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S.C. SUPREME COURT

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.

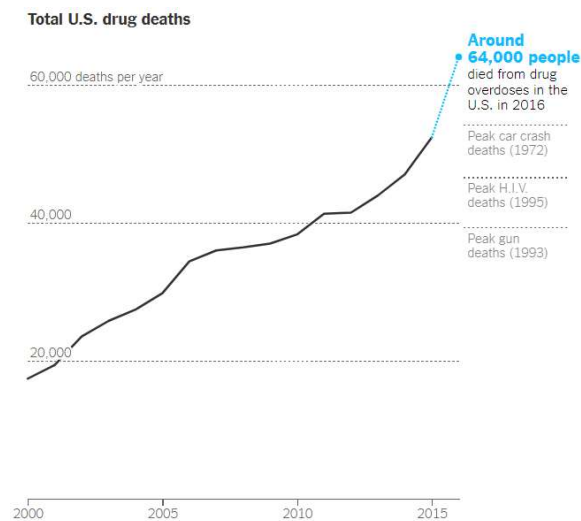
40. According to the Centers for Disease Control and Prevention ("CDC"), more than 115 Americans die every day from an opioid overdose, and, in 2017, more than 191 million opioid prescriptions were dispensed to Americans.

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.

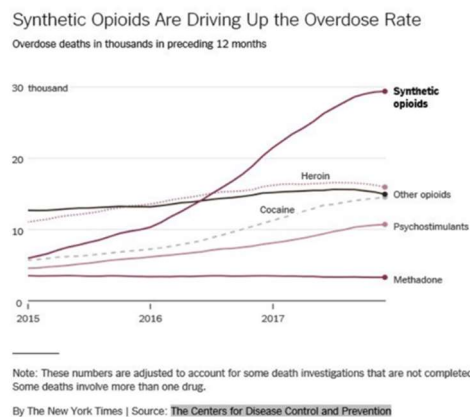
44. The below graph from *The New York Times* shows the trend relating to overdose deaths since 2000:



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.

JANE PORTER

HERSHEL JICK, M.D.

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1. Jick H, Mietinen 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]aintain 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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