

51. The National Institute on Drug Abuse identifies misuse and addiction to opioids as “a serious national crisis that affects public health as well as social and economic welfare.”²² The economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.²³

52. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.²⁴

53. The rate of death from opioid overdose has quadrupled during the past fifteen (15) years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six (6) in the past fifteen (15) years.²⁵

²⁰ See Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter, “Brief of HDMA”].

²¹ Opioid Crisis, NIH, National Institute on Drug Abuse (available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis>, last visited Sept. 19, 2017) (“Opioid Crisis, NIH”) (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, *MMWR MORB MORTAL WKLY REP.* 2016;65, doi:10.15585/mmwr.mm6505051e1).

²² Opioid Crisis, NIH.

²³ *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

²⁴ See Rose A. Rudd *et al.*, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 *Morbidity & Mortality Wkly. Rep.* 1445 (2016).

²⁵ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 *N. Eng. J. Med.* 1253 (2016).

54. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are “everywhere” and mistaken for candy.²⁶

55. In 2016, the President of the United States declared an opioid and heroin epidemic.²⁷

56. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.²⁸ Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience hundreds of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

57. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to cause the national, state, and local opioid epidemic.

2. Alabama’s Opioid Epidemic.

58. The national opioid crisis has especially ravaged Alabama.

59. Alabama has the ***highest opioid prescription rate in the nation***, at a rate of 142.9 prescriptions per 100 persons (U.S. median rate: 82.5). Alabama is second in the nation for

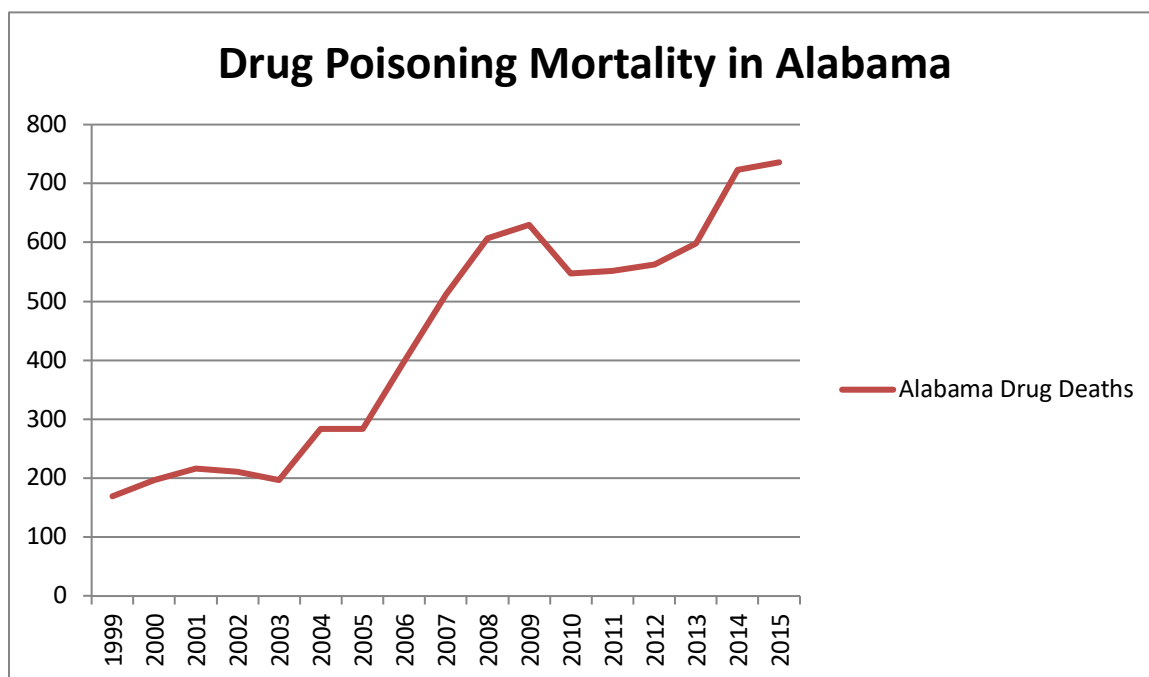
²⁶ Julie Turkewitz, *‘The Pills are Everywhere’: How the Opioid Crisis Claims Its Youngest Victims*, N.Y. Times, Sept. 20, 2017 (“‘It’s a cancer,’ said [grandmother of dead one-year old], of the nation’s opioid problem, ‘with tendrils that are going everywhere.’”).

²⁷ See Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming “Prescription Opioid and Heroin Epidemic Awareness Week”).

²⁸ See Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), <https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf>.

benzodiazepine prescriptions, at a rate of 61.9 per 100 persons (U.S. median rate: 37.6).²⁹ Over 6.5 million opioid prescriptions were filled in Alabama in 2015, supplying over 437 million pills, which equates to a total days' supply of 127,159,152 – or 348,381 years' worth.³⁰

60. Overdose mortalities in Alabama have increased sharply in recent years:³¹



61. From 2013 to 2014 alone, Alabama saw a twenty percent (20%) increase in overdose fatalities.³² In 2014, there were 723 Alabama overdose deaths, up from 598 Alabama overdose deaths in 2013.³³

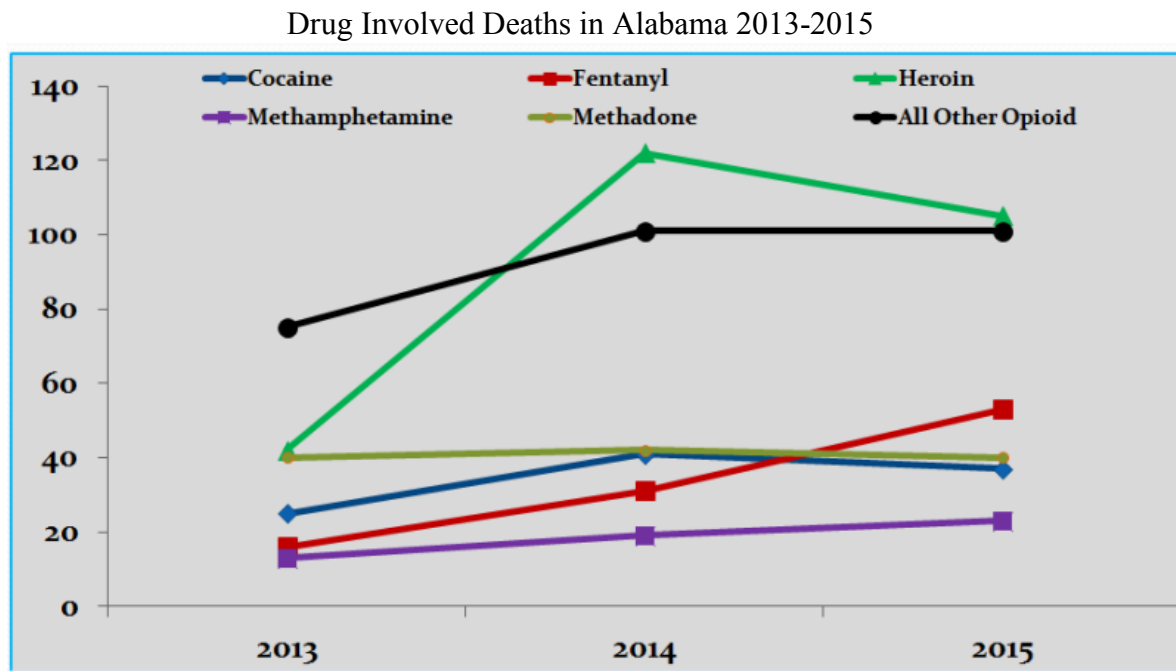
²⁹ See Leonard J. Paulozzi, M.D., *et al.*, *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (July 4, 2014). The combination of hydrocodone, oxycodone, and benzodiazepines is referred to as the “holy trinity” and significantly increases the risk of harm to those that abuse prescription pills.

³⁰ George C. Smith, Jr., M.D., *ALBME Efforts to Combat Opioid Overuse*, Alabama Board of Medical Examiners (March 10, 2017), http://www.alabamapublichealth.gov/pharmacy/assets/presentation_smith_2017.pdf, last visited October 11, 2017.

³¹ U.S. Centers for Disease Control and Prevention, National Center for Health Statistics’ Drug Poisoning Mortality dataset, accessible at: <https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/> (last visited October 11, 2017).

³² Centers for Disease Control and Prevention, Drug Overdose Death Data at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited October 11, 2017).

62. These deaths are overwhelmingly caused by opioids:³⁴



63. The percentage of Alabama children in foster care because of parental drug abuse has risen from 11.5% in 2006 to 37% in 2016.³⁵ Children with parents addicted to drugs tend to stay in foster care longer and often enter the system having experienced significant trauma, which makes their care more expensive.³⁶

64. Alabama and neighboring states have now become ground zero for an explosion of cases in newborns with Neonatal Abstinence Syndrome (“NAS”), a collection of symptoms

³³ *Id.*

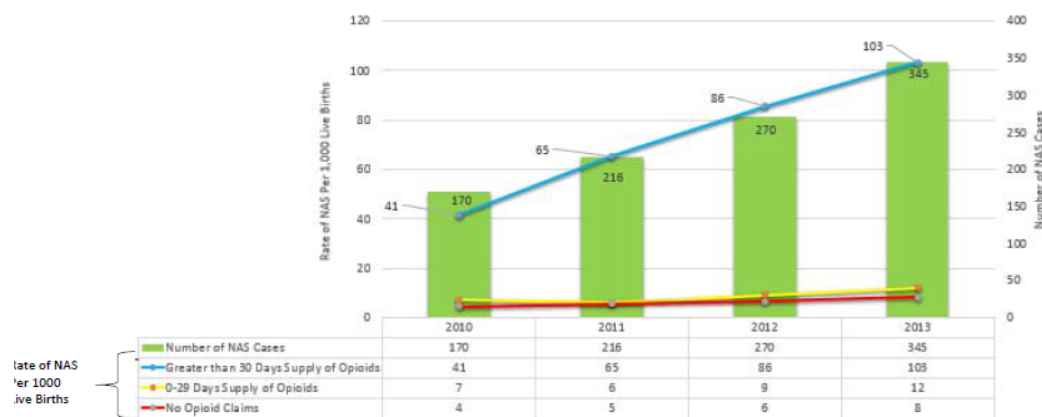
³⁴ X.J. Shen, Ph.D., Director, Division of Statistical Analysis, Alabama Department of Public Health, Center for Health Statistics, *Data-Driven Prevention Initiative (DDPI) for Heroin and Opioid Abuse/Overdose* (April 28, 2017). Available at http://www.alabamapublichealth.gov/pharmacy/assets/ddpi_opioidoverdose.pdf, last visited October 11, 2017.

³⁵ Mary Sell, *Parental drug use putting more children in foster care*, Decatur Daily, Montgomery Bureau, January 29, 2017, at http://www.decatordaily.com/news/local/parental-drug-use-putting-more-children-in-foster-care/article_957642a9-e3d5-52a3-b8d9-d881be352aab.html, last visited October 11, 2017, citing Alabama Department of Human Resources.

³⁶ Trista Thurston, *Drug addiction drives spike in Ohio foster care*, Newark Advocate (Mar. 23, 2017), available at <http://www.newarkadvocate.com/story/news/crime/high-in-ohio/2017/03/23/drug-addiction-drives-spike-ohio-foster-care/99545804/>, last visited July 12, 2017.

babies experience in withdrawing from opioid medications taken by the mother. “The region that includes Alabama, Mississippi, Tennessee and Kentucky has the highest rate in the country, with NAS occurring in 16.2 out of every 1,000 hospital births in 2012.”³⁷ Furthermore, ‘The number of cases of NAS covered by Medicaid in Alabama more than doubled from 170 cases in 2010 to 345 in 2013.’³⁸ NAS is closely associated with opioid use:³⁹

Association Between Opioid Use and Neonatal Abstinence Syndrome (NAS)



65. Alabama has the second-highest rate of nonmedical use of prescription pain relievers in the nation, covering one (1) out of every nineteen (19) Alabamians aged twelve (12)

³⁷ Amy Yurkanin, *A grim and growing trend: Alabama sees increased cases of drug-dependent newborns* (Sep. 29, 2015), available at http://www.al.com/news/index.ssf/2015/09/a_grim_and_growing_trend_alaba.html, last visited October 11, 2017.

³⁸ *Id.*

³⁹ Casey Wylie, Quality Analytics, Alabama Medicaid Agency, *Neonatal Abstinence Syndrome (NAS) Adverse Fetal Outcomes in Mothers with Prescribed Opioid Medications Compared to Mothers With No Prescribed Opioid Medications Data-Driven Prevention Initiative (DDPI) for Heroin and Opioid Abuse/Overdose* (December 10, 2014). Available at <http://www.alabamapublichealth.gov/perinatal/assets/NASPresentationforSCPH.pdf>, last visited October 11, 2017.

or older.⁴⁰ Alabama is also second in the nation for Blue Cross Blue Shield patients diagnosed with opioid use disorders.⁴¹

3. The Opioid Epidemic in Plaintiff's Community.

66. The opioid epidemic is particularly devastating in Plaintiff's Community.

67. Plaintiff's Community is experiencing an excessive drug overdose rate related to an excessive volume of prescription opiates proximately caused by the wrongful conduct by the Defendants described and named herein.

68. Excessive numbers of opioid prescriptions have been dispensed in the Plaintiff's Community.⁴² Drug poisoning deaths are significantly impacting Plaintiff's Community.⁴³ Significant numbers of the residents of Plaintiff's Community report drug dependence and non-medical use of pain relievers.⁴⁴ Many residents of Plaintiff's Community who need addiction treatment don't receive it.⁴⁵

69. The opioid epidemic has placed increased budgetary constraints upon *inter alia* the public health and medical care expenditures of Plaintiff's Community. Opioid addiction is one of the primary reasons citizens in Plaintiff's Community seek substance abuse treatment.

70. Criminal charges associated with the diversion of opioids have increased. This has placed increased budgetary costs upon law enforcement expenses in Plaintiff's Community.

⁴⁰ Rachel N. Lipari, Ph.D., *et al.*, *State and Substate Estimates of Nonmedical Use of Prescription Pain Relievers*, National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration, Jul. 13, 2017, at: https://www.samhsa.gov/data/sites/default/files/report_3187/ShortReport-3187.html, visited Oct. 11, 2017.

⁴¹ Amy Yurkanin, *Blue Cross report finds alarming trends in Alabama opioid prescriptions*, AL.com, Jul. 1, 2017, at: http://www.al.com/news/index.ssf/2017/07/blue_cross_report_finds_alarmi.html, visited Oct. 11, 2017.

⁴² U.S. Prescribing Rate Maps, Centers for Disease Control and Prevention (2017), <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Nov 13, 2017).

⁴³ U.S. Centers for Disease Control and Prevention, National Center for Health Statistics' Drug Poisoning Mortality dataset, <https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/> (last visited Nov 11, 2017).

⁴⁴ *See, e.g.*, Alabama Opioid Epidemic, amfAR, <http://opioid.amfar.org/AL>, at View Counties: Opioid Use (last visited Oct. 13, 2017).

⁴⁵ *Id.* at View Counties: Healthcare.

71. Opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community, and constitute a temporary and continuing public nuisance, which remains unabated.

**B. THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE,
AND UNFAIR MARKETING OF OPIOIDS.**

72. The opioid epidemic did not happen by accident.

73. Before the 1990s, generally accepted standards of medical practice dictated that patients only should use opioids short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time, the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

74. Each Manufacturer Defendant has conducted and has continued to conduct a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent and continues to spend millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

75. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that doctors should treat the signs of

addiction with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that it is easy to manage opioid dependence and withdrawal; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction. The Manufacturer Defendants also have falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants’ claims.

76. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups.

77. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009.⁴⁶ In an open letter to the nation’s physicians in August 2016, the then-U.S. Surgeon General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.”⁴⁷ This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply) and a population of patients physically and

⁴⁶ See Katherine Eban, *Oxycontin: Purdue Pharma’s Painful Medicine*, Fortune, Nov. 9, 2011, <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>; David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, Fin. Times, Aug. 10, 2016, <https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95>.

⁴⁷ Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), <http://turnthetiderx.org/>.

psychologically dependent on them (the demand). When those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

78. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids.

79. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around the State, including in Plaintiff's Community. The Manufacturer Defendants also deployed seemingly unbiased and independent third parties whom they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's Community.

80. The Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around the State, including in Plaintiff's Community, as they did nationwide. Across the pharmaceutical industry, corporate headquarters fund and oversee "core message" on a national basis. This comprehensive approach ensures that the Manufacturer Defendants accurately and consistently deliver their messages across marketing channels – including detailing visits, speaker events and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

81. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the

company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants required their sales representatives and physician speakers to stick to prescribed talking points, sales messages and slide decks, and supervisors rode along with them periodically to check on both their performance and compliance.

i. Direct Marketing.

82. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two (2) tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

83. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads called "Pain vignettes" for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

84. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Manufacturer Defendant devoted massive resources

to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of \$168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

85. The Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate, and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

86. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."⁴⁸

ii. Indirect Marketing.

87. The Manufacturer Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

⁴⁸ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.

88. The Manufacturer Defendants deceptively marketed opioids in the State and Plaintiff's Community through unbranded advertising – *e.g.*, advertising that promotes opioid use generally but does not name a specific opioid. Independent third parties ostensibly created and disseminated this advertising. However, by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages these third parties disseminated and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as the Manufacturer Defendants controlled the distribution of their “core messages” via their own detailers and speaker programs, they similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education (“CME”) programs, medical conferences, and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

89. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

90. The Manufacturer Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors

selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

91. Borrowing a page from Big Tobacco's playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors who served as KOLs, and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences, seminars, and scientific articles. Thus, working individually and collectively and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue and that the compassionate treatment of pain required opioids.

92. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions included contributing to the

creation of misleading publications and prescribing guidelines, which lack reliable scientific basis and promote prescribing practices that have worsened the opioid crisis.

93. Pro-opioid doctors are some of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website “In the Face of Pain” failed to disclose that Purdue paid doctors who provided testimonials on the site and concluded that Purdue’s failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

94. Defendants utilized many KOLs, including many of the same ones.

95. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees and honoraria from Cephalon, Endo, Janssen and Purdue (among others) and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) / American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by the Manufacturer Defendants.

96. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that “the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”⁴⁹

97. Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that fewer than one percent (1%) of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”⁵⁰ Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”⁵¹

98. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of American Academy of Pain Medicine (“AAPM”) in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising

⁴⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

⁵⁰ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

⁵¹ *Id.*

supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly \$2 million from Cephalon).

99. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the DEA closed the investigation without charges in 2014, more than twenty (20) of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

100. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on or are linked to websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

101. In 2011, Dr. Webster presented via webinar a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing and patient agreements as a way to

prevent “overuse of prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach doctors in the State and doctors treating members of Plaintiff’s Community.⁵²

102. Dr. Webster also was a leading proponent of the concept of “pseudoaddiction,” the notion that doctors should see addictive behaviors not as warnings, but as indications of undertreated pain. In Dr. Webster’s description, the only way to differentiate the two was to increase a patient’s dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.”⁵³ Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”⁵⁴

103. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these “Front Groups” generated treatment guidelines, unbranded materials and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence and conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

⁵² See Emerging Solutions in Pain, *Managing Patient’s Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

⁵³ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

⁵⁴ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>.

104. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

105. Defendants Cephalon, Endo, Janssen, and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”), and Pain & Policy Studies Group (“PPSG”).⁵⁵

106. The most prominent of the Manufacturer Defendants’ Front Groups was the American Pain Foundation (“APF”), which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia

⁵⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015), <https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>.

campaign – through radio, television, and the internet – to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of the State and Plaintiff’s Community.

107. In 2009 and 2010, more than eighty percent (80%) of APF’s operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of a total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

108. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescriptions and thus the profitability of its sponsors. Upon information and belief, the Manufacturer Defendants often called upon it to provide “patient representatives” for the promotional activities, including for Purdue’s Partners Against Pain and Janssen’s Let’s Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in nonprofit organizations that share [its] business interests.”

109. Upon information and belief, on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities, and publications for APF to pursue. APF then submitted grant proposals seeking to fund these

activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

110. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."⁵⁶

111. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

112. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet

⁵⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

113. Upon information and belief, Endo internally views AAPM as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – thirty-seven (37) out of roughly forty (40) at one conference alone. AAPM’s presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. The AAPM even elected Dr. Webster president while he was under a DEA investigation.

114. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

115. In 1996, AAPM and APS jointly issued a consensus statement, “The Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain and claimed that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011, and, upon information and belief, the AAPM only removed it from the website after a doctor complained.⁵⁷

116. AAPM and APS issued their own treatment guidelines in 2009 (“AAPM/APS Guidelines”) and continued to recommend the use of opioids to treat chronic pain.⁵⁸ Doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants,

⁵⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

⁵⁸ Roger Chou *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 *J. Pain* 113 (2009).

have relied upon treatment guidelines. Treatment guidelines not only directly inform doctors' prescribing practices but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis and Purdue discussed treatment guidelines with doctors during individual sales visits.

117. At least fourteen (14) of the twenty-one (21) panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.⁵⁹ One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the State and/or Plaintiff's Community during the relevant time period, are still available online and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants' financial support to members of the panel.

⁵⁹ *Id.*

118. The Manufacturer Defendants worked together through Front Groups to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF comprises representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

2. The Manufacturer Defendants’ Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

i. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

119. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC have conclusively debunked. These misrepresentations – described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted and because doctors could identify and manage those at greatest risk for addiction; (2) patients who displayed signs of addiction probably were not addicted, and, in any event, doctors could easily wean them from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both

prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations; they continue to make them today.

120. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use in the State and Plaintiff's Community and each continues to fail to correct its past misrepresentations.

121. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

- a. Actavis's predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.⁶⁰

⁶⁰ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”
- f. Janssen currently runs a website, Prescriberresponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claims that less than one percent (1%) of children

prescribed opioids will become addicted and that pain is undertreated due to “[m]isconceptions about opioid addiction.”⁶¹

- h. Consistent with the Manufacturer Defendants’ published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon in the State and Plaintiff’s Community minimized or omitted any discussion with doctors of the risk of addiction, misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations and routinely did not correct the misrepresentations noted above.
- i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NPF argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that “patients rarely become addicted to prescribed opioids,” citing research by their KOL, Dr. Portenoy.⁶²

122. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the “2016 CDC Guideline”) explains that there is “[e]xtensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .).”⁶³ The 2016 CDC Guideline further explains that “[o]pioid pain medication use presents serious risks, including overdose and opioid

⁶¹ Am. Pain Found., *A Policymaker’s Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker’s Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

⁶² Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

⁶³ Deborah Dowell *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”⁶⁴

123. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting (“ER/LA”) opioids in 2013 and for immediate release (“IR”) opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed.⁶⁵

124. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.”⁶⁶ Endo had claimed on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the

⁶⁴ *Id.* at 2, 25.

⁶⁵ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf>; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf>.

⁶⁶ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. Endo remains free, however, to make those statements in this State.

125. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented to doctors and patients that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (*i.e.*, pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

126. To this end, one of Purdue’s employees, Dr. David Haddox, invented a phenomenon called “pseudoaddiction.” KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids and hoarding are all signs of pseudoaddiction, rather than true addiction.⁶⁷ The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.⁶⁸
- b. Janssen sponsored, funded and edited the Let’s Talk Pain website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated Pseudoaddiction is different from true

⁶⁷ Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2007) at 62.

⁶⁸ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

addiction because such behaviors can be resolved with effective pain management.”

- c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,” which, upon information and belief, promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated.”
- e. Upon information and belief, Purdue sponsored a CME program titled “Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse.” In a roleplay, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long-acting opioid.

127. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already-addicted patients.

128. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
- b. Purdue, upon information and belief, sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

- c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that “bad apple” patients – and not opioids – are the source of the addiction crisis and that once those “bad apples” are identified, doctors can safely prescribe opioids without causing addiction.

129. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies “for improving outcomes related to overdose, addiction, abuse or misuse.”⁶⁹

130. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants’ false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that doctors can easily address opioid dependence by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion, and premature labor in pregnant women.⁷⁰

131. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by ten percent (10%) to twenty percent (20%) for ten (10) days. And Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually

⁶⁹ *Id.* at 11.

⁷⁰ *Id.* at 26.

decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.⁷¹

132. A fifth category of false, deceptive, and unfair statements the Manufacturer Defendants made to sell more drugs is that patients could increase opioid dosages indefinitely without added risk. The ability to escalate dosages was critical to Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants’ deceptive claims include:

- a. Upon information and belief, Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Based on Actavis’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have “no ceiling dose” and insinuated that they are therefore the most appropriate treatment for severe pain.⁷² This publication is still available online.

⁷¹ APF, *Policymaker’s Guide*, at 32.

⁷² APF, *Treatment Options*, at 12.

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that opioid dosages may be increased until “you are on the right dose of medication for your pain.”
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased. . . . You won’t ‘run out’ of pain relief.”⁷³
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its sales force distributed. This guide listed dosage limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. Upon information and belief, Purdue’s In the Face of Pain website promoted the notion that if a patient’s doctor does not prescribe what, in the patient’s view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which taught that dosage escalations are “sometimes necessary” and that “the need for higher doses of medication is not necessarily indicative of addiction,” but inaccurately downplayed the risks from high opioid dosages.⁷⁴

⁷³ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁷⁴ APF, *Policymaker’s Guide*, *supra*, at 32.

- h. In 2007, Purdue sponsored a CME entitled “Overview of Management Options” that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, “the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,” challenging the correlation between opioid dosage and overdose.⁷⁵
- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NPF argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁷⁶

133. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants’ representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the “[b]enefits of high-dose opioids for chronic pain are not established,” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.”⁷⁷ More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.”⁷⁸ The CDC also states that there is an increased risk “for opioid use disorder, respiratory depression, and death at higher

⁷⁵ The College on Problems of Drug Dependence, *About the College*, <http://cpdd.org> (last visited Aug. 21, 2017).

⁷⁶ Brief of APF, *supra*, at 9.

⁷⁷ 2016 CDC Guideline, *supra*, at 22–23.

⁷⁸ *Id.* at 23–24.

dosages.”⁷⁹ That is why the CDC advises doctors to “avoid increasing dosage” to above 90 morphine milligram equivalents per day.⁸⁰

134. Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse.

135. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo’s advertisements for the 2012 reformulation of Opana ER claimed Endo had designed it to be crush-resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets’ “extended-release features can be compromised, causing the medication to ‘dose dump,’ when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing.”⁸¹ Also troubling, Opana ER can be prepared for snorting using commonly available methods and “readily prepared for injection.”⁸² The letter discussed “the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection.”⁸³ Endo’s own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Endo remove Opana ER from the market.

ii. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly overstating the benefits of the opioid drugs.

⁷⁹ *Id.* at 21.

⁸⁰ *Id.* at 16.

⁸¹ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

⁸² *Id.* at 6.

⁸³ *Id.* at 6 n.21.

136. To convince doctors and patients that they should use opioids to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.⁸⁴ The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

137. Some illustrative examples of the Manufacturer Defendants’ false claims are:

- a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health” and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

⁸⁴ *Id.* at 15.

- d. Janssen promoted Ultracet for everyday chronic pain and distributed posters for display in doctors' offices of presumed patients in active professions. The caption read: "Pain doesn't fit into their schedules."
- e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.
- f. *Responsible Opioid Prescribing* (2007), which Cephalon, Endo, and Purdue sponsored and distributed, taught that relief of pain by opioids, by itself, improved patients' function.
- g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."⁸⁵ This publication is still available online.
- h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved

⁸⁵ APF, *Treatment Options*.

for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

- i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."⁸⁶ Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."
- j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."
- k. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health" and "[o]verall health-related quality of life for chronic pain."⁸⁷ The Policymaker's Guide was originally published in 2011.
- l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

⁸⁶ E.g., NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

⁸⁷ APF, *Policymaker's Guide*, *supra*, at 29.

138. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

139. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that “we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”⁸⁸ And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

140. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.⁸⁹ Purdue misleadingly promoted OxyContin as being unique among opioids in providing twelve (12) continuous hours of pain relief with one

⁸⁸ Letter from Thomas Abrams to Doug Boothe, *supra*, at 2.

⁸⁹ 2016 CDC Guideline, *supra*, at 12.

dose. In fact, OxyContin does not last for twelve (12) hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue’s own research shows that OxyContin wears off in under six (6) hours in one quarter of patients and in under ten (10) hours in more than half. This is because OxyContin tablets release approximately forty percent (40%) of their active medicine immediately, after which release tapers. This triggers a powerful initial response but provides little or no pain relief at the end of the dosing period, when the tablet releases less medicine. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial proportion” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of twelve (12) hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

141. Purdue’s competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to “real” twelve (12) hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full twelve (12) hours. Upon information and belief, Purdue’s sales representatives continue to tell doctors that OxyContin lasts a full twelve (12) hours.

142. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain

renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.⁹⁰

143. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain, even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for nor has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007, emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain or pain due to injury.⁹¹ Specifically, the FDA advised that Fentora “is only approved for breakthrough cancer pain in patients who are *opioid-tolerant*, meaning those patients who take a regular, daily, around-the-clock narcotic pain medication.”⁹²

144. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved and is not appropriate or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give

⁹⁰ Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

⁹¹ See U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

⁹² *Id.*

doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain.
- b. Upon information and belief, Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- c. In December 2011, Cephalon widely disseminated a journal supplement entitled “Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)” to Anesthesiology News, Clinical Oncology News and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just cancer pain.

145. Cephalon’s deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain but were also approved by the FDA for such uses.

146. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue’s sales representatives have

maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five (5) years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue’s district manager described it internally as “an organized drug ring” until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.⁹³

147. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

⁹³ Harriet Ryan *et al.*, *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

3. The Manufacturer Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

148. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including this State and Plaintiff's Community. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

149. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients, even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance and a smaller window between safe and unsafe dosages.⁹⁴ The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. *Id.* at 27. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

4. The Manufacturer Defendants Made Materially Deceptive Statements and Concealed Material Facts.

150. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course

⁹⁴ 2016 CDC Guideline, *supra*, at 13.

of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

151. Defendant Purdue made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain,

including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff, while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioids, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials, advertisements, and CMEs they knew would reach these same prescribers.

152. Defendant Endo made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations – including over \$5 million to the organization responsible for many of the most

egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

153. Defendant Janssen made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites, over which Janssen exercised final editorial control and approval, stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites, over which Janssen exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain,

including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

154. Defendant Cephalon made and/or disseminated untrue, false, and deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

155. Defendant Actavis made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

5. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.

156. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain, even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience, establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

157. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like

Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which the NIPC runs, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

158. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who

relied upon them in making treatment decisions, nor could the Plaintiff or Plaintiff's Community have detected it. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

**C. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL
DISTRIBUTION OF OPIOIDS.**

159. The Distributor Defendants owe a duty under both federal law and Alabama law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community, as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

160. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

161. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

162. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic, prescription opioid abuse, addiction, morbidity, and mortality in the State and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

163. The opioid epidemic in the State, including, *inter alia*, in Plaintiff's Community, remains an immediate ***hazard to public health and safety***.

164. The opioid epidemic in Plaintiff's Community is a temporary and continuous *public nuisance* and remains unabated.

165. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Wholesale Drug Distributors Have a Duty Under State and Federal Law to Guard Against and Report Unlawful Diversion and to Report and Prevent Suspicious Orders.

166. Opioids are a controlled substance, and Alabama law categorizes them as having a "high potential for abuse." *See* ALA. CODE §20-2-24(1)(a). These "Schedule II" drugs are controlled substances with a "high potential for abuse," 21 U.S.C.A. §§ 812(b), 812(2)(A)-(C).

167. Alabama law required each Defendant to first be registered with and permitted by the Alabama State Board of Pharmacy. ALA. CODE §§ 20-2-51 and 34-23-32; and ALA. ADMIN. CODE §§ 680-X-2-.25, 680-X-3-.01 and 680-X-3-.05.

168. Alabama's Pharmacy Board Regulations predicate such registration for both manufacturers and distributors upon, *inter alia*, "[m]aintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels" and "[p]ast experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion." ALA. CODE § 20-2-52(a)(1) and (4).

169. Alabama Pharmacy Board Regulations also require manufacturers and distributors of controlled substances doing business in Alabama to "submit to the Alabama State Board of Pharmacy legible copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies within 30 days." ALA. ADMIN. CODE § 680-X-3-.05. *See also* ALA. ADMIN. CODE §

680-X-2-.23e (requiring wholesale distributors to forward all “records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies. . . to the Board of Pharmacy.”) *See also* ALA. CODE §20-2-56 (“Persons registered to manufacture, distribute, or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and with any additional rules issued by the State Board of Medical Examiners, the State Board of Health, or the State Board of Pharmacy”); ALA. CODE § 20-2-71(a)(3) (“It is unlawful for any person: . . . To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice, or information required under this chapter”); and ALA. CODE § 20-2-72 (a)(4) (“It is unlawful for any person: . . . To furnish false or fraudulent material information in or omit any material information from any application, report, or other document required to be kept or filed under [the Alabama Uniform Controlled Substances Act] or any record required to be kept by [the Alabama Uniform Controlled Substances Act]; . . .”).

170. Furthermore, Alabama law incorporates federal requirements set out under the Controlled Substance Act and related controlled substance laws and regulations. *See* ALA. CODE § 20-2-52(d) (each manufacturer and distributor, was required to “compl[y] with the provisions of the federal law respecting registration”); ALA. ADMIN. CODE 680-X-2-.23(k) (“Wholesale drug distributors shall operate in compliance with applicable Federal, State and Municipal laws and regulations.”); and ALA. CODE § 20-2-56 (“Persons registered to manufacture, distribute, or dispense controlled substances under [Article 3 of the Alabama Uniform Controlled Substances Act] shall keep records and maintain inventories in conformance with the record keeping and

inventory requirements of federal law and with any additional rules issued by the State Board of Medical Examiners, the State Board of Health, or the State Board of Pharmacy.”).

171. The federal Controlled Substance Act further required each Distributor Defendant to register with the DEA. *See* 21 U.S.C. § 823(b), (e) and 28 C.F.R. § 0.100. Each Distributor Defendant is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Alabama law adopts and incorporates those requirements, as set out above. *See, e.g.*, ALA. CODE § 20-2-52(d).

172. Each Distributor Defendant has an affirmative duty under federal and Alabama law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. § 823(b)(1). Alabama law adopts and incorporates those requirements, as set out above.

173. The Alabama Legislature has found that “the diversion, abuse, and misuse of prescription medications classified as controlled substances under the Alabama Uniform Controlled Substances Act constitutes a serious threat to the health and welfare of the citizens of the State of Alabama.” ALA. CODE § 20-2-210. *See also* ALA. ADMIN. CODE 680-X-2-.23(k) (“It shall be a violation of these rules for a wholesale drug distributor to . . . operate in such a manner as to endanger the public health.”). The Legislature has further termed this diversion constitutes a “drug crisis in the State of Alabama which is plaguing our neighborhoods.” ALA. CODE § 6-5-155.

174. Federal regulations, incorporated by Alabama law, impose a non-delegable duty upon wholesale drug distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

175. “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR § 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the distributor should report the order as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

176. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders that were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement*

Administration, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, distributors must report all flagged orders. *Id.*

177. The law regulates these prescription drugs for the purpose of providing a “closed” system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.⁹⁵

178. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant’s role and responsibilities.⁹⁶

179. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”⁹⁷

⁹⁵ See 1970 U.S.C.C.A.N. 4566, 4571-72.

⁹⁶ Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf’t Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. See generally HDA, *About*, <https://www.healthcaredistribution.org/about> (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. See generally NACDS, *Mission*, <https://www.nacds.org/about/mission/> (last visited Aug. 21, 2017).

⁹⁷ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter “Rannazzisi Letter”] (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors

180. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.⁹⁸

181. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, *in addition* to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”⁹⁹ The letter also instructs that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”¹⁰⁰ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”¹⁰¹

182. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.¹⁰² This letter reminds the Defendants of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”¹⁰³ The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly

in view of the prescription drug abuse problem our nation currently faces.”), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

⁹⁸ See Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4 (“[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”).

⁹⁹ Rannazzisi Letter, *supra*, at 2.

¹⁰⁰ *Id.* at 1.

¹⁰¹ *Id.* at 2.

¹⁰² See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

¹⁰³ *Id.*

report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824,

and may result in the revocation of the registrant's DEA Certificate of Registration.¹⁰⁴

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”¹⁰⁵

183. The Distributor Defendants admit that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”¹⁰⁶

184. The Distributor Defendants knew they were required to monitor, detect and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or the distributor otherwise characterizes it as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ See Brief of HDMA, *supra*, 2012 WL 1637016, at *2.

exceeded a threshold or as to which the order was otherwise characterized as an order of interest.¹⁰⁷

185. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

186. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

187. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

188. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

189. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

190. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

191. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity, and mortality in Plaintiff's Community and the damages caused thereby.

2. The Distributor Defendants Breached Their Duties.

192. Because distributors handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective

¹⁰⁷ Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.¹⁰⁸

193. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's Community is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.¹⁰⁹

194. The Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community or that the Distributor Defendants knew were likely to be diverted to Plaintiff's Community to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

195. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

196. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates originating from Plaintiff's Community and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

¹⁰⁸ See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

¹⁰⁹ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

197. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific and industrial channels.

198. The Distributor Defendants breached their duty to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

199. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.¹¹⁰

200. The federal and state laws at issue here are public safety laws.

201. The Distributor Defendants’ violations of public safety statutes constitute prima facie evidence of negligence under State law.

202. The Distributor Defendants supplied prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

203. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal and state law, which require Distributor Defendants to legally acquire and maintain a license to distribute prescription opiates.

¹¹⁰ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

204. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

205. The Distributor Defendants' repeated shipments of suspicious orders over an extended period of time, in violation of public safety statutes and without reporting the suspicious orders to the relevant authorities demonstrate wanton, willful or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

3. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties.

206. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

207. The Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association the Distributor Defendants run, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."¹¹¹

¹¹¹ Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4–5.

- b. The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”¹¹²
- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”¹¹³
- d. The Association complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”¹¹⁴
- e. The Associations alleged (inaccurately) that “DEA’s regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”¹¹⁵
- f. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical

¹¹² *Id.* at *8 (citations and quotation marks omitted).

¹¹³ *Id.* at *14.

¹¹⁴ *Id.* at *22.

¹¹⁵ *Id.* at *24–25.

expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”¹¹⁶

208. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.¹¹⁷

209. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical’s license and determined that DEA regulations require that, in addition to reporting suspicious orders, distributors must “decline to ship the order, or conduct some ‘due diligence’ and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order.” *Id.* at 212. Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor’s investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above) that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

210. Wholesale Distributor McKesson recently has been forced to specifically admit to breaches of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement (“2017 Agreement”) between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January

¹¹⁶ *Id.* at 26.

¹¹⁷ See Brief of HDMA, *supra*, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry “does not know the rules of the road because” they claim (inaccurately) that the “DEA has not adequately explained them”).

1, 2009 through the effective date of the Agreement (January 17, 2017), it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”¹¹⁸ Further, the 2017 Agreement specifically finds that McKesson “distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).”¹¹⁹ McKesson admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers,” including the McKesson Distribution Center located in “Washington Courthouse, Ohio.”¹²⁰ Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility (among other facilities) would be partially suspended.¹²¹

211. The 2017 Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.¹²² In the 2008 Settlement Agreement, McKesson “recognized that it had a duty to monitor its sales of all

¹¹⁸ See Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and the McKesson Corp. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

¹¹⁹ *Id.* at 4.

¹²⁰ *Id.*

¹²¹ *Id.* at 6.

¹²² *Id.* at 4.

controlled substances and report suspicious orders to DEA,” but had failed to do so.¹²³ The 2017 Agreement documents that McKesson continued to breach its admitted duties by “fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson’s obligations.”¹²⁴ As a result of these violations, McKesson was fined and required to pay to the United States \$150,000,000.¹²⁵

212. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

213. Because of the Distributor Defendants’ refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.¹²⁶ The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final

¹²³ *Id.*

¹²⁴ *Id.*; see also Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] (“McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.”), <https://www.justice.gov/opa/press-release/file/928471/download>.

¹²⁵ See 2017 Settlement Agreement and Release, *supra*, at 6.

¹²⁶ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, *The Drug Enforcement Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.¹²⁷ These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution

¹²⁷ *Id.*

Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;

- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA, which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;”
- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”); Valencia, California (“Valencia Facility”); and Denver, Colorado (“Denver Facility”);
- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against the Lakeland Facility; and

- j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.

214. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act,” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before the DEA can issue a suspension order.¹²⁸

215. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying

¹²⁸ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

216. For example, a Cardinal Health executive claimed that it uses “advanced analytics” to monitor its supply chain and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”¹²⁹ Given the sales volumes and the company’s history of violations, this executive was either not telling the truth or, if Cardinal Health had such a system, it ignored the results.

217. Similarly, Defendant McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”¹³⁰ Again, given McKesson’s historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

218. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of Distributor Defendants’ industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

219. Meanwhile, the opioid epidemic rages unabated in the Nation, the State, and Plaintiff’s Community.

¹²⁹ Lenny Bernstein, *et al.*, *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

¹³⁰ Scott Higham, *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

220. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers, and when the DEA suspends one facility, they simply ship from another facility.

221. Plaintiff's racketeering allegations below allege in greater detail the wrongful actions and omissions of the Distributor Defendants, which have caused the diversion of opioids and have been a substantial contributing factor to and/or proximate cause of the opioid crisis.

222. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement and abused the privilege of distributing controlled substances in the State and Plaintiff's Community.

**D. THE MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE
TO PREVENT DIVERSION AND MONITOR, REPORT AND
PREVENT SUSPICIOUS ORDERS.**

223. The same legal duties to prevent diversion and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal and Alabama law.

224. Under Alabama and federal law, the Manufacturer Defendants were required to comply with substantially the same licensing and permitting requirements as the Distributor Defendants and the same rules regarding prevention of diversion and reporting suspicious orders, as set out above.

225. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes...

21 U.S.C. § 823(a)(1).

226. Additionally, as “registrants” under Section 823, the Manufacturer Defendants also were required to monitor, report and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).”) Like the Distributor Defendants, the Manufacturer Defendants breached these duties.

227. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer

Defendants knew – just as the Distributor Defendants knew – the volume, frequency and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

228. Federal statutes and regulations – and Alabama law incorporating those requirements – are clear: just like opioid distributors, the law requires opioid manufacturers to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.” 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1).

229. The Department of Justice recently has confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.¹³¹

230. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt “did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands[.]”¹³²

¹³¹ See Press Release, U.S. Dep’t of Justice, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

¹³² *Id.*

231. The settlement resolved, *inter alia*, government's allegations that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."¹³³

232. The Memorandum of Agreement Mallinckrodt entered into ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."¹³⁴

233. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

- i. conduct adequate due diligence of its customers;
- ii. detect and report to the DEA orders of unusual size and frequency;
- iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

¹³³ *Id.*

¹³⁴ Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download>. ("2017 Mallinckrodt MOA").

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
- iv. use “chargeback” information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
- v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.¹³⁵

234. Mallinckrodt agreed that its “system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and would “design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”¹³⁶

235. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers

¹³⁵ 2017 Mallinckrodt MOA at p. 2-3.

¹³⁶ *Id.* at 3-4.

(distributors). The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”¹³⁷

236. The same duties federal law imposed on Mallinckrodt were imposed upon all Manufacturer Defendants.

237. The same business practices Mallinckrodt utilized regarding “charge backs” and receipt and review of data from opioid distributors as to orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

238. Through, *inter alia*, the chargeback data, the Manufacturer Defendants could monitor suspicious orders of opioids.

239. The Manufacturer Defendants failed to monitor, report and halt suspicious orders of opioids as required by federal law.

240. The Manufacturer Defendants’ failures to monitor, report and halt suspicious orders of opioids were intentional and unlawful.

241. The Manufacturer Defendants have misrepresented their compliance with federal law.

242. The Manufacturer Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity and disseminated massive quantities of prescription opioids into the black market.

¹³⁷ *Id.* at p.5.

243. Plaintiff's racketeering allegations below allege in greater detail the wrongful actions and omissions of the Manufacturer Defendants, which have caused the diversion of opioids and have been a substantial contributing factor to and/or proximate cause of the opioid crisis.

244. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff's Community.

**E. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF
LEGAL DUTIES CAUSED THE HARM ALLEGED HEREIN AND
SUBSTANTIAL DAMAGES.**

245. As the Manufacturer Defendants' efforts to expand the market for opioids have increased, so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the State and the Plaintiff's Community. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like the Plaintiff's Community, fueling the epidemic.

246. There is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”¹³⁸

247. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.¹³⁹

248. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”¹⁴⁰

¹³⁸ See Dart, *et al.*, *supra*.

¹³⁹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

249. The increased abuse of prescription painkillers, along with growing sales, has contributed to a large number of overdoses and deaths.¹⁴¹

250. As shown above, the opioid epidemic has escalated in Plaintiff's Community with devastating effects: substantial opiate-related substance abuse, hospitalization, and death that mirrors Defendants' increased distribution of opiates.

251. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Plaintiff's Community and areas from which such opioids are being diverted into Plaintiff's Community has resulted in the Defendant-caused opioid epidemic including heroin addiction, abuse and death.

252. Prescription opioid abuse, addiction, morbidity and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

253. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

254. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of and/or substantial factors leading to the widespread diversion of prescription opioids for nonmedical purposes into the Plaintiff's Community.

255. The unlawful diversion of prescription opioids is a direct and proximate cause of and/or substantial factor leading to the opioid epidemic, prescription opioid abuse, addiction, morbidity, and mortality in the State and Plaintiff's Community. This diversion and the epidemic are direct causes of foreseeable harms the Plaintiff and Plaintiff's Community have incurred.

¹⁴⁰ See Califf *et al.*, *supra* .

¹⁴¹ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra*.

256. Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing economic damages for which Plaintiff seeks relief, as alleged herein. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

257. Plaintiff seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

258. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

259. To eliminate the hazard to public health and safety and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."¹⁴²

260. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying opioid-addicted individuals early and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.¹⁴³

261. These community-based problems require community-based solutions that "budgetary constraints at the state and Federal levels" have limited.¹⁴⁴

262. Having profited enormously through the aggressive sale, misleading promotion and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff's Community.

¹⁴² See Rudd *et al.*, *supra*, at 1145.

¹⁴³ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander *et al.* eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

¹⁴⁴ See Office of Nat'l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

F. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES.

1. Continuing Conduct.

263. Plaintiff contends it continues to suffer harm from Defendants' unlawful actions.

264. Defendants' continued tortious and unlawful conduct causes a repeated or continuous injury. The damages have not occurred all at once, but have continued to occur and increase as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. Defendants' wrongdoing and unlawful activity have not ceased. The public nuisance remains unabated.

2. Equitable Estoppel.

265. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and continuing to generate profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff and Plaintiff's Community, that they are working to curb the opioid epidemic.

266. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."¹⁴⁵

¹⁴⁵ Bernstein *et al.*, *supra*.

267. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”¹⁴⁶

268. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:¹⁴⁷

a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”

b. “DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”

c. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.”

d. “A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy.”

e. “Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash.”

Through the above statements made on their behalf by their trade associations and other similar statements assuring their continued compliance with their legal obligations, the

¹⁴⁶ Higham *et al.*, *supra*.

¹⁴⁷ Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *3-4, *25.

Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

269. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities.

270. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented “pseudoaddiction” and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks and promoting sales. The Manufacturer Defendants’ campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff’s Community deceived the medical community, consumers, the State and Plaintiff’s Community.

271. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff’s Community. Plaintiff and Plaintiff’s Community did not know and did not have the means to know the truth, due to Defendants’ actions and omissions.

272. The Plaintiff and Plaintiff’s Community reasonably relied on Defendants’ affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

3. Fraudulent Concealment.

273. The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants' knowing and fraudulent concealment of the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, had material information pertinent to their discovery, and concealed them from the Plaintiff and Plaintiff's Community. The Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its causes of action, as a result of Defendants' conduct.

274. The purposes of the statutes of limitations periods are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

275. In light of their statements to the media, in legal filings and in settlements, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

276. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, the Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

V. LEGAL CAUSES OF ACTION

COUNT I PUBLIC NUISANCE (Against All Defendants)

277. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

278. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of and/or a substantial factor leading to Plaintiff's injury. *See* Restatement Second, Torts § 821B.

279. Under Alabama Law, a nuisance "is anything that works hurt, inconvenience, or damage to another." ALA. CODE § 6-5-120. "A public nuisance is one which damages all persons who come within the sphere of its operation, though it may vary in its effects on individuals." ALA. CODE § 6-5-121.

280. Alabama law further declares "[t]he conducting of a business, trade, industry or occupation . . . in such a manner as to make it a menace, or likely to become a menace, to public health" constitutes a "public nuisance per se." ALA. CODE § 22-10-1.

281. Defendants have created a public nuisance under Alabama law.

282. Plaintiff has standing to bring claims for nuisance due to the opioid epidemic affecting and causing harm in Plaintiff's Community.

283. Plaintiff also specifically has standing to pursue an action against Defendants for public nuisance under Alabama law. *See e.g.,* ALA. CODE § 6-5-122 (1975) ("[a]ll municipalities in the State of Alabama may commence an action in the name of the city to abate or enjoin any public nuisance injurious to the health, morals, comfort, or welfare of the community or any portion thereof.").

284. By causing dangerously addictive drugs to flood the community and be diverted for illicit purposes, in contravention of federal and State law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the people of the Plaintiff's Community to public health, public safety, public peace, public comfort, and

public convenience. The public nuisance caused by the diversion of dangerous drugs has caused substantial annoyance, inconvenience and injury to the public.

285. By selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific, or industrial purpose, Defendants have committed a course of conduct that injuriously affects the safety, health, and morals of the people of the Plaintiff's Community.

286. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes, Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the people of the Plaintiff's Community.

287. Plaintiff alleges that Defendants' wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public.

288. The Defendants have intentionally and/or unlawfully created an absolute nuisance.

289. The residents of Plaintiff's Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare, and safety and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

290. Defendants intentionally, unlawfully and recklessly manufacture, market, distribute, and sell prescription opioids that Defendants know or reasonably should know will be diverted, causing widespread distribution of prescription opioids in and/or to Plaintiff's Community, resulting in addiction and abuse; an elevated level of crime, death and injuries to the residents of Plaintiff's Community; a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community; and direct costs to Plaintiff's Community.

291. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the Plaintiff's Community and its residents.

292. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct is illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

293. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort, convenience and ability to be free from disturbance and reasonable apprehension of danger to person or property.

294. Defendants' conduct in illegally distributing and selling prescription opioids or causing such opioids to be distributed and sold where Defendants know or reasonably should know such opioids will be diverted, possessed, and/or used illegally in Plaintiff's Community is of a continuing nature.

295. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

296. A violation of any rule or law controlling the distribution of a drug of abuse in Plaintiff's Community and the State is a public nuisance.

297. Statute and regulation proscribe Defendants' distribution of opioids while failing to maintain effective controls against diversion.

298. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiff's Community will be diverted, leading to abuse, addiction, crime, and public health costs.

299. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety, and welfare and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

300. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety, and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

301. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety, and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

302. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Plaintiff's Community. Defendants are in the business of manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which Defendants specifically know to be dangerous under federal law. *See e.g.*, 21 U.S.C. § 812 (b)(2).

303. Defendants' conduct in marketing, distributing, and selling prescription opioids which the Defendants know, or reasonably should know, likely will be diverted for non-legitimate, non-medical use creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents in Plaintiff's Community and otherwise significantly and unreasonably interfere with public health, safety, and welfare and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

304. It is, or should be, reasonably foreseeable to Defendants that their conduct will cause deaths and injuries to residents in Plaintiff's Community and will otherwise significantly and unreasonably interfere with public health, safety, and welfare and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

305. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Plaintiff's Community not only causes deaths and injuries, but also creates a palpable climate of fear among residents in Plaintiff's Community where opioid diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

306. Defendants' conduct makes it easier for persons to divert prescription opioids, constituting a dangerous threat to the public.

307. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, but for Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse and addiction that now exists would have been averted.

308. The presence of diverted prescription opioids in Plaintiff's Community and the consequence of prescription opioids having been diverted in Plaintiff's Community proximately results in and/or substantially contributes to the creation of significant costs to the Plaintiff and to Plaintiff's Community in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

309. Stemming the flow of illegally distributed prescription opioids and abating the nuisance caused by the illegal flow of opioids will help to alleviate this problem, save lives, prevent injuries, and make Plaintiff's Community a safer place to live.

310. Defendants' conduct is a direct and proximate cause of and/or a substantial contributing factor to opioid addiction and abuse in Plaintiff's Community and costs borne by Plaintiff's Community and the Plaintiff, as well as a significant and unreasonable interference with public health, safety, and welfare and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

311. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety, and welfare of the residents of Plaintiff's Community, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

312. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Plaintiff's Community; however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids or caused such orders to be shipped. Defendants

intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

313. Defendants knew prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting and refusing shipment of suspicious orders, that the opioids would be diverted and create an opioid abuse nuisance in Plaintiff's Community.

314. Defendants' actions also created a qualified nuisance. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

315. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

316. The damages available to the Plaintiff include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance that the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

317. As a direct result of Defendants' conduct, the Plaintiff and Plaintiff's Community have suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, and other services. The Plaintiff here seeks recovery for its own harm.

318. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because their damages include, *inter alia*, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

319. The Plaintiff further seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

320. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages and punitive damages from the Defendants for the creation of a public nuisance, attorneys' fees and costs, and pre- and post-judgment interest.

321. Defendants' intentional and unlawful actions and omissions, as well as their unreasonable interference with a right common to the public are of a continuing nature.

322. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the Plaintiff's Community. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because, *inter alia*, federal and state law define these drugs as substances posing a high potential for abuse and severe addiction. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

323. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties and the

Manufacturer Defendants' fraudulent marketing activities have caused harm to the entire community that includes, but is not limited to, the following:

- a. The high rates of use have led and continue to lead to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.
- b. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- c. Even those residents of Plaintiff's Community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids and the loss of companionship, wages or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.
- d. The opioid epidemic has increased health care costs.
- e. Employers have lost the value of productive and healthy employees.
- f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse and injury.
- g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell and the ensuing demand of addicts to buy them. More prescription opioids sold by

Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

- h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.
- i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the Plaintiff's Community.
- j. Defendants' interference with the comfortable enjoyment of life in the Plaintiff's Community is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm Defendants' actions inflicted.

324. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because their damages include, *inter alia*, health services and law enforcement expenditures, as described in this Complaint.

325. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations.

326. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory, and punitive damages, all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT II
DRUG-RELATED NUISANCE
ALABAMA CODE § 6-5-155, *et seq.*
(Against All Defendants)

327. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

328. Alabama law defines a “Drug-Related Nuisance” as “[t]he use, sale, distribution, possession, storage, transportation, or manufacture of any controlled substances in violation of the controlled substance acts, or similar act of the United States or any other state.” ALA. CODE § 6-5-155.1.

329. For purposes of the Drug-Related Nuisance statute, “controlled substance acts” are defined as “[t]he provisions of Sections 20-2-1 *et seq.*, known as the “Alabama Uniform Controlled Substance Act,” and Sections 13A-12-201 *et seq.*, known as “The Drug Predator Control Act of 1987,” and Sections 13A-12-210 *et seq.*, known as “The Drug Crimes Amendments Act of 1987.” ALA. CODE § 6-5-155.1.

330. The Alabama Uniform Controlled Substance Act, the U.S. Controlled Substances Act and regulations promulgated by the Alabama State Board of Pharmacy proscribe Defendants’ manufacture and distribution of opioids while failing to maintain effective controls against diversion. *See, e.g.*, 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(a)(1), (b)(1); ALA. CODE §§ 20-2-56 and 57; ALA. ADMIN. CODE § 680-X-3-.05. This manufacture and distribution in violation of the controlled substance acts or similar act of the United States constitutes a Drug-Related Nuisance.

331. “Wherever there is reason to believe that a drug-related nuisance exists, ... the attorney for the county or municipality, ... may file an action . . . to abate, enjoin, and prevent

the drug-related nuisance.” ALA. CODE § 6-5-155.2. Any person residing in the county where the nuisance exists may also bring such action. *Id.*

332. Defendants’ ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiff’s Community will be diverted, leading to abuse, addiction, crime, and public health and safety costs.

333. As a result of the Drug-Related Nuisance caused by Defendants, the Plaintiff has suffered numerous adverse impacts, including, *inter alia*, an increase in the number of ambulance and police calls related to the use of opioids and/or to violence stemming from drug-related activity. In addition, the staggering rates of prescription opioid abuse and heroin use resulting from Defendants’ abdication of their gate-keeping duties have caused harm to the entire community, as set out in previous allegations, which are incorporated herein.

334. The notice provisions of ALA. CODE § 6-5-155.3 are inapplicable here, as the Drug-Related Nuisance is not confined to any single property, but rather, the Drug-Related Nuisance is situated throughout the Plaintiff’s Community. Thus, the Plaintiff is in the position of notifying themselves of the nuisance, the existence of which the Plaintiff is keenly aware.

335. Plaintiff requests, pursuant to ALA. CODE § 6-5-155.7, that the Court order the maximum per day civil penalty for each day the nuisance exists.

336. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants’ fraudulent activity and fraudulent misrepresentations.

337. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages, and punitive damages, from the Defendants for the creation

of a drug-related nuisance, attorneys' fees and costs, and pre- and post-judgment interest, as well as any and all civil remedies specifically enumerated in ALA. CODE § 6-5-156.3.

COUNT III
RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1961, *et seq.*
(Against All Defendants)

338. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

339. Plaintiff brings this Count against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

340. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

341. Section 1962(c) of Racketeer-Influenced and Corrupt Organizations Act ("RICO") makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United States v. Turkette*, 452 U.S. 576, 580 (1981).

342. The term "enterprise" includes "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556

U.S. 938, 944 (2009). The definition of “enterprise” in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section “describes two separate categories of associations that come within the purview of an ‘enterprise’ -- the first encompassing organizations such as corporations, partnerships, and other ‘legal entities,’ and the second covering ‘any union or group of individuals associated in fact although not a legal entity.’” *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id.*

343. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As “registrants,” the RICO Defendants operated and continue to operate within the “closed system” created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the “CSA”). The CSA restricts the RICO Defendants’ ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

344. Congress specifically intended the closed system created by the CSA, including the establishment of quotas, to reduce or eliminate the diversion of Schedule II substances like

opioids from “legitimate channels of trade” to the illicit market by controlling “the quantities of the basic ingredients needed for the manufacture of [controlled substances].”¹⁴⁸

345. Finding it impossible to legally achieve their ever-increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.¹⁴⁹ As discussed in detail below, through the RICO Defendants’ scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers, which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.¹⁵⁰ In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market, which allowed them to generate obscene profits.

346. An association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants hatched Defendants’ illegal scheme, and each of them executed it in perfect harmony. In particular, each of the RICO Defendants were associated with and conducted or participated in the affairs of the RICO enterprise (defined below and referred to collectively as the “Opioid Diversion Enterprise”), the purpose of which was to engage in the unlawful sales of opioids, while deceiving the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants’ scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain

¹⁴⁸ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

¹⁴⁹ 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

¹⁵⁰ 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

high production quotas with the purpose of ensuring unlawfully increasing revenues, profits and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like the Plaintiff experienced multi-millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c), and 18 U.S.C. § 1964(c) entitles Plaintiff to treble damages for its injuries.

347. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")¹⁵¹ is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

348. On information and belief, each of the RICO Defendants is a member, participant and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

349. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. Additionally, the HDA serves the interests of distributors and manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and

¹⁵¹ Health Distribution Alliance, History, Health Distribution Alliance, (last visited on September 15, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

350. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

A. THE OPIOID DIVERSION ENTERPRISE

351. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.¹⁵² The CSA and its implementing regulations created a closed system of distribution for all controlled substances and listed chemicals.¹⁵³ Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.¹⁵⁴ As reflected in comments from United States Senators during deliberation on the CSA, the “[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls.”¹⁵⁵ Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the “widespread diversion of [controlled substances] out of legitimate

¹⁵² Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

¹⁵³ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

¹⁵⁴ *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20); 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

¹⁵⁵ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).

channels into the illegal market.”¹⁵⁶ Moreover, Congress specifically designed the closed system to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.¹⁵⁷ All registrants – manufacturers and distributors alike – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.¹⁵⁸ When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.¹⁵⁹ The result is the scourge of addiction that has occurred.

352. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and inform the DEA of any suspicious orders.¹⁶⁰ The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to “know their customers.”¹⁶¹

353. Central to the closed system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled

¹⁵⁶ See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

¹⁵⁷ See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at <https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf>).

¹⁵⁸ *Id.*

¹⁵⁹ Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

¹⁶⁰ Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).

¹⁶¹ Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf).

substances] and requiring order forms for all transfers of these drugs.”¹⁶² When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of disposal of the basic class;
- d. An applicant’s production cycle and current inventory position;
- e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.¹⁶³

354. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA or (2) in excess of a quota assigned to it by the DEA.¹⁶⁴

355. At all relevant times, the RICO Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market in order to unlawfully increase the

¹⁶² 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

¹⁶³ *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

¹⁶⁴ *Id.* (citing 21 U.S.C. 842(b)).

quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

356. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.¹⁶⁵ On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.¹⁶⁶

357. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. However, it was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

358. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) was characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.

¹⁶⁵ Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. *Am J Public Health*. 2014;104(2):e52-9.

¹⁶⁶ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>.

Turkette, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and requests that the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

359. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations¹⁶⁷ The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. Plaintiff is informed and believes that the Pain Care Forum and its members and the HDA devoted millions dollars to its lobbying efforts in this jurisdiction between 2011 and 2016.

¹⁶⁷ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

360. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids and the identification, investigation and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. However, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate, and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

361. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across state lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the country and this jurisdiction and the corresponding payment and/or receipt of money from the sale of the same.

362. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

363. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in and are members of the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

364. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum and the HDA and through their contractual relationships.

365. The Pain Care Forum (“PCF”) is a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when reporters discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

366. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”¹⁶⁸ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.¹⁶⁹

¹⁶⁸ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

¹⁶⁹ *Id.*

367. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.¹⁷⁰ In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis (*i.e.*, Allergan) and Teva (the parent company of Cephalon).¹⁷¹ Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. However, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.¹⁷² Upon information and belief, the Distributor Defendants participated directly in the PCF as well.

368. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. Additionally, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

369. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies, sole purpose of which was to shape

¹⁷⁰ PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>.

¹⁷¹ *Id.* Upon information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.

¹⁷² *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/executive-committee>.

the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

370. Second, the HDA – or Healthcare Distribution Alliance – led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt, and Cephalon, were members of the HDA.¹⁷³ Additionally, the HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

371. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners” and “make connections.”¹⁷⁴ Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

¹⁷³ Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/membership/manufacturer>.

¹⁷⁴ Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en>.

372. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants.¹⁷⁵ A “senior company executive” must sign the manufacturer membership application, and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year-end net sales through any HDA distributors, including, but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.¹⁷⁶

373. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”¹⁷⁷
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributors and manufacturer members.¹⁷⁸

¹⁷⁵ Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en>.

¹⁷⁶ *Id.*

¹⁷⁷ Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/councils-and-committees>.

¹⁷⁸ *Id.*

- c. Health, Beauty and Wellness Committee: “This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain.” Participation in this committee includes distributor and manufacturer members.¹⁷⁹
- d. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributors and manufacturer members.¹⁸⁰
- e. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.¹⁸¹
- f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁸²

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

- g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁸³
- h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁸⁴
- i. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation includes Distributor and Manufacturer Members.¹⁸⁵

374. The councils, committees, task forces, and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise’s organization.

375. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”¹⁸⁶ The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers>.

healthcare distribution industry.”¹⁸⁷ The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.¹⁸⁸

376. Third, the RICO Defendants maintained their interpersonal relationships by working together, exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

377. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.¹⁸⁹ As reported in the Washington Post, identified by Senator McCaskill and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.¹⁹⁰ On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship

¹⁸⁷ *Id.*

¹⁸⁸ 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/events/2015-distribution-management-conference>.

¹⁸⁹ Lenny Bernstein & Scott Higham, The government’s struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letters From Sen. Claire McCaskill, (March 28, 2017), <https://www.mccaskill.senate.gov/opioid-investigation>; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), <http://www.purduepharma.com/payers/managed-markets/>.

¹⁹⁰ *Id.*

notices, and invoices.¹⁹¹ The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

378. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that Manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

379. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants were in communication and cooperation.

380. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum – the members of which include the Manufacturers and

¹⁹¹ Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/resources/webinar-leveraging-edu>.

the Distributors' trade association – has been lobbying on behalf of the Manufacturers and Distributors for “more than a decade.”¹⁹² Additionally, from 2006 to 2016, the Distributors and Manufacturers worked together through the Pain Care Forum to spend over \$740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.¹⁹³ Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.¹⁹⁴

381. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

382. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate, and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market and to halt such unlawful sales so as to increase production quotas and generate unlawful profits, as follows:

383. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

¹⁹² Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (accessed September 19, 2017), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>.

¹⁹³ *Id.*

¹⁹⁴ HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

384. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

385. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

386. Defendants paid nearly \$800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

387. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

388. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."¹⁹⁵

¹⁹⁵ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

389. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Upon information and belief, the Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. Additionally, upon information and belief, the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

390. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids the RICO Defendants had not properly investigated or reported.

391. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids.¹⁹⁶ On information and belief, the "know your customer" questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances they sold compared to controlled substances, whether the pharmacy buys from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

¹⁹⁶ Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcquirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

392. The RICO Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012¹⁹⁷ and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six (76) actions involving orders to show cause and forty-one (41) actions involving immediate suspension orders -- all for failure to report suspicious orders.¹⁹⁸

393. Defendants' scheme had a decision-making structure driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

394. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

395. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious

¹⁹⁷ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

¹⁹⁸ *Id.*

orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the PCF;
- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioid prescriptions filled by the Distributor Defendants;
- d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."¹⁹⁹
- f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor

¹⁹⁹ Harriet Ryan, *et al.*, More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

- h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and
- j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the “medical need” for and the net disposal of their drugs did not justify the production quotas set by the DEA.

396. The scheme the RICO Defendants devised and implemented amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

C. PATTERN OF RACKETEERING ACTIVITY.

397. The RICO Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343 and 18 U.S.C. § 1961(D)) by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1. The RICO Defendants Engaged in Mail and Wire Fraud.

398. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

399. The RICO Defendants committed, conspired to commit and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Defendants’ regular use of the facilities, services, distribution channels and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the internet to transmit mailings and wires in interstate or foreign commerce.

400. The RICO Defendants used, directed the use of and/or caused to be used thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

401. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose

of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

402. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

403. The RICO Defendants' use of the mail and wires includes, but is not limited to, Manufacturers, Distributors or third parties that were foreseeably caused to conduct the transmission, delivery or shipment of the following as a result of the RICO Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase, and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;

- d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- f. Defendants' records and reports that 21 U.S.C. § 827 required Defendants to submit to the DEA;
- g. Documents and communications related to the Defendant's mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;
- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- l. Payments to Defendants' lobbyists through the PCF;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

404. On information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or

received) shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

- a. Purdue manufactures multiple forms of prescription opioids, including, but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.
- b. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.
- c. Cephalon manufactures multiple forms of prescription opioids, including, but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.
- d. The Distributor Defendants shipped Teva's prescription opioids throughout this jurisdiction.
- e. Janssen manufactures a prescription opioid known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.
- f. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.
- g. Endo manufactures multiple forms of prescription opioids, including, but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydene. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in the State.

- h. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.
- i. Actavis manufactures multiple forms of prescription opioids, including, but not limited to: Kadian and Norco, as well as generic versions of the drugs known as Kadian, Duragesic, and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.
- j. The Distributor Defendants shipped Actavis' prescription opioids throughout this jurisdiction.
- k. Mallinckrodt manufactures multiple forms of prescription opioids, including, but not limited to: Exalgo and Roxicodone.
- l. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

405. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

406. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

407. Upon information and belief, the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates / chargebacks.

408. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile and by interstate electronic mail with each other and various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

409. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids, all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants intended their scheme and common course of conduct to increase or maintain high production quotas for their prescription opioids from which they could profit.

410. Defendants have deliberately hid many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities, and these cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of and, in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

411. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the

RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share and /or minimize the losses for the RICO Defendants.

412. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

413. The RICO Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities the reality of the suspicious orders that the RICO Defendants were filling on a daily basis -- leading to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

414. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

415. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

416. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenue from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

417. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants, while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The RICO Defendants committed or

caused to be committed the predicate acts through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

418. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

419. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

420. RICO Defendants have hidden many of the precise dates of the criminal actions at issue here, and these cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

421. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff's Community and the Plaintiff. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on Plaintiff's Community or the Plaintiff. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of

this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

422. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

423. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

424. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

**2. The RICO Defendants Manufactured, Sold and/or Dealt in
Controlled Substances, and Their Crimes Are Punishable as Felonies.**

425. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

426. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

427. Each of the RICO Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

428. The CSA and the Code of Federal Regulations required the RICO Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

429. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders and/or omitted material information from reports, records and other documents they were required to file with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

430. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form 8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.²⁰⁰

²⁰⁰ McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017), <http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/>.

431. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as they relate to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles, yet failed to alert the DEA.²⁰¹ The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."²⁰² Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."²⁰³

432. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt, arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.²⁰⁴ After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying

²⁰¹ Harriet Ryan, *et al.*, More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

that Mallinckrodt's response was that everyone knew what was going on in Florida, but they had no duty to report it.²⁰⁵

433. Upon information and belief, the foregoing examples reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. The sheer volume of enforcement actions available in the public record against the Distributor Defendants supports this conclusion.²⁰⁶ For example:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

²⁰⁵ *Id.*

²⁰⁶ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA, which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;”
- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”); Valencia, California (“Valencia Facility”); and Denver, Colorado (“Denver Facility”);

- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Livonia, Michigan; Methuan, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.

434. These actions against the Distributor Defendants confirm that the Distributor Defendants knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

435. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

436. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

437. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission and had similar results affecting similar victims, including Plaintiff's Community and the Plaintiff. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

438. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

439. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

440. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. DAMAGES

441. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

442. Defendants' racketeering activities proximately caused Plaintiff's. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

443. The RICO Defendants' racketeering activities directly caused Plaintiff's injuries.

444. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

445. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit, and pre- and post-judgment interest.

COUNT IV RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1962(d), *et seq.* (Against All Defendants)

446. Plaintiff hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

447. Plaintiff brings this claim on its own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and

agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d), it is unlawful for “any person to conspire to violate” Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

448. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

A. THE OPIOID DIVERSION ENTERPRISE.

449. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the “Opioid Diversion Enterprise.”

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.

450. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the “Conduct of the Opioid Diversion Enterprise.”

C. PATTERN OF RACKETEERING ACTIVITY.

451. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the “Pattern of Racketeering Activity.”

D. DAMAGES.

452. The RICO Defendants’ violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff

paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

453. The RICO Defendants' racketeering activities proximately caused Plaintiff's injuries. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

454. The RICO Defendants' racketeering activities directly caused Plaintiff's injuries.

455. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

456. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees, and all costs and expenses of suit and pre- and post-judgment interest.

COUNT V
NEGLIGENCE AND NEGLIGENT MISREPRESENTATION
(Against All Defendants)

457. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

458. Plaintiff seeks economic damages that were the foreseeable result of Defendants' intentional and/or unlawful actions and omissions.

459. Under State law, to establish actionable negligence, one must show, in addition to the existence of a duty, a breach of that duty and injury resulting proximately therefrom and/or that was substantially caused thereby. All such essential elements exist here.

460. In Alabama, the "key factor" for determining whether a duty should be imposed as a matter of law is the "foreseeability" of the harm that might result if care is not exercised. *See, e.g., Taylor v. Smith*, 892 So. 2d 887, 892 (Ala. 2004) (quoting *Key v. Compass Bank, Inc.*, 826

So. 2d 159, 170 (Ala. Civ. App. 2001) (in turn quoting *Patrick v. Union State Bank*, 681 So. 2d 1364, 1368 (Ala. 1996). Each Defendant owed a duty to the Plaintiff and to the public health and safety in the Plaintiff's Community because the injury was foreseeable and, in fact, foreseen by the Defendants. If a course of action creates a foreseeable risk of injury, the individual engaged in that course of action has a duty to protect others from such injury. Each Defendant owed a duty to the Plaintiff and to the public in the Plaintiff's Community, because the injury was foreseeable and, in fact, foreseen by the Defendants.

461. In Alabama, a legal duty to "exercise care . . . arises where the parties are bound by contract, . . . or where the obligations are expressly or impliedly imposed by statute, municipal ordinance, or by administrative rules or regulations, or by judicial decisions." *King v. National Spa & Pool Institute*, 570 So. 2d 612, 614 (Ala. 1990) (citations and internal quotation marks omitted).

462. Further, as Section 302B of the Restatement of Torts provides: "An act or an omission may be negligent if the actor realizes or should realize that it involves an unreasonable risk of harm to another through the conduct of the other or a third person which is intended to cause harm, even though such conduct is criminal."

463. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, selling and distributing highly dangerous opioid drugs to the State and Plaintiff's Community.

464. Each Defendant had an obligation to exercise due care in manufacturing, marketing, selling and distributing highly dangerous opioid drugs in the State and Plaintiff's Community.

465. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and impose significant costs upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

466. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

467. Moreover, law enforcement repeatedly warned Defendants of the unlawfulness and consequences of their actions and omissions.

468. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

469. As described above in allegations expressly incorporated herein, Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non-

medical purposes – the causal connection between Defendants’ breach of duties and the ensuing harm was entirely foreseeable.

470. As described elsewhere in the Complaint in allegations expressly incorporated herein, Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiff’s Community and destinations from which they knew opioids were likely to be diverted into Plaintiff’s Community, in addition to other misrepresentations alleged and incorporated herein.

471. As described elsewhere in the Complaint in allegations expressly incorporated herein, Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable.

472. The Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and their lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

473. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

474. Defendants’ breaches were intentional and/or unlawful, and Defendants’ conduct was willful, wanton, malicious, reckless, oppressive and/or fraudulent.

475. The causal connection between Defendants’ breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

476. As described above in allegations expressly incorporated herein, Defendants' breaches of duty and misrepresentations caused, bear a causal connection with, and/or proximately resulted in the damages sought herein.

477. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Defendants breached their duties to monitor for, report and halt suspicious orders; breached their duties to prevent diversion; and, further, misrepresented what their duties were and their compliance with their legal duties.

478. The Defendants failed to disclose the material facts that, *inter alia*, they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell opioids.

479. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed and sold had characteristics, uses or benefits that they do not have. The Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective when the Manufacturer Defendants knew, or should have known, such representations were untrue, false, and misleading.

480. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value and in fact caused addiction and overdose deaths.

481. The Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

482. Defendants' unlawful and/or intentional actions create a rebuttable presumption of negligence under State law.

483. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' actions and omissions.

484. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VI
CIVIL CONSPIRACY
(Against All Defendants)

485. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

486. As set forth herein, Defendants engaged in a civil conspiracy to create a public nuisance in conjunction with their unlawful marketing, sale, distribution and/or diversion of opioids into the State and Plaintiff's Community.

487. As set forth herein, Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful distribution and diversion of opioids into the State and Plaintiff's Community.

488. As set forth herein, Defendants engaged in a civil conspiracy to unlawfully divert opioids and create opioid dependence and abuse in the State and Plaintiff's Community.

489. Distributor and Manufacturer Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report and prevent suspicious orders of opioids.

490. The Manufacturer Defendants further unlawfully marketed opioids in the State and Plaintiff's Community in furtherance of that conspiracy.

491. Defendants acted tortiously in concert with each other and/or in pursuit of a common design, and/or Defendants knew each other's conduct constituted a breach of their legal duties and provided substantial assistance and/or encouragement in the conduct.

492. Defendants' conspiracy is a continuing conspiracy, and the overt acts performed in compliance with the conspiracy's objective(s) are ongoing and/or have occurred within the last year.

493. Plaintiff alleges Defendants' conspiracy and acts in furtherance in greater detail earlier in the Complaint, including, without limitation, in Plaintiff's racketeering allegations. Such allegations are incorporated herein.

494. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the injuries alleged herein.

495. Defendants acted with malice, purposely, intentionally, unlawfully and without a reasonable or lawful excuse.

496. Defendants' conspiracy and Defendants' actions and omissions in furtherance thereof proximately caused and/or substantially contributed to the direct and foreseeable losses alleged herein.

497. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' civil conspiracy.

498. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VII
FRAUD AND FRAUDULENT MISREPRESENTATION
(Against All Defendants)

499. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

500. Defendants violated their general duty not to actively deceive, have made knowingly false statements and have omitted and/or concealed information that made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

501. As alleged herein, Defendants made false statements as to their compliance with state and federal law regarding their duties to prevent diversion and their duties to monitor, report and halt suspicious orders and/or concealed their noncompliance with these requirements.

502. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic, non-cancer pain.

503. As alleged herein, Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their

representations, and did so with the intent of misleading Plaintiff, Plaintiff's Community, the public and persons on whom Plaintiff relied.

504. These false representations and concealments were reasonably calculated to deceive Plaintiff, Plaintiff's Community and the physicians who prescribed opioids for persons in Plaintiff's Community; were made with the intent to deceive; and did in fact deceive these persons, Plaintiff and Plaintiff's Community.

505. Plaintiff, Plaintiff's Community and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

506. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. This reliance proximately caused Plaintiff's injuries.

507. Defendants' fraudulent conduct was a direct and proximate cause of the injuries Plaintiff alleges herein.

508. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment.

509. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

PUNITIVE DAMAGES

510. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

511. By engaging in the above-described intentional and/or unlawful acts or practices, Defendants acted with actual malice, wantonly, and oppressively. Defendants acted with conscious disregard for the rights of others and/or in a reckless, wanton, willful, or grossly negligent manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Defendants acted toward the Plaintiff with fraud, oppression, and/or malice and/or were grossly negligent in failing to perform the duties and obligations imposed upon them under applicable federal and state statutes and common law.

512. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the State and Plaintiff's Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence and the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrence.

513. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and gross negligence and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

RELIEF

WHEREFORE, the Plaintiff respectfully prays that this Court grant the following relief:

514. Enter a Judgment in favor of the Plaintiff in a final order against each of the Defendants;

515. Enjoin the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with them from engaging in unfair or deceptive practices in violation of law and ordering temporary, preliminary, or permanent injunction;

516. Order that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

517. Order Defendants to fund an “abatement fund” for the purposes of abating the opioid nuisance;

518. Award actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorneys’ fees and all costs and expenses of suit pursuant to Plaintiff’s racketeering claims;

519. Award the Plaintiff the damages caused by the opioid epidemic, including (A) costs for providing medical care, additional therapeutic and prescription drug purchase, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services; (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (E) costs associated with law enforcement and public safety relating to the opioid epidemic.

520. Enter a judgment against the Defendants requiring Defendants to pay punitive damages;

521. Grant the Plaintiff

- a. The costs of investigation, reasonable attorneys’ fees, and all other costs and expenses;

- b. Pre-judgment and post-judgment interest; and
- c. All other relief as provided by law and/or as the Court deems appropriate and just.

Dated: February 1, 2018

Respectfully Submitted,

/s/ Peter J. Mougey

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