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S.C. SUPREME COURT

EXHIBIT 7

THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PANAMA CITY DIVISION

BAY COUNTY, FLORIDA,)

Plaintiff,)

v.)

AMERISOURCEBERGEN DRUG)

CORPORATION; CARDINAL)

HEALTH, INC.; McKESSON)

CORPORATION;)

PURDUE PHARMA L.P.; PURDUE)

PHARMA, INC.; THE PURDUE)

FREDERICK COMPANY, INC.; TEVA)

PHARMACEUTICAL INDUSTRIES,)

LTD.; TEVA PHARMACEUTICALS)

USA, INC.; CEPHALON, INC.;)

JOHNSON & JOHNSON; JANSSEN)

PHARMACEUTICALS, INC.; ORTHO-)

MCNEIL-JANSSEN)

PHARMACEUTICALS, INC. n/k/a)

JANSSEN PHARMACEUTICALS,)

INC.; JANSSEN PHARMACEUTICA)

INC. n/k/a JANSSEN)

PHARMACEUTICALS, INC.;)

NORAMCO, INC.; ENDO HEALTH)

SOLUTIONS INC.; ENDO)

PHARMACEUTICALS, INC.;)

ALLERGAN PLC f/k/a ACTAVIS PLS;)

WATSON PHARMACEUTICALS,)

INC. n/k/a ACTAVIS, INC.; WATSON)

LABORATORIES, INC.; ACTAVIS)

LLC; ACTAVIS PHARMA, INC. f/k/a)

WATSON PHARMA, INC.;)

MALLINCKRODT PLC and)

MALLINCKRODT LLC.)

Defendants.)

CASE NO.:

COMPLAINT

Complaint for Public Nuisance,
Violations of Racketeer Influenced
and Corrupt Organizations Act
(RICO) 18 U.S.C. § 1961 *et seq.*,
Violations of 18 U.S.C. § 1962 *et*
seq., Negligence and Negligent
Misrepresentation, Negligence Per
Se, Civil Conspiracy, Fraud and
Fraudulent Misrepresentation
(F.S.A. § 817.41 and common law),
and Unjust Enrichment.

JURY TRIAL DEMANDED AND
ENDORSED HEREON

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Plaintiff, BAY COUNTY, FLORIDA, brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively “Defendants”) and alleges as follows:

INTRODUCTION

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby and to recoup monies spent because of Defendants’ false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids.¹ Such economic damages were foreseeable to Defendants and were sustained because of Defendants’ intentional and/or unlawful actions and omissions.

¹ As used herein, the term “opioid” refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

2. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.²

3. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”³

4. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, which turned patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

5. Plaintiff also brings this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

PARTIES

A. PLAINTIFF.

² See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

³ See Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

6. Plaintiff BAY COUNTY, FLORIDA (“Bay County” or “Plaintiff”) has the power to bring the claims asserted herein. *See generally* FLA. STAT. §§ 125.15; 125.01.

7. Plaintiff has standing to take action to protect the public health, safety and welfare of its citizens.

8. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity and mortality have created a serious public health and safety crisis and are a public nuisance and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

9. The distribution and diversion of opioids into Florida (the “State”), and into BAY COUNTY and its surrounding areas (collectively, “Plaintiff’s Community”), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

10. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants’ conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling and rehabilitation services; (3) costs for providing

treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; and (5) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. The Plaintiff has suffered and continues to suffer these damages directly.

11. Plaintiff also seeks the means to abate the epidemic Defendants' wrongful and/or unlawful conduct has created.

12. Plaintiff has standing to bring an action for the opioid epidemic nuisance created by Defendants.

13. Plaintiff has standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiff has standing to bring all claims pled herein, including, *inter alia*, to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

14. Plaintiff does not bring, or seek to bring, a product liability action.

B. DEFENDANTS.

1. Manufacturer Defendants.

15. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted

and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

16. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA, INC. is a New York corporation with its principal place of business in Stamford, Connecticut and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, “Purdue”).

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

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

Petah Tikva, Israel. In October 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. (“Teva USA”) is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania.

19. Cephalon, Inc. manufactures, promotes, sells and distributes opioids, such as Actiq and Fentora, in the United States. The FDA has approved Actiq only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.”⁴ The FDA has approved Fentora only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”⁵ In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.⁶

20. Teva Ltd., Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA

⁴ *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.

⁵ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.

⁶ Press Release, U.S. Dep’t of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon-branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that Teva USA submitted the guide and directs physicians to contact Teva USA to report adverse events.

21. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.⁷ Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including, *inter alia*, sales of Fentora®.⁸ Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries, Cephalon and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits

⁷ E.g., ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (last visited Aug. 21, 2017).

⁸ Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; and Cephalon, Inc. are referred to as “Cephalon.”

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

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

24. ENDO HEALTH SOLUTIONS, INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS, INC. is a wholly owned subsidiary of Endo Health Solutions, Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. are referred to as “Endo.”

25. Endo develops, markets and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet and Zydene, in the United States. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013 and accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids, such as oxycodone, oxymorphone, hydromorphone and hydrocodone products, in the United States, by itself and through its subsidiary, QUALITEST PHARMACEUTICALS, INC.

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

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

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

29. Mallinckrodt manufactures, markets and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.⁹

⁹ Press Release, U.S. Dep’t of Justice, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations*, July 11, 2017, <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>, last visited October 26, 2017.

2. Distributor Defendants.

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

31. McKESSON CORPORATION (“McKesson”) at all relevant times operated as a licensed pharmacy wholesaler in Florida. McKesson is a Delaware corporation. McKesson has its principal place of business located in San Francisco, California.

32. CARDINAL HEALTH, INC. (“Cardinal”) at all relevant times operated as a licensed pharmacy wholesaler in Florida. Cardinal’s principal office located in Dublin, Ohio.

33. AMERISOURCEBERGEN DRUG CORPORATION (“AmerisourceBergen”) at all relevant times operated as a licensed pharmacy

wholesaler in Florida. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania.

34. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA¹⁰ nor the wholesale distributors¹¹ will voluntarily disclose the data necessary to identify with specificity the transactions that will form the evidentiary basis for the claims asserted herein.

35. Consequently, Plaintiff has named the three (3) wholesale distributors (*i.e.*, AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation) that dominate 85% of the market share for the distribution of prescription opioids. These "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Drug Corporation predecessors).

¹⁰ See Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

¹¹ See Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

The DEA has investigated and/or fined each for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct that resulted in the diversion of prescription opioids into Plaintiff's Community, and that discovery will likely reveal others who likewise engaged in unlawful conduct. Plaintiff names each of the "Big 3" herein as defendants and places the industry on notice that the Plaintiff is acting to abate the public nuisance plaguing the community. Plaintiff will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

JURISDICTION & VENUE

36. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

37. This Court also has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a) because the Plaintiff is a "citizen" of this State, the named Defendants are citizens of different states and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

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

39. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher’s Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

40. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965 because a substantial part of the events or omissions giving rise to the claims stated herein occurred in this District and each Defendant transacted

affairs and conducted activity that gave rise to the claims for relief in this District.
28 U.S.C. § 1391(b); 18 U.S.C. §1965(a).

FACTUAL BACKGROUND

C. THE OPIOID EPIDEMIC.

1. The National Opioid Epidemic.

41. Increasing abuse and diversion of prescription drugs, including opioid medications, have characterized the past two decades in the United States.¹²

42. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.¹³

43. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention declared prescription painkiller overdoses to be at epidemic levels. The news release noted:

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

¹² See Richard C. Dart *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

¹³ Katherine M. Keyes, *et al.*, *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

- c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
- e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
- f. Almost 5,500 people start to misuse prescription painkillers every day.¹⁴

44. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.¹⁵

¹⁴ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Prescription Painkiller Overdoses at Epidemic Levels* (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

¹⁵ See Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

45. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than twenty-two percent (22%) over the 52,404 drug deaths recorded the previous year.¹⁶

46. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.¹⁷

47. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.¹⁸

48. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in four (4) years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. ***Past***

¹⁶ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Provisional Counts of Drug Overdose Deaths*, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

¹⁷ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, <https://www.cdc.gov/vitalsigns/heroin/index.html> (last updated July 7, 2015).

¹⁸ See Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

misuse of prescription opioids is the strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or abuse. The increased availability of heroin combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.¹⁹

49. The societal costs of prescription drug abuse are “huge.”²⁰

50. Across the nation, local governments are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day, more than ninety (90) Americans lose their lives after overdosing on opioids.²¹

51. The National Institute on Drug Abuse identifies misuse and addiction to opioids as “a serious national crisis that affects public health as well as social and economic welfare.”²² The economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment and criminal justice expenditures.²³

¹⁹ See Rose A. Rudd *et al.*, *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 *Morbidity & Mortality Wkly. Rep.* 1378 (2016).

²⁰ See Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter, “Brief of HDMA”].

²¹ Opioid Crisis, NIH, National Institute on Drug Abuse (available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis>, last visited Sept. 19, 2017) (“Opioid Crisis, NIH”) (citing at note 1 Rudd RA, Seth P, David F, Scholl L, *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, *MMWR MORB MORTAL WKLY REP.* 2016;65, doi:10.15585/mmwr.mm65051e1).

²² Opioid Crisis, NIH.

²³ *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

52. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.²⁴

53. The rate of death from opioid overdose has quadrupled during the past fifteen (15) years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six (6) in the past fifteen (15) years.²⁵

54. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are “everywhere” and mistaken for candy.²⁶

55. In 2016, the President of the United States declared an opioid and heroin epidemic.²⁷

56. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.²⁸ Meanwhile, the

²⁴ See Rose A. Rudd *et al.*, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 *Morbidity & Mortality Wkly. Rep.* 1445 (2016).

²⁵ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 *N. Eng. J. Med.* 1253 (2016).

²⁶ Julie Turkewitz, *‘The Pills are Everywhere’: How the Opioid Crisis Claims Its Youngest Victims*, N.Y. Times, Sept. 20, 2017 (“‘It’s a cancer,’ said [grandmother of dead one-year old], of the nation’s opioid problem, ‘with tendrils that are going everywhere.’”).

²⁷ See Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming “Prescription Opioid and Heroin Epidemic Awareness Week”).

manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience hundreds of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

57. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to cause the national, state and local opioid epidemic.

2. Florida's Opioid Epidemic.

58. The national opioid crisis has especially ravaged Florida.

59. Overdose mortalities in Florida have increased in recent years. From 1999 to 2015, Florida saw a 153% percent increase in overdose fatalities. In 2015, there were 3,292 Florida overdose deaths, up from 2,676 Florida overdose deaths in 2014.²⁹ Drug overdose deaths jumped by 23% in just one year between 2014 and 2015.³⁰

60. Florida has a high-dose opioid pain reliever prescription rate of 6.6 per 100 persons, which ranks 5th in the country (U.S. median rate: 4.3) and a

²⁸ See Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), <https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf>.

²⁹ L.M. ROSSEN ET AL., NAT'L CTR. FOR HEALTH STAT., DRUG POISONING MORTALITY: UNITED STATES, 1999–2015 (2017), <https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/> (last visited Dec. 12, 2017).

³⁰ R.A. Rudd et al., Ctr. for Disease Control, *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*. MMWR MORBIDITY AND MORTALITY WKLY. REP. 2016;65:1445–1452, <https://www.cdc.gov/mmwr/volumes/65/wr/mm65051e1.htm> (last visited Dec. 12, 2017).

benzodiazepine prescription rate of 46.9 per 100 persons, which ranks 10th nationally (U.S. median rate: 37.6).³¹ Using another measure, in 2016, there were 66.6 prescriptions per hundred people in Florida, and that only after the State managed to draw down the amount from a peak of 87.6 prescriptions per 100 people in 2010.³² Based on the amount prescribed, Florida had over 670.9 morphine milligram equivalents of opioids prescribed per capita in 2015,³³ equivalent to 13.42 days' high-dose supply for every person in the state.³⁴ This compares to the national rate of 642.05 morphine milligram equivalents per capita in 2015.

61. This high rate of prescriptions only scratches the surface of the full extent of the problem in Florida. 89.5% of people in Florida who need addiction treatment do not receive it. 2.56% of people in 2016 reported drug dependence, and 3.47% reported non-medical use of pain relievers.³⁵

³¹ Leonard J. Paulozzi, M.D., et al., Ctr. for Disease Control, *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, MORBIDITY AND MORTALITY WKLY. REP. (Jul. 4, 2014), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm> (last visited Dec. 12, 2017). The combination of hydrocodone, oxycodone, and benzodiazepines is referred to as the “holy trinity” and significantly increases the risk of harm to those that abuse prescription pills.

³² CTR. FOR DISEASE CONTROL, U.S. PRESCRIBING RATE MAPS (2017), <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Dec. 12, 2017).

³³ AMFAR, OPIOID & HEALTH INDICATORS DATABASE, FLORIDA OPIOID EPIDEMIC, <http://opioid.amfar.org/FL> (last visited Dec. 12, 2017).

³⁴ CTR. FOR DISEASE CONTROL, CALCULATING TOTAL DAILY DOSAGE OF OPIOIDS FOR SAFER DOSAGE, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf (last visited Dec. 12, 2017).

³⁵ AMFAR, OPIOID & HEALTH INDICATORS DATABASE, FLORIDA OPIOID EPIDEMIC, <http://opioid.amfar.org/FL> (last visited Dec. 12, 2017).

62. The rate of opioid-related inpatient stays in Florida surged by 39.3% between 2009 and 2014 at 234.9 per 100,000 people, more than the national rate of 224.6.³⁶

63. The Drug Utilization Review Board recently examined Florida Medicaid recipients' use of opioid medications and determined "inappropriate prescription practices have been shown to be a contributor to the rising prescription drug abuse problem in the United States."³⁷ Due to the severity of Florida's expanding opioid epidemic, Governor Rick Scott declared a state of public health emergency in 2017.³⁸

64. The number of newborns suffering from neonatal abstinence syndrome increased more than 10-fold in the past 20 years, according to a report by the Centers for Disease Control (CDC).³⁹ Over 4,000 babies were born addicted to opioids in the state of Florida in 2016 alone. This is a 1,000% increase over the past ten years. Newborns are not the only children affected by opioid dependence in adults. In cases where children were removed from homes, the presence of

³⁶ AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, HEALTHCARE COST AND UTILIZATION PROJECT, STATISTICAL BRIEF #219, OPIOID-RELATED INPATIENT STAYS AND EMERGENCY DEPARTMENT VISITS BY STATE, 2009-2014 (Jan. 2017), <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf> (last visited Dec. 12, 2017).

³⁷ AGENCY FOR HEALTH CARE ADMINISTRATION, REMITTANCE ADVICE PROVIDER ALERTS, [HTTP://AHCA.MYFLORIDA.COM/MEDICAID/PREScribed_DRUG/BANNERS.SHTML](http://AHCA.MYFLORIDA.COM/MEDICAID/PREScribed_DRUG/BANNERS.SHTML) (last visited Dec. 18, 2017).

³⁸ DSHP GOALS AND OVERVIEW, [HTTP://AHCA.MYFLORIDA.COM/MEDICAID/POLICY_AND_QUALITY/POLICY/BEHAVIORAL_HEALTH_COVERAGE/BHFU/PDF/DSHP_WHITE_PAPER_DRAFT.PDF](http://AHCA.MYFLORIDA.COM/MEDICAID/POLICY_AND_QUALITY/POLICY/BEHAVIORAL_HEALTH_COVERAGE/BHFU/PDF/DSHP_WHITE_PAPER_DRAFT.PDF) (last visited Dec. 18, 2017).

³⁹ CTR. FOR DISEASE CONTROL, INFANT AND MATERNAL CHARACTERISTICS IN NEONATAL ABSTINENCE SYNDROME, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6408a3.htm?s_cid=mm6408a3_w (last visited Dec. 18, 2017).

substance abuse points to longer out-of-home care and a higher likelihood of previous investigations.⁴⁰

65. According to a news article published in the Tampa Bay Times, Naloxone, an overdose-reversal drug, is now available throughout the state of Florida without an individual prescription. Patients may purchase an auto-injector or intranasal version of the drug through a Florida pharmacy after a doctor issues a blanket “standing order.”⁴¹

3. The Opioid Epidemic in Plaintiff’s Community.

66. The opioid epidemic is particularly devastating in Plaintiff’s Community.

67. Plaintiff’s Community is experiencing an excessive drug overdose rate related to an excessive volume of prescription opiates proximately caused by the wrongful conduct by the Defendants described and named herein. The opioid prescription rates in Plaintiff’s Community exceeded any legitimate medical, scientific, or industrial purpose.

⁴⁰ Kam, Dara. Panama City News Herald, *Opioid crisis taking toll on Florida children*, Nov. 9, 2017. <http://www.newsherald.com/news/20171109/opioid-crisis-taking-toll-on-florida-children> (last visited Dec. 18, 2017).

⁴¹ Suntrup, Jack. Tampa Bay Times, *Overdose-reversal drug naloxone now available in Florida without an individual prescription*, Dec. 18, 2017. <http://www.tampabay.com/news/health/medicine/overdose-reversal-drug-naloxone-now-available-in-florida-without-an/2286681> (last visited Dec. 18, 2017).

68. Excessive numbers of opioid prescriptions have been dispensed in the Plaintiff's Community.⁴² Significant numbers of the residents of Plaintiff's Community report drug dependence and non-medical use of pain relievers.⁴³ Many residents of Plaintiff's Community who need addiction treatment don't receive it.⁴⁴ Drug poisoning and opioid related deaths in Plaintiff's Community have significantly impacted the community in recent years.⁴⁵

69. The opioid epidemic has placed increased budgetary constraints upon *inter alia* the public health and medical care expenditures of the State and Plaintiff's Community. Opioid addiction is one of the primary reasons citizens of the State and Plaintiff's Community seek substance abuse treatment.

70. Criminal activity associated with the diversion of opioids have increased. This has placed increased budgetary costs upon law enforcement expenses in the State and Plaintiff's Community.

71. Opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community, and constitute a temporary and continuing public nuisance, which remains unabated.

⁴² U.S. Prescribing Rate Maps, Centers for Disease Control and Prevention (2017), <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Nov 13, 2017).

⁴³ See, e.g., <http://opioid.amfar.org>.

⁴⁴ *Id.* at View Counties: Healthcare.

⁴⁵ See, e.g., L.M. ROSSEN ET AL., NAT'L CTR. FOR HEALTH STAT., DRUG POISONING MORTALITY: UNITED STATES, 1999–2015 (2017), <https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/> (last visited Dec. 13, 2017).

**D. THE MANUFACTURER DEFENDANTS' FALSE,
DECEPTIVE AND UNFAIR MARKETING OF OPIOIDS.**

72. The opioid epidemic did not happen by accident.

73. Before the 1990s, generally accepted standards of medical practice dictated that patients should only use opioids short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time, the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

74. Each Manufacturer Defendant has conducted and has continued to conduct a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent and continues to spend millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

75. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their

drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of “pseudoaddiction” when signs of actual addiction began appearing and advocated that doctors should treat the signs of addiction with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that it is easy to manage opioid dependence and withdrawal; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction. The Manufacturer Defendants also have falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants’ claims.

76. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups.

77. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the

United States have exceeded \$8 billion in revenue annually since 2009.⁴⁶ In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."⁴⁷ This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply) and a population of patients physically and psychologically dependent on them (the demand). When those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

78. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids.

79. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around the State, including in Plaintiff's Community. Defendants also

⁴⁶ See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011, <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>; David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, Fin. Times, Aug. 10, 2016, <https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95>.

⁴⁷ Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), <http://turnthetidex.org/>.

deployed seemingly unbiased and independent third parties whom they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's Community.

80. The Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around the State, including in Plaintiff's Community, as they did nationwide. Across the pharmaceutical industry, corporate headquarters fund and oversee "core message" on a national basis. This comprehensive approach ensures that the Manufacturer Defendants accurately and consistently deliver their messages across marketing channels – including detailing visits, speaker events and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

81. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants required their sales representatives and physician speakers to stick to prescribed talking points, sales messages and slide decks, and

supervisors rode along with them periodically to check on both their performance and compliance.

i. Direct Marketing.

82. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

83. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads called "Pain vignettes" for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

84. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through “detailers” – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Manufacturer Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of \$168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

85. The Manufacturer Defendants’ detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

86. The Manufacturer Defendants’ detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that “minimize[] the risks

associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated.” Those materials in particular “fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed.”⁴⁸

ii. Indirect Marketing.

87. The Manufacturer Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and “key opinion leaders” (“KOLs”), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”).

88. The Manufacturer Defendants deceptively marketed opioids in the State and Plaintiff’s Community through unbranded advertising – *e.g.*, advertising that promotes opioid use generally but does not name a specific opioid. Independent third parties ostensibly created and disseminated this advertising. However, by funding, directing, reviewing, editing and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages these third parties disseminated and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as the Manufacturer Defendants controlled the distribution of their “core messages” via their own detailers and speaker programs, they similarly controlled the distribution

⁴⁸ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.

of these messages in scientific publications, treatment guidelines, Continuing Medical Education (“CME”) programs, medical conferences, and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

89. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

90. The Manufacturer Defendants also identified doctors to serve, for payment, on their speakers’ bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script

prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

91. Borrowing a page from Big Tobacco's playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging and directing doctors who served as KOLs, and (b) funding, assisting, directing and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences, seminars and scientific articles. Thus, working individually and collectively and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue and that the compassionate treatment of pain required opioids.

92. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally

circumvented these restrictions. Such actions included contributing to the creation of misleading publications and prescribing guidelines, which lack reliable scientific basis and promote prescribing practices that have worsened the opioid crisis.

93. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website “In the Face of Pain” failed to disclose that Purdue paid doctors who provided testimonials on the site and concluded that Purdue’s failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

94. Defendants utilized many KOLs, including many of the same ones.

95. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees and honoraria from Cephalon, Endo, Janssen and Purdue (among

others) and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) / American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by the Manufacturer Defendants.

96. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that “the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”⁴⁹

97. Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely

⁴⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

claimed that fewer than one percent (1%) of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”⁵⁰ Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”⁵¹

98. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of American Academy of Pain Medicine (“AAPM”) in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly \$2 million from Cephalon).

99. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice’s Drug Enforcement Agency, which raided his clinic in 2010. Although the DEA closed

⁵⁰ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

⁵¹ *Id.*

the investigation without charges in 2014, more than twenty (20) of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

100. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on or are linked to websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

101. In 2011, Dr. Webster presented via webinar a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose

deaths.” This webinar was available to and was intended to reach doctors in the State and doctors treating members of Plaintiff’s Community.⁵²

102. Dr. Webster also was a leading proponent of the concept of “pseudoaddiction,” the notion that doctors should see addictive behaviors not as warnings, but as indications of undertreated pain. In Dr. Webster’s description, the only way to differentiate the two was to increase a patient’s dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.”⁵³ Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”⁵⁴

103. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these “Front Groups” generated treatment

⁵² See Emerging Solutions in Pain, *Managing Patient’s Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

⁵³ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

⁵⁴ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>.

guidelines, unbranded materials and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

104. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing and approving their content and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

105. Defendants Cephalon, Endo, Janssen and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”),

the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and Pain & Policy Studies Group (“PPSG”).⁵⁵

106. The most prominent of the Manufacturer Defendants’ Front Groups was the American Pain Foundation (“APF”), which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of the State and Plaintiff’s Community.

107. In 2009 and 2010, more than eighty percent (80%) of APF’s operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of

⁵⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015), <https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>.

total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of a total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo and others to avoid using its line of credit.

108. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescriptions and thus the profitability of its sponsors. Upon information and belief, the Manufacturer Defendants often called upon it to provide “patient representatives” for the promotional activities, including for Purdue’s Partners Against Pain and Janssen’s Let’s Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in nonprofit organizations that share [its] business interests.”

109. Upon information and belief, on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

110. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."⁵⁶

111. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

112. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in

⁵⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

connection with AAPM's marquee event – its annual meeting held in Palm Springs, California or other resort locations. AAPM describes the annual event as an “exclusive venue” for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

113. Upon information and belief, Endo internally views AAPM as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – thirty-seven (37) out of roughly forty (40) at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. The AAPM even elected Dr. Webster president while he was under a DEA investigation.

114. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

115. In 1996, AAPM and APS jointly issued a consensus statement, “The Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat

chronic pain and claimed that the risk of a patient's addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, the AAPM only removed it from the website after a doctor complained.⁵⁷

116. AAPM and APS issued their own treatment guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.⁵⁸ Doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants, have relied upon treatment guidelines. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis and Purdue discussed treatment guidelines with doctors during individual sales visits.

117. At least fourteen (14) of the twenty-one (21) panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating

⁵⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

⁵⁸ Roger Chou *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.⁵⁹ One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the State and/or Plaintiff's Community during the relevant time period, are still available online and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants' financial support to members of the panel.

118. The Manufacturer Defendants worked together through Front Groups to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF comprises

⁵⁹ *Id.*

representatives from opioid manufacturers (including Cephalon, Endo, Janssen and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

**2. The Manufacturer Defendants' Marketing Scheme
Misrepresented the Risks and Benefits of Opioids.**

i. The Manufacturer Defendants embarked upon a campaign of false, deceptive and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

119. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC have conclusively debunked. These misrepresentations – described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted and because doctors could identify and manage those at greatest risk for addiction; (2) patients who displayed signs of addiction probably were not addicted, and, in any event, doctors could easily wean them from the drugs; (3) the use of higher opioid doses, which many

patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations; they continue to make them today.

120. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use in the State and Plaintiff's Community and each continues to fail to correct its past misrepresentations. They also continue to support, fund and control those misrepresentations through the direct and indirect marketing methods identified above.

121. Some illustrative examples of the Manufacturer Defendants' false, deceptive and unfair claims about the purportedly low risk of addiction include:

- a. Actavis's predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing

materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.⁶⁰
- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

⁶⁰ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

- d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”
- e. Janssen reviewed, edited, approved and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”
- f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claims that less than one percent (1%) of children prescribed opioids will become addicted and that pain is undertreated due to “[m]isconceptions about opioid addiction.”⁶¹

⁶¹ Am. Pain Found., *A Policymaker’s Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker’s Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

- h. In 2010, Mallinckrodt sponsored an initiative “Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book “Defeat Chronic Pain Now!” aimed at chronic pain patients. The book, which is still available for sale in New Mexico and elsewhere, and is promoted online at www.defeatchronicpainnow.com, advises laypeople who are considering taking opioid drugs that “[o]nly rarely does opioid medication cause a true addiction.”⁶² Further, the book advises that even the issue of tolerance is “overblown,” because “[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance.” In response to a hypothetical question from a chronic back pain patient who expresses a fear of becoming addicted, the book advises that “[i]t 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.”
- i. Upon information and belief, consistent with the Manufacturer Defendants’ published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, Cephalon, and

⁶² Charles E. Argoff & Bradley S. Galer, *Defeat Chronic Pain Now!* (2010).

Mallinckrodt in the State and Plaintiff's Community minimized or omitted any discussion with doctors of the risk of addiction, misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations and routinely did not correct the misrepresentations noted above.

- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NPF argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.⁶³

122. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."⁶⁴ The 2016 CDC Guideline further explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder"

⁶³ Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

⁶⁴ Deborah Dowell *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”⁶⁵

123. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting (“ER/LA”) opioids in 2013 and for immediate release (“IR”) opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed.⁶⁶

124. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in

⁶⁵ *Id.* at 2, 25.

⁶⁶ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf>; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf>.

specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.”⁶⁷ Endo had claimed on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. Endo remains free, however, to make those statements in this State.

125. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented to doctors and patients that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (*i.e.*, pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

126. To this end, one of Purdue’s employees, Dr. David Haddox, invented a phenomenon called “pseudoaddiction.” Upon information and belief, KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive and unfair statements regarding pseudoaddiction include:

⁶⁷ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids and hoarding are all signs of pseudoaddiction, rather than true addiction.⁶⁸ The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.⁶⁹
- b. Janssen sponsored, funded and edited the Let’s Talk Pain website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”
- c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,” which, upon information and belief, promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC

⁶⁸ Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2007) at 62.

⁶⁹ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

projects; developing, specifying and reviewing content; and distributing NIPC materials.

- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated.”
- e. Upon information and belief, Purdue sponsored a CME program titled “Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse.” In a roleplay, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long-acting opioid.
- f. In 2010, Mallinckrodt sponsored an initiative “Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book “Defeat Chronic Pain Now!”

aimed at chronic pain patients. The book, which is still available for sale in New Mexico and elsewhere, and is promoted online at www.defeatchronicpainnow.com, teaches laypeople that “pseudoaddiction” is “caused by their doctor not appropriately prescribing the opioid medication.” It teaches that “[p]seudoaddiction happens when a patient’s opioid medication is not being prescribed in doses strong enough to provide good pain relief, or if the drug is not being prescribed often enough throughout the day. . . . When a pseudoaddicted patient is prescribed the proper amount of opioid medication, he or she doesn’t take any extra pills because his or her pain is relieved.”

127. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already-addicted patients.

128. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive and unfair practice is the Manufacturer Defendants’ false instructions that addiction risk screening tools, patient contracts, urine drug screens and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer

Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
- b. Purdue, upon information and belief, sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests and patient agreements prevent "overuse of prescriptions" and "overdose deaths."
- c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients –

and not opioids – are the source of the addiction crisis and that once those “bad apples” are identified, doctors can safely prescribe opioids without causing addiction.

129. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies “for improving outcomes related to overdose, addiction, abuse or misuse.”⁷⁰

130. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants’ false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that doctors can easily address opioid dependence by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.⁷¹

131. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal

⁷⁰ *Id.* at 11.

⁷¹ *Id.* at 26.

symptoms can be avoided by tapering a patient's opioid dose by ten percent (10%) to twenty percent (20%) for ten (10) days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.⁷² Similarly, in the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!", potential opioid users are advised that tolerance to opioids is "easily remedied," and that "[a]ll patients can be safely taken off opioid medication if the dose is slowly tapered down by their doctor."

132. A fifth category of false, deceptive and unfair statements the Manufacturer Defendants made to sell more drugs is that patients could increase opioid dosages indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

- a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a

⁷² Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>, at 32.

dose adjustment to get the right amount of pain relief. This is not addiction.” Based on Actavis’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.

- b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have “no ceiling dose” and insinuated that they are therefore the most appropriate treatment for severe pain.⁷³ This publication is still available online.
- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that opioid dosages may be increased until “you are on the right dose of medication for your pain.”
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked “If I

⁷³ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>, at 12.

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.”⁷⁴

- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its sales force distributed. This guide listed dosage limitations as “disadvantages” of other pain medicines, but omitted any discussion of risks of increased opioid dosages.
- f. Upon information and belief, Purdue’s In the Face of Pain website promoted the notion that if a patient’s doctor does not prescribe what, in the patient’s view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which taught that dosage escalations are “sometimes necessary” and that “the need for higher doses of medication is not necessarily indicative of addiction,” but inaccurately downplayed the risks from high opioid dosages.⁷⁵

⁷⁴ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁷⁵ APF, *Policymaker’s Guide*, at 32.

- h. In 2007, Purdue sponsored a CME entitled “Overview of Management Options” that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that Non-Steroidal Anti-Inflammatory Drugs (“NSAIDs”) and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, “the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,” challenging the correlation between opioid dosage and overdose.⁷⁶
- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NPF argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁷⁷
- k. In the 2010 Mallinckrodt/C.A.R.E.S. publication “Defeat Chronic Pain Now!”, potential opioid users are warned about the risk of “[p]seudoaddiction [b]ecause of a [l]ow [d]ose,” and advised that this condition may be corrected through the prescription of a

⁷⁶ The College on Problems of Drug Dependence, *About the College*, <http://cpdd.org> (last visited Aug. 21, 2017).

⁷⁷ Brief of APF, at 9.

higher dose. Similarly, the book recommends that for chronic pain patients, the opioid dose should be “gradually increased to find the best daily dose, as is done with all the other oral drugs.” The book discusses the risks of NSAIDs and other drugs at higher doses, but not explain this risk for opioids.

133. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants’ representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the “[b]enefits of high-dose opioids for chronic pain are not established,” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.”⁷⁸ More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.”⁷⁹ The CDC also states that there is an increased risk “for opioid use disorder, respiratory depression, and death at higher dosages.”⁸⁰ That is why the CDC advises doctors to “avoid increasing dosage” to above 90 morphine milligram equivalents per day.⁸¹

⁷⁸ 2016 CDC Guideline, at 22–23.

⁷⁹ *Id.* at 23–24.

⁸⁰ *Id.* at 21.

⁸¹ *Id.* at 16.

134. Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse.

135. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo’s advertisements for the 2012 reformulation of Opana ER claimed Endo had designed it to be crush-resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets’ “extended-release features can be compromised, causing the medication to ‘dose dump,’ when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing.”⁸² Also troubling, Opana ER can be prepared for snorting using commonly available methods and “readily prepared for injection.”⁸³ The letter discussed “the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection.”⁸⁴ Endo’s own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Endo remove Opana ER from the market.

⁸² Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

⁸³ *Id.* at 6.

⁸⁴ *Id.* at 6 n.21.

ii. The Manufacturer Defendants embarked upon a campaign of false, deceptive and unfair assurances grossly overstating the benefits of the opioid drugs.

136. To convince doctors and patients that they should use opioids to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.⁸⁵ The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

137. Some illustrative examples of the Manufacturer Defendants’ false claims are:

- a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health” and help patients enjoy their lives.

⁸⁵ *Id.* at 15.

- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking and climbing stairs.
- d. Janssen promoted Ultracet for everyday chronic pain and distributed posters for display in doctors’ offices of presumed patients in active professions. The caption read: “Pain doesn’t fit into their schedules.”
- e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled “Pain vignettes,” which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients’ function.

- f. *Responsible Opioid Prescribing* (2007), which Cephalon, Endo and Purdue sponsored and distributed, taught that relief of pain by opioids, by itself, improved patients' function.
- g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."⁸⁶ This publication is still available online.
- h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

⁸⁶ APF, *Treatment Options*.

- i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled “Persistent Pain in the Older Patient.”⁸⁷ Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.”
- j. Janssen sponsored and funded a multimedia patient education campaign called “Let’s Talk Pain.” One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the “Let’s Talk Pain” campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to “continue to function.”
- k. Purdue sponsored the development and distribution of APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[m]ultiple clinical studies” have shown that opioids are effective in improving “[d]aily function,” “[p]sychological health” and “[o]verall health-related quality of

⁸⁷ E.g., NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

life for chronic pain.”⁸⁸ The Policymaker’s Guide was originally published in 2011.

1. Purdue’s, Cephalon’s, Endo’s and Janssen’s sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

138. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

139. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that “we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”⁸⁹ And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

⁸⁸ APF, *Policymaker’s Guide*, *supra*, at 29.

⁸⁹ Letter from Thomas Abrams to Doug Boothe, at 2.

140. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for extended-release and long-acting (“ER/LA”) opioids in 2013 and immediate-release (“IR”) opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.⁹⁰ Purdue misleadingly promoted OxyContin as being unique among opioids in providing twelve (12) continuous hours of pain relief with one dose. In fact, OxyContin does not last for twelve (12) hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue’s own research shows that OxyContin wears off in under six hours in one quarter of patients and in under ten (10) hours in more than half. This is because OxyContin tablets release approximately forty percent (40%) of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or

⁹⁰ 2016 CDC Guideline, at 12.

no pain relief at the end of the dosing period, when the tablet releases less medicine. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial proportion” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of twelve (12) hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

141. Purdue’s competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to “real” twelve (12) hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full twelve (12) hours. Upon information and belief, Purdue’s sales representatives continue to tell doctors that OxyContin lasts a full twelve (12) hours.

142. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a

roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.⁹¹

143. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain, even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for nor has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007, emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain or pain due to injury.⁹² Specifically, the FDA advised that Fentora “is only approved for breakthrough cancer pain in

⁹¹ Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

⁹² See U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

patients who are *opioid-tolerant*, meaning those patients who take a regular, daily, around-the-clock narcotic pain medication.”⁹³

144. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved and is not appropriate or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain.
- b. Upon information and belief, Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

⁹³ *Id.*

c. In December 2011, Cephalon widely disseminated a journal supplement entitled “Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)” to Anesthesiology News, Clinical Oncology News and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just cancer pain.

145. Cephalon’s deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

146. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue’s sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic

copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five (5) years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as “an organized drug ring” until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.⁹⁴

147. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

⁹⁴ Harriet Ryan *et al.*, *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

3. The Manufacturer Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

148. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including this State and Plaintiff's Community. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

149. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients, even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance and a smaller window between safe and unsafe dosages.⁹⁵ The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. *Id.* at 27. The same is true for veterans, who are more likely to use anti-

⁹⁵ 2016 CDC Guideline, at 13.

anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

**4. The Manufacturer Defendants Made Materially
Deceptive Statements and Concealed Material Facts.**

150. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course of manufacturing, marketing and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

151. Defendant Purdue made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- f. Endorsing, directly distributing and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient

education materials, concerning the use of opioids to treat chronic non-cancer pain;

- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- m. Creating, endorsing and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of

abuse and addiction and the lack of validation for long-term efficacy;

- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff, while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioids, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials,

advertisements and CMEs they knew would reach these same prescribers.

152. Defendant Endo made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal or intravenous abuse;
- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of

pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

- f. Endorsing, directly distributing and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations – including over \$5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- m. Creating, endorsing and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

153. Defendant Janssen made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites, over which Janssen exercised final editorial control and approval, stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites, over which Janssen exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced

treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- i. Targeting the elderly by sponsoring, directly distributing and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

154. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

155. Defendant Actavis made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

156. Defendant Mallinckrodt made and/or disseminated deceptive statements, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain; and
- d. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain.

5. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.

157. The Manufacturer Defendants, both individually and collectively, made, promoted and profited from their misrepresentations about the risks and benefits of opioids for chronic pain, even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience, establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data and reports of adverse events, including reports of addiction, hospitalization and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements,

based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

158. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence and meetings with KOLs, Front Groups and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which the NIPC runs, did not disclose

Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

159. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks and promoting sales. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could the Plaintiff or Plaintiff's Community have detected it. The Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and

could not have acquired such knowledge earlier through the exercise of reasonable diligence.

160. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could Plaintiff or Plaintiff's Community have detected it. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

E. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS.

161. The Distributor Defendants owe a duty under both federal law and State law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community, as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

162. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

163. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

164. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

165. The opioid epidemic in the State, including, *inter alia*, in Plaintiff's Community, remains an immediate ***hazard to public health and safety***.

166. The opioid epidemic in Plaintiff's Community is a temporary and continuous ***public nuisance*** and remains unabated.

167. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Wholesale Drug Distributors Have a Duty Under State and Federal Law to Guard Against and Report Unlawful Diversion and to Report and Prevent Suspicious Orders.

168. Opioids are a controlled substance, and Florida law categorizes them as having a "high potential for abuse." F.S.A. § 893.03; 21 U.S.C.A. §§ 812(b),

812(2)(A)-(C). These drugs may lead to “severe psychological or physical dependence.” F.S.A. § 893.03.

169. Florida law required each manufacturer and distributor of prescription opioids, including Defendants, to first be registered with and/or permitted by the State. Florida law predicate such registration for both manufacturers and distributors upon compliance with applicable law. *See* F.S.A. §§ 499.01; 499.012. Criteria for permitting includes whether the manufacturer or distributor is operating in a manner “relevant to and consistent with the public health and safety” and whether “manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.” F.S.A. § 499.012

170. Furthermore, Florida law incorporates federal requirements set out under the Controlled Substance Act and related controlled substance laws and regulations. *See e.g.* F.S.A. § 499.012; 499.0121.

171. The federal Controlled Substance Act further required each Distributor Defendant to register with the DEA. *See* 21 U.S.C. § 823(b), (e) and 28 C.F.R. § 0.100. Each Distributor Defendant is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Florida law adopts and incorporates those requirements.

172. Each Distributor Defendant has an affirmative duty under federal and Florida law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. § 823(b)(1). Florida law adopts and incorporates those requirements. *See e.g.* F.S.A. § 499.012; 499.0121.

173. Federal regulations, incorporated by Florida law, impose a non-delegable duty upon wholesale drug distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

174. “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR § 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the distributor should report the order as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop

over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

175. Florida law further mandates that all wholesale distributors “must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature.” F.S.A. § 499.028

176. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders that were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, distributors must report all flagged orders. *Id.*

177. The law regulates these prescription drugs for the purpose of providing a “closed” system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.⁹⁶

178. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant’s role and responsibilities.⁹⁷

179. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is

⁹⁶ See 1970 U.S.C.C.A.N. 4566, 4571-72.

⁹⁷ Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf’t Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. See generally HDA, *About*, <https://www.healthcaredistribution.org/about> (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. See generally NACDS, *Mission*, <https://www.nacds.org/about/mission/> (last visited Aug. 21, 2017).

critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”⁹⁸

180. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.⁹⁹

181. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, *in addition* to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”¹⁰⁰ The letter also instructs that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”¹⁰¹ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”¹⁰²

⁹⁸ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

⁹⁹ See Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4 (“[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”).

¹⁰⁰ Rannazzisi Letter, at 2.

¹⁰¹ *Id.* at 1.

¹⁰² *Id.* at 2.

182. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.¹⁰³ This letter reminds the Defendants of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”¹⁰⁴ The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (*e.g.*, “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the

¹⁰³ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

¹⁰⁴ *Id.*

patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.¹⁰⁵

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which

¹⁰⁵ *Id.*

discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”¹⁰⁶

183. The Distributor Defendants admit that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”¹⁰⁷

184. The Distributor Defendants knew they were required to monitor, detect and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process and note in particular: If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or the distributor otherwise characterizes it as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug

¹⁰⁶ *Id.*

¹⁰⁷ See Brief of HDMA, 2012 WL 1637016, at *2.

code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.¹⁰⁸

185. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

186. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

187. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

188. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

189. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

190. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

¹⁰⁸ Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

191. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Plaintiff's Community and the damages caused thereby.

2. The Distributor Defendants Breached Their Duties.

192. Because distributors handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.¹⁰⁹

193. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's Community is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.¹¹⁰

194. The Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community or that the Distributor Defendants knew

¹⁰⁹ See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

¹¹⁰ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

were likely to be diverted to Plaintiff's Community to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

195. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

196. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Plaintiff's Community and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

197. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific and industrial channels.

198. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

199. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.¹¹¹

200. The federal and state laws at issue here are public safety laws.

201. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under State law.

202. The Distributor Defendants supplied prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity and disseminated massive quantities of prescription opioids into the black market.

203. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal and state law, which require Distributor Defendants to legally acquire and maintain a license to distribute prescription opiates.

204. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

¹¹¹ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

205. The Distributor Defendants' repeated shipments of suspicious orders over an extended period of time, in violation of public safety statutes and without reporting the suspicious orders to the relevant authorities demonstrate wanton, willful or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

3. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties.

206. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

207. The Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association the Distributor Defendants run, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate*

orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”¹¹²

- b. The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”¹¹³
- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”¹¹⁴
- d. The Association complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the

¹¹² Brief for HDMA and NACDS, 2016 WL 1321983, at *4–5.

¹¹³ *Id.* at *8 (citations and quotation marks omitted).

¹¹⁴ *Id.* at *14.

importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”¹¹⁵

- e. The Associations alleged (inaccurately) that “DEA’s regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”¹¹⁶

208. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”¹¹⁷

209. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.¹¹⁸

210. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master

¹¹⁵ *Id.* at *22.

¹¹⁶ *Id.* at *24–25.

¹¹⁷ *Id.* at 26.

¹¹⁸ See Brief of HDMA, *supra*, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry “does not know the rules of the road because” they claim (inaccurately) that the “DEA has not adequately explained them”).

Pharmaceutical's license and determined that DEA regulations require that, in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id.* at 212. Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above) that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

211. Wholesale Distributor McKesson recently has been forced to specifically admit to breaches of its duties to monitor, report and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 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.”¹¹⁹ Further, the 2017 Agreement specifically finds that McKesson “distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a).”¹²⁰ McKesson admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers,” including the McKesson Distribution Center located in “Washington Courthouse, Ohio.”¹²¹ Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility (among other facilities) would be partially suspended.¹²²

¹¹⁹ See Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and the McKesson Corp. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

¹²⁰ *Id.* at 4.

¹²¹ *Id.*

¹²² *Id.* at 6.

212. The 2017 Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.¹²³ In the 2008 Settlement Agreement, McKesson “recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA,” but had failed to do so.¹²⁴ The 2017 Agreement documents that McKesson continued to breach its admitted duties by “fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson’s obligations.”¹²⁵ As a result of these violations, McKesson was fined and required to pay to the United States \$150,000,000.¹²⁶

213. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

¹²³ *Id.* at 4.

¹²⁴ *Id.*

¹²⁵ *Id.*; see also Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] (“McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.”), <https://www.justice.gov/opa/press-release/file/928471/download>.

¹²⁶ See 2017 Settlement Agreement and Release, *supra*, at 6.

214. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.¹²⁷ The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.¹²⁸ These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health

¹²⁷ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

¹²⁸ *Id.*

Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;

- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA, which provided that McKesson would “maintain a

compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;”

- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”); Valencia, California (“Valencia Facility”); and Denver, Colorado (“Denver Facility”);
- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against the Lakeland Facility; and

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.

215. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act,” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the

industry the right to “cure” any violations of law before the DEA can issue a suspension order.¹²⁹

216. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

217. For example, a Cardinal Health executive claimed that it uses “advanced analytics” to monitor its supply chain and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”¹³⁰ Given the sales volumes and the company’s history of violations, this executive was either not telling the truth or, if Cardinal Health had such a system, it ignored the results.

¹²⁹ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

¹³⁰ Lenny Bernstein, *et al.*, *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

218. Similarly, Defendant McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”¹³¹ Again, given McKesson’s historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

219. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of Distributor Defendants’ industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

220. Meanwhile, the opioid epidemic rages unabated in the Nation, the State and Plaintiff’s Community.

221. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA

¹³¹ Scott Higham, *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

registration numbers, and when the DEA suspends one facility, they simply ship from another facility.

222. Plaintiff's racketeering allegations below allege in greater detail the wrongful actions and omissions of the Distributor Defendants, which have caused the diversion of opioids and have been a substantial contributing factor to and/or proximate cause of the opioid crisis.

223. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement and abused the privilege of distributing controlled substances in the State and Plaintiff's Community.

**F. THE MANUFACTURER DEFENDANTS' UNLAWFUL
FAILURE TO PREVENT DIVERSION AND MONITOR,
REPORT AND PREVENT SUSPICIOUS ORDERS.**

224. The same legal duties to prevent diversion and to monitor, report and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal and State law.

225. Under State and federal law, the Manufacturer Defendants were required to comply with substantially the same licensing and permitting requirements as the Distributor Defendants and the same rules regarding prevention of diversion and reporting suspicious orders, as set out above.

226. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes...

21 U.S.C. § 823(a)(1).

227. Additionally, as “registrants” under Section 823, the Manufacturer Defendants were also required to monitor, report and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21

U.S.C. 823 or 958).”) Like the Distributor Defendants, the Manufacturer Defendants breached these duties.

228. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

229. Federal statutes and regulations – and State law incorporating those requirements – are clear: just like opioid distributors, the law requires opioid manufacturers to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.” 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1).

230. The Department of Justice recently has confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.¹³²

231. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt “did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands[.]”¹³³

232. The settlement resolved, *inter alia*, government’s allegations that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors,

¹³² See Press Release, U.S. Dep’t of Justice, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

¹³³ *Id.*

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.”¹³⁴

233. The Memorandum of Agreement Mallinckrodt entered into (“2017 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.”¹³⁵

234. The 2017 Mallinckrodt MOA further details the DEA’s allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer:

With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt’s alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt’s alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt’s alleged failure to:

- i. conduct adequate due diligence of its customers;
- ii. detect and report to the DEA orders of unusual size and frequency;

¹³⁴ *Id.*

¹³⁵ Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download>. (“2017 Mallinckrodt MOA”).

iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and

3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

iv. use “chargeback” information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.¹³⁶

235. Mallinckrodt agreed that its “system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the

¹³⁶ 2017 Mallinckrodt MOA at p. 2-3.

importance of the prevention of diversion of the controlled substances they manufacture” and would “design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”¹³⁷

236. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”¹³⁸

237. The same duties federal law imposed on Mallinckrodt were imposed upon all Manufacturer Defendants.

238. The same business practices Mallinckrodt utilized regarding “charge backs” and receipt and review of data from opioid distributors as to orders of

¹³⁷ *Id.* at 3-4.

¹³⁸ *Id.* at p.5.

opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

239. Through, *inter alia*, the chargeback data, the Manufacturer Defendants could monitor suspicious orders of opioids.

240. The Manufacturer Defendants failed to monitor, report and halt suspicious orders of opioids as required by federal law.

241. The Manufacturer Defendants' failures to monitor, report and halt suspicious orders of opioids were intentional and unlawful.

242. The Manufacturer Defendants have misrepresented their compliance with federal and state law.

243. The Manufacturer Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity and disseminated massive quantities of prescription opioids into the black market.

244. Plaintiff's racketeering allegations below allege in greater detail the wrongful actions and omissions of the Manufacturer Defendants, which have caused the diversion of opioids and have been a substantial contributing factor to and/or proximate cause of the opioid crisis.

245. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff's Community.

**G. DEFENDANTS' UNLAWFUL CONDUCT AND
BREACHES OF LEGAL DUTIES CAUSED THE HARM
ALLEGED HEREIN AND SUBSTANTIAL DAMAGES.**

246. As the Manufacturer Defendants' efforts to expand the market for opioids have increased, so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization and death among the people of the State and the Plaintiff's Community. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like the Plaintiff's Community, fueling the epidemic.

247. There is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”¹³⁹

248. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.¹⁴⁰

¹³⁹ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

¹⁴⁰ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

249. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”¹⁴¹

250. The increased abuse of prescription painkillers, along with growing sales, has contributed to a large number of overdoses and deaths.¹⁴²

251. As shown above, the opioid epidemic has escalated in Plaintiff’s Community with devastating effects: substantial opiate-related substance abuse, hospitalization and death that mirrors Defendants’ increased distribution of opiates.

252. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Plaintiff’s Community and areas from which such opioids are being diverted into Plaintiff’s Community has resulted in the Defendant-caused opioid epidemic including heroin addiction, abuse and death.

253. Prescription opioid abuse, addiction, morbidity and mortality are hazards to public health and safety in the State and in Plaintiff’s Community.

254. Heroin abuse, addiction, morbidity and mortality are hazards to public health and safety in the State and in Plaintiff’s Community.

255. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of and/or

¹⁴¹ See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

¹⁴² See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., *supra*.

substantial factors leading to the widespread diversion of prescription opioids for nonmedical purposes into the Plaintiff's Community.

256. The unlawful diversion of prescription opioids is a direct and proximate cause of and/or substantial factor leading to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and Plaintiff's Community. This diversion and the epidemic are direct causes of foreseeable harms the Plaintiff and Plaintiff's Community have incurred.

257. Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing economic damages for which Plaintiff seeks relief, as alleged herein. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

258. Plaintiff seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

259. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

260. To eliminate the hazard to public health and safety and abate the public nuisance, a “multifaceted, collaborative public health and law enforcement approach is urgently needed.”¹⁴³

261. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying opioid-addicted individuals early and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.¹⁴⁴

262. These community-based problems require community-based solutions that “budgetary constraints at the state and Federal levels” have limited.¹⁴⁵

263. Having profited enormously through the aggressive sale, misleading promotion and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff’s Community.

**H. STATUTES OF LIMITATIONS ARE TOLLED AND
DEFENDANTS ARE ESTOPPED FROM ASSERTING
STATUTES OF LIMITATIONS AS DEFENSES.**

¹⁴³ See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 *Morbidity & Mortality Wkly. Rep.* 1378 (2016), at 1145.

¹⁴⁴ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al. eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

¹⁴⁵ See Office of Nat’l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America’s Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

1. Continuing Conduct.

264. Plaintiff contends it continues to suffer harm from Defendants' unlawful actions.

265. Defendants' continued tortious and unlawful conduct causes a repeated or continuous injury. The damages have not occurred all at once, but have continued to occur and increase as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. Defendants' wrongdoing and unlawful activity have not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel.

266. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and continuing to generate profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff and Plaintiff's Community, that they are working to curb the opioid epidemic.

267. For example, a Cardinal Health executive claimed that it uses “advanced analytics” to monitor its supply chain and assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”¹⁴⁶

268. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”¹⁴⁷

269. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:¹⁴⁸

- a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”

¹⁴⁶ Bernstein *et al.*, *supra*.

¹⁴⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

¹⁴⁸ Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

- b. “DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”
- c. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.”
- d. “A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy.”
- e. “Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash.”

Through the above statements made on their behalf by their trade associations and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

270. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities.

271. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented “pseudoaddiction” and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks and promoting sales. The Manufacturer Defendants’ campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff’s Community deceived the medical community, consumers, the State and Plaintiff’s Community.

272. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff’s Community. Plaintiff and Plaintiff’s Community did not know and did not have the means to know the truth, due to Defendants’ actions and omissions.

273. The Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

3. Fraudulent Concealment.

274. The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants' knowing and fraudulent concealment of the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, had material information pertinent to their discovery, and concealed them from the Plaintiff and Plaintiff's Community. The Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its causes of action, as a result of Defendants' conduct.

275. The purposes of the statutes of limitations periods are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

276. In light of their statements to the media, in legal filings and in settlements, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

277. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, the Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

LEGAL CAUSES OF ACTION

**COUNT I
PUBLIC NUISANCE
(Against All Defendants)**

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

279. Plaintiff alleges that Defendants wrongful and illegal actions have created a public nuisance.

280. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of and/or a substantial factor leading to Plaintiff's injury. *See* Restatement Second, Torts § 821B.

281. Defendants have created a public nuisance under State law.

282. Plaintiff has standing to bring claims for nuisance due to the opioid epidemic affecting and causing harm in Plaintiff's Community.

283. By causing dangerously addictive drugs to flood the community and be diverted for illicit purposes, in contravention of federal and State law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the people of the Plaintiff's Community to public health, public safety, public peace, public comfort and public convenience. The public nuisance caused by the diversion of dangerous drugs has caused substantial annoyance, inconvenience and injury to the public.

284. Each Manufacturing Defendant unreasonably and substantially interfered with the public health, safety, peace, comfort and convenience of the Plaintiff's Community by, inter alia, promoting and marketing the use of opioids in a misleading and fraudulent manner, and circulating false and misleading information concerning their safety and efficacy and/or minimizing or omitting the risk of addiction from their use.

285. By distributing and selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific or industrial purpose, Defendants have committed a course of conduct that injuriously affects the safety, health and morals of the people of the Plaintiff's Community.

286. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes, Defendants injuriously affected

public rights, including the right to public health, public safety, public peace and public comfort of the people of the Plaintiff's Community.

287. Plaintiff alleges that Defendants' wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public.

288. The Defendants have intentionally and/or unlawfully created an absolute nuisance.

289. The residents of Plaintiff's Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

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

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

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

293. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort, convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

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

295. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

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

297. Statute and regulation proscribe Defendants' distribution of opioids while failing to maintain effective controls against diversion.

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

299. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

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

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

302. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Plaintiff's Community. Defendants are in the business of manufacturing, marketing, selling and distributing prescription drugs, including opioids, which Defendants specifically know to be dangerous under federal and state law. *See e.g.*, 21 U.S.C. § 812 (b)(2).

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

304. It is, or should be, reasonably foreseeable to Defendants that their conduct will cause deaths and injuries to residents in Plaintiff's Community and will otherwise significantly and unreasonably interfere with public health, safety and welfare and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

305. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Plaintiff's

Community not only causes deaths and injuries, but also creates a palpable climate of fear among residents in Plaintiff's Community where opioid diversion, abuse and addiction are prevalent and where diverted opioids tend to be used frequently.

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

307. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, but for Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse and addiction that now exists would have been averted.

308. The presence of diverted prescription opioids in Plaintiff's Community and the consequence of prescription opioids having been diverted in Plaintiff's Community proximately results in and/or substantially contributes to the creation of significant costs to the Plaintiff and to Plaintiff's Community in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

309. Stemming the flow of illegally distributed prescription opioids and abating the nuisance caused by the illegal flow of opioids will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Community a safer place to live.

310. Defendants' conduct is a direct and proximate cause of and/or a substantial contributing factor to opioid addiction and abuse in Plaintiff's Community and costs borne by Plaintiff's Community and the Plaintiff, as well as a significant and unreasonable interference with public health, safety and welfare and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

311. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of Plaintiff's Community, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

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

orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

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

314. Defendants' actions also created a qualified nuisance. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

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

316. The damages available to the Plaintiff include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance that the government seeks to abate. Defendants' conduct is ongoing and persistent, and

the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

317. As a direct result of Defendants' conduct, the Plaintiff and Plaintiff's Community have suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. The Plaintiff here seeks recovery for its own harm.

318. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because their damages include, *inter alia*, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

319. The Plaintiff further seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing and persistent actions and omissions and interference with a right common to the public.

320. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages and punitive damages from the Defendants for the creation of a public nuisance, attorneys' fees and costs, and pre- and post-judgment interest.

321. Defendants' intentional and unlawful actions and omissions, as well as their unreasonable interference with a right common to the public are of a continuing nature.

322. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the Plaintiff's Community. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because, *inter alia*, federal and state law define these drugs as substances posing a high potential for abuse and severe addiction. Defendants created an absolute and/or intentional nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

323. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties and the Manufacturer Defendants' fraudulent marketing activities have caused harm to the entire community that includes, but is not limited to, the following:

- a. The high rates of use have led and continue to lead to unnecessary opioid abuse, addiction, overdose, injuries and deaths.
- b. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- c. Even those residents of Plaintiff's Community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids and the loss of companionship, wages or other support from family members who have used, abused, become addicted to, overdosed on or been killed by opioids.
- d. The opioid epidemic has increased health care costs.
- e. Employers have lost the value of productive and healthy employees.
- f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse and injury.

- g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.
- h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.
- i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement and financial resources of the Plaintiff's Community.
- j. Defendants' interference with the comfortable enjoyment of life in the Plaintiff's Community is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm Defendants' actions inflicted.

324. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because their damages include, *inter alia*, health services and law enforcement expenditures, as described in this Complaint.

325. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations.

326. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT II
RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1961, *et seq.*
(Against All Defendants)

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

328. Plaintiff brings this Count against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

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

330. Section 1962(c) of RICO makes it unlawful “for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity or collection of unlawful debt.” 18 U.S.C. § 1962(c); *United States v. Turkette*, 452 U.S. 576, 580 (1981).

331. The term “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009). The definition of “enterprise” in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section “describes two separate categories of associations that come within the purview of an ‘enterprise’ -- the first encompassing organizations such as corporations, partnerships, and other ‘legal entities,’ and the second covering ‘any union or group of individuals associated in

fact although not a legal entity.” *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id.*

332. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As “registrants,” the RICO Defendants operated and continue to operate within the “closed system” created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the “CSA”). The CSA restricts the RICO Defendants’ ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

333. Congress specifically intended the closed system created by the CSA, including the establishment of quotas, to reduce or eliminate the diversion of Schedule II substances like opioids from “legitimate channels of trade” to the illicit

market by controlling “the quantities of the basic ingredients needed for the manufacture of [controlled substances].”¹⁴⁹

334. Finding it impossible to legally achieve their ever-increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders and to notify the DEA of suspicious orders.¹⁵⁰ As discussed in detail below, through the RICO Defendants’ scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers, which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.

¹⁵¹ In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market, which allowed them to generate obscene profits.

335. An association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants hatched Defendants’ illegal scheme, and each of them executed it in perfect harmony. In particular, each of the RICO Defendants were associated with and conducted or participated in the affairs of the RICO

¹⁴⁹ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

¹⁵⁰ 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

¹⁵¹ 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

enterprise (defined below and referred to collectively as the “Opioid Diversion Enterprise”), the purpose of which was to engage in the unlawful sales of opioids, while deceiving the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants’ scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits and market share. As a direct result of the RICO Defendants’ fraudulent scheme, course of conduct and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like the Plaintiff experienced multi-millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants’ misconduct violated Section 1962(c), and 18 U.S.C. § 1964(c) entitles Plaintiff to treble damages for its injuries.

336. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance

(the “HDA”)¹⁵² is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an “enterprise” within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

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

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

339. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and

¹⁵² Health Distribution Alliance, History, Health Distribution Alliance, (last visited on September 15, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

subsequent paragraphs are pleaded in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

A. THE OPIOID DIVERSION ENTERPRISE

340. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.¹⁵³ The CSA and its implementing regulations created a closed system of distribution for all controlled substances and listed chemicals.¹⁵⁴ Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.¹⁵⁵ As reflected in comments from United States Senators during deliberation on the CSA, the “[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls.”¹⁵⁶ Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into

¹⁵³ Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

¹⁵⁴ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

¹⁵⁵ *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20); 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

¹⁵⁶ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).

the illegal market.”¹⁵⁷ Moreover, Congress specifically designed the closed system to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.¹⁵⁸ All registrants – manufacturers and distributors alike – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.¹⁵⁹ When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.¹⁶⁰ The result is the scourge of addiction that has occurred.

341. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and inform the DEA of any suspicious orders.¹⁶¹ The

¹⁵⁷ See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

¹⁵⁸ See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at <https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf>).

¹⁵⁹ *Id.*

¹⁶⁰ Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

¹⁶¹ Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).

DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to “know their customers.”¹⁶²

342. Central to the closed system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances] and requiring order forms for all transfers of these drugs.”¹⁶³ When evaluating production quotas, the DEA was instructed to consider the following information:

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

¹⁶² Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.dea/diversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf).

¹⁶³ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.¹⁶⁴

343. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA or (2) in excess of a quota assigned to it by the DEA.¹⁶⁵

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

¹⁶⁴ See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

¹⁶⁵ *Id.* (citing 21 U.S.C. 842(b)).

345. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone and oxycodone increased 13-fold, 4-fold and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.¹⁶⁶ On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.¹⁶⁷

346. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. However, it was not until recently that federal and state regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

347. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) was characterized by interpersonal

¹⁶⁶ Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. *Am J Public Health*. 2014;104(2):e52-9.

¹⁶⁷ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>.

relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and requests that the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

348. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations¹⁶⁸ The HDA and other members of the Pain Care Forum contributed

¹⁶⁸ See *HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, <https://www.washingtonpost.com/investigations/the-dea->

substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Upon information and belief, the Pain Care Forum and its members and the HDA devoted millions of dollars to its lobbying efforts in this jurisdiction between 2011 and 2016.

349. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids and the identification, investigation and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. However, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production

slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

350. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across state lines, such as manufacture, sale, distribution and shipment of prescription opioids throughout the country and Plaintiff's Community and the corresponding payment and/or receipt of money from the sale of the same.

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

352. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in and are members of the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and

roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements and financial statements.

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

354. The Pain Care Forum (“PCF”) is a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when reporters discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

355. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”¹⁶⁹ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.¹⁷⁰

356. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant

¹⁶⁹ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

¹⁷⁰ *Id.*

in the PCF.¹⁷¹ In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis (*i.e.*, Allergan) and Teva (the parent company of Cephalon).¹⁷² Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. However, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.¹⁷³ Upon information and belief, the Distributor Defendants participated directly in the PCF as well.

357. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. Additionally, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

¹⁷¹ PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>.

¹⁷² *Id.* Upon information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.

¹⁷³ *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/executive-committee>.

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

359. Second, the HDA – or Healthcare Distribution Alliance – led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt and Cephalon, were members of the HDA.¹⁷⁴ Additionally, the HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

360. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s

¹⁷⁴ Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/membership/manufacturer>.

members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners” and “make connections.”¹⁷⁵ Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

361. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants.¹⁷⁶ A “senior company executive” must sign the manufacturer membership application, and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year-end net sales through any HDA distributors, including, but not limited to, Defendants AmerisourceBergen, Cardinal Health and McKesson.¹⁷⁷

¹⁷⁵ Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en>.

¹⁷⁶ Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en>.

¹⁷⁷ *Id.*

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

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”¹⁷⁸
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributors and manufacturer members.¹⁷⁹
- c. Health, Beauty and Wellness Committee: “This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply

¹⁷⁸ Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/councils-and-committees>.

¹⁷⁹ *Id.*

chain.” Participation in this committee includes distributor and manufacturer members.¹⁸⁰

d. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributors and manufacturer members.¹⁸¹

e. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.¹⁸²

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

- f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁸³
- g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁸⁴
- h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁸⁵
- i. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation includes Distributor and Manufacturer Members.¹⁸⁶

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

364. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

advertise these conferences to the Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”¹⁸⁷ The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”¹⁸⁸ The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.¹⁸⁹

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

366. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.¹⁹⁰ As reported in the Washington Post, identified by Senator

¹⁸⁷ Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers>.

¹⁸⁸ *Id.*

¹⁸⁹ 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/events/2015-distribution-management-conference>.

¹⁹⁰ Lenny Bernstein & Scott Higham, The government’s struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), <https://www.washingtonpost.com/graphics/investigations/dea->

McCaskill and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.¹⁹¹ On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.¹⁹² The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

367. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Upon information and belief, the Manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in

mallinckrodt/?utm_term=b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letters From Sen. Claire McCaskill, (March 28, 2017), <https://www.mccaskill.senate.gov/opioid-investigation>; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), <http://www.purduepharma.com/payers/managed-markets/>.

¹⁹¹ *Id.*

¹⁹² Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/resources/webinar-leveraging-ed>.

exchange for agreements to maintain minimum sales performance thresholds. Upon information and belief, these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

368. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants were in communication and cooperation.

369. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum – the members of which include the Manufacturers and the Distributors’ trade association – has been lobbying on behalf of the Manufacturers and Distributors for “more than a decade.”¹⁹³

¹⁹³ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (accessed September 19, 2017), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>.

Additionally, from 2006 to 2016, the Distributors and Manufacturers worked together through the Pain Care Forum to spend over \$740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.¹⁹⁴ Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.¹⁹⁵

370. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Upon information and belief, the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

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

¹⁹⁴ *Id.*

¹⁹⁵ HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

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

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

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

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

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

377. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription

opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the “Ensuring Patient Access and Effective Drug Enforcement Act.”¹⁹⁶

378. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Upon information and belief, the Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. Additionally, upon information and belief, the Manufacturer Defendants used this high-level information to direct the Distributor Defendants’ sales efforts to regions where prescription opioids were selling in larger volumes.

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

¹⁹⁶ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had no Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->

380. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids.¹⁹⁷ On information and belief, the “know your customer” questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances they sold compared to controlled substances, whether the pharmacy buys from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

381. The RICO Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between

¹⁹⁷ Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.dea diversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

2008 and 2012¹⁹⁸ and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six (76) actions involving orders to show cause and forty-one (41) actions involving immediate suspension orders – all for failure to report suspicious orders.¹⁹⁹

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

383. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

384. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the

¹⁹⁸ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

¹⁹⁹ *Id.*

DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the PCF;
- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces and working groups;
- c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioid prescriptions filled by the Distributor Defendants;
- d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of

data showing how individual doctors across the nation were prescribing opioids.”²⁰⁰

- f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- g. The Manufacturer Defendants used the Distributor Defendants’ sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and
- j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have

²⁰⁰ Harriet Ryan, *et al.*, More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

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

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

C. PATTERN OF RACKETEERING ACTIVITY.

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

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

387. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §

1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

388. The RICO Defendants committed, conspired to commit and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Defendants’ regular use of the facilities, services, distribution channels and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the internet to transmit mailings and wires in interstate or foreign commerce.

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

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

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

- a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market and sell the prescription opioids by means of false pretenses, misrepresentations, promises and omissions.
- b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market and sell the

prescription opioids by means of false pretenses, misrepresentations, promises and omissions.

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

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas and procurement quotas;
- f. Defendants' records and reports that 21 U.S.C. § 827 required Defendants to submit to the DEA;
- g. Documents and communications related to the Defendant's mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;
- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- l. Payments to Defendants' lobbyists through the PCF;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

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

- a. Purdue manufactures multiple forms of prescription opioids, including, but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.
- b. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.
- c. Cephalon manufactures multiple forms of prescription opioids, including, but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.
- d. The Distributor Defendants shipped Teva's prescription opioids throughout this jurisdiction.
- e. Janssen manufactures a prescription opioid known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.
- f. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.
- g. Endo manufactures multiple forms of prescription opioids, including, but not limited to: Opana/Opana ER, Percodan, Percocet

and Zydene. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in the State.

- h. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.
- i. Actavis manufactures multiple forms of prescription opioids, including, but not limited to: Kadian and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.
- j. The Distributor Defendants shipped Actavis' prescription opioids throughout this jurisdiction.
- k. Mallinckrodt manufactures multiple forms of prescription opioids, including, but not limited to: Exalgo and Roxicodone.
- l. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

394. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and

report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

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

396. Upon information and belief, the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales and to transmit payments and rebates / chargebacks.

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

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

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

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

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

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

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

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

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

405. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenue from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results,

participants, victims and methods of commission. The predicate acts were related and not isolated events.

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

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

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

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

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

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

412. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would

harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

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

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

414. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(1)(D) by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

415. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

416. Each of the RICO Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

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

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

419. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form 8-K announcing a settlement with the

DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.²⁰¹

420. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as they relate to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles, yet failed to alert the DEA.²⁰² The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."²⁰³ Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1

²⁰¹ McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017), <http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/>.

²⁰² Harriet Ryan, *et al.*, More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

²⁰³ *Id.*

million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals.”²⁰⁴

421. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt, arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.²⁰⁵ After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt’s response was that everyone knew what was going on in Florida, but they had no duty to report it.²⁰⁶

422. Upon information and belief, the foregoing examples reflect the RICO Defendants’ pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. The sheer volume of enforcement actions available in the public record against the Distributor Defendants supports this conclusion.²⁰⁷ For example:

²⁰⁴ *Id.*

²⁰⁵ Lenny Bernstein & Scott Higham, The government’s struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

²⁰⁶ *Id.*

²⁰⁷ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, *The Drug Enforcement Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro

Facility”) for failure to maintain effective controls against diversion of hydrocodone;

- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA, which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;”
- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough,

Georgia (“McDonough Facility”); Valencia, California (“Valencia Facility”); and Denver, Colorado (“Denver Facility”);

- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility; and
- j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.

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

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

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

426. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission and had similar results affecting similar victims, including Plaintiff's Community and the Plaintiff. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids,

without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

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

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

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

D. DAMAGES

430. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

431. Defendants' racketeering activities proximately caused Plaintiff's injuries. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

432. The RICO Defendants' racketeering activities directly caused Plaintiff's injuries.

433. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

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

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

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

436. Plaintiff brings this claim on its own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in

the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d), it is unlawful for “any person to conspire to violate” Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

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

A. THE OPIOID DIVERSION ENTERPRISE.

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

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.

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

C. PATTERN OF RACKETEERING ACTIVITY.

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

D. DAMAGES.

441. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

442. The RICO Defendants' racketeering activities proximately caused Plaintiff's injuries and those of her citizens. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

443. The RICO Defendants' racketeering activities directly caused Plaintiff's injuries and those of her citizens.

444. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

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

COUNT IV
NEGLIGENCE AND NEGLIGENT MISREPRESENTATION
(Against All Defendants)

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

447. Plaintiff seeks economic damages that were the foreseeable result of Defendants' intentional and/or unlawful actions and omissions.

448. Under State law, to establish actionable negligence, one must show, in addition to the existence of a duty, a breach of that duty and injury resulting proximately therefrom and/or that was substantially caused thereby. All such essential elements exist here.

449. Each Defendant owed a duty to the Plaintiff and to the public health and safety in the Plaintiff's Community because the injury was foreseeable and, in fact, foreseen by the Defendants. If a course of action creates a foreseeable risk of injury, the individual engaged in that course of action has a duty to protect others from such injury. Each Defendant owed a duty to the Plaintiff and to the public in the Plaintiff's Community, because the injury was foreseeable and, in fact, foreseen by the Defendants.

450. Further, as Section 302B of the Restatement of Torts provides: "An act or an omission may be negligent if the actor realizes or should realize that it involves an unreasonable risk of harm to another through the conduct of the other

or a third person which is intended to cause harm, even though such conduct is criminal.”

451. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, selling and distributing highly dangerous opioid drugs to the State and Plaintiff’s Community.

452. Each Defendant had an obligation to exercise due care in manufacturing, marketing, selling and distributing highly dangerous opioid drugs in the State and Plaintiff’s Community.

453. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and impose significant costs upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

454. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek

increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

455. Moreover, law enforcement repeatedly warned Defendants of the unlawfulness and consequences of their actions and omissions.

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

457. As described above in allegations expressly incorporated herein, Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

458. As described elsewhere in the Complaint in allegations expressly incorporated herein, Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiff's Community and destinations from which

they knew opioids were likely to be diverted into Plaintiff's Community, in addition to other misrepresentations alleged and incorporated herein.

459. As described elsewhere in the Complaint in allegations expressly incorporated herein, Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable.

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

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

462. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive and/or fraudulent.

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

464. As described above in allegations expressly incorporated herein, Defendants' breaches of duty and misrepresentations caused, bear a causal connection with and/or proximately resulted in the damages sought herein.

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

466. The Defendants failed to disclose the material facts that, *inter alia*, they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell opioids.

467. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed and sold had characteristics, uses or benefits that they do not have. The Manufacturer Defendants also wrongfully misrepresented that the opioids were

safe and effective when the Manufacturer Defendants knew, or should have known, such representations were untrue, false and misleading.

468. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value and in fact caused addiction and overdose deaths.

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

470. Defendants' unlawful and/or intentional actions create a rebuttable presumption of negligence under State law.

471. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' actions and omissions.

472. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT V
NEGLIGENCE PER SE
(Against All Defendants)

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

474. The statutes cited herein are public safety laws. Each Defendant had a duty under, *inter alia*, these laws maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids.

475. Defendants' actions and omissions in violation of the law constitute negligence per se.

476. Defendants' actions and omissions were intentional and/or unlawful, and Defendants acted with actual malice.

477. It was foreseeable that the breach of duty described herein would result in the economic damages for which Plaintiff seeks recovery.

478. As described above in language expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes requiring that as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

479. As described above in language expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, and proximately resulted in, harm and damages sought by the Plaintiff.

480. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence per se. Plaintiff does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

481. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT VI
CIVIL CONSPIRACY
(Against All Defendants)

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

483. As set forth herein, Defendants engaged in a civil conspiracy to create a public nuisance in conjunction with their unlawful marketing, sale, distribution and/or diversion of opioids into the State and Plaintiff's Community.

484. As set forth herein, Defendants engaged in a civil conspiracy to commit negligent acts, fraudulent acts and omissions, and misrepresentations in conjunction with their unlawful distribution and diversion of opioids into the State and Plaintiff's Community.

485. As set forth herein, Defendants engaged in a civil conspiracy to unlawfully divert opioids and create opioid dependence and abuse in the State and Plaintiff's Community.

486. Distributor and Manufacturer Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report and prevent suspicious orders of opioids.

487. The Manufacturer Defendants further unlawfully marketed opioids in the State and Plaintiff's Community in furtherance of that conspiracy.

488. Defendants acted tortiously in concert with each other and/or in pursuit of a common design, and/or Defendants knew each other's conduct constituted a breach of their legal duties and provided substantial assistance and/or encouragement in the conduct.

489. Defendants' conspiracy is a continuing conspiracy, and the overt acts performed in compliance with the conspiracy's objective(s) are ongoing and/or have occurred within the last year.

490. Plaintiff alleges Defendants' conspiracy and acts in furtherance in greater detail earlier in the Complaint, including, without limitation, in Plaintiff's racketeering allegations. Such allegations are incorporated herein.

491. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the injuries alleged herein.

492. Defendants acted with malice, purposely, intentionally, unlawfully and without a reasonable or lawful excuse.

493. Defendants' conspiracy and Defendants' actions and omissions in furtherance thereof proximately caused and/or substantially contributed to the direct and foreseeable losses alleged herein.

494. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' civil conspiracy.

495. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VII
FRAUD AND FRAUDULENT MISREPRESENTATION
Florida Statutes § 817.41 and Common Law
(Against All Defendants)

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

497. Defendants violated their general duty not to actively deceive, have made knowingly false statements and have omitted and/or concealed information that made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

498. Florida Statutes § 817.41 provides that it is “unlawful for any person to make or disseminate or cause to be made or disseminated before the general public of the state, or any portion thereof, any misleading advertisement. Such making or dissemination of misleading advertising shall constitute and is hereby declared to be fraudulent and unlawful, designed and intended for obtaining money or property under false pretenses.”

499. As alleged herein, Defendants made false statements as to their compliance with state and federal law regarding their duties to prevent diversion and their duties to monitor, report and halt suspicious orders and/or concealed their noncompliance with these requirements.

500. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic, non-cancer pain.

501. As alleged herein, Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading Plaintiff, Plaintiff's Community, the public and persons on whom Plaintiff relied.

502. These false representations and concealments were reasonably calculated to deceive Plaintiff, Plaintiff's Community and the physicians who prescribed opioids for persons in Plaintiff's Community; were made with the intent to deceive; and did in fact deceive these persons, Plaintiff and Plaintiff's Community.

503. Plaintiff, Plaintiff's Community and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

504. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. This reliance proximately caused Plaintiff's injuries.

505. Defendants' fraudulent conduct was a direct and proximate cause of the injuries Plaintiff alleges herein.

506. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment.

507. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VIII
UNJUST ENRICHMENT
(Against All Defendants)

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

509. Under the doctrine of unjust enrichment, a party who receives a benefit must return the benefit if retention would be inequitable. Unjust enrichment is established where: (a) the plaintiff conferred a benefit upon the defendant; (b) the

defendant has knowledge of the benefit; (c) the defendant accepted or retained the benefit conferred; and (d) the circumstances are such that it would be inequitable for the defendant to retain the benefit without paying the plaintiff for its fair value.

510. Plaintiff conferred a benefit on each Manufacturer Defendant. By paying for law enforcement, treatment, and emergency services, Plaintiff has assumed the financial burden of paying for services and goods that allow defendants to continue their scheme, including treatment and emergency services, which benefit was known to and accepted by each Manufacturing Defendant, which inured to the profits of each Manufacturing Defendant, and for which retention of such benefit is inequitable based on the Manufacturing Defendants' false and misleading marketing and omissions of and failure to state material facts in connection with marketing opioids, and by failing to prevent diversion by reporting and preventing suspicious orders of opioids in violation of their legal duties, as set forth herein. The Manufacturing Defendants have thus been unjustly enriched by deceptive marketing, contributing to Plaintiff's current opioid epidemic.

511. Plaintiff conferred a benefit on each Distributor Defendant. By paying for law enforcement, treatment, and emergency services, Plaintiff has assumed the financial burden of paying for services and goods that allow defendants to continue their scheme, including treatment and emergency services, which benefit was

known to and accepted by each Distributor Defendant, which inured to the profits of each Distributor Defendant, and for which retention of such benefit is inequitable based on the Distributor Defendants' intentional and unlawful actions and omissions, as set forth herein. The Distributor Defendants have thus been unjustly enriched by neglecting their duty to distribute prescription opioids only for proper medical purposes, and by failing to prevent diversion by reporting and preventing suspicious orders of opioids in violation of their legal duties, contributing to Plaintiff's current opioid epidemic.

512. Plaintiff's opioid addiction and overdose epidemic has cost it millions of dollars including *inter alia*: (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; and (5) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation.

513. The unjust enrichment of the Manufacturer and Distributor Defendants is directly related to the damage, loss, and detriment to Plaintiff caused by Defendants' false marketing and failure to report and/or prevent suspicious sales.

It would be inequitable under these circumstances for the Defendants to retain this benefit without compensating Plaintiff for its value. Plaintiff seeks recovery of the amounts by which the Defendants were enriched as a result of their inequitable conduct.

PUNITIVE DAMAGES

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

515. By engaging in the above-described intentional and/or unlawful acts or practices, Defendants acted with actual malice, wantonly and oppressively. Defendants acted with conscious disregard for the rights of others and/or in a reckless, wanton, willful or grossly negligent manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Defendants acted toward the Plaintiff with fraud, oppression and/or malice and/or were grossly negligent in failing to perform the duties and obligations imposed upon them under applicable federal and state statutes and common law.

516. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger

if prescribed incorrectly or diverted to other than legitimate medical, scientific or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the State and Plaintiff's Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence and the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrence.

517. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and gross negligence and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

RELIEF

WHEREFORE, the Plaintiff respectfully prays that this Court grant the following relief:

518. Enter a Judgment in favor of the Plaintiff in a final order against each of the Defendants;

519. Enjoin the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries and all other persons acting in concert or participation with

them from engaging in unfair or deceptive practices in violation of law and ordering temporary, preliminary or permanent injunction;

520. Order that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

521. Order Defendants to fund an “abatement fund” for the purposes of abating the opioid nuisance;

522. Award actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorneys’ fees and all costs and expenses of suit pursuant to Plaintiff’s racketeering claims;

523. Award damages, costs, and fees pursuant to Plaintiff’s deceptive trade practices claims;

524. Award the Plaintiff the damages caused by the opioid epidemic, including (A) costs for providing medical care, additional therapeutic and prescription drug purchase, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services; (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (E) costs associated with law enforcement and public safety relating to the opioid epidemic.

525. Enter a judgment against the Defendants requiring Defendants to pay punitive damages;

526. Grant the Plaintiff

- a. The costs of investigation, reasonable attorneys' fees, and all other costs and expenses;
- b. Pre-judgment and post-judgment interest; and
- c. All other relief as provided by law and/or as the Court deems appropriate and just.

Dated: April 4, 2018 Respectfully Submitted,

/s/ Peter J. Mougey

Peter J. Mougey
Archie C. Lamb, Jr.
**LEVIN, PAPANTONIO, THOMAS, MITCHELL,
RAFFERTY & PROCTOR, P.A.**
316 S. Baylen Street, Suite 600
Pensacola, FL 32502-5996
Tel.: 850-435-7068
Fax: 850-436-6068
pmougey@levinlaw.com

M. Stephen Dampier (*pro hac vice* pending)
THE DAMPIER LAW FIRM, P.C.
55 N. Section Street
P.O. Box 161 (36533)
Fairhope, AL 36532
Tel.: 251-929-0900
Fax: 251-929-0800
stevedampier@dampierlaw.com

Clifford C. Higby
Kevin David Barr
BRYANT & HIGBY, CHTD.
833 Harrison Ave. (32401)
Post Office Drawer 860
Panama City, FL 32402-0860
Tel.: 850-763-1787
Fax: 850-785-1533
chigby@bryanthigby.com
kbarr@bryanthigby.com

EXHIBIT 8

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF GEORGIA
ALBANY DIVISION**

CITY OF ALBANY, GEORGIA,

Plaintiff,

v.

CASE NO.:

AMERISOURCEBERGEN DRUG
CORPORATION; CARDINAL HEALTH,
INC.; McKESSON CORPORATION;
PURDUE PHARMA L.P.; PURDUE
PHARMA, INC.; THE PURDUE FREDERICK
COMPANY, INC.; TEVA
PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; NORAMCO,
INC.; ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLS;
WATSON PHARMACEUTICALS, INC. n/k/a
ACTAVIS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS LLC;
ACTAVIS PHARMA, INC. f/k/a WATSON
PHARMA, INC.;
MALLINCKRODT PLC; MALLINCKRODT
LLC; INSYS THERAPEUTICS, INC.; CVS
HEALTH CORP.; THE KROGER CO.; RITE
AID OF MARYLAND, INC., WALGREENS
BOOTS ALLIANCE, INC.; WAL-MART,
INC. and J.M. SMITH CORP.

Defendants.

COMPLAINT

Complaint for Public Nuisance, Violations
of Racketeer Influenced and Corrupt
Organizations Act (RICO) 18 U.S.C. §
1961 *et seq.*, Violations of 18 U.S.C. §
1962 *et seq.*, Violations of Georgia RICO
Act, O.C.G.A. § 16-14-1 *et seq.*,
Negligence and Negligent
Misrepresentation, Negligence Per Se;
Fraud and Fraudulent Misrepresentation.

**JURY TRIAL DEMANDED AND
ENDORSED HEREON**

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Plaintiff, CITY OF ALBANY, GEORGIA, brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLC; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; Insys Therapeutics, Inc., McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Drug Corporation; CVS Health Corporation; The Kroger Co.; Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc.; Walgreens Boots Alliance, Inc. a/k/a Walgreen Co., and Wal-Mart Inc., f/k/a Wal-Mart Stores, Inc., and J.M. Smith Corporation a/k/a Smith Drug Company (collectively “Defendants”) and alleges as follows:

I. INTRODUCTION

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby and to recoup monies spent because of Defendants’ false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids.¹ Such economic damages were foreseeable to Defendants and were sustained because of Defendants’ intentional and/or unlawful actions and omissions.

¹ As used herein, the term “opioid” refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

2. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.²

3. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”³

4. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, which turned patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

5. Plaintiff also brings this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

II. PARTIES

A. Plaintiff.

6. Plaintiff CITY OF ALBANY, GEORGIA (“Albany” or “Plaintiff”) is a body corporate with the power to sue or be sued in any court. Albany, Georgia – Code of Ordinances, Part I, Subpart A, Sec. 1.

7. Plaintiff is responsible for the public health, safety and welfare of its citizens.

² See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

³ See Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

8. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity and mortality have created a serious public health and safety crisis and are a public nuisance and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

9. The distribution and diversion of opioids into Georgia (the “State”), and into the City and its surrounding areas (collectively, “Plaintiff’s Community”), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

10. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants’ conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; and (5) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. The Plaintiff has suffered and continues to suffer these damages directly.

11. Plaintiff also seeks the means to abate the epidemic Defendants’ wrongful and/or unlawful conduct has created.

12. Plaintiff has standing to bring an action for the opioid epidemic nuisance created by Defendants. O.C.G.A. § 36-1-3.

13. Plaintiff has standing to recover damages incurred as a result of Defendants’ actions and omissions. Plaintiff has standing to bring all claims pled herein, including, *inter alia*,

to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) (“persons” include entities which can hold legal title to property) and 18 U.S.C. § 1964 (“persons” have standing). Defendants.

B. Defendants.

1. Manufacturer Defendants.

14. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA, INC. is a New York corporation with its principal place of business in Stamford, Connecticut and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, “Purdue”).

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

17. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. (“Teva USA”) is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

18. Cephalon, Inc. manufactures, promotes, sells and distributes opioids, such as Actiq and Fentora, in the United States. The FDA has approved Actiq only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.”⁴ The FDA has approved Fentora only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”⁵ In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.⁶

19. Teva Ltd., Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products

⁴ *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.

⁵ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.

⁶ Press Release, U.S. Dep’t of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

to the public. Teva USA sells all former Cephalon-branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that Teva USA submitted the guide and directs physicians to contact Teva USA to report adverse events.

20. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.⁷ Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including, *inter alia*, sales of Fentora®.⁸ Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries, Cephalon and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; and Cephalon, Inc. are referred to as “Cephalon.”

21. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. (“Noramco”) is a Delaware company

⁷ *E.g.*, ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (last visited Aug. 21, 2017).

⁸ Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco and J&J are referred to as "Janssen."

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

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

24. Endo develops, markets and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet and Zydane, in the United States. Opioids made up

roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013 and accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, such as oxycodone, oxymorphone, hydromorphone and hydrocodone products, in the United States, by itself and through its subsidiary, QUALITEST PHARMACEUTICALS, INC.

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

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

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

28. Mallinckrodt manufactures, markets and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.⁹

29. INSYS THERAPEUTICS, INC. is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys’s principal product and source of revenue is Subsys.

30. Insys made thousands of payments to physicians nationwide, including in the State, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

⁹ Press Release, U.S. Dep’t of Justice, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations*, July 11, 2017, <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>, last visited October 26, 2017.

31. Subsys is a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under the tongue administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain.

32. In 2016, Insys made approximately \$330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United States, the City, and Plaintiff's Community.

33. Insys's founder and owner 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.

2. Distributor Defendants.

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

35. McKESSON CORPORATION ("McKesson") at all relevant times operated as a licensed pharmacy wholesaler in Georgia. McKesson is a Delaware corporation. McKesson has its principal place of business located in San Francisco, California. McKesson operates distribution centers in Georgia, including in Duluth, Georgia.

36. CARDINAL HEALTH, INC. (“Cardinal”) at all relevant times operated as a licensed pharmacy wholesaler in Georgia. Cardinal’s principal office located in Dublin, Ohio. Cardinal operates distribution centers in Georgia.

37. AMERISOURCEBERGEN DRUG CORPORATION (“AmerisourceBergen”) at all relevant times operated as a licensed pharmacy wholesaler in Georgia. AmerisourceBergen’s principal place of business is located in Chesterbrook, Pennsylvania. AmerisourceBergen operates distribution centers in Georgia, including in Buford, Georgia.

38. Defendant CVS HEALTH CORPORATION is a Delaware corporation with its principal place of business in Rhode Island. CVS Health Corporation conducts business as a licensed wholesale distributor under the following named business entities: CVS Indiana, L.L.C.; CVS Orlando FL Distribution; CVS Pharmacy, Inc.; CVS RX Services, Inc, d/b/a CVS Pharmacy Distribution Center; CVS TN Distribution, LLC ; and CVS VERO FL Distribution, L.L.C (collectively “CVS”). At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in the State and the City and Plaintiff’s Community specifically. At all relevant times, this Defendant operated as a licensed wholesale distributor in Georgia, licensed by the Georgia Board of Pharmacy.

39. Defendant THE KROGER CO. is an Ohio corporation with headquarters in Cincinnati, OH. Kroger operates 2,268 pharmacies in the United States, including in the State. The Kroger Co. conducts business as a licensed wholesale distributor under the following named business entities: Kroger Limited Partnership I and Kroger Limited Partnership II (collectively “Kroger”). At all times relevant to this Complaint, Kroger distributed and dispensed prescription opioids throughout the United States, including in the State and the City and Plaintiff’s Community specifically.

40. Defendant Rite Aid of Maryland, Inc., dba Rite Aid Mid-Atlantic Customer Support Center, Inc. (“Rite Aid”), is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid distributed prescription opioids throughout the United States, including in the State, the City and Plaintiff’s Community specifically. Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. (collectively “Rite Aid”) conducts business as a licensed wholesale distributor under the name Rite Aid Mid-Atlantic Customer Support Center, Inc. At all relevant times through June 30, 2017, this Defendant operated as a licensed wholesale distributor in Georgia, licensed by the Georgia Board of Pharmacy.

41. Defendant WALGREENS BOOTS ALLIANCE, INC., also known as Walgreen Co. (“Walgreens”) is a Delaware corporation with its principal place of business in Illinois. Walgreens Boots Alliance Inc. conducts business as a licensed wholesale distributor under the following named business entities: Walgreen Co.; Walgreen Eastern Co., Inc.; Walgreen Arizona Drug Co. (collectively “Walgreens”). At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in the State, the City and Plaintiff’s Community specifically. At all relevant times, this Defendant operated as a licensed wholesale distributor in Georgia, licensed by the Georgia Board of Pharmacy.

42. Defendant WAL-MART INC., formerly known as Wal-Mart Stores, Inc. (“Wal-Mart”), is a Delaware corporation with its principal place of business in Arkansas. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including in the State, the City and Plaintiff’s Community specifically. Wal-Mart Stores, Inc. conducts business as a licensed wholesale distributor under the following named business entities: Wal-Mart Warehouse #28; Wal-Mart Warehouse #6045 aka Wal-Mart Warehouse #45;

Wal-Mart Warehouse # 6046 aka Wal-Mart Warehouse #46; and Wal-Mart Pharmacy Warehouse #13 (“collectively “Wal-Mart”). At all relevant times, this Defendant operated a licensed wholesale distributor in Georgia, licensed by the Georgia Board of Pharmacy.

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

44. Collectively, Defendants CVS, Kroger, Rite Aid, Walgreens, Wal-Mart and J.M. Smith are referred to as “National Retail Pharmacies.” Cardinal, McKesson, AmerisourceBergen, and the National Retail Pharmacies are collectively referred to as the “Distributor Defendants.”

45. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution sale and/or dispensing of opioids.

III. JURISDICTION & VENUE

46. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* (“RICO”). This Court has supplemental jurisdiction over Plaintiff’s state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff’s federal claims that they form part of the same case or controversy.

47. This Court also has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a) because the Plaintiff is a “citizen” of this State, the named Defendants are citizens of different states and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

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

49. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher’s Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

50. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claims stated herein occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claims for relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. § 1965(a).

IV. FACTUAL BACKGROUND

A. THE OPIOID EPIDEMIC.

1. The National Opioid Epidemic.

51. Increasing abuse and diversion of prescription drugs, including opioid medications, have characterized the past two decades in the United States.¹⁰

52. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.¹¹

53. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention declared prescription painkiller overdoses to be at epidemic levels. The news release noted:

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- b. More than 40 people died every day in 2011 from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
- c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

¹⁰ See Richard C. Dart *et al*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

¹¹ Katherine M. Keyes, *et al.*, *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

f. Almost 5,500 people start to misuse prescription painkillers every day.¹²

54. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.¹³

55. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.¹⁴

56. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.¹⁵

57. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.¹⁶

¹² See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Prescription Painkiller Overdoses at Epidemic Levels* (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

¹³ See Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

¹⁴ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Provisional Counts of Drug Overdose Deaths*, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

¹⁵ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, <https://www.cdc.gov/vitalsigns/heroin/index.html> (last updated July 7, 2015).

¹⁶ See Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

58. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or abuse. The increased availability of heroin combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.¹⁷

59. The societal costs of prescription drug abuse are “huge.”¹⁸

60. Across the nation, local governments are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. As of March 2018, more than 115 Americans lose their lives per day after overdosing on opioids.¹⁹

61. The National Institute on Drug Abuse identifies misuse and addiction to opioids as “a serious national crisis that affects public health as well as social and economic welfare.”²⁰ The economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment and criminal justice expenditures.²¹

¹⁷ See Rose A. Rudd *et al.*, *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 *Morbidity & Mortality Wkly. Rep.* 1378 (2016).

¹⁸ See Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter, “Brief of HDMA”].

¹⁹ Opioid Overdose Crisis, NIH, National Institute on Drug Abuse (available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis>, last visited April 9, 2018) (“Opioid Crisis, NIH”) (citing at note 1 CDC/NCHS, National Vital Statistics System, Mortality. CDC Wonder, Atlanta, GA : US Department of Health and Human Services, CDC; 2017. <https://wonder.cdc.gov>).

²⁰ Opioid Crisis, NIH.

²¹ *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

62. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.²²

63. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.²³

64. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are “everywhere” and mistaken for candy.²⁴

65. In 2016, the President of the United States declared an opioid and heroin epidemic.²⁵

66. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.²⁶ Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

²² See Rose A. Rudd *et al.*, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 *Morbidity & Mortality Wkly. Rep.* 1445 (2016).

²³ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 *N. Eng. J. Med.* 1253 (2016).

²⁴ Julie Turkewitz, *‘The Pills are Everywhere’: How the Opioid Crisis Claims Its Youngest Victims*, *N.Y. Times*, Sept. 20, 2017 (“‘It’s a cancer,’ said [grandmother of dead one-year old], of the nation’s opioid problem, ‘with tendrils that are going everywhere.’”).

²⁵ See Proclamation No. 9499, 81 *Fed. Reg.* 65,173 (Sept. 16, 2016) (proclaiming “Prescription Opioid and Heroin Epidemic Awareness Week”).

²⁶ See Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 *Daily Comp. Pres. Doc.* 743 (Oct. 21, 2015), <https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf>.

67. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to cause the national, state and local opioid epidemic.

2. Georgia's Opioid Epidemic

68. The national opioid crisis has especially ravaged Georgia.

69. The opioid scourge has visited devastating harm upon this State. At the 2017 University of Georgia College of Public Health's "State of the Public's Health" conference, experts explained that the deepening opioid epidemic is hitting Georgia harder than most states, and that from 2009 to 2014, Georgia's rate of increase in the number of opioid-related patient encounters led the nation.²⁷

70. Georgia is among the top 11 states in terms of the most prescription opioid overdose deaths.²⁸ Almost as many Georgians die of drug overdoses as in car accidents.²⁹ Georgia suffered 1,394 overdose deaths in 2016,³⁰ 1,302 deaths in 2015,³¹ and 1,206 deaths in 2014.³²

71. Of the over 1,300 drug overdose deaths in 2015, 900 of them – or 68 percent – were due to opioid overdoses, including heroin.³³ Overdose deaths tripled in Georgia from 1999

²⁷ *Experts: Opioid crisis is hitting Georgia*, The Augusta Chronicle (Oct. 21, 2017), available at <http://chronicle.augusta.com/news/2017-10-21/experts-opioid-crisis-hitting-georgia>.

²⁸ Substance Abuse Research Alliance (SARA), Georgia Prevention Project, *Prescription Opioids and Heroin Epidemic in Georgia – a White Paper*, 2017, at 2, available at <http://www.senate.ga.gov/sro/Documents/StudyCommRpts/OpioidsAppendix.pdf> (last visited January 29, 2018).

²⁹ *Id.* at 5.

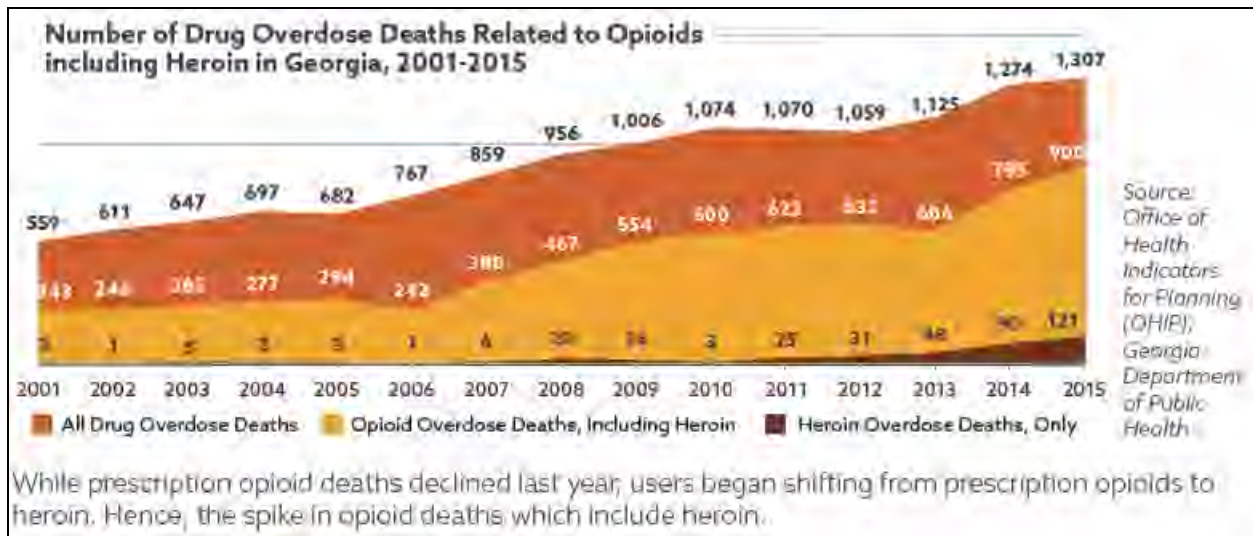
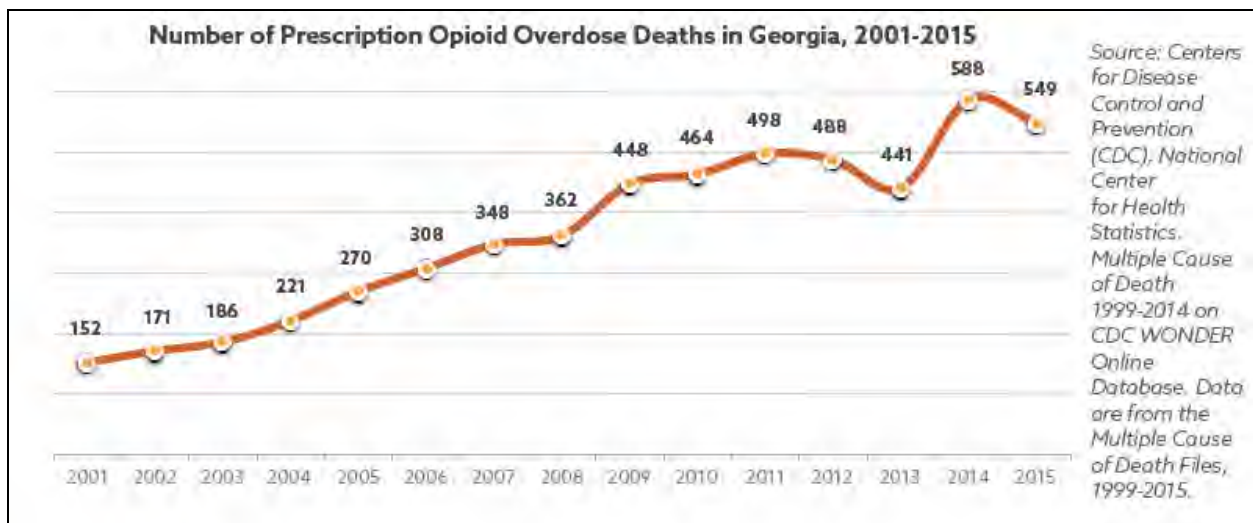
³⁰ CDC, Drug Overdose Death Data, available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> ("2016 Deaths" tab) (last visited January 19, 2018).

³¹ *Id.* at "2015 Deaths" tab, (last visited January 19, 2018).

³² *Id.* at "2014 Deaths" tab, (last visited January 19, 2018).

³³ Substance Abuse Research Alliance (SARA), *supra*, at 5.

to 2013. Prescription opioid overdose deaths grew tenfold between 1999 and 2014 to 549 deaths, or a rate of 5.5 deaths per 100,000 people.³⁴



72. According to the Centers for Disease Control and Prevention (“CDC”), Georgia was among the States to experience a statistically significant (10.2 percent) increase in drug overdose death rates in 2014 as compared to 2013:³⁵

³⁴ *Id.*

³⁵ See Substance Abuse Research Alliance (SARA), *supra*, at 14.

75. Georgia is also seeing an increase in cases of newborns with Neonatal Abstinence Syndrome (“NAS”), a collection of symptoms babies experience in withdrawing from opioid medications taken by the mother.⁴⁰ NAS is closely associated with opioid use.

76. Opioid addiction is part of the reason the number of children in Georgia state custody has almost doubled in the last three years.⁴¹

3. The Opioid Epidemic in Plaintiff’s Community.

77. The opioid epidemic is particularly devastating in Plaintiff’s Community.

78. In 2017, the coroner for Dougherty County, where Albany is located, saw seventeen deaths related to overdoses, up from five in 2015. Additionally, the County’s EMS director reported around 90 overdose cases in 2017, with 2018 predicted to see at least 95 cases.

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79. The opioid epidemic has placed increased budgetary constraints upon inter alia the public health and medical care expenditures of the State and Plaintiff’s Community. Opioid addiction is one of the primary reasons citizens of the State and Plaintiff’s Community seek substance abuse treatment.

80. Opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff’s Community, and constitute a temporary and continuing public nuisance, which remains unabated.

B. THE MANUFACTURER DEFENDANTS’ FALSE, DECEPTIVE AND UNFAIR MARKETING OF OPIOIDS.

81. The opioid epidemic did not happen by accident.

⁴⁰ Substance Abuse Research Alliance (SARA), *supra*, at 30.

⁴¹ WRDW, *News 12 Investigates: Children of Opioids*, Oct. 9, 2017, available at <http://www.wrdw.com/content/news/Children-of-Opioids-450115313.html> (last visited January 29, 2018).

⁴² WFXL, *Dougherty County coroner hosts opioid epidemic reenactment to educate students*, April 17, 2018, available at <https://wfxl.com/news/local/dougherty-county-coroner-hosts-opioid-epidemic-re-enactment-to-educate-students> (last visited September 21, 2018).

82. Before the 1990s, generally accepted standards of medical practice dictated that patients should only use opioids short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time, the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

83. Each Manufacturer Defendant has conducted and has continued to conduct a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent and continues to spend millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

84. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that doctors should treat the signs of addiction with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that it is easy to manage opioid dependence and withdrawal; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants also have falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to

improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

85. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups.

86. The Manufacturer Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009.⁴³ In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."⁴⁴ This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply) and a population of patients physically and psychologically dependent on them (the demand). When those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

87. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

⁴³ See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011, <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>; David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, Fin. Times, Aug. 10, 2016, <https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95>.

⁴⁴ Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), <http://turnthetidex.org/>.

1. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids.

88. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around the State, including in Plaintiff's Community. Defendants also deployed seemingly unbiased and independent third parties whom they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's Community.

89. The Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around the State, including in Plaintiff's Community, as they did nationwide. Across the pharmaceutical industry, corporate headquarters fund and oversee "core message" on a national basis. This comprehensive approach ensures that the Manufacturer Defendants accurately and consistently deliver their messages across marketing channels – including detailing visits, speaker events and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

90. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants required their sales representatives and physician speakers to stick to prescribed talking points, sales messages and slide decks, and supervisors rode along with them periodically to check on both their performance and compliance.

i. Direct Marketing.

91. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

92. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads called "Pain vignettes" for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

93. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of \$168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

94. The Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest

influence. Even without such studies, the Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

95. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."⁴⁵

ii. Indirect Marketing.

96. The Manufacturer Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

97. The Manufacturer Defendants deceptively marketed opioids in the State and Plaintiff's Community through unbranded advertising – *e.g.*, advertising that promotes opioid use generally but does not name a specific opioid. Independent third parties ostensibly created and disseminated this advertising. However, by funding, directing, reviewing, editing and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages these third parties disseminated and acted in concert with them to falsely and

⁴⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.

misleadingly promote opioids for the treatment of chronic pain. Much as the Manufacturer Defendants controlled the distribution of their “core messages” via their own detailers and speaker programs, they similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education (“CME”) programs, medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

98. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

99. The Manufacturer Defendants also identified doctors to serve, for payment, on their speakers’ bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information and failed to correct Defendants’ prior misrepresentations about the risks and benefits of opioids.

100. Borrowing a page from Big Tobacco’s playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging and directing doctors who served as KOLs, and (b) funding, assisting, directing and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly “neutral” guidance, such as treatment guidelines, CME programs, medical conferences, seminars and scientific articles. Thus, working individually and collectively and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue and that the compassionate treatment of pain required opioids.

101. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions included contributing to the creation of misleading publications and prescribing guidelines, which lack reliable scientific basis and promote prescribing practices that have worsened the opioid crisis.

102. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its

settlement with Purdue that the Purdue website “In the Face of Pain” failed to disclose that Purdue paid doctors who provided testimonials on the site and concluded that Purdue’s failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

103. Defendants utilized many KOLs, including many of the same ones.

104. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees and honoraria from Cephalon, Endo, Janssen and Purdue (among others) and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) / American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by the Manufacturer Defendants.

105. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that “the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of

substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”⁴⁶

106. Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”⁴⁷ Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”⁴⁸

107. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of American Academy of Pain Medicine (“AAPM”) in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly \$2 million from Cephalon).

108. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice’s Drug Enforcement Agency, which raided his clinic in 2010. Although the DEA closed the investigation without charges in 2014, more than 20 of Dr. Webster’s former patients at the Lifetree Clinic have died of opioid overdoses.

⁴⁶ Good Morning America (ABC television broadcast Aug. 30, 2010).

⁴⁷ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

⁴⁸ *Id.*

109. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on or are linked to websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

110. In 2011, Dr. Webster presented via webinar a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in the State and doctors treating members of Plaintiff's Community.⁴⁹

111. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that doctors should see addictive behaviors not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's

⁴⁹ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

first response.”⁵⁰ Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”⁵¹

112. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these “Front Groups” generated treatment guidelines, unbranded materials and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence and conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

113. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing and approving their content and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

114. Defendants Cephalon, Endo, Janssen and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American Geriatrics

⁵⁰ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

⁵¹ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>.

Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and Pain & Policy Studies Group (“PPSG”).⁵²

115. The most prominent of the Manufacturer Defendants’ Front Groups was the American Pain Foundation (“APF”), which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of the State and Plaintiff’s Community.

116. In 2009 and 2010, more than 80% of APF’s operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of a total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo and others to avoid using its line of credit.

⁵² See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015), <https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>.

117. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescriptions and thus the profitability of its sponsors. Upon information and belief, the Manufacturer Defendants often called upon it to provide “patient representatives” for the promotional activities, including for Purdue’s Partners Against Pain and Janssen’s Let’s Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in nonprofit organizations that share [its] business interests.”

118. Upon information and belief, on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

119. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF’s credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF’s board voted to dissolve the organization “due to irreparable economic circumstances.” APF “cease[d] to exist, effective immediately.”⁵³

⁵³ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies’ Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

120. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants’ deceptive marketing of chronic opioid therapy.

121. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM’s marquee event – its annual meeting held in Palm Springs, California or other resort locations. AAPM describes the annual event as an “exclusive venue” for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet 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.

122. Upon information and belief, Endo internally views AAPM as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM’s presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. The AAPM even elected Dr. Webster president while he was under a DEA investigation.

123. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

124. In 1996, AAPM and APS jointly issued a consensus statement, “The Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain and claimed that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011, and, upon information and belief, the AAPM only removed it from the website after a doctor complained.⁵⁴

125. AAPM and APS issued their own treatment guidelines in 2009 (“AAPM/APS Guidelines”) and continued to recommend the use of opioids to treat chronic pain.⁵⁵ Doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants, have relied upon treatment guidelines. Treatment guidelines not only directly inform doctors’ prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis and Purdue discussed treatment guidelines with doctors during individual sales visits.

126. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo and Purdue. The 2009 Guidelines promote opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.⁵⁶ One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and

⁵⁴ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

⁵⁵ Roger Chou *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 *J. Pain* 113 (2009).

⁵⁶ *Id.*

founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the State and/or Plaintiff's Community during the relevant time period, are still available online and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants' financial support to members of the panel.

127. The Manufacturer Defendants worked together through Front Groups to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF comprises representatives from opioid manufacturers (including Cephalon, Endo, Janssen and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

2. The Manufacturer Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

i. The Manufacturer Defendants embarked upon a campaign of false, deceptive and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

128. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC have conclusively debunked. These misrepresentations – described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted and because doctors could identify and manage those at greatest risk for addiction; (2) patients who displayed signs of addiction probably were not addicted, and, in any event, doctors could easily wean them from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations; they continue to make them today.

129. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use in the State and Plaintiff's Community and each continues to fail to correct its past misrepresentations.

130. Some illustrative examples of the Manufacturer Defendants' false, deceptive and unfair claims about the purportedly low risk of addiction include:

- a. Actavis's predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.⁵⁷
- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."
- e. Janssen reviewed, edited, approved and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."
- f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will

⁵⁷ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

become addicted and that pain is undertreated due to “[m]isconceptions about opioid addiction.”⁵⁸

- h. In 2010, Mallinckrodt sponsored an initiative “Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book “Defeat Chronic Pain Now!” aimed at chronic pain patients. The book, which is still available for sale in New Mexico and elsewhere, and is promoted online at www.defeatchronicpainnow.com, advises laypeople who are considering taking opioid drugs that “[o]nly rarely does opioid medication cause a true addiction.”⁵⁹ Further, the book advises that even the issue of tolerance is “overblown,” because “[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance.” In response to a hypothetical question from a chronic back pain patient who expresses a fear of becoming addicted, the book advises that “[i]t 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.”
- i. Consistent with the Manufacturer Defendants’ published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen and Cephalon in the State and Plaintiff’s Community minimized or omitted any discussion with doctors of the risk of addiction, misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations and routinely did not correct the misrepresentations noted above.
- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NPF argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that “patients rarely become addicted to prescribed opioids,” citing research by their KOL, Dr. Portenoy.⁶⁰

131. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the “2016 CDC Guideline”) explains that there is “[e]xtensive evidence” of the “possible harms of opioids (including opioid use disorder [an

⁵⁸ Am. Pain Found., *A Policymaker’s Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker’s Guide*], <http://s3.documentcloud.org/documents/277603/apf-policy-makers-guide.pdf>.

⁵⁹ Charles E. Argoff & Bradley S. Galer, *Defeat Chronic Pain Now!* (2010).

⁶⁰ Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

alternative term for opioid addiction], [and] overdose . . .).”⁶¹ The 2016 CDC Guideline further explains that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”⁶²

132. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting (“ER/LA”) opioids in 2013 and for immediate release (“IR”) opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed.⁶³

133. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers

⁶¹ Deborah Dowell *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

⁶² *Id.* at 2, 25.

⁶³ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf>; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf>.

meeting the clinical criteria for an opioid use disorder.”⁶⁴ Endo had claimed on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. Endo remains free, however, to make those statements in this State.

134. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented to doctors and patients that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (*i.e.*, pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

135. To this end, one of Purdue’s employees, Dr. David Haddox, invented a phenomenon called “pseudoaddiction.” KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive and unfair statements regarding pseudoaddiction include:

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids and hoarding are all signs of pseudoaddiction, rather than true addiction.⁶⁵ The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.⁶⁶

⁶⁴ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

⁶⁵ Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2007) at 62.

⁶⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

- b. Janssen sponsored, funded and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."
- e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse." In a roleplay, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

136. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already-addicted patients.

137. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the

time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain.

Illustrative examples include:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
- b. Purdue, upon information and belief, sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests and patient agreements prevent "overuse of prescriptions" and "overdose deaths."
- c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

138. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."⁶⁷

139. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that doctors can easily address opioid dependence by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea,

⁶⁷ *Id.* at 11.

sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.⁶⁸

140. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.⁶⁹

141. A fifth category of false, deceptive and unfair statements the Manufacturer Defendants made to sell more drugs is that patients could increase opioid dosages indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

- a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that

⁶⁸ *Id.* at 26.

⁶⁹ APF, *Policymaker's Guide*, at 32.

opioids have “no ceiling dose” and insinuated that they are therefore the most appropriate treatment for severe pain.⁷⁰ This publication is still available online.

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that opioid dosages may be increased until “you are on the right dose of medication for your pain.”
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased. . . . You won’t ‘run out’ of pain relief.”⁷¹
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its sales force distributed. This guide listed dosage limitations as “disadvantages” of other pain medicines, but omitted any discussion of risks of increased opioid dosages.
- f. Upon information and belief, Purdue’s In the Face of Pain website promoted the notion that if a patient’s doctor does not prescribe what, in the patient’s view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which taught that dosage escalations are “sometimes necessary” and that “the need for higher doses of medication is not necessarily indicative of addiction,” but inaccurately downplayed the risks from high opioid dosages.⁷²
- h. In 2007, Purdue sponsored a CME entitled “Overview of Management Options” that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, “the oldest and largest organization in the US dedicated to

⁷⁰ APF, *Treatment Options*, at 12.

⁷¹ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁷² APF, *Policymaker’s Guide*, *supra*, at 32.

advancing a scientific approach to substance use and addictive disorders,” challenging the correlation between opioid dosage and overdose.⁷³

- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NPF argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁷⁴

142. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants’ representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the “[b]enefits of high-dose opioids for chronic pain are not established,” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.”⁷⁵ More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.”⁷⁶ The CDC also states that there is an increased risk “for opioid use disorder, respiratory depression, and death at higher dosages.”⁷⁷ That is why the CDC advises doctors to “avoid increasing dosage” to above 90 morphine milligram equivalents per day.⁷⁸

143. Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse.

144. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo’s advertisements for the 2012 reformulation of Opana ER claimed Endo had designed it to be crush-resistant, in a

⁷³ The College on Problems of Drug Dependence, *About the College*, <http://cpdd.org> (last visited Aug. 21, 2017).

⁷⁴ Brief of APF, *supra*, at 9.

⁷⁵ 2016 CDC Guideline, *supra*, at 22–23.

⁷⁶ *Id.* at 23–24.

⁷⁷ *Id.* at 21.

⁷⁸ *Id.* at 16.

way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets’ “extended-release features can be compromised, causing the medication to ‘dose dump,’ when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing.”⁷⁹ Also troubling, Opana ER can be prepared for snorting using commonly available methods and “readily prepared for injection.”⁸⁰ The letter discussed “the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection.”⁸¹ Endo’s own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Endo remove Opana ER from the market.

ii. The Manufacturer Defendants embarked upon a campaign of false, deceptive and unfair assurances grossly overstating the benefits of the opioid drugs.

145. To convince doctors and patients that they should use opioids to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.⁸² The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

⁷⁹ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

⁸⁰ *Id.* at 6.

⁸¹ *Id.* at 6 n.21.

⁸² *Id.* at 15.

146. Some illustrative examples of the Manufacturer Defendants' false claims are:

- a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health" and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking and climbing stairs.
- d. Janssen promoted Ultracet for everyday chronic pain and distributed posters for display in doctors' offices of presumed patients in active professions. The caption read: "Pain doesn't fit into their schedules."
- e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.
- f. *Responsible Opioid Prescribing* (2007), which Cephalon, Endo and Purdue sponsored and distributed, taught that relief of pain by opioids, by itself, improved patients' function.
- g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."⁸³ This publication is still available online.
- h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project

⁸³ APF, *Treatment Options*.

specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

- i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."⁸⁴ Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."
- j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."
- k. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health" and "[o]verall health-related quality of life for chronic pain."⁸⁵ The Policymaker's Guide was originally published in 2011.
- l. Purdue's, Cephalon's, Endo's and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

147. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

148. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁸⁶ And in 2008, upon information and belief, the FDA sent a warning letter to

⁸⁴ E.g., NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

⁸⁵ APF, *Policymaker's Guide*, *supra*, at 29.

⁸⁶ Letter from Thomas Abrams to Doug Boothe, *supra*, at 2.

an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

149. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.⁸⁷ Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue’s own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when the tablet releases less medicine. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial proportion” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of

⁸⁷ 2016 CDC Guideline, *supra*, at 12.

12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

150. Purdue's competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

151. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.⁸⁸

152. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain, even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for nor has been shown to be safe or effective for chronic pain. Indeed, the FDA

⁸⁸ Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

expressly prohibited Cephalon from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007, emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain or pain due to injury.⁸⁹ Specifically, the FDA advised that Fentora “is only approved for breakthrough cancer pain in patients who are *opioid-tolerant*, meaning those patients who take a regular, daily, around-the-clock narcotic pain medication.”⁹⁰

153. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved and is not appropriate or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain.
- b. Upon information and belief, Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

⁸⁹ See U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

⁹⁰ *Id.*

- c. In December 2011, Cephalon widely disseminated a journal supplement entitled “Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)” to Anesthesiology News, Clinical Oncology News and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just cancer pain.

154. Cephalon’s deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

155. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue’s sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue’s district manager described it internally as “an organized

drug ring” until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.⁹¹

156. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

3. The Manufacturer Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

157. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including this State and Plaintiff’s Community. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants’ misrepresentations.

158. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients, even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing

⁹¹ Harriet Ryan *et al.*, *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance and a smaller window between safe and unsafe dosages.⁹² The 2016 CDC Guideline concludes that there must be “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients. *Id.* at 27. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

4. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys.

159. Insys’s opioid, Subsys, was approved by the FDA in 2012 for “management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.” Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl (“TIRF”).

160. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy (“REMS”) for Subsys and other TIRF products, such as Cephalon’s Actiq and Fentora. The purpose of REMS was to educate “prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose” for this type of drug and to “ensure safe use and access to these drugs for patients who need them.”⁹³ Prescribers must enroll in the TIRF REMS before writing a prescription for Subsys.

161. Since its launch, Subsys has been an extremely expensive medication, and its price continues to rise each year. Depending on a patient’s dosage and frequency of use, a month’s supply of Subsys could cost in the thousands of dollars.

⁹² 2016 CDC Guideline, *supra*, at 13.

⁹³ Press Release, FDA, *FDA Approves Shared System REMS for TIRF Products*, Dec. 29, 2011.

162. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report (“Staff Report”), the prior authorization process includes “confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied”⁹⁴

163. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center (“IRC”), to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients’ diagnoses and medical conditions.

164. Subsys has proved to be extremely profitable for Insys. Insys made approximately \$330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock rose 296%.

165. Since its launch in 2012, Insys aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment those

⁹⁴ U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*, <https://www.documentcloud.org/documents/3987564-REPORT-Fueling-an-Epidemic-Insys-Therapeutics.html>.

conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers programs in exchange for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing Insys's dangerous opioid onto patients who did not need it.

166. Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded reps more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.⁹⁵

167. The Insys "speakers program" was perhaps its most widespread and damaging scheme. A former Insys salesman, Ray Furchak, alleged in a qui tam action that the sole purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks."⁹⁶ It was a pay-to-prescribe program.

168. Insys's sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

169. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In February of 2016, a former Insys sales manager

⁹⁵ *Id.*

⁹⁶ Roddy Boyd, *Insys Therapeutics and the New 'Killing It'*, Southern Investigative Reporting Foundation, The Investigator, April 24, 2015.

pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of these doctors to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients. In May of 2017, one of the doctors was sentenced to 20 years in prison.

170. In June of 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, pled guilty to receiving \$83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at approximately \$1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted receiving the speaker fees in exchange for writing prescriptions for Subsys.

171. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to incentivize doctors to prescribe Subsys.

172. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The Illinois Complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received an "honorarium" ranging from \$700 to \$5,100, and they were allowed to order as much food and alcohol as they wanted. At most of the events, the "speaker" being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the speaker and an Insys sales representative.

173. In December of 2016, six Insys executives and managers were indicted and then, in October 2017, Insys's founder and owner was arrested and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud

insurance companies. A U.S. Department of Justice press release explained that, among other things: “Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis.”⁹⁷ A Drug Enforcement Administration (“DEA”) Special Agent in Charge further explained that: “Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers’ health and safety and, indeed, very lives depend on it.”⁹⁸

5. The Manufacturer Defendants Made Materially Deceptive Statements and Concealed Material Facts.

174. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course of manufacturing, marketing and selling prescription opioids. The Manufacturer Defendants’ actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

175. Defendant Purdue made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

⁹⁷ Press Release, DOJ, U.S. Attorney’s Office, Dist. of Mass., *Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering* (Oct. 26, 2017), available at <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering>.

⁹⁸ *Id.*

- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- f. Endorsing, directly distributing and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- m. Creating, endorsing and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including

known rates of abuse and addiction and the lack of validation for long-term efficacy;

- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff, while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioids, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials, advertisements and CMEs they knew would reach these same prescribers.

176. Defendant Endo made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal or intravenous abuse;

- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations – including over \$5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- m. Creating, endorsing and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

177. Defendant Janssen made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites, over which Janssen exercised final editorial control and approval, stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites, over which Janssen exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- i. Targeting the elderly by sponsoring, directly distributing and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids and made false statements that opioids are safe and effective for the

long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

178. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

179. Defendant Actavis made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

6. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.

180. The Manufacturer Defendants, both individually and collectively, made, promoted and profited from their misrepresentations about the risks and benefits of opioids for chronic pain, even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience, establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data and reports of adverse events, including reports of addiction, hospitalization and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants’ misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

181. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants’ false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional

and “educational” materials in emails, correspondence and meetings with KOLs, Front Groups and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which the NIPC runs, did not disclose Endo’s involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

182. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented “pseudoaddiction” and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks and promoting sales. The lack of support for the Manufacturer Defendants’ deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could the Plaintiff or Plaintiff’s Community have detected it. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants’ industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

C. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS.

183. The Distributor Defendants owe a duty under both federal law and Georgia law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community, as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

184. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

185. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

186. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

187. The opioid epidemic in the State, including, *inter alia*, in Plaintiff's Community, remains an immediate ***hazard to public health and safety***.

188. The opioid epidemic in Plaintiff's Community is a temporary and continuous ***public nuisance*** and remains unabated.

189. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Wholesale Drug Distributors Have a Duty Under State and Federal Law to Guard Against and Report Unlawful Diversion and to Report and Prevent Suspicious Orders.

190. Opioids are a controlled substance, and Georgia law categorizes them as having a “high potential for abuse.” *See* O.C.G.A. § 16-13-24(b)(2)(A). These “Schedule II” drugs are controlled substances with a “high potential for abuse.” 21 U.S.C.A. §§ 812(b), 812(2)(A)-(C). *See also* O.C.G.A. § 16-13-26.

191. Georgia law required each Defendant to first be registered with the Georgia State Board of Pharmacy. O.C.G.A. §§ 16-13-35 (Georgia Controlled Substances Act) and § 26-4-115(a) (Georgia Pharmacy Practice Act); and Ga. Comp. R. & Regs. 480-7-.03(1).

192. The Georgia Controlled Substances Act requires “[e]very person who manufactures, distributes, or dispenses any controlled substances within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state must obtain annually a registration issued by the State Board of Pharmacy in accordance with its rules.” O.C.G.A. § 16-13-35(a).

193. Similarly, the Georgia Pharmacy Practice Act requires all “persons, firms or corporations, whether located in this state or in any other states, engaged in the business of selling or distributing drugs at wholesale in this state, in the business of supplying drugs to manufacturers, compounders, and processors in the state, or in the business of a reverse drug distributor shall biennially register with the [Board of Pharmacy] as a drug wholesaler, distributor, reverse drug distributor, or supplier.” O.C.G.A. § 26-4-115(a).

194. The State Board of Pharmacy is required to register manufacturers and distributors “unless it determines that the issuance of that registration would be inconsistent with the public interest.” O.C.G.A. § 16-13-36(a). Factors to be considered in determining the public interest include, *inter alia*, “[m]aintenance of effective controls against diversion of controlled

substances into other than legitimate medical, scientific, or industrial channels” and “[p]ast experience in the manufacture or distribution of controlled substances and the existence in the applicant’s establishment of effective controls against illegal diversion.” O.C.G.A. § 16-13-36(a)(1) and (4).

195. Georgia Board of Pharmacy Regulations require manufacturers and distributors of controlled substances to “maintain records of unusual orders of controlled substances received by the registrant and shall inform the Office of the Director of the Georgia Drugs and Narcotics Agency (GDNA) of unusual orders when discovered by the registrant.” Ga. Comp. R. & Regs. 480-20-.02(1). *See also* O.C.G.A. § 16-13-39 (“Persons registered to manufacture, distribute, or dispense controlled substances under this article shall keep a complete and accurate record of all controlled substances . . . and shall maintain such records and inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules issued by the State Board of Pharmacy”); O.C.G.A. § 16-13-42(a)(3) (“It is unlawful for any person: . . . To refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this article”); and O.C.G.A. § 16-13-37(a)(1) (registration to manufacture or distribute a controlled substance may be suspended or revoked if the registrant has “furnished false or fraudulent material information in any application filed under [the Georgia Uniform Controlled Substances Act]”).

196. Furthermore, Georgia law incorporates federal requirements set out under the Controlled Substance Act and related controlled substance laws and regulations. *See* Ga. Comp. R. & Regs. 480-7-.03(10)(b) (“Wholesale drug distributors . . . shall comply with all applicable State, Local, and DEA regulations.”); O.C.G.A. § 16-13-36(d) (“[c]ompliance by manufacturers and distributors with the provisions of federal law respecting registration . . . entitles them to be

registered under [Article 16 of the Georgia Controlled Substances Act].”) and O.C.G.A. § 16-13-39 (“Persons registered to manufacture, distribute, or dispense controlled substances under [Article 16 of the Georgia Controlled Substances Act] shall keep a complete and accurate record of all controlled substances . . . and shall maintain such records and inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules issued by the State Board of Pharmacy”).

197. The federal Controlled Substance Act further required each Distributor Defendant to register with the DEA. *See* 21 U.S.C. § 823(b), (e) and 28 C.F.R. § 0.100. Each Distributor Defendant is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Georgia law adopts and incorporates those requirements, as set out above. *See, e.g.,* Ga. Comp. R. & Regs. 480-7-.03(10) (“Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.”); O.C.G.A. § 26-4-115(a) (registration may be suspended or revoked, among other punishments, “if the registrant fails to comply with any law of this state [or] the United States”); O.C.G.A. § 26-4-115(b)(2) (registered wholesalers and distributors shall “[a]utomatically submit reports of any excessive purchases of controlled substances by licensed persons or firms located within this state using the federal Drug Enforcement Administration guidelines to define excessive purchases as set forth under the provisions of 21 C.F.R. Section 1301”); O.C.G.A. § 16-13-37(a)(3) (registration can be suspended or revoked if the registrant has had its “federal registration to manufacture, distribute, or dispense controlled substances suspended or revoked”).

198. Each Distributor Defendant has an affirmative duty under federal and Georgia law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid

drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. § 823(b)(1). Georgia law adopts and incorporates those requirements, as set out above. *See also* O.C.G.A. § 16-13-37(a)(5) (registration can be suspended or revoked by the State Board of Pharmacy upon a finding that the registrant has “failed to maintain sufficient controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.”).

199. Federal regulations and Georgia law impose a non-delegable duty upon wholesale drug distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b). *See also* Ga. Comp. R. & Regs. 480-20-.02(1) (“Each registrant shall maintain records of unusual orders of controlled substances received by the registrant and shall inform the Office of the Director of the Georgia Drugs and Narcotics Agency (GDNA) of unusual orders when discovered by the registrant. For purposes of this section, an unusual order shall include orders of greatly increased quantity, orders deviating substantially from a normal pattern, and orders of highly abnormal frequency.”).

200. “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR § 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the distributor should report the order as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over

time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

201. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders that were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, distributors must report all flagged orders. *Id.*

202. The law regulates these prescription drugs for the purpose of providing a "closed" system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.⁹⁹

203. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.¹⁰⁰

⁹⁹ *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

¹⁰⁰ Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors

204. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”¹⁰¹

205. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.¹⁰²

206. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, *in addition* to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”¹⁰³ The letter also instructs that “distributors must be vigilant in deciding whether a prospective

whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, <https://www.healthcaredistribution.org/about> (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, <https://www.nacds.org/about/mission/> (last visited Aug. 21, 2017).

¹⁰¹ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

¹⁰² See Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4 (“[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”).

¹⁰³ Rannazzisi Letter, *supra*, at 2.

customer can be trusted to deliver controlled substances only for lawful purposes.”¹⁰⁴ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”¹⁰⁵

207. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.¹⁰⁶ This letter reminds the Defendants of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”¹⁰⁷ The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (*e.g.*, “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the patterns throughout the segment of the regulated industry.

¹⁰⁴ *Id.* at 1.

¹⁰⁵ *Id.* at 2.

¹⁰⁶ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

¹⁰⁷ *Id.*

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.¹⁰⁸

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”¹⁰⁹

208. The Distributor Defendants admit that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”¹¹⁰

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ See Brief of HDMA, *supra*, 2012 WL 1637016, at *2.

209. The Distributor Defendants knew they were required to monitor, detect and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process and note in particular: If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or the distributor otherwise characterizes it as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.¹¹¹

210. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff’s Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff’s Community.

211. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

212. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

213. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

¹¹¹ Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B).

214. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

215. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

216. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Plaintiff's Community and the damages caused thereby.

2. The Distributor Defendants Breached Their Duties.

217. Because distributors handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.¹¹²

218. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's Community is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.¹¹³

219. The Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community or that the Distributor Defendants knew were likely to be diverted to

¹¹² See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

¹¹³ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

Plaintiff's Community to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

220. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

221. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Plaintiff's Community and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

222. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific and industrial channels.

223. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

224. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.¹¹⁴

225. The federal and state laws at issue here are public safety laws.

¹¹⁴ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

226. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under State law.

227. The Distributor Defendants supplied prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity and disseminated massive quantities of prescription opioids into the black market.

228. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal and state law, which require Distributor Defendants to legally acquire and maintain a license to distribute prescription opiates.

229. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

230. The Distributor Defendants' repeated shipments of suspicious orders over an extended period of time, in violation of public safety statutes and without reporting the suspicious orders to the relevant authorities demonstrate wanton, willful or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

3. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties.

231. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

232. The Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association the Distributor Defendants run, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”¹¹⁵
- b. The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”¹¹⁶
- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”¹¹⁷
- d. The Association complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”¹¹⁸
- e. The Associations alleged (inaccurately) that “DEA’s regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”¹¹⁹

¹¹⁵ Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4–5.

¹¹⁶ *Id.* at *8 (citations and quotation marks omitted).

¹¹⁷ *Id.* at *14.

¹¹⁸ *Id.* at *22.

¹¹⁹ *Id.* at *24–25.

- f. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”¹²⁰

233. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.¹²¹

234. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical’s license and determined that DEA regulations require that, in addition to reporting suspicious orders, distributors must “decline to ship the order, or conduct some ‘due diligence’ and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order.” *Id.* at 212. Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor’s investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above) that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

235. Wholesale Distributor McKesson recently has been forced to specifically admit to breaches of its duties to monitor, report and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement (“2017 Agreement”) between McKesson and the

¹²⁰ *Id.* at 26.

¹²¹ See Brief of HDMA, *supra*, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry “does not know the rules of the road because” they claim (inaccurately) that the “DEA has not adequately explained them”).

DEA in January 2017, 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.”¹²² Further, the 2017 Agreement specifically finds that McKesson “distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).”¹²³ McKesson admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers,” including the McKesson Distribution Center located in “Washington Courthouse, Ohio.”¹²⁴ Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility (among other facilities) would be partially suspended.¹²⁵

236. The 2017 Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.¹²⁶ In the

¹²² See Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and the McKesson Corp. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

¹²³ *Id.* at 4.

¹²⁴ *Id.*

¹²⁵ *Id.* at 6.

¹²⁶ *Id.* at 4.

2008 Settlement Agreement, McKesson “recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA,” but had failed to do so.¹²⁷ The 2017 Agreement documents that McKesson continued to breach its admitted duties by “fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson’s obligations.”¹²⁸ As a result of these violations, McKesson was fined and required to pay to the United States \$150,000,000.¹²⁹

237. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

238. Because of the Distributor Defendants’ refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.¹³⁰ The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final

¹²⁷ *Id.*

¹²⁸ *Id.*; see also Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] (“McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.”), <https://www.justice.gov/opa/press-release/file/928471/download>.

¹²⁹ See 2017 Settlement Agreement and Release, *supra*, at 6.

¹³⁰ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, *The Drug Enforcement Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.¹³¹ These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA, which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;”
- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford

¹³¹ *Id.*

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

- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against the Lakeland Facility; and
- j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.

239. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act,” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before the DEA can issue a suspension order.¹³²

¹³² See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017,

240. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

241. For example, a Cardinal Health executive claimed that it uses “advanced analytics” to monitor its supply chain and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”¹³³ Given the sales volumes and the company’s history of violations, this executive was either not telling the truth or, if Cardinal Health had such a system, it ignored the results.

242. Similarly, Defendant McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”¹³⁴ Again, given McKesson’s historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

243. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the

https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

¹³³ Lenny Bernstein, et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

¹³⁴ Scott Higham, et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

existence or scope of Distributor Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

244. Meanwhile, the opioid epidemic rages unabated in the Nation, the State and Plaintiff's Community.

245. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers, and when the DEA suspends one facility, they simply ship from another facility.

246. Plaintiff's racketeering allegations below allege in greater detail the wrongful actions and omissions of the Distributor Defendants, which have caused the diversion of opioids and have been a substantial contributing factor to and/or proximate cause of the opioid crisis.

247. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement and abused the privilege of distributing controlled substances in the State and Plaintiff's Community.

4. The National Retail Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids.

248. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids.¹³⁵ They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

¹³⁵ The allegations contained in this Complaint are based, in part, on discovery that is in its infancy. Plaintiffs do not have access to transactional ARCOS data for Wisconsin. Accordingly, Plaintiffs reserve their right to further amend this complaint to add supporting allegations, claims and parties.

249. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids.

250. On information and belief, the National Retail Pharmacies distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in Georgia. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Georgia. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

251. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Georgia in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion, but failed to do so.

a. The National Retail Pharmacies Have a Duty to Prevent Diversion

252. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

253. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of

controlled substances.” See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

254. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

255. 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.

256. Additional types of suspicious orders 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.

257. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

258. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of 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.

259. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

260. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly.

261. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. 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 National Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

262. Upon information and belief, this problem was compounded by the Pharmacies' failure 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.

263. Upon information and belief, the National Retail Pharmacies 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 crisis.

264. Upon information and belief, the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

265. Upon information and belief, the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

266. Upon information and belief, the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

267. The National Retail Pharmacies 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.

b. Multiple Enforcement Actions against the National Retail Pharmacies Confirm their Compliance Failures.

268. The National Retail Pharmacies 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. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. 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 National Retail Pharmacies.

i. CVS

269. 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.

270. CVS is a repeat offender and recidivist: 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 the 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 its recordkeeping and dispensing obligations under the CSA.

271. 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.¹³⁶

272. This fine was preceded by numerous others throughout the country.

273. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filled prescriptions with no legitimate medical purpose.¹³⁷

274. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.¹³⁸

275. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.¹³⁹

276. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.¹⁴⁰

277. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The

¹³⁶ Press Release, U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays \$5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't of Just. (July 11, 2017), <https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act>.

¹³⁷ Press Release, U.S. Attorney's Office Dist. of Md., *United States Reaches \$8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances*, U.S. Dep't of Just. (Feb. 12, 2016), <https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled>.

¹³⁸ Press Release, U.S. Attorney's Office Dist. of Conn., *CVS Pharmacy Pays \$600,000 to Settle Controlled Substances Act Allegations*, U.S. Dep't of Just. (Oct. 20, 2016), <https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-act-allegations>.

¹³⁹ Dialynn Dwyer, *CVS will pay \$795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), <https://www.boston.com/news/local-news/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-in-agreement-with-state>.

¹⁴⁰ Press Release, U.S. Attorney's Office Dist. of Mass., *CVS to Pay \$3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions*, U.S. Dep't of Just. (June 30, 2016), <https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions>.

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.¹⁴¹

278. 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.”¹⁴²

279. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.¹⁴³

280. 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.¹⁴⁴

281. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.¹⁴⁵

¹⁴¹ Press Release, U.S. Attorney’s Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved With \$450,000 Civil Settlement, U.S. Dep’t of Just. (Aug. 10, 2015), <https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement>.

¹⁴² Press Release, U.S. Attorney’s Office M. Dist. of Fla., United States Reaches \$22 Million Settlement Agreement With CVS For Unlawful Distribution of Controlled Substances, U.S. Dep’t of Just. (May 13, 2015), <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution>.

¹⁴³ Patrick Danner, *H-E-B, CVS Fined Over Prescriptions*, San Antonio Express-News (Sept. 5, 2014), <http://www.expressnews.com/business/local/article/H-E-BCVS-fined-over-prescriptions-5736554.php>.

¹⁴⁴ Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NewsOK (May 3, 2015), <http://newsok.com/article/5415840>.

ii. Walgreens

282. 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.

283. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.¹⁴⁶

284. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

285. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.¹⁴⁷

286. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of

¹⁴⁵ Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay \$11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act, U.S. Dep't of Just. (Apr. 3, 2013), <https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled>.

¹⁴⁶ Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of \$80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled>.

¹⁴⁷ Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

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 the CSA or the health of communities.¹⁴⁸

287. Defendant Walgreens’ settlement with the DEA stemmed from the DEA’s investigation into Walgreens’ distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens’ corporate headquarters pushed to increase the number of oxycodone sales to Walgreens’ Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.¹⁴⁹

288. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).¹⁵⁰

289. 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.

290. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients’ drug use patterns and didn’t use sound professional judgment when dispensing opioids and other controlled substances—despite

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Walgreens to pay \$200,000 settlement for lapses with opioids*, APhA (Jan. 25, 2017), <https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids>.

the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.¹⁵¹

iii. Rite Aid

291. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.

292. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.¹⁵²

293. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that led to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).¹⁵³

294. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

295. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operating procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

¹⁵¹ *Id.*

¹⁵² Press Release, Dep't of Just., *Rite Aid Corporation and Subsidiaries Agree to Pay \$5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act*, U.S. Dep't of Just. (Jan. 12, 2009), <https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations>.

¹⁵³ *Id.*

296. Throughout the country and the State, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

297. On information and belief, from the catbird seat of their retail pharmacy operations, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into Georgia and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

298. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

299. On information and belief, because of (among others sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

300. The National Retail Pharmacies’ actions and omission 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.

D. THE MANUFACTURER DEFENDANTS’ UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT AND PREVENT SUSPICIOUS ORDERS.

301. The same legal duties to prevent diversion and to monitor, report and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal and Georgia law.

302. Under Georgia and federal law, the Manufacturer Defendants were required to comply with substantially the same licensing and permitting requirements as the Distributor Defendants and the same rules regarding prevention of diversion and reporting suspicious orders, as set out above. See, e.g., Ga. Comp. R. & Regs. 480-7-.02; Ga. Comp. R. & Regs. 480-20-.02(1); O.C.G.A. § 16-13-35; O.C.G.A. § 16-13-36; O.C.G.A. § 16-13-37(a); O.C.G.A. § 16-13-39.

303. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances like prescription opioids. See 21 U.S.C. § 823(a). A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes...

21 U.S.C. § 823(a)(1).

304. Additionally, as “registrants” under Section 823, the Manufacturer Defendants were also required to monitor, report and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. See also 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303

or section 1008 of the Act (21 U.S.C. 823 or 958).”) Like the Distributor Defendants, the Manufacturer Defendants breached these duties.

305. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

306. Federal statutes and regulations are clear: just like opioid distributors, the law requires opioid manufacturers to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.” 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1). Georgia law also requires manufacturers to maintain sufficient controls against diversion. *See, e.g.*, O.C.G.A. § 16-13-36(a)(1); O.C.G.A. § 16-13-37(a)(5); Ga. Comp. R. & Regs. 480-7-.03(7)(b) (minimum requirements for storage and handling of prescription drugs and for establishment and maintenance of prescription drug distribution records includes protections against diversion).

307. The Department of Justice recently has confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt \$35 million for

failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.¹⁵⁴

308. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt “did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . ‘Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . .’”¹⁵⁵

309. Among the allegations resolved by the settlement, the government alleged “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”¹⁵⁶

310. The Memorandum of Agreement Mallinckrodt entered into (“2017 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain

¹⁵⁴ See Press Release, U.S. Dep’t of Justice, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.”¹⁵⁷

311. The 2017 Mallinckrodt MOA further details the DEA’s allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer:

With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt’s alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt’s alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt’s alleged failure to:

- i. conduct adequate due diligence of its customers;
- ii. detect and report to the DEA orders of unusual size and frequency;
- iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
- iv. use “chargeback” information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

¹⁵⁷ Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download>. (“2017 Mallinckrodt MOA”).

- v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.¹⁵⁸

312. Mallinckrodt agreed that its “system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and would “design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”¹⁵⁹

313. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”¹⁶⁰

314. The same duties federal law imposed on Mallinckrodt were imposed upon all Manufacturer Defendants.

¹⁵⁸ 2017 Mallinckrodt MOA at p. 2-3.

¹⁵⁹ *Id.* at 3-4.

¹⁶⁰ *Id.* at p.5.

315. The same business practices Mallinckrodt utilized regarding “charge backs” and receipt and review of data from opioid distributors as to orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

316. Through, inter alia, the chargeback data, the Manufacturer Defendants could monitor suspicious orders of opioids.

317. The Manufacturer Defendants failed to monitor, report and halt suspicious orders of opioids as required by federal law.

318. The Manufacturer Defendants’ failures to monitor, report and halt suspicious orders of opioids were intentional and unlawful.

319. The Manufacturer Defendants have misrepresented their compliance with federal law.

320. The Manufacturer Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity and disseminated massive quantities of prescription opioids into the black market.

321. Plaintiff’s racketeering allegations below allege in greater detail the wrongful actions and omissions of the Manufacturer Defendants, which have caused the diversion of opioids and have been a substantial contributing factor to and/or proximate cause of the opioid crisis.

322. The Manufacturer Defendants’ actions and omissions in failing to effectively prevent diversion and failing to monitor, report and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff’s Community.

E. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM ALLEGED HEREIN AND SUBSTANTIAL DAMAGES.

323. As the Manufacturer Defendants' efforts to expand the market for opioids have increased, so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization and death among the people of the State and the Plaintiff's Community. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like the Plaintiff's Community, fueling the epidemic.

324. There is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”¹⁶¹

325. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.¹⁶²

326. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”¹⁶³

327. The increased abuse of prescription painkillers, along with growing sales, has contributed to a large number of overdoses and deaths.¹⁶⁴

328. As shown above, the opioid epidemic has escalated in Plaintiff's Community with devastating effects: substantial opiate-related substance abuse, hospitalization and death that mirror Defendants' increased distribution of opiates.

¹⁶¹ See Dart, *et al.*, *supra*.

¹⁶² See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

¹⁶³ See Califf *et al.*, *supra*.

¹⁶⁴ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra*.

329. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Plaintiff's Community and areas from which such opioids are being diverted into Plaintiff's Community has resulted in the Defendant-caused opioid epidemic including heroin addiction, abuse and death.

330. Prescription opioid abuse, addiction, morbidity and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

331. Heroin abuse, addiction, morbidity and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

332. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of and/or substantial factors leading to the widespread diversion of prescription opioids for nonmedical purposes into the Plaintiff's Community.

333. The unlawful diversion of prescription opioids is a direct and proximate cause of and/or substantial factor leading to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and Plaintiff's Community. This diversion and the epidemic are direct causes of foreseeable harms the Plaintiff and Plaintiff's Community have incurred.

334. Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing economic damages for which Plaintiff seeks relief, as alleged herein. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

335. Plaintiff seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

336. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

337. To eliminate the hazard to public health and safety and abate the public nuisance, a “multifaceted, collaborative public health and law enforcement approach is urgently needed.”¹⁶⁵

338. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying opioid-addicted individuals early and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.¹⁶⁶

339. These community-based problems require community-based solutions that “budgetary constraints at the state and Federal levels” have limited.¹⁶⁷

340. Having profited enormously through the aggressive sale, misleading promotion and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff’s Community.

F. STATUTES OF LIMITATIONS ARE TOLLED BECAUSE DEFENDANTS’ CONDUCT HAS NOT CEASED AND THEY FRAUDULENTLY CONCEALED THEIR UNLAWFUL CONDUCT.

1. Continuing Conduct.

341. Defendants’ continued tortious and unlawful conduct has not ceased.

342. Plaintiff contends it continues to suffer harm from Defendants’ unlawful actions.

343. Defendant’s persistent wrongful conduct is continuous in nature and causes a repeated or continuous injury. The damages have not occurred all at once, but have continued to

¹⁶⁵ See Rudd *et al.*, *supra*, at 1145.

¹⁶⁶ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander *et al.* eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

¹⁶⁷ See Office of Nat’l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America’s Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

occur and increase as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. Defendants' wrongdoing and unlawful activity have not ceased. The public nuisance continues and remains unabated.

2. Fraudulent Concealment.

344. Defendants cannot rely upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and continuing to generate profits.

345. Defendants committed actual fraud as alleged herein and also actively concealed information which deterred and prevented Plaintiff, in the exercise of ordinary diligence, from discovering Defendants' wrongful conduct. O.C.G.A. § 9-3-96.

346. Defendants' knowing and fraudulent concealment of the facts alleged herein tolls the limitations periods of Plaintiff's claims. As alleged herein, Defendants knew of the wrongful acts set forth above, had material information pertinent to their discovery, and concealed them from the Plaintiff and Plaintiff's Community. The Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its causes of action, as a result of Defendants' conduct.

347. The purposes of the statutes of limitations periods are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

348. In light of their statements to the media, in legal filings and in settlements, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

349. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, the Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

350. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff and Plaintiff's Community, that they are working to curb the opioid epidemic.

351. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."¹⁶⁸

352. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."¹⁶⁹

353. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:¹⁷⁰

¹⁶⁸ Bernstein *et al.*, *supra*.

¹⁶⁹ Higham *et al.*, *supra*.

¹⁷⁰ Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *3-4, *25.

- a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
- b. “DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”
- c. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.”
- d. “A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy.”
- e. “Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash.”

Through the above statements made on their behalf by their trade associations and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

354. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities.

355. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented “pseudoaddiction” and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without

disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks and promoting sales. The Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's Community deceived the medical community, consumers, the State and Plaintiff's Community.

356. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's Community. Plaintiff and Plaintiff's Community did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

357. The Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

V. LEGAL CAUSES OF ACTION

COUNT I PUBLIC NUISANCE (Against All Defendants)

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

359. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of and/or a substantial factor leading to Plaintiff's injury. *See* Restatement Second, Torts § 821B. *See City of Coll. Park v. 2600 Camp Creek, LLC*, 666 S.E.2d 607, 608 (Ga. Ct. App. 2008) (citing Restatement Second, Torts § 821B).

360. Under Georgia Law, a nuisance is also "anything that causes hurt, inconvenience, or damage to another and the fact that the act done may otherwise be lawful shall not keep it

from being a nuisance.” O.C.G.A. § 41-1-1. A public nuisance “is one which damages all persons who come within the sphere of its operation, though it may vary in its effects on individuals.” O.C.G.A. § 41-1-2.

361. Defendants have created a public nuisance under Georgia law.

362. Plaintiff has standing to bring claims for nuisance due to the opioid epidemic affecting and causing harm in Plaintiff’s Community.

363. By causing dangerously addictive drugs to flood the community and be diverted for illicit purposes, in contravention of federal and State law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the people of the Plaintiff’s Community to public health, public safety, public peace, public comfort and public convenience. The public nuisance caused by the diversion of dangerous drugs has caused substantial annoyance, inconvenience and injury to the public.

364. By selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific or industrial purpose, Defendants have committed a course of conduct that injuriously affects the safety, health and morals of the people of the Plaintiff’s Community.

365. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes, Defendants injuriously affected public rights, including the right to public health, public safety, public peace and public comfort of the people of the Plaintiff’s Community.

366. Plaintiff alleges that Defendants’ wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public.

367. The Defendants have intentionally and/or unlawfully created an absolute nuisance.

368. The residents of Plaintiff's Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

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

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

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

372. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort, convenience and ability to be free from disturbance and reasonable apprehension of danger to person or property.

373. Defendants' conduct in illegally distributing and selling prescription opioids or causing such opioids to be distributed and sold where Defendants know or reasonably should

know such opioids will be diverted, possessed and/or used illegally in Plaintiff's Community is of a continuing nature.

374. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

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

376. Statute and regulation proscribe Defendants' distribution of opioids while failing to maintain effective controls against diversion.

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

378. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

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

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

381. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Plaintiff's Community. Defendants are in the business of manufacturing, marketing, selling and distributing prescription drugs,

including opioids, which Defendants specifically know to be dangerous under federal law. *See e.g.*, 21 U.S.C. § 812 (b)(2).

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

383. It is, or should be, reasonably foreseeable to Defendants that their conduct will cause deaths and injuries to residents in Plaintiff's Community and will otherwise significantly and unreasonably interfere with public health, safety and welfare and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

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

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

386. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, but for Defendants' actions, opioid use

would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse and addiction that now exists would have been averted.

387. The presence of diverted prescription opioids in Plaintiff's Community and the consequence of prescription opioids having been diverted in Plaintiff's Community proximately results in and/or substantially contributes to the creation of significant costs to the Plaintiff and to Plaintiff's Community in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

388. Stemming the flow of illegally distributed prescription opioids and abating the nuisance caused by the illegal flow of opioids will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Community a safer place to live.

389. Defendants' conduct is a direct and proximate cause of and/or a substantial contributing factor to opioid addiction and abuse in Plaintiff's Community and costs borne by Plaintiff's Community and the Plaintiff, as well as a significant and unreasonable interference with public health, safety and welfare and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

390. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of Plaintiff's Community, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

391. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Plaintiff's Community; however, Defendants

intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

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

393. Defendants' actions also created a qualified nuisance. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

394. 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.

395. The damages available to the Plaintiff include, inter alia, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance that the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages

flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

396. As a direct result of Defendants' conduct, the Plaintiff and Plaintiff's Community have suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. The Plaintiff here seeks recovery for its own harm.

397. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because their damages include, inter alia, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

398. The Plaintiff further seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing and persistent actions and omissions and interference with a right common to the public.

399. Plaintiff seeks all legal and equitable relief as allowed by law, including, inter alia, abatement, compensatory damages and punitive damages from the Defendants for the creation of a public nuisance, attorneys' fees and costs, and pre- and post-judgment interest.

400. Defendants' intentional and unlawful actions and omissions, as well as their unreasonable interference with a right common to the public are of a continuing nature.

401. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the Plaintiff's Community. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because, inter alia, federal and state law define these drugs as substances posing a high potential for abuse and severe addiction.

Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

402. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties and the Manufacturer Defendants' fraudulent marketing activities have caused harm to the entire community that includes, but is not limited to, the following:

- a. The high rates of use have led and continue to lead to unnecessary opioid abuse, addiction, overdose, injuries and deaths.
- b. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- c. Even those residents of Plaintiff's Community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids and the loss of companionship, wages or other support from family members who have used, abused, become addicted to, overdosed on or been killed by opioids.
- d. The opioid epidemic has increased health care costs.
- e. Employers have lost the value of productive and healthy employees.
- f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse and injury.
- g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription

opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

- h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.
- i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement and financial resources of the Plaintiff's Community.
- j. Defendants' interference with the comfortable enjoyment of life in the Plaintiff's Community is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm Defendants' actions inflicted.

403. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because their damages include, inter alia, health services and law enforcement expenditures, as described in this Complaint.

404. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations.

405. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, inter alia, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT II
RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1961, et seq.
(Against Defendants Purdue, Cephalon, Janssen, and Endo)
(The "Opioid Marketing Enterprise")

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

407. Plaintiff brings this Count on behalf of itself against the following Defendants, as defined above: Purdue, Cephalon, Janssen, and Endo (referred to collectively for this Claim as the “RICO Marketing Defendants”).

408. At all relevant times, the RICO Marketing Defendants were and are “persons” under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

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

410. The term “enterprise” is defined as including “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4). The definition of “enterprise” in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section “describes two separate categories of associations that come within the purview of an ‘enterprise’ -- the first encompassing organizations such as corporations, partnerships, and other ‘legal entities,’ and the second covering ‘any union or group of individuals associated in fact although not a legal entity.’” *United State v. Turkette*, 452 U.S. 576, 577 (1981).

411. Beginning in the early 1990s, the RICO Marketing Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully increasing the volume of opioids they sold. The RICO Marketing Defendants knew that they could not increase their profits without misrepresenting that opioids were non-addictive and safe for the long-term treatment of chronic pain.

412. The generally accepted standards of medical practice prior to the 1990s dictated that opioids should only be used in short durations to treat acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the evidence of addiction and lack of evidence indicating that opioids improved patients' ability to overcome pain and function, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

413. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO Marketing Defendants formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

414. The RICO Marketing Defendants formed an association-in-fact enterprise consisting of "advocacy groups and professional societies" ("Front Groups") and paid "physicians affiliated with these groups" (KOLs") in order to unlawfully increase the demand for opioids. Through their personal relationships, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The RICO Marketing Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.¹⁷¹

415. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, made misleading statements and misrepresentations about opioids that downplayed the risk of

¹⁷¹ *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 <https://www.hsdl.org/?abstract&did=808171> ("*Fueling an Epidemic*"), at 1.

addiction and exaggerated the benefits of opioid use, including: (1) downplaying the serious risk of addiction; (2) creating and promoting the concept of “pseudoaddiction” when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerating the effectiveness of screening tools to prevent addiction; (4) claiming that opioid dependence and withdrawal are easily managed; (5) denying the risks of higher opioid dosages; and (6) exaggerating the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction.

416. The RICO Marketing Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the RICO Marketing Defendants’ claims.

417. The RICO Marketing Defendants’ scheme, and the common purpose of the Opioid Marketing Enterprise, has been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009.¹⁷² In an open letter to the nation’s physicians in August 2016, the then-U.S. Surgeon General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.”¹⁷³

¹⁷² See Katherine Eban, *OxyContin: Purdue Pharma’s Painful Medicine*, *Fortune*, Nov. 9, 2011, <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>; David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, *Fin. Times*, Aug. 10, 2016, <https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95>.

¹⁷³ Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), <http://turnthetidex.org/>; *Fueling An Epidemic*, *supra* n.3, at 1.

418. The scheme devised and implemented by the RICO Marketing Defendants amounted to a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants' drugs. As Senator McCaskill aptly recognized:

The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.¹⁷⁴

A. THE OPIOID MARKETING ENTERPRISE

419. The Opioid Marketing Enterprise consists of the RICO Marketing Defendants, the Front Groups, and the KOLs – each of whom is identified below:

- **The RICO Defendants**

- Purdue
- Cephalon
- Janssen
- Endo

- **The Front Groups**

- American Pain Foundation (“APF”)
- American Academy of Pain Medicine (“AAPM”)
- American Pain Society (“APS”)
- Federation of State Medical Boards (“FSMB”)
- U.S. Pain Foundation (“USPF”)
- American Geriatrics Society (“AGS”)

- **The KOLs**

- Dr. Russell Portenoy (“Dr. Portenoy”)
- Dr. Lynn Webster (“Dr. Webster”)
- Dr. Perry Fine (“Dr. Fine”)

¹⁷⁴ See, *LIVESTREAM: Insys Opioid Sales and Marketing Practices Roundtable*, September 12, 2017, at 31:03-31:37, https://www.youtube.com/watch?v=k9mrQa8_vAo (accessed on March 1, 2018).

○ Dr. Scott M. Fishman (“Dr. Fishman”)

420. The Opioid Marketing Enterprise is an ongoing and continuing business organization that created and maintained systematic links, interpersonal relationships and engaged in a pattern of predicate acts (i.e. racketeering activity) in order to further the common purpose of the enterprise: unlawfully increasing profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Each of the individuals and entities who formed the Opioid Marketing Enterprise is an entity or person within the meaning of 18 U.S.C. § 1961(3) and acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

421. In order to accomplish the common purpose, members of the Opioid Marketing Enterprise repeatedly and systematically misrepresented – affirmatively, and through half-truths and omissions – that opioids are non-addictive and safe for the effective treatment of long-term, chronic, non-acute and non-cancer pain, and for other off-label uses not approved by the FDA. The Opioid Marketing Enterprise misrepresented and concealed the serious risks and lack of corresponding benefits of using opioids for long-term chronic pain. By making these misrepresentations, the Opioid Marketing Enterprise ensured that a large number of opioid prescriptions would be written and filled for chronic pain.

422. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including

between the RICO Marketing Defendants and each of the Front Groups and KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.

423. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

424. Each of the RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. Each of the RICO Marketing Defendants coordinated their marketing efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise.

1. The RICO Defendants

425. In addition to their systematic links to and personal relationships with the Front Groups and KOLs, described below, the RICO Marketing Defendants had systematic links to and personal relationships with each other through their participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities, including but not limited to, the Pain Care Forum (“PCF”) and the Healthcare Distribution Alliance (“HDA”).

426. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. Plaintiff is informed and believes that the PCF was created with the stated goal of offering a “setting where multiple organizations can

share information” and “promote and support taking collaborative action regarding federal pain policy issues.” Plaintiff is informed and believes that past APF President Will Rowe described the PCF as “a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations.”

427. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF, including the RICO Marketing Defendants, quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

428. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”¹⁷⁵ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.¹⁷⁶

429. Not surprisingly, each of the RICO Marketing Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.¹⁷⁷ In 2012, membership and participating organizations in the PCF included the HDA (of which all the RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), and Teva (the parent company of Cephalon).¹⁷⁸ Each of the RICO Marketing Defendants worked together through the PCF to advance the interests of the Opioid Marketing Enterprise. But, the RICO Marketing Defendants were not alone, many of the RICO

¹⁷⁵ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

¹⁷⁶ *Id.*

¹⁷⁷ PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf> (last visited March 8, 2018).

¹⁷⁸ *Id.* Upon information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.

Marketing Defendants' Front Groups were also members of the PCF, including the American Academy of Pain Management, the American Pain Foundation, and the American Pain Society. Upon information and belief, the RICO Marketing Defendants' KOLs were also members of and participated in the PCF.

430. Through the Pain Care Forum, the RICO Marketing Defendants met regularly and in person to form and take action to further the common purpose of the Opioid Marketing Enterprise and shape the national response to the ongoing prescription opioid epidemic.

431. Through the HDA – or Healthcare Distribution Alliance – the RICO Marketing Defendants “strengthen[ed] . . . alliances”¹⁷⁹ and took actions to further the common purpose of the Opioid Marketing Enterprise.

432. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”¹⁸⁰ Clearly, membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the RICO Marketing Defendants.

433. The closed meetings of the HDA’s councils, committees, task forces and working groups provided the RICO Marketing Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the Opioid Marketing Enterprise.

¹⁷⁹ Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en> (emphasis added).

¹⁸⁰ *Id.*

434. The HDA also offered multiple conferences, including annual business and leadership conferences through which the RICO Marketing Defendants had an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”¹⁸¹ The HDA and its conferences were significant opportunities for the RICO Marketing Defendants to interact at the executive level and form and take actions in furtherance of the common purpose of the Opioid Marketing Enterprise. It is clear that the RICO Marketing Defendants embraced this opportunity by attending and sponsoring these events.¹⁸²

435. The systematic contacts and personal relationships developed by the RICO Marketing Defendants through the PCF and the HDA furthered the common purpose of the Opioid Marketing Enterprise because it allowed the RICO Marketing Defendants to coordinate the conduct of the Opioid Marketing Enterprise by, including but not limited to, coordinating their interaction and development of relationships with the Front Groups and KOLs.

2. The Front Groups

436. Each of the RICO Marketing Defendants had systematic links to and personal relationships with Front Groups that operated as part of the Opioid Marketing Enterprise to further the common purpose of unlawfully increasing sales by misrepresenting the non-addictive and effective use of opioids for the treatment of long-term chronic pain. As recently reported by the U.S. Senate in “*Fueling an Epidemic*”:

The fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate

¹⁸¹ Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers> (last accessed on September 14, 2017).

¹⁸² 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/events/2015-distribution-management-conference> (last accessed on September 14, 2017).

donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.¹⁸³

437. “Patient advocacy organizations and professional societies like the Front Groups ‘play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.’”¹⁸⁴ “Even small organizations—with ‘their large numbers and credibility with policymakers and the public’—have ‘extensive influence in specific disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”¹⁸⁵ Indeed, as reflected below, the U.S. Senate’s report found that the RICO Marketing Defendants made nearly \$9 million worth of contributions to various Front Groups, including members of the Opioid Marketing Enterprise.¹⁸⁶

¹⁸³ Fueling an Epidemic, at p. 1.

¹⁸⁴ *Id.* at p. 2

¹⁸⁵ *Id.*

¹⁸⁶ *Id.* at p. 3.

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue ²²	Janssen ²³	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	\$1,091,024.86	\$128,000.00	\$43,491.95	\$3,050.00 ²⁴	\$0.00	\$1,265,566.81
American Academy of Pain Medicine	\$725,584.95	\$83,975.00	\$332,100.00	\$57,750.00	\$0.00	\$1,199,409.95
AAPM Foundation	\$0.00	\$0.00	\$304,605.00	\$0.00	\$0.00	\$304,605.00
ACS Cancer Action Network	\$168,500.00 ²⁵	\$0.00	\$0.00	\$0.00	\$0.00	\$168,500.00
American Chronic Pain Association	\$312,470.00	\$50,000.00	\$54,670.00	\$0.00	\$0.00	\$417,140.00
American Geriatrics Society	\$11,785.00 ²⁶	\$0.00	\$0.00	\$0.00	\$0.00	\$11,785.00
American Pain Foundation	\$25,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$25,000.00
American Pain Society	\$542,259.52	\$88,500.00	\$288,750.00	\$22,965.00	\$20,250.00	\$962,724.52
American Society of Pain Educators	\$30,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$30,000.00
American Society of Pain Management Nursing	\$242,535.00	\$55,177.85 ²⁷	\$25,500.00 ²⁸	\$0.00	\$0.00	\$323,212.85
The Center for Practical Bioethics	\$145,095.00	\$18,000.00	\$0.00	\$0.00	\$0.00	\$163,095.00
The National Pain Foundation ²⁹	\$0.00	\$0.00	\$0.00	\$562,500.00	\$0.00	\$562,500.00
U.S. Pain Foundation	\$359,300.00	\$41,500.00	\$22,000.00	\$2,500,000.00 ³⁰	\$0.00	\$2,922,800.00
Washington Legal Foundation	\$500,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$500,000.00
	\$4,153,554.33	\$465,152.85	\$1,071,116.95	\$3,146,265.00	\$20,250.00	\$8,856,339.13

438. The Front Groups included in the Opioid Marketing Enterprise “have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own

constituencies.¹⁸⁷ And, as reflected below, many of the RICO Marketing Defendants' Front Groups received the largest contributions:

FIGURE 5: Group Rankings by Manufacturer Payments, 2012-2017

U.S. Pain Foundation	\$2,922,800.00
Academy of Integrative Pain Management	\$1,265,566.81
American Academy of Pain Medicine	\$1,199,409.95
American Pain Society	\$962,724.52
The National Pain Foundation	\$562,500.00
Washington Legal Foundation	\$500,000.00
American Chronic Pain Association	\$417,140.00
American Society of Pain Management Nursing	\$323,212.85
AAPM Foundation	\$304,605.00
ACS Cancer Action Network	\$168,500.00
The Center for Practical Bioethics	\$163,095.00
American Society of Pain Educators	\$30,000.00
American Pain Foundation	\$25,000.00
American Geriatrics Society	\$11,785.00

439. But, the RICO Marketing Defendants connection with and control over the Front Groups did not end with financial contributions. Rather, the RICO Marketing Defendants made substantial contributions to physicians affiliated with the Front Groups totaling more than \$1.6 million.¹⁸⁸ Moreover, the RICO Marketing Defendants “made substantial payments to individual group executives, staff members, board members, and advisory board members” affiliated with the Front Groups subject to the Senate Committee’s study.¹⁸⁹

¹⁸⁷ *Id.* at p. 3.

¹⁸⁸ *Id.* at p. 3.

¹⁸⁹ *Id.* at p. 10.

FIGURE 7: Purdue, Janssen, Insys, Depomed, and Mylan Payments to Groups and Group-Affiliated Individuals, 2012-Present⁴¹

	Payments to Group	Payments to Group-Affiliated Individuals	Total
U.S. Pain Foundation	\$2,922,800.00	\$126.20	\$2,922,926.20
The National Pain Foundation	\$562,500.00	\$839,848.84	\$1,402,348.84
Academy of Integrative Pain Management	\$1,265,566.81	\$30,223.42	\$1,295,790.23
American Academy of Pain Medicine	\$1,199,409.95	\$16,462.42	\$1,215,872.37
American Pain Society	\$962,724.52	\$95,474.56	\$1,058,199.08
AAPM Foundation	\$304,605.00	\$314,175.58	\$618,780.58
Washington Legal Foundation	\$500,000.00	N/A	\$500,000.00
American Chronic Pain Association	\$417,140.00	\$31,265.87	\$448,405.87
American Society of Pain Management Nursing	\$323,212.85	N/A	\$323,212.85
American Society of Pain Educators	\$30,000.00	\$280,765.92	\$310,765.92
The Center for Practical Bioethics	\$163,095.00	\$7,116.86	\$170,211.86
ACS Cancer Action Network	\$168,500.00	N/A	\$168,500.00
American Pain Foundation	\$25,000.00	N/A	\$25,000.00
American Geriatrics Society	\$11,785.00	\$194.13	\$11,979.13
Total	\$8,856,339.13	\$1,615,653.80	\$10,471,992.93

440. As described in more detail below¹⁹⁰, the RICO Marketing Defendants “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”¹⁹¹ They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding.”¹⁹²

441. The systematic contacts and interpersonal relationships of the RICO Marketing Defendants, and the Front Groups are further described below:

¹⁹⁰ The activities that the Front Groups engaged in, and the misrepresentations that they made, in furtherance of the common purpose of the Opioid Marketing Enterprise are alleged more fully below, under the heading “Conduct of the Opioid Marketing Enterprise.”

¹⁹¹ *Id.* at 12-15.

¹⁹² *Id.* at 12.

442. The American Pain Foundation (“APF”) - The American Pain Foundation was the most prominent member of the RICO Defendants’ Front Groups and was funded almost exclusively by the RICO Marketing Defendants. Plaintiff is informed and believes that APF received more than \$10 million in funding from the RICO Marketing Defendants between 2007 and the close of its business in May 2012. The APF had multiple contacts and personal relationships with the RICO Marketing Defendants through its many publishing and educational programs, funded and supported by the RICO Marketing Defendants. Plaintiff is further informed and believes that between 2009 and 2010, APF received more than eighty percent (80%) of its operating budget from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others.

443. On information and belief, APF was often called upon to provide “patient representatives” for the RICO Marketing Defendants’ promotional activities, including for Purdue’s “Partners Against Pain” and Janssen’s “Let’s Talk Pain.” APF functioned largely as an advocate for the interests of the RICO Marketing Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in nonprofit organizations that share [its] business interests.”

444. APF is also credited with creating the PCF in 2004. Plaintiff is informed and believes that the PCF was created with the stated goal of offering a “setting where multiple

organizations can share information” and “promote and support taking collaborative action regarding federal pain policy issues.” Plaintiff is informed and believes that past APF President Will Rowe described the PCF as “a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations.”

445. Upon information and belief, representatives of the RICO Marketing Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

446. Furthermore, APF’s Board of Directors was largely comprised of doctors who were on Defendants’ payrolls, either as consultants or speakers at medical events.¹⁹³ As described below, many of the KOLs involved in the Opioid Marketing Enterprise also served in leadership positions within the APF.

447. In December 2011, a ProPublica investigation found that in 2010, nearly 90% of APF’s funding came from the drug and medical device community, including RICO Marketing Defendants.¹⁹⁴ More specifically, APF received approximately \$2.3 million from industry sources out of total income of \$2.85 million in 2009. It’s budget for 2010 projected receipt of approximately \$2.9 million from drug companies, out of total income of approximately \$3.5 million. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid

¹⁹³ Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011), <https://www.propublica.org/article/the-champion-of-painkillers>.

¹⁹⁴ Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011), https://www.washingtonpost.com/national/healthscience/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probefinds/2011/12/20/gIQAgvzDP_story.html?utm_term=.22049984c606.

painkillers. Within days of being targeted by the Senate investigation, APF's Board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."¹⁹⁵

448. The American Academy of Pain Medicine ("AAPM") – The AAPM was another Front Group that had systematic ties and personal relationships with the RICO Defendants. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allowed drug company executives and marketing staff to meet with AAPM executive committee members in small settings. The RICO Marketing Defendants were all members of the council and presented deceptive programs to doctors who attended this annual event.¹⁹⁶

449. The RICO Marketing Defendants internally viewed AAPM as "industry friendly," with RICO Defendants' advisors and speakers among its active members. The RICO Marketing Defendants attended AAPM conferences, funded its CMEs and satellite symposia, and distributed its publications. AAPM conferences heavily emphasized sessions on opioids.

¹⁹⁵ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

¹⁹⁶ The American Academy of Pain Medicine, *Pain Medicine DC The Governing Voices of Pain: Medicine, Science, and Government*, March 24-27, 2011, <http://www.painmed.org/files/2011-annual-meeting-program-book.pdf>.

AAPM presidents have included top industry-supported KOLs like Perry Fine and Lynn Webster.

450. Upon information and belief, representatives of the RICO Marketing Defendants, often at informal meetings at conferences, suggested activities and publications for AAPM to pursue. AAPM 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.

451. Plaintiff is informed and believes that members of AAPM's Board of Directors were doctors who were on the RICO Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs involved in the Opioid Marketing Enterprise also served in leadership positions within the AAPM.

452. The American Pain Society ("APS") – The APS was another Front Group with systematic connections and interpersonal relationships with the RICO Marketing Defendants. APS was one of the Front Groups investigated by Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their investigation of “extensive ties between companies that manufacture and market opioids and non-profit organizations” that “helped created a body of dubious information favoring opioids.”¹⁹⁷

453. Upon information and belief, representatives of the RICO Marketing Defendants, often at informal meetings at conferences, suggested activities and publications for APS to pursue. APS then submitted grant proposals seeking to fund these activities and publications,

¹⁹⁷ Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director (May 8, 2012), American Pain Society, [https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American %20Pain%20Society.pdf](https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf).

knowing that drug companies would support projects conceived as a result of these communications.

454. Plaintiff is informed and believes that members of APS's Board of Directors were doctors who were on the RICO Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs involved in the Opioid Marketing Enterprise also served in leadership positions within the APS.

455. The Federation of State Medical Boards ("FSMB") - FSMB was another Front Group with systematic connections and interpersonal relationships with the RICO Marketing Defendants. In addition to the contributions reported in *Fueling an Epidemic*, a June 8, 2012 letter submitted by FSMB to the Senate Finance Committee disclosed substantial payments from the RICO Marketing Defendants beginning in 1997 and continuing through 2012.¹⁹⁸ Not surprisingly, the FSMB was another one of the Front Groups investigated by Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their investigation of "extensive ties between companies that manufacture and market opioids and non-profit organizations" that "helped created a body of dubious information favoring opioids."¹⁹⁹

456. The U.S. Pain Foundation ("USPF") – The USPF was another Front Group with systematic connections and interpersonal relationships with the RICO Marketing Defendants. The USPF was one of the largest recipients of contributions from the RICO Marketing Defendants, collection nearly \$3 million in payments between 2012 and 2015 alone.²⁰⁰ The USPF was also a critical component of the Opioid Marketing Enterprise's lobbying efforts to

¹⁹⁸ June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.

¹⁹⁹ Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director (May 8, 2012), American Pain Society, [https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American %20Pain%20Society.pdf](https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf).

²⁰⁰ *Fueling an Epidemic*, at p. 4.

reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the RICO Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as “Platinum,” “Gold,” and “Basic” corporate members.²⁰¹ Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

457. American Geriatrics Society (“AGS”) – The AGS was another Front Group with systematic connections and interpersonal relationships with the RICO Defendants. The AGS was a large recipient of contributions from the RICO Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with the RICO Marketing Defendants 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,²⁰² hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009.²⁰³ AGS’s complicity in the common purpose of the Opioid Marketing Enterprise 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.

²⁰¹ *Id.* at 12; Transparency, U.S. Pain Foundation, <https://uspainfoundation.org/transparency/> (last accessed on March 9, 2018).

²⁰² *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last accessed on March 9, 2018).

²⁰³ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J.

Sentinel, May 30, 2012.

458. Upon information and belief, representatives of the RICO Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

459. Plaintiff is informed and believes that members of AGS Board of Directors were doctors who were on the RICO Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs involved in the Opioid Marketing Enterprise also served in leadership positions within the AGS.

460. There was regular communication between each of the RICO Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations were coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the use of the wires and mail in which the RICO Markets Defendants, Front Groups, and KOLs share information necessary to overcome objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed to take actions to hide the scheme and continue its existence.

461. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would

have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

3. The KOLs

462. Similarly, each of the RICO Marketing Defendants financed, supported, utilized and relied on the same KOLs by paying, financing, supporting, managing, directing, or overseeing, and/or relying on their work. On Information and belief, the RICO Marketing Defendants cultivated this small circle of doctors solely because they favored the aggressive treatment of chronic pain with opioids.

463. The RICO Marketing Defendants and the Opioid Marketing Enterprise relied on their KOLs to serve as part of their speakers bureaus and to attend programs with speakers bureaus. The RICO Marketing Defendants graded their KOLs on performance, post-program sales, and product usage. Furthermore, the RICO Marketing Defendants expected their KOLs to stay "on message," and obtained agreements from them, in writing, that "all slides must be presented in their entirety and without alterations . . . and in sequence."

464. The RICO Marketing Defendants' KOLs have been at the center of the Opioid Marketing Enterprise's marketing efforts, presenting the false appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. As described in more detail below, the KOLs have written, consulted, edited, and lent their names to books and articles, and given speeches, and CMEs supporting chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of the pro-opioid Front Groups identified above.

465. The RICO Marketing Defendants and KOLS all had systematic connections and interpersonal relationships, as described below, through the KOLs receipt of payments from the RICO Marketing Defendants and Front Groups, the KOLs' authoring, publishing, speaking, and educating on behalf of the RICO Marketing Defendants, and their leadership roles and participation in the activities of the Front Groups, which were in turn financed by the RICO Marketing Defendants.

466. The systematic contacts and interpersonal relationships of the KOLs with the RICO Marketing Defendants and Front Groups are described below:

467. Dr. Russell Portenoy – Dr. Portenoy was one of the main KOLs that the RICO Marketing Defendants identified and promoted to further the common purpose of the Opioid Marketing Enterprise. Dr. Portenoy received research support, consulting fees, and honoraria from the RICO Defendants, and was a paid consultant to various RICO Marketing Defendants. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. Dr. Portenoy is credited as one of the authors on a primary pillar of the RICO Marketing Defendants' misrepresentation regarding the risks and benefits of opioid use.²⁰⁴ Dr. Portenoy

²⁰⁴ In 1986, the medical journal *Pain*, which would eventually become the official journal of the American Pain Society ("APS"), published an article by Portenoy and Foley summarizing the results of a "study" of 38 chronic non-cancer pain patients who had been treated with opioid painkillers. Portenoy and Foley concluded that, for non-cancer pain, opioids "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse." However, their study was neither scientific nor did it meet the rigorous standards commonly used to evaluate the validity and strength of such studies in the medical community. For instance, there was no placebo control group, and the results were retroactive (asking patients to describe prior experiences with opioid treatment rather than less biased, in-the-moment reports). The authors themselves advised caution, stating that the drugs should be used as an "alternative therapy" and recognizing that longer term studies of patients on opioids would have to be performed. None were. See Russell K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25(2) *Pain* 171-86 (May 1986).

had financial relationships with at least a dozen pharmaceutical companies, most of which produced prescription opioids.²⁰⁵

468. In exchange for the payments he received from the RICO Marketing Defendants, Dr. Portenoy is credited as one of the authors on a primary pillar of the RICO Marketing Defendants' misrepresentation regarding the risks and benefits of opioids.²⁰⁶ Dr. Portenoy, published, spoke, consulted, appeared in advertisements and on television broadcasts, and traveled the country to travel the country to promote more liberal prescribing for many types of pain and conduct continuing medical education ("CME") seminars sponsored by the RICO Marketing Defendants and Front Groups.

469. Dr. Portenoy was also a critical component of the RICO Marketing Defendants' control over their Front Groups, and the Front Groups support of the Opioid Marketing Enterprise's common purpose. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

470. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Dr. Portenoy admitted that his earlier work relied on evidence that was not "real" and left real evidence behind, all in furtherance of the Opioid Marketing Enterprise's common purpose:

²⁰⁵ Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*, (Johns Hopkins University Press 2016), at 59 (citing Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (St. Martin's Press, 1st Ed 2003).

²⁰⁶ In 1986, the medical journal *Pain*, which would eventually become the official journal of the American Pain Society ("APS"), published an article by Portenoy and Foley summarizing the results of a "study" of 38 chronic non-cancer pain patients who had been treated with opioid painkillers. Portenoy and Foley concluded that, for non-cancer pain, opioids "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse." However, their study was neither scientific nor did it meet the rigorous standards commonly used to evaluate the validity and strength of such studies in the medical community. For instance, there was no placebo control group, and the results were retroactive (asking patients to describe prior experiences with opioid treatment rather than less biased, in-the-moment reports). The authors themselves advised caution, stating that the drugs should be used as an "alternative therapy" and recognizing that longer term studies of patients on opioids would have to be performed. None were. See Russell K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25(2) *Pain* 171-86 (May 1986).

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.²⁰⁷

471. Dr. Lynn Webster – Dr. Webster was a critical component of the Opioid Marketing Enterprise, including advocating the RICO Marketing Defendants' fraudulent messages regarding prescription opioids and had systematic contacts and personal relationships with the RICO Marketing Defendants and the Front Groups.

472. Dr. Webster was the co-founder and Chief Medical Director of an otherwise unknown pain clinic in Salt Lake City, Utah (Lifetree Clinical Research), who went on to become one of the RICO Marketing Defendants' main KOLs. Dr. Webster was the President of American Academy of Pain Medicine ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from the RICO Marketing Defendants (including nearly \$2 million from Cephalon alone).

473. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than twenty (20) of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

474. 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

²⁰⁷ Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), <https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

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.

475. Dr. Webster is also credited as one of the leading proponents of “pseudoaddiction” that the RICO Marketing Defendants, Front Groups and KOLs disseminated as part of the common purpose of the Opioid Marketing Enterprise.

476. Plaintiff is informed and believes that in exchange for the payments he received from the RICO Marketing Defendants, Dr. Webster published, spoke, consulted, appeared in advertisements and on television broadcasts, and traveled the country to promote more liberal prescribing of opioids for many types of pain and conduct CME seminars sponsored by the RICO Marketing Defendants and Front Groups.

477. Like Dr. Portenoy, Dr. Webster later reversed his opinion and disavowed his previous work on and opinions regarding pseudoaddiction. Specifically, Dr. Webster acknowledged that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”²⁰⁸

478. Dr. Perry Fine – Dr. Webster was a critical component of the Opioid Marketing Enterprise, including advocating the RICO Marketing Defendants' fraudulent messages regarding prescription opioids and had systematic contacts and personal relationships with the RICO Marketing Defendants and the Front Groups.

²⁰⁸ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>.

479. Dr. Fine was originally a doctor practicing in Utah, who received support from the RICO Marketing Defendants, including Janssen, Cephalon, Endo, and Purdue. Dr. Fine's ties to the RICO Marketing Defendants have been well documented.²⁰⁹ He has authored articles and testified in court cases and before state and federal committees, and he served as president of the AAPM, and argued against legislation restricting high-dose opioid prescription for non-cancer patients. Multiple videos featured Fine delivering educational talks about prescription opioids. He even testified in a 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.²¹⁰ He has also acknowledged having failed to disclose numerous conflicts of interest.

480. Dr. Fine was also a critical component of the RICO Marketing Defendants' control over their Front Groups, and the Front Groups support of the Opioid Marketing Enterprise's common purpose. Specifically, Dr. Fine served on the Board of Directors of APF and served as the President of the AAPM in 2011.

481. Plaintiff is informed and believes that in exchange for the payments he received from the RICO Marketing Defendants, Dr. Fine published, spoke, consulted, appeared in advertisements and on television broadcasts, and traveled the country to promote more liberal prescribing of opioids for many types of pain and conduct CME seminars sponsored by the RICO Marketing Defendants and Front Groups.

482. Dr. Scott M. Fishman – Dr. Fishman was a critical component of the Opioid Marketing Enterprise, including advocating the RICO Marketing Defendants' fraudulent

²⁰⁹ Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>

²¹⁰ Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, Seattle Times (Sept. 22, 2010, 5:16 PM), <http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smithwas-addicted/>.

messages regarding prescription opioids and had systematic contacts and personal relationships with the RICO Marketing Defendants and the Front Groups.

483. Although Dr. Fishman did not receive direct financial payments from the RICO Marketing Defendants, his ties to the opioid drug industry are legion.²¹¹

484. As Dr. Fishman's personal biography indicates, he is critical component of the RICO Marketing Defendants' control over their Front Groups, and the Front Groups support of the Opioid Marketing Enterprise's common purpose. Specifically, Dr. Fishman is an "internationally recognized expert on pain and pain management" who has served in "numerous leadership roles with the goal to alleviate pain."²¹² Dr. Fishman's roles in the pain industry include "past president of the American Academy of Pain Medicine [AAPM], past chairman of the board of directors of the American Pain Foundation [APF], and past board member of the American Pain Society [APS]."²¹³ Dr. Fishman is also "the immediate past chair and current member of the Pain Care Coalition of the American Society of Anesthesiologists, American Pain Society, and Academy of Pain Medicine."²¹⁴ Dr. Fishman's leadership positions within the central core of the RICO Marketing Defendants' Front Groups was a direct result of his participation in the Opioid Marketing Enterprise and agreement to cooperate with the RICO Marketing Defendants' pattern of racketeering activity.

485. Plaintiff is informed and believes that in exchange for the payments he received from the RICO Marketing Defendants, Dr. Fishman published, spoke, consulted, appeared in advertisements and on television broadcasts, and traveled the country to promote more liberal

²¹¹ Scott M. Fishman, M.D., Professor, U.C. Davis Health, Center for Advancing Pain Relief, https://www.ucdmc.ucdavis.edu/advancingpainrelief/our_team/Scott_Fishman.html (accessed on February 28, 2018).

²¹² *Id.*

²¹³ *Id.*

²¹⁴ *Id.*

prescribing of opioids for many types of pain and conduct CME seminars sponsored by the RICO Marketing Defendants and Front Groups.

486. There was regular communication between each of the RICO Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations are coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the use of the wires and mail in which the RICO Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed to take actions to hide the scheme and continue its existence.

487. At all relevant times, the KOLs were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The RICO Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of

other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

488. As public scrutiny and media coverage focused on how opioids ravaged communities in Georgia and throughout the United States, the Front Groups and KOLS did not challenge the RICO Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

489. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As reported in *Fueling an Epidemic*, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain; (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability. The misrepresentations made in these publications are described in the following section.

490. Efforts to Minimize the Risk of Addiction and Promote Opioid Use As Safe for Long-Term Treatment of Chronic Pain – Members of the Opioid Marketing Enterprise furthered the common purpose of the enterprise by publishing and disseminating statements that minimized the risk of addiction and misrepresented the safety of using prescription opioids for long-term treatment of chronic, non-acute, and non-cancer pain. The categories of

misrepresentations made by the Opioid Marketing Enterprise and the RICO Defendants included the following:²¹⁵

- *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997). The “landmark consensus” was published by the AAPM and APS. Dr. Portenoy was the sole consultant. A member of Purdue’s speaker bureau authored the consensus.
- *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (1998, 2004, 2007).²¹⁶ These guidelines, originally published by the FSMB in collaboration with RICO Defendants, advocated that opioids were “essential” and that “misunderstanding of addiction” contributed to undertreated pain.
- *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, Testimony by John D. Giglio, M.A., J.D., Executive Direction of the APF (2002.)²¹⁷
- *The Management of Persistent Pain in Older Persons* (2002). These guidelines were published by AGS with substantial funding from Endo, Purdue and Janssen.
- *Overview of Management Options* (2003, 2007, 2010, and 2013).²¹⁸ This CME was edited by Dr. Portenoy, sponsored by Purdue, and published by the American Medical Association. It taught that opioids, unlike non-prescription pain medication are safe at high doses.
- *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004).²¹⁹ This article, published by Endo Pharmaceuticals advocated that withdrawal and needing to take higher dosages are not signs of addiction.

²¹⁵ As noted below, the earliest misrepresentations disseminated by the RICO Defendants and the Opioid Marketing Enterprise began in 1997 and has continued unabated since that time. Therefore, this list is alleged as fully and completely as possible.

²¹⁶ *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, Federation of State Medical Boards of the United States, May 2004, https://www.ihs.gov/painmanagement/includes/themes/newihstheme/display_objects/documents/modelpolicytreatm entpain.pdf (last accessed on March 9, 2018).

²¹⁷ *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, Testimony by John D. Giglio, M.A., J.D., Executive Direction of the APF (2002.)

²¹⁸ Portenoy, et al., *Overview of Management Options*, <https://cme.ama-assn.org/activity/1296783/detail.aspx>. On information and belief, this CME was published by the American Medical Association in 2003, 2007, 2010, and 2013.

²¹⁹ Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), <https://www.yumpu.com/en/document/view/35479278/understanding-your-pain-taking-oral-opioid-analgesics> (last accessed March 8, 2018).

- Interview by Paula Moyer with Scott M. Fishman, M.D. (2005). Dr. Fishman advocated that “the risks of addiction are . . . small and can be managed.”²²⁰
- *Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: interim safety and tolerability results* (2006).²²¹ Dr. Webster gave this CME, sponsored by Cephalon, that misrepresented that opioids were safe for the treatment of non-cancer pain.
- *Treatment Options: A Guide for People Living With Pain* (2007). This document was published by the APF and sponsored by Cephalon and Purdue.²²²
- *Responsible Opioid Prescribing: A Physician’s Guide* (2007).²²³ This book, authored by Dr. Fishman was financed by the FSMB with funding from Cephalon, Endo and Purdue.
- *Avoiding Opioid Abuse While Managing Pain* (2007).²²⁴ This book, co-authored by Dr. Webster, misrepresented that for prescribers facing signs of aberrant behavior, increasing the dose in “most cases . . . should be a clinician’s first response.”
- *Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0-SF* (2008).²²⁵ This screening tool was published by the National Institutes of Health with support from Endo through an educational grant, and advocated that most patients are able to successfully remain on long-term opioid therapy without significant problems.
- *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (2007).²²⁶ This article, sponsored by Endo, misrepresented that opioids are a highly effective class of analgesic drugs.

²²⁰ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005),

available at <http://www.medscape.org/viewarticle/500829>.

²²¹ Hale ME, Webster LR, Peppin JF, Messina J. *Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: interim safety and tolerability results. Program and abstracts of the annual meeting of the American Academy of Pain Medicine*; February 22-25, 2006; San Diego, California. Abstract 120. Published with permission of Lynn R. Webster, MD, https://www.medscape.org/viewarticle/524538_2 (accessed on March 6, 2018).

²²² Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed on March 8, 2018).

²²³ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9 (Waterford Life Sciences 2007).

²²⁴ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

²²⁵ *Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0-SF*, PainEdu.org, 2008, <https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf> (last accessed on March 8, 2018).

²²⁶ Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, https://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last visited on March 8, 2018).

- *Opioid-Based Management of Persistent and Breakthrough Pain* (2008).²²⁷ This document was written by Dr. Fine and sponsored by an educational grant from Cephalon. Dr. Fine advocated for the prescription of rapid onset opioids “in patients with non-cancer pain.”
- *Optimizing Opioid Treatment for Breakthrough Pain* (2008).²²⁸ Dr. Webster presented an online seminar (webinar) sponsored by Cephalon, that misrepresented that non-opioid analgesics and combination opioids containing non-opioids are less effective because of dose limitations.
- *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain* (2009).²²⁹ These guidelines were published by AAPM and APS. Fourteen of the twenty-one panel members, including Dr. Portenoy and Dr. Fine, received support from the RICO Defendants.
- *Pharmacological Management of Persistent Pain in Older Persons* (2009).²³⁰ These guidelines were published by AGS, with substantial funding from Endo, Purdue, and Janssen, updated the 2002 guidelines and misrepresented that the risks of addiction are exceedingly low.
- *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*,²³¹ American Pain Foundation, 2009. This article was published in 2009 and sponsored by Purdue.
- *Finding Relief: Pain Management for Older Adults*, (2009).²³² This article was a collaboration between the American Geriatrics Society, AAPM and Janssen.
- Good Morning America (2010). Dr. Portenoy appeared on Good Morning America and stated that “Addiction, when treating pain, is distinctly uncommon.”²³³

²²⁷ Perry G Fine, MD, et al. *Opioid-Based Management of Persistent and Breakthrough Pain*, Pain Medicine News, <https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain> (accessed on February 27, 2018).

²²⁸ Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, http://www.medscape.org/viewarticle/563417_6 (last visited Dec. 11, 2017).

²²⁹ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

²³⁰ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last accessed on March 9, 2018).

²³¹ *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, Coalition for Iraq + Afghanistan Veterans, <http://web.archive.org/web/20100308224011/http://coalitionforveterans.org:80/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families> (last visited March 1, 2018)

²³² *Finding Relief, Pain Management for Older Adults*, (2009).

- *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation (2011).²³⁴ APF published this document, that was sponsored by Purdue, which argued that the notion of strong pain leading to addiction is a common misconception.
- *Managing Patient's Opioid Use: Balancing the Need and the Risk* (2011).²³⁵ Dr. Webster presented a webinar, sponsored by Purdue, that misrepresented the ability to use risk screen tools, urine samples and patient agreements to prevent overuse and overdose death.
- *Safe and Effective Opioid Rotation* (2012).²³⁶ This CME, delivered by Dr. Fine, that is also available online, advocated for the safe and non-addictive use of opioids to treat cancer and non-cancer patients over a person's "lifetime."
- *Pain: Opioid Facts* (2012).²³⁷ This document was published online on Endo's website [painknowledge.org](http://www.painknowledge.org) and advocated for the use of opioids and downplayed the risk of addiction, even for people with a history of addiction and opioid use, and supported the concept of pseudoaddiction.

491. Efforts to Criticize or Undermine CDC Guidelines – Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guidelines which represented “an important step – and perhaps the first major step from the federal government – toward limiting opioid prescriptions for chronic pain.” The following are examples of the actions taken by Opioid Marketing Enterprise members to prevent restriction on over-prescription:

- Several Front Groups, including the U.S. Pain Foundation, and the AAPM criticized the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not

²³³ Good Morning America (ABC television broadcast Aug. 30, 2010).

²³⁴ *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation (2011) at 5, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last visited March 6, 2018).

²³⁵ See, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, Emerging Solutions in Pain http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

²³⁶ Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

²³⁷ *Pain: Opioid Facts*, http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opioid.pdf (last visited March 6, 2018).

transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines.”²³⁸

- The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating “that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”²³⁹

492. In each of the actions performed by members of the Opioid Marketing Enterprise, described above, the members of the Opioid Marketing Enterprise made branded and unbranded marketing claims about prescription opioids that misrepresented prescription opioids as non-addictive and safe for use as identified in following section.

4. Members of the Opioid Marketing Enterprise Furthered the Common Purpose by Making Misrepresentations.

493. The RICO Marketing Defendants, Front Groups and KOLs participated in the conduct of the Opioid Marketing Enterprise and shared in the common purpose of marketing opioids for chronic pain through a pattern of racketeering activity (including multiple instances of mail and wire fraud) by knowingly making material misrepresentations or omissions to Georgia prescribers, consumers, the general public, regulators and Plaintiff. All of the misrepresentations made by members of the Opioid Marketing Enterprise furthered the common purpose of the Enterprise.

494. Members of the Opioid Marketing Enterprise, including the RICO Marketing Defendants, Front Groups and KOLs made multiple unbranded marketing misrepresentations about the benefits and risks of opioid use, in furtherance of the Opioid Marketing Enterprise’s common purpose, as follows:

²³⁸ Pat Anson, *Chronic Pain Group Blasts CDC for Opioid Guidelines*, Pain News Networks, <https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines> (last accessed on March 8, 2018).

²³⁹ Practical Pain Management, *Responses and Criticisms Over New CDC Opioid Prescribing Guidelines* (<https://www.practicalpainmanagement.com/resources/news-and-research/responses-criticisms-over-new-cdc-opioid-prescribing-guidelines>) (accessed Sept. 28, 2017).

495. Members of the Opioid Marketing Enterprise minimized the risks of addiction and/or construed opioids as non-addictive:

- AAMP and APS endorsed the use of opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low.²⁴⁰
- “[O]pioids are safe and effective, and only in rare cases lead to addiction.”²⁴¹
- “[T]he risks of addiction are . . . small and can be managed.”²⁴²

Medscape: Controversy surrounds both the undertreatment and overtreatment of pain. Overtreatment of pain obviously involves the fear of causing or perpetuating opioid drug dependency. What recommendations can you give to primary care physicians who are reluctant to prescribe opioids, either as adjuncts or primary agents for pain control, because of these fears?

Dr. Fishman: It used to be that when you had a patient with pain and you were worried about giving him or her a drug that may be abusable or may cause addiction, the safest thing to do was nothing, as though doing nothing would have no risks in and of itself. We know that the risks of addiction are there, but they are small and can be managed. The AAPM is going to be at the forefront, educating

- Represented that calling opioids “‘narcotics’ reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines.”²⁴³

OPIOID ANALGESICS (NARCOTICS)

Opioid analgesics are another important class of medications that are very effective pain relievers. As mentioned before, they may also be called “narcotics.” Unfortunately, this term is used by law enforcement to refer to drugs that are abused. Cocaine and heroin are called narcotics even though they are very different kinds of drugs. Calling opioid analgesics “narcotics” reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines. In the pain treatment world, the word opioid is used when speaking about this class of medications.

²⁴⁰ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

²⁴¹ *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of John D. Giglio, M.A., J.D., Executive Director, American Pain Foundation), <https://www.help.senate.gov/imo/media/doc/Giglio.pdf>.

²⁴² Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005),

available at <http://www.medscape.org/viewarticle/500829>.

²⁴³ APF, *Treatment Options*, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed on March 8, 2018).

- “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”²⁴⁴
- The risk of addiction is manageable for patients regardless of past abuse histories.²⁴⁵
- “[T]he likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.”²⁴⁶
- Patients might experience withdrawal symptoms associated with physical dependence as the decrease their dose, “[b]ut unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain.”²⁴⁷
- The notion that “strong pain medication leads to addiction” is a “common misconception.”²⁴⁸

SOME COMMON MISCONCEPTIONS ABOUT PAIN

Use of strong pain medication leads to addiction. Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit www.painsafe.org.

- “Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don’t need it for pain, maybe just to escape your problems.”²⁴⁹

²⁴⁴ Good Morning America (ABC television broadcast Aug. 30, 2010).

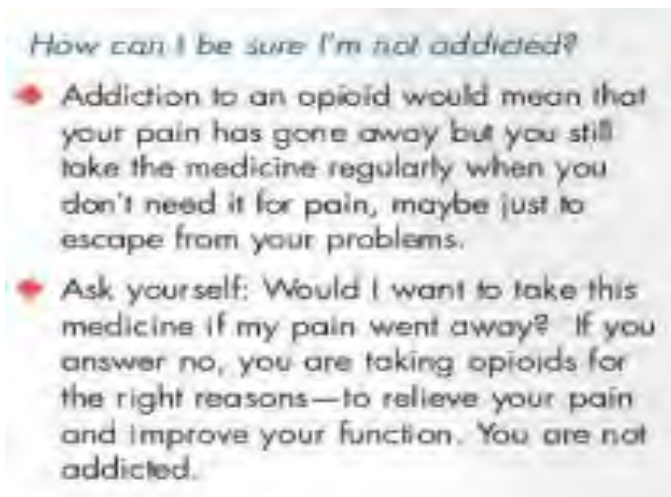
²⁴⁵ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

²⁴⁶ Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

²⁴⁷ Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.

²⁴⁸ *A Policymaker’s Guide to Understanding Pain & Its Management*, American Pain Foundation (2011) at 5, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last visited March 6, 2018).

²⁴⁹ Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), <https://www.yumpu.com/en/document/view/35479278/understanding-your-pain-taking-oral-opioid-analgesics> (last accessed March 8, 2018).



- Even for patients assessed to have a risk of abuse, “it does not mean that opioid use will become problematic or that opioids are contraindicated.”²⁵⁰
- [P]eople who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.”²⁵¹



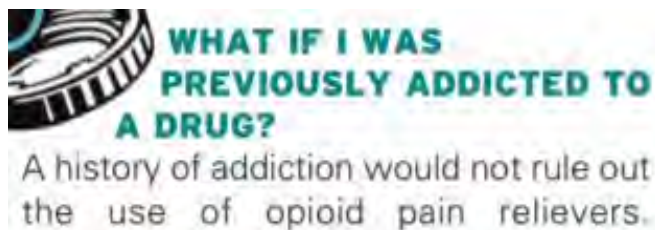
²⁵⁰ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (Waterford Life

Sciences 2007).

²⁵¹ *Pain: Opioid Facts*,

http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20pf%20opioid.pdf (last visited March 6, 2018).

- “A history of addiction would not rule out the use of opioid pain relievers.”²⁵²



- APF published exit wounds, wherein it represented that “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.”²⁵³



- Patients rarely become addicted to prescribed opioids.²⁵⁴
- Concern about patients becoming addicted reflects widespread failure to appreciate the distinction between “(1) *tolerance* – the body’s tendency to become accustomed to a substance so that, over time, a larger amount is needed to produce the same physical effect (pain relief) and *physical dependence* – the state defined by the experience of adverse symptoms if a drug is abruptly withdrawn . . each of which is common with pain patients” . . . “and, on the other hand, (2) the psychological and behavioral patterns – an

²⁵² *Id.*

²⁵³ *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, Coalition for Iraq + Afghanistan Veterans, <http://web.archive.org/web/20100308224011/http://coalitionforveterans.org:80/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families> (last visited March 1, 2018).

²⁵⁴ Brief of Amici the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain, 2005 WL 2405247, *9 (citing Portenoy, Russell, et al., *Acute and Chronic Pain*, in *COMPREHENSIVE TEXTBOOK OF SUBSTANCE ABUSE*, 863-903 (Lowinson et al. eds., 4th ed. 2005), *United States v. Hurowitz*, 459 F.3d 463 (2006) (citing Portenoy et. al, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, PAIN, Vol. 25, 171-186, (1986)).

unhealthy craving for, compulsive use of, and unhealthy fixation – that characterize *addiction*.²⁵⁵

- Evidence establishes that the risk of drug addiction (historically the principal *medical* justification for withholding or limiting opioids) is far *less* substantial than long and widely assumed.²⁵⁶
- The “risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.”²⁵⁷

the addiction. Although the risks are exceedingly low in older patients with no current or past history of substance abuse, it is impossible to identify every patient who will abuse or divert prescribed opioids.¹¹⁷ Therefore, many clinicians have adopted a Universal Precautions approach to pain management.¹¹⁸ This paradigm stresses that every pa-

496. Members of the Opioid Marketing Enterprise advocated that opioids were safe and effective for long-term treatment of chronic, non-acute and non-cancer pain:

- “Opioids are an essential option for treating *moderate* to severe pain associated with surgery or trauma. They may also be an important part of the management of persistent pain unrelated to cancer.”²⁵⁸

Clinical uses

Opioids are an essential option for treating moderate to severe pain associated with surgery or trauma, and for pain related to cancer. They may also be an important part of the management of persistent pain unrelated to cancer. These medicines block pain

- Opioids were a safe and effective treatment for of pain as part of a physicians’ treatment guidelines.²⁵⁹
- The “small risk of abuse does not justify the withholding of these highly effective analgesics from chronic pain patients.”²⁶⁰

²⁵⁵ Brief of Amici Russel K. Portenoy, *et al.*, 2005 WL 2405249, *United States v. Hurwitz*, 459 F.3d 463 (2006) (emphasis in original).

²⁵⁶ *Id.* and sources cited at note 9.

²⁵⁷ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last accessed on March 9, 2018).

²⁵⁸ APF, *Treatment Options*, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

²⁵⁹ Roger Chou *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

²⁶⁰ Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.

- Opioids, unlike some non-prescription pain medications, are safe at high doses.²⁶¹
- Falsely representing “recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems.”²⁶²
- Opioid therapy is an appropriate treatment for chronic, non-cancer pain and integral to good medical practice.²⁶³
- Even for patients assessed to have a risk of abuse, “it does not mean that opioid use will become problematic or that opioids are contraindicated.”²⁶⁴
- Opioid therapy is an appropriate treatment for chronic, non-cancer pain and integral to good medical practice.²⁶⁵
- Broadly classifying pain syndromes as “either cancer- or non-cancer-related has limited utility,” and recommended dispensing rapid onset opioids “in patients with non-cancer pain.”²⁶⁶
- Opioids are safe and well-tolerated in patients with chronic pain and break through pain.²⁶⁷

The data suggest that FEBT is safe and well tolerated in opioid-tolerant patients with chronic noncancer pain. There was no respiratory depression, and a low incidence of treatment-related adverse events was reported. Thirty-five patients (37%) reported having at least 1 adverse event, the most common of which were nausea (7%) and dizziness (5%).

²⁶¹ Portenoy, et al., *Overview of Management Options*, <https://cme.ama-assn.org/activity/1296783/detail.aspx>. On information and belief, this CME was published in 2003, 2007, 2010, and 2013.

²⁶² *Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0-SF*, PainEdu.org, 2008, <https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf> (last accessed on March 8, 2018).

²⁶³ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (Waterford Life Sciences 2007).

²⁶⁴ *Id.*

²⁶⁵ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (Waterford Life Sciences 2007).

²⁶⁶ Perry G Fine, MD, et al. *Opioid-Based Management of Persistent and Breakthrough Pain*, Pain Medicine News, <https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain> (accessed on February 27, 2018).

²⁶⁷ Hale ME, Webster LR, Peppin JF, Messina J. *Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: interim safety and tolerability results. Program and abstracts of the annual meeting of the American Academy of Pain Medicine*; February 22-25, 2006; San Diego, California. Abstract 120. Published with permission of Lynn R. Webster, MD, https://www.medscape.org/viewarticle/524538_2 (accessed on March 6, 2018).

- Non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective than opioids because of dose limitations on non-opioids.²⁶⁸

adverse events. Furthermore, although nonopioid analgesics, such as acetaminophen and NSAIDs/COX-2 inhibitors, are effective for nociceptive pain, their use in BTP is likewise restricted by dose-limiting toxicities, an onset of action that is delayed by 30 minutes or more, a long duration of action that could augment sedation and other side effects of the agent used for the baseline pain, and fears about renal and cardiovascular complications. Agents that combine an SAO, such as hydrocodone plus acetaminophen, aspirin, or ibuprofen, also are limited by potential adverse events and ceiling effects from the nonopioid component.

- Opioids can safely alleviate chronic pain unresponsive to other medication.²⁶⁹
- Medical organization and government-sponsored clinical guidelines support and encourage opioid treatment for chronic pain.²⁷⁰
- Respiratory depression, even at extremely high levels, does not occur in the context of appropriate clinical treatment.²⁷¹
- There is no “ceiling dose” for opioids.²⁷²
- Opioid analgesics are the most effective way to treat pain of moderate to severe intensity and often the only treatment that provides significant relief.²⁷³
- “Opioid rotations” (switching from one opioid to another) not only for cancer patients, but also for non-cancer patients, may need to occur four or five times over a person’s “lifetime” to manage pain.²⁷⁴
- Opioids represent a highly effective . . . 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,

²⁶⁸ Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, http://www.medscape.org/viewarticle/563417_6 (last visited Dec. 11, 2017).

²⁶⁹ Brief of Amici the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain, 2005 WL 2405247, *8, *United States v. Hurowitz*, 459 F.3d 463 (2006) (citing Portenoy et. al, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, PAIN, Vol. 25, 171-186, (1986)).

²⁷⁰ *Id.* at *8, and sources cited in note 11.

²⁷¹ *Id.*

²⁷² *Id.*

²⁷³ ²⁷³ Brief of Amici Russel K. Portenoy, et al., 2005 WL 2405249, *United States v. Hurwitz*, 459 F.3d 463.

²⁷⁴ Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.²⁷⁵

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.³

497. Members of the Opioid Marketing Enterprise created and championed the concept of “pseudoaddiction,” advocating that signs of addiction were actually pseudoaddiction that required prescribing additional opioids:

- Patients might experience withdrawal symptoms associated with physical dependence as the decrease their dose, “[b]ut unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain.”²⁷⁶
- “Addiction **IS NOT** when a person develops ‘withdrawal’ (such as abdominal cramping or sweating) after the medicine is stopped or the dose is reduced by a large amount. . . . Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal ‘tolerance’ to opioid medications doesn’t affect everyone who takes them and does not, by itself, imply addiction.”²⁷⁷

²⁷⁵ Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, 2007, https://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last visited on March 8, 2018).

²⁷⁶ Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.

²⁷⁷ Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf (emphasis in original) (last accessed on March 9, 2018).

WHAT SHOULD I KNOW ABOUT OPIOIDS AND ADDICTION?

You or your family may have questions about addiction. It is important to understand what addiction is. Addiction **IS** a chronic brain disease that can occur in some people exposed to certain substances such as alcohol, cocaine, and opioids. Taking opioids for pain relief is not addiction. People addicted to opioids crave the opioid and use it regularly for reasons other than pain relief.

Addiction **IS NOT** when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.

- “Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don’t need it for pain, maybe just to escape your problems.”²⁷⁸

How can I be sure I’m not addicted?

- ◆ Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don’t need it for pain, maybe just to escape from your problems.
- ◆ Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve your pain and improve your function. You are not addicted.

²⁷⁸ *Id.*

- Behaviors such as “[r]equesting [drugs] by name,” “[d]emanding or manipulative behavior,” “[o]btaining drugs from more than one physician,” and “[h]oarding opioids,” are all really signs of pseudoaddiction, rather than genuine addiction.”²⁷⁹
- “Sometimes people behave as if they are addicted, when they are really in need of more medication.”²⁸⁰

• **ADDICTION** - A craving that drives a person to take an opioid even though it causes harm. This is a problem that needs immediate treatment. This happens to some patients who use opioids.

Sometimes people behave as if they are addicted, when they are really in need of more medication. This can be treated with higher doses of medicine.

- For prescribers facing signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.”²⁸¹

498. Members of the Opioid Marketing Enterprise advocated that long-term use of prescription opioids would improve function, including but not limited to, psychological health, and health-related quality of life:

- When opioids are managed, properly prescribed and taken as directed, they are effective in improving daily function, psychological health and health-related quality of life.²⁸²

²⁷⁹ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9 (Waterford Life

Sciences 2007).

²⁸⁰ *Pain: Opioid Facts*,

http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited March 6, 2018).

²⁸¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

²⁸² *A Policymaker’s Guide to Understanding Pain & Its Management*, American Pain Foundation (2011) at 5, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last visited March 6, 2018).

Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain¹²

- Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins.²⁸³
- “[Y]our 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.”²⁸⁴
- “The goal of opioid therapy is to . . . improve your function.”²⁸⁵

The goal of opioid therapy is to control pain and improve your function.

- The “goal” for chronic pain patients is to “improve effectiveness which is different from efficacy and safety.”²⁸⁶

²⁸³ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9 (Waterford Life

Sciences 2007); Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician’s Guide*, 10-11 (2d ed. 2012).

²⁸⁴ Plaintiffs are informed and believe that this misrepresentation was made on the website [painknowledge.org](http://www.painknowledge.org).

²⁸⁵ *Pain: Opioid Facts*,

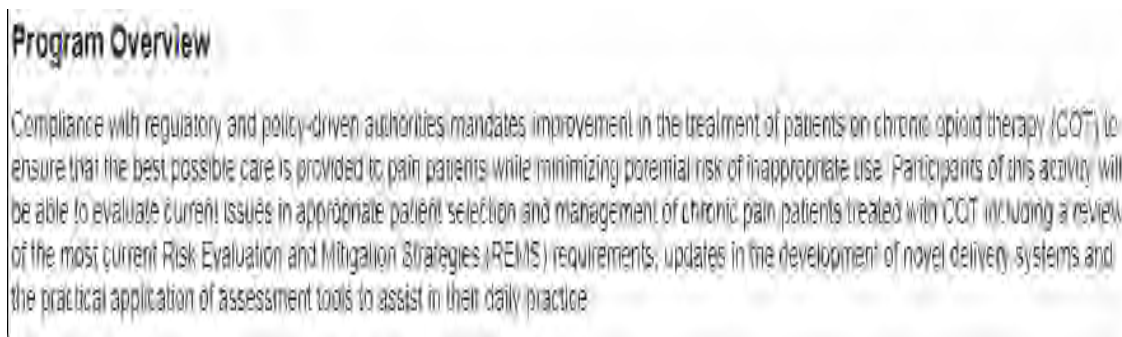
http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opioid.pdf (last visited March 6, 2018).

²⁸⁶ Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.



499. Members of the Opioid Marketing Enterprise represented that screening questions and professional guidelines would help curb addiction and potential abuse:

- Screening questions and professional guidelines will “easily and efficiently” allow physicians to manage risk and “minimize the potential for abuse.”²⁸⁷
- Risk screening tools, urine testing, and patient agreements are a way to prevent “overuse of prescriptions” and “overdose deaths.”²⁸⁸



- The risks of addiction and abuse can be managed by doctors and evaluated with “tools.”²⁸⁹

²⁸⁷ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (Waterford Life

Sciences 2007).

²⁸⁸ See, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, Emerging Solutions in Pain http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

500. In addition to the unbranded marketing misrepresentations made by members of the Opioid Marketing Enterprise, the RICO Marketing Defendants made misrepresentations in their branded marketing activities. The RICO Marketing Defendants' branded marketing misrepresentations furthered the common purpose of the Opioid Marketing Enterprise because they advanced the common messages of the Opioid Marketing Enterprise. For example:

501. The RICO Marketing Defendants misrepresented that opioids were non-addictive or posed less risk of addiction or abuse:

- **Purdue:**

- "Fear of addiction is exaggerated."²⁹⁰

The fear of addiction is exaggerated.
One cause of patient resistance to appropriate pain treatment – the fear of addiction – is largely unfounded. According to Dr. Max, "Experts agree that most pain caused by surgery or cancer can be relieved, primarily by carefully adjusting the dose of opioid (narcotic) pain reliever to each patient's need, and that there is very little risk of addiction from the proper uses of these drugs for pain relief."
Paul D. Goldenheim, M.D., Vice President of **Purdue Pharma** L.P. in Norwalk, Connecticut, agrees with this assessment. "Proper use of medication is an essential weapon in the battle against persistent pain. But too often fear, misinformation and poor communication stand in the way of their legitimate use."

- "[W]e've discovered that the simplicity and convenience of twice-daily dosing also enhances patient compliance with their doctor's instructions."²⁹¹

²⁸⁹ Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

²⁹⁰ Harriet Ryan, et al., "You Want A Description of Hell?" *OxyContin's 12-Hour Problem*, L.A. Times (May 5, 2016), <http://documents.latimes.com/oxycontin-press-release-1996/> (hereinafter "Ryan, Description of Hell")

²⁹¹ *Id.*

taking tablets every four to six hours. Moreover, we've discovered that the simplicity and convenience of twice-daily dosing also enhances

https://www.nexis.com/results/enhdocview.do?docLinkInd=true&ersKey=23_T23962617276&format=GNBF

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patient compliance with their doctor's instructions."

- Long-acting, extended release formulations are safe and "less prone" to abuse by patients and addiction.²⁹²
- OxyContin is safe and non-addictive when using extended release formulations, and appropriate for use in non-cancer patients.²⁹³
- Consistently minimizing the risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain.²⁹⁴
- OxyContin is virtually non-addicting.²⁹⁵
- "Assur[ing] doctors – repeatedly and without evidence – that 'fewer than one percent' of patients who took OxyContin became addicted."²⁹⁶

²⁹² Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. Times (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html> (hereinafter "Meier, Guilty Plea").

²⁹³ Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), http://www.opb.org/news/article/america_pain_foundation_shuts_down_as_senators_launch_investigation_of_prescription_narcotics/ (hereinafter "Ornstein, American Pain Foundation").

²⁹⁴ Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph*, Public Health Tragedy, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009) (hereinafter, "Van Zee, Promotion and Marketing").

²⁹⁵ Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>

²⁹⁶ *Id.*; see also "I got my life back," OxyContin Promotional Video, 1998, <https://www.youtube.com/watch?v=Er78Dj5hyeI> (last accessed on March 8, 2018).



- OxyContin was addiction resistant and had “abuse-deterrent properties.”²⁹⁷
- Misrepresented the risk of addiction using misleading and inaccurate promotions of OxyContin that were unsupported by science.²⁹⁸
- It was more difficult to extract the oxycodone from an OxyContin tablet for intravenous abuse.²⁹⁹
- OxyContin created fewer chances for addiction than immediate-release opioids.³⁰⁰
- OxyContin had fewer “peak and trough” effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.³⁰¹
- Patients could abruptly stop opioid therapy without experiencing withdrawal symptoms, and patients who took OxyContin would not develop tolerance.³⁰²
- OxyContin did not cause a “buzz,” caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to “weed out” addicts and drug seekers.³⁰³

²⁹⁷ *Id.*

²⁹⁸ Press Release, U.S. Attorney for the Western District of Virginia, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), <https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf>.

²⁹⁹ *Id.*

³⁰⁰ *Id.*

³⁰¹ *Id.*

³⁰² *Id.*

³⁰³ *Id.*

- Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading, “Indications of Possible Drug Abuse,” shows pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. Thus, these misrepresentations wrongly reassured doctors that as long as they do not observe those signs, they need not worry that their patients are abusing or addicted to opioids.
- Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. This publication is still available online. This publication also asserted that pain is undertreated due to “misconceptions about opioid addiction.”
- Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.
- A Purdue-funded study with a Purdue co-author claimed that “evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse.”³⁰⁴ The study relied only on the 1980 Porter-Jick letter to the editor concerning a chart review of hospitalized patients, not patients taking Purdue’s long-acting, take-home opioid. Although the term “low” is not defined, the overall presentation suggests the risk is so low as not to be a worry.
- Purdue contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines’ content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.
- Purdue sponsored APF’s *Exit Wounds* (2009), which counseled veterans that “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.” Although the term “very unlikely” is not defined, the overall presentation suggests it is so low as not to be a worry.

³⁰⁴ C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy*, 105 *Pain* 71 (2003).

- Purdue sales representatives told prescribers that its drugs were “steady state,” the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.
 - Purdue sales representatives told prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamperproof and, after a certain point, patients no longer experience a “buzz” from increased dosage.
 - Advertisements that Purdue sent to prescribers stated that OxyContin ER was less likely to be favored by addicts, and, therefore, less likely to be abused or diverted, or result in addiction.
 - In discussions with prescribers, Purdue sales representatives omitted discussion of addiction risks related to Purdue’s drugs.
- **Janssen:**
 - **Myth:** Opioid medications are always addictive.
Fact: Many studies show that opioids are rarely addictive when used properly for the management of chronic pain.³⁰⁵
 - **Myth:** Opioid doses have to get bigger over time because the body gets used to them.
Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.³⁰⁶
 - “[Q]uestions of addiction,” “are often overestimated” because, “[a]ccording to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics.”³⁰⁷

Other Opioid Analgesic Concerns

Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and **questions of addiction**.^{15, 16} By the same token, patients report similar concerns about developing an addiction to opioid analgesics.¹⁷ While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics analgesic therapy.¹⁸

³⁰⁵ *Finding Relief, Pain Management for Older Adults*, (2009) (emphasis in original).

³⁰⁶ *Finding Relief, Pain Management for Older Adults*, (2009) (emphasis in original).

³⁰⁷ *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last visited Dec. 11, 2017).

- Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a “myth” that opioids are addictive, and asserts as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” Although the term “rarely” is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use is not a problem.
- Janssen contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” The study supporting this assertion does not analyze addiction rates by age and, as already noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines’ content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.
- Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.” Although the term “very unlikely” is not defined, the overall presentation suggests the risk is so low as not to be a worry.
- Janssen currently runs a website, Prescriberresponsibly.com (last modified July 2, 2015), which claims that concerns about opioid addiction are “overstated.”
- A June 2009 Nucynta Training module warns Janssen’s sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because “the risks . . . are much smaller than commonly believed.”
- Janssen sales representatives told prescribers that its drugs were “steady state,” the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.
- Janssen sales representatives told prescribers that Nucynta and Nucynta ER were “not opioids,” implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen’s drugs. In truth, however, as set out in Nucynta’s FDA-mandated label, Nucynta “contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit.”
- Janssen’s sales representatives told prescribers that Nucynta’s unique properties eliminated the risk of addiction associated with the drug.
- In discussions with prescribers, Janssen sales representatives omitted discussion of addiction risks related to Janssen’s drugs.

- **Cephalon:**

- Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which claims, among other things, that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.”
- Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.
- In discussions with prescribers, Cephalon sales representatives omitted any discussion of addiction risks related to Cephalon’s drugs.

- **Endo:**

- Opana ER was designed to be crush resistant
- Opana ER was crush and abuse resistant and not addictive.³⁰⁸
- “[T]he Reformulated Opana ER as ‘designed to be’ crush resistant.”³⁰⁹
- “[P]atients treated with prolonged opioid medicines usually do not become addicted.”³¹⁰
- Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence.
- Endo’s advertisements for the 2012 reformulation of Opana ER claimed it was designed to be crush resistant, in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence Endo’s design “would provide a reduction in oral, intranasal or intravenous abuse” and Endo’s “post-marketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse.” Further, Endo instructed its sales representatives to repeat this claim about “design,” with the intention of conveying Opana ER was less subject to abuse.
- Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that: “[p]eople who take opioids as prescribed usually do not

³⁰⁸ *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15, at 5 (Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

³⁰⁹ *Id.* at 6.

³¹⁰ *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15, at 5 (Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

become addicted.” Although the term “usually” is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

- Endo sponsored a website, PainAction.com, which stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”
- Endo sponsored CMEs published by APF’s NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult and Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present “possibly less potential for abuse than in younger patients[,]” which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients.
- Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction: “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”
- Endo distributed a patient education pamphlet edited by key opinion leader Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that “[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems.” This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue.
- Endo contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines’ content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.
- Endo sales representatives told prescribers that its drugs were “steady state,” the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.
- Endo provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.” Although the term “very unlikely” is not defined, the overall presentation suggests that the risk is so low as not to be a worry.

- In discussions with prescribers, Endo sales representatives omitted discussion of addiction risks related to Endo's drugs.

502. The RICO Marketing Defendants misrepresented that opioids improved function and quality of life:

- **Purdue:**

- “[W]e’ve discovered that the simplicity and convenience of twice-daily dosing also enhances patient compliance with their doctor’s instructions.”³¹¹

taking tablets every four to six hours. Moreover, we’ve discovered that the simplicity and convenience of twice-daily dosing also enhances

https://www.nexis.com/results/enhdocview.do?docLinkInd=true&ersKey=23_T23962617276&format=GNBF

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patient compliance with their doctor’s instructions.”

- Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled “Pain vignettes,” which were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, “Paul,” is described to be a “54-year-old writer with osteoarthritis of the hands,” and the vignettes imply that an OxyContin prescription will help him work more effectively.
- Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which inaccurately 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.” The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: “For functional outcomes, the other analgesics were significantly more effective than were opioids.” *The Policymaker’s Guide* is still available online.
- Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, “give [pain patients] a quality of life we deserve.” APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the guide currently is available online.

³¹¹ Ryan, *Description of Hell*, <http://documents.latimes.com/oxycontin-press-release-1996/>

- Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans that opioid medications "increase your level of functioning." *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.
- Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over \$100,000 to support distribution of the book.
- **Janssen:**
 - Misrepresented that patients experienced "[s]ignificantly reduced nighttime awakenings."³¹²
 - Misrepresented "[s]ignificant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index."³¹³
 - Misrepresented "[s]ignificant improvement in social functioning."
 - Misrepresented outcome claims that were misleading because they lacked substantial support, evidence or clinical experience and "impl[ied] that patients will experience improved social or physical functioning or improved work productivity when using Duragesic," including: "1,360 loaves . . . and counting, [w]ork, uninterrupted, [l]ife, uninterrupted, [g]ame, uninterrupted, [c]hronic pain relief that supports functionality, [h]elps patients think less about their pain, and [i]mprove[s] . . . physical and social functioning."³¹⁴
 - Misrepresented that "[o]pioid analgesics, for example, have no true 'ceiling dose' for analgesia and do not cause direct organ damage."³¹⁵

³¹² NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

³¹³ *Id.*

³¹⁴ *Id.* at 3 (internal quotations omitted).

³¹⁵ *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last visited Dec. 11, 2017).

Use of Opioid Analgesics in Pain Management

Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true “ceiling dose” for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.³¹⁶

- **Myth:** Opioids make it harder to function normally.
Fact: When used correctly for appropriate conditions, opioids may make it easier for people to live normally.³¹⁶
- Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a “fact” that “opioids may make it easier for people to live normally” (emphasis in the original). The myth/fact structure implies authoritative backing for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population.
- Janssen sponsored, developed, and approved content of a website, *Let’s Talk Pain* in 2009, acting in conjunction with the APF and AAPM whose participation in Let’s Talk Pain Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to “continue to function,” inaccurately implying her experience would be representative. This video is still available today on youtube.com.
- Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications “increase your level of functioning” (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

- **Cephalon:**

- Cephalon sponsored the FSMB’s Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients’ function.

³¹⁶ *Finding Relief, Pain Management for Older Adults*, (2009) (emphasis in original).

Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a “long-term therapeutic treatment course.” Cephalon also spent \$150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

- Cephalon sponsored the American Pain Foundation’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids when used properly “give [pain patients] a quality of life we deserve.” The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the publication is currently available online.
- Cephalon sponsored a CME written by Dr. Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007, through December 15, 2008. The CME taught that Cephalon’s Actiq and Fentora improve patients’ quality of life and allow for more activities when taken in conjunction with long-acting opioids.

- **Endo:**

- Opana ER “will benefit patients, physicians and payers.”³¹⁷

"Patient safety is our top concern and addressing appropriate use of opioids is a responsibility that we take very seriously. We firmly believe this new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."

- “Endo distributed a pamphlet in New York and posted on its public website, www.opana.com, photographs of purported Opana ER patients that implied that patients can achieve higher function with Opana ER.”³¹⁸
- Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 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.” Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

³¹⁷ FDA Approves Endo Pharmaceuticals’ Crush-Resistant Opana ER, December 12, 2011,

<https://www.biospace.com/article/releases/fda-approves-endo-pharmaceuticals-crush-resistant-opana-er/>.

³¹⁸ *Id.* at 8.

- A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.”
- Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This flyer also emphasized Opana ER’s indication without including equally prominent disclosure of the “moderate to severe pain” qualification.
- Endo’s sales force distributed FSMB’s *Responsible Opioid Prescribing* (2007). This book taught that relief of pain itself improved patients’ function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a “long-term therapeutic treatment course.”
- Endo provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications “increase your level of functioning” (emphasis in the original). Exit Wounds also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

503. The RICO Marketing Defendants misrepresented that addiction risks can be avoided or managed through screening tools and prescription guidelines:

- **Purdue:**

- Purdue’s unbranded website, In the Face of Pain (inthefaceofpain.com) states that policies that “restrict[] access to patients with pain who also have a history of substance abuse” and “requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe” are “at odds with” best medical practices.³¹⁹
- Purdue sponsored a 2012 CME program taught by a KOL titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior.
- Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, titled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.”

³¹⁹ See In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment, Purdue Pharma L.P. (Resources verified Mar. 2012), www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf.

- Purdue sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction.
- **Cephalon:**
 - Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."
- **Endo:**
 - Endo paid for a 2007 supplement³²⁰ available for continuing education credit in the Journal of Family Practice and written by a doctor who later became a member of Endo's speakers bureau. This publication, titled *Pain Management Dilemmas in Primary Care: Use of Opioids*, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely (e.g., without becoming addicted) receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

504. The RICO Marketing Defendants misrepresented that signs of opioid addiction were not addiction, withdrawal could be simply managed, and promoted the concept of pseudoaddiction:

- **Purdue:**
 - Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."
 - Purdue distributed to physicians, at least as of November 2006 and posted on its unbranded website, Partners Against Pain, a pamphlet copyrighted 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct including "illicit drug use and deception" it defined as indicative of pseudoaddiction or untreated pain. It also states: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

³²⁰ The Medical Journal, The Lancet found that all of the supplement papers it received failed peer-review. Editorial, "The Perils of Journal and Supplement Publishing," 375 The Lancet 9712 (347) 2010.

- Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name, “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction. Purdue also spent over \$100,000 to support distribution of the book.
- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which states: “Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.”
- *A Policymaker's Guide to Understanding Pain & Its Management* also taught that “Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation,” but did not disclose the significant hardships that often accompany cessation of use.
- Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be successfully managed.
- Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans' low potency and its extended release mechanism.
- **Janssen:**
 - Janssen's website, Let's Talk Pain, stated from 2009 through 2011 that “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated” and “[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”
 - A Janssen PowerPoint presentation used for training its sales representatives titled “*Selling Nucynta ER*” indicates that the “low incidence of withdrawal symptoms” is a “core message” for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use, when Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered

by patients who use opioids for chronic pain—the use for which Janssen promoted Nucynta ER.

- Janssen sales representatives told prescribers that patients on Janssen's drugs were less susceptible to withdrawal than those on other opioids.

- **Cephalon:**

- Cephalon sponsored FSMB's Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction. Cephalon also spent \$150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

- **Endo:**

- Endo distributed copies of a book by KOL Dr. Lynn Webster entitled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as pseudoaddiction and thus, increasing the dose in most cases . . . should be the clinician's first response."
- Endo spent \$246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."
- A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.
- Endo misrepresented that "symptoms of withdrawal do not indicate addiction."³²¹
- "Endo also trained its sales representatives to distinguish addiction from 'pseudoaddiction.'"³²²

505. The RICO Defendants misrepresented that opioids were safe for the long-term treatment of chronic, non-acute, and non-cancer pain:

³²¹ *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15, at 7 (Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

³²² *Id.*

- **Purdue:**

- “[W]e do not want to niche OxyContin just for cancer pain.”³²³

three tablet strengths were passed around. OxyContin will be indicated for the relief of pain with the convenience of q12h dosing. OxyContin's primary market positioning will be for cancer pain and the secondary market will be for non-malignant pain (musculoskeletal, injury and trauma). It was reinforced that we do not want to niche OxyContin just for cancer pain. OxyContin will be positioned into Step 2 of the

- OxyContin was safe and non-addictive when using extended release formulations, and appropriate for use in non-cancer patients.³²⁴
- OxyContin should be prescribed not merely for severe short-term pain associated with surgery or cancer, but also for less acute, longer-lasting pain like arthritis, back pain, sports injuries, fibromyalgia with almost limitless treatment potential.³²⁵

- **Janssen:**

- Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence.”³²⁶
- Duragesic was “not just for end stage cancer anymore” when the FDA only approved Duragesic for “the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means.”³²⁷
- Misrepresented that “Duragesic can be used for any type of pain management” despite the fact that the FDA approved warning stated that “BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED: In the management of acute or post-operative pain, including use in outpatient surgeries”³²⁸
- Misrepresented “numerous claims for the efficacy and safety of Duragesic,” but failed to “present[] any risk information concerning the boxed warnings,

³²³ Ryan, *Description of Hell*, <http://documents.latimes.com/oxycontin-launch-1995/> (emphasis in the L.A. Times document).

³²⁴ Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), http://www.opb.org/news/article/america_pain_foundation_shuts_down_as_senators_launch_investigation_of_prescription_narcotics/ (hereinafter “Ornstein, *American Pain Foundation*”).

³²⁵ Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>

³²⁶ NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

³²⁷ *Id.*

³²⁸ *Id.*

contraindications, warnings, or side effects associated with Duragesic's use . . . [and] . . . fail[ed] to address important risks and restrictions associated with Duragesic therapy.”³²⁹

- Misrepresented “[d]emonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep.”³³⁰

- **Cephalon:**

- “[P]romoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy.”³³¹
- “[P]romot[ing] Actiq for use in patients who were not yet opioid tolerant, and for whom it could have life-threatening results.”³³²
- In 2011, Cephalon wrote an article titled “*2011 Special Report: An Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA®) AND Oral Transmucosal Fentanyl Citrate (Actiq®)*,” published in *Pain Medicine News*. Plaintiff is informed and believes that Cephalon misrepresented that its drugs were “shown to be effective in treatment of [break through pain] associated with multiple causes of pain,” not just cancer.

506. The RICO Defendants also misrepresented that opioids were safer than non-opioid analgesics because there is no ceiling dose for opioid treatment.

- **Purdue:**

- Purdue's In the Face of Pain website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what—in their view—is a sufficient dose of opioids, they should find another doctor who will. In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands.
- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are “sometimes necessary,” even indefinitely high ones, which suggested that high dose opioids are safe and

³²⁹ *Id.*

³³⁰ *Id.* at 2-3.

³³¹ Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay \$425 Million For Off-Label Drug Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf>.

³³² *Id.*

appropriate and did not disclose the risks from high dose opioids. This publication is still available online.

- Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients “need” a larger dose of the drug, regardless of the dose currently prescribed. This language fails to disclose heightened risks at elevated doses.
- *Treatment Options*, also taught that opioids differ from NSAIDs in that they have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. *Treatment Options* continued, warning that risks of NSAIDs increase if “taken for more than a period of months,” with no corresponding warning about opioids. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose.
- Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit.
- *Overview of Management Options* also taught NSAIDs and other drugs, but not opioids, are unsafe at high doses.
- Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing
- Purdue sales representatives told prescribers that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses.
- Purdue sales representatives told prescribers that NSAIDs were more toxic than opioids.

- **Janssen:**

- Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of increased doses from opioids. The publication also falsely claimed that it is a “myth” that “opioid doses have to be bigger over time.”
- *Finding Relief: Pain Management for Older Adults* also 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.

- Janssen sponsored APF’s *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines. Janssen’s label for Duragesic, however, states that use with benzodiazepines “may cause respiratory depression, [low blood pressure], and profound sedation or potentially result in coma. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.
- Janssen sales representatives told prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is an opioid and has the same effects as other opioids.

- **Cephalon:**

- Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of their opioid, regardless of the dose currently prescribed.
- *Treatment Options*, also taught patients that opioids differ from NSAIDs in that they have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. *Treatment Options* continued, warning that risks of NSAIDs increase if “taken more than a period of months.” With no corresponding warning about opioids. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose.
- Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations.
- Cephalon sales representatives assured prescribers that opioids were safe, even at high doses.
- Cephalon sales representatives told prescribers that NSAIDs were more toxic than opioids.

- “[P]romot[ing] Actiq for use in patients who were not yet opioid tolerant, and for whom it could have life-threatening results.”³³³

- **Endo:**

- Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that opioids may be increased until “you are on the right dose of medication for your pain,” and once that occurs, further dose increases would not occur. Endo funded the site, which was a part of Endo’s marketing plan, and tracked visitors to it.
- Through painknowledge.com Endo distributed a flyer called “Pain: Opioid Therapy.” This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.
- Endo provided grants to APF to distribute Exit Wounds (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Exit Wounds also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.
- Endo sales representatives told prescribers that NSAIDs were more toxic than opioids.
- Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked: “If I take the opioid now, will it work later when I really need it?” The response was: “The dose can be increased You won’t ‘run out’ of pain relief.”
- Endo distributed a “case study” to prescribers titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. The study cites an example, meant to be representative, of a patient “with a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs” (over eight years), and recommends treating with opioids instead.

507. These misrepresentations, and the legion of other representations made by the RICO Defendants and members of Opioid Marketing Enterprise all furthered the common purpose and fraudulent scheme of the Opioid Marketing Enterprise. But they were demonstrably

³³³ *Id.*

false, as confirmed by investigations and enforcement actions against the RICO Marketing Defendants.

508. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. The Order adopting the guilty pleas provides:

effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

- d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
- e. Told certain health care providers that OxyContin did not cause a “buzz” or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to “weed out” addicts and drug seekers.

(Information ¶ 19.) Purdue has agreed that these facts are true, and the individual defendants, while they do not agree that they had knowledge of these things, have agreed that the court may accept these facts in support of their guilty pleas. (Agreed Statement of Facts ¶ 46.)

509. Additionally, Michael Friedman (“Friedman”), the company’s president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell (“Udell”), Purdue’s top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul

D. Goldenheim (“Goldenheim”), its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.³³⁴

510. In a statement announcing the guilty plea, John Brownlee (“Brownlee”), the U.S. Attorney for the Western District of Virginia, stated:

Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. Purdue’s marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.

But OxyContin offered no miracles to those suffering in pain. Purdue’s claims that OxyContin was less addictive and less subject to abuse and diversion were false – and Purdue knew its claims were false. The result of their misrepresentations and crimes sparked one of our nation’s greatest prescription drug failures. . . . OxyContin was the child of marketers and bottom line financial decision making.³³⁵

511. Brownlee characterized Purdue’s criminal activity as follows:

First, Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

Second, Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction than immediate-release opioids.

Third, Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer “peak and trough” blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.

Fourth, Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug.

³³⁴ *Id.*

³³⁵ Press Release, U.S. Attorney for the Western District of Virginia, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), <https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf>.

And fifth, Purdue falsely told health care providers that OxyContin did not cause a “buzz” or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to “weed out” addicts and drug seekers.³³⁶

512. Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers, while Friedman, Udell and Goldenheim pled guilty to the misdemeanor charge of misbranding OxyContin for introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(1)-(2) and 352(a).

513. Similarly, Endo’s marketing of Purdue was criticized and punished by the FDA and New York Attorney General.

514. On February 18, 2017, the State of New York announced a settlement with Endo requiring it “to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER.”³³⁷ In the Assurance of Discontinuance that effectuated the settlement, the State of New York stated that Endo knew about the risks arising from the reformulated Opana ER even before it received FDA approval. Among other things, the investigation concluded that:

- Endo improperly marketed Opana ER as designed to be crush resistant, when Endo’s own studies dating from 2009 and 2010 showed that the pill could be crushed and ground;
- Endo improperly instructed its sales representatives to diminish and distort the risks associated with Opana ER, including the serious danger of addiction; and
- Endo made unsupported claims comparing Opana ER to other opioids and failed to disclose accurate information regarding studies addressing the negative effects of Opana ER.³³⁸

³³⁶ *Id.*

³³⁷ Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of Prescription Opioid Drugs (Mar. 3, 2016), <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals> (last accessed on March 9, 2018).

³³⁸ *Id.*

515. The 2017 settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company, in which the consultant concluded that “[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant.” The same consultant also reported that the distribution of the reformulated Opana ER had already led to higher levels of abuse of the drug via injection.³³⁹

516. The Office of the Attorney General of New York also revealed that the “managed care dossier” Endo provided to formulary committees of healthcare plans and pharmacy benefit managers misrepresented the studies that had been conducted on Opana ER. According to Endo’s vice president for pharmacovigilance and risk management, the dossier was presented as a complete compendium of all research on the drug. However, it omitted certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that reformulated Opana ER could be ground and chewed.

517. The settlement also detailed Endo’s false and misleading representations about the non-addictiveness of opioids and Opana. For example, until April 2012, Endo’s website for the drug, www.opana.com, contained the following representation: “Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”³⁴⁰ However, Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat patients with pain agree with that representation.

518. The Office of the Attorney General of New York also disclosed the following facts that it determined to violate Opana’s obligations to truthfully market its products:

- a. Training materials provided by Endo to sales representatives stated: “Symptoms of withdrawal do not indicate addiction.”³⁴¹ This

³³⁹ *Id.* at 6.

³⁴⁰ *Id.*

³⁴¹ *Id.* at 7.

representation is inconsistent with the diagnosis of opioid-use disorder as provided in the Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association (Fifth Edition).

- b. Endo trained its sales representatives to falsely distinguish addiction from “pseudoaddiction,” which it defined as a condition in which patients exhibit drug-seeking behavior that resembles but is not the same as addiction. Endo’s vice president for pharmacovigilance and risk management testified that he was not aware of any research validating the concept of pseudoaddiction.

519. On June 9, 2017, the FDA asked Endo to voluntarily cease sales of Opana ER after determining that the risks associated with its abuse outweighed the benefits. According to Dr. Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research, the risks include “several serious problems,” including “outbreaks of HIV and Hepatitis C from sharing the drug after it was extracted by abusers” and “a serious disease outbreak.”³⁴² If Endo did not comply, the FDA stated that it “intends to take steps to formally require its removal by withdrawing approval.”³⁴³

520. Like Purdue and Endo, Janssen was the subject of an FDA enforcement action that identified its marketing statements as misrepresentations. For example:

521. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of “homemade” promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the “homemade” promotional pieces were “false or misleading because they contain misrepresentations of safety information, broaden Duragesic’s indication, contain unsubstantiated claims, and lack fair balance.”³⁴⁴

³⁴² *FDA requests removal of Opana ER for risks related to abuse*, June 8, 2017, <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

³⁴³ *Id.*

³⁴⁴ NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

522. The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse:

- You present the claim, “Low abuse potential!” This claim suggests that Duragesic has less potential for abuse than other currently available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, “Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine.” Therefore, this claim is false or misleading.³⁴⁵

523. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence.”³⁴⁶ Specifically, the FDA stated that Janssen was marketing Duragesic for indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was approved:

- You present the claim, “It’s not just for end stage cancer anymore!” This claim suggests that Duragesic can be used for any type of pain management. However, the PI for Duragesic states, “Duragesic (fentanyl transdermal system) is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means” Therefore, the suggestion that Duragesic can be used for any type of pain management promotes Duragesic[] for a much broader use than is recommended in the PI, and thus, is misleading. In addition, the suggestion that Duragesic can be used to treat any kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI states,

BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION
COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM)
IS CONTRAINDICATED:

- In the management of acute or post-operative pain, including use in outpatient surgeries . . .³⁴⁷

524. The March 30, 2000 letter also stated Janssen failed to adequately present “contraindications, warnings, precautions, and side effects with a prominence and readability

³⁴⁵ *Id.*

³⁴⁶ *Id.*

³⁴⁷ *Id.* at 2-3.

reasonably comparable to the presentation of information relating to the effectiveness of the product.”³⁴⁸

525. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of “homemade” promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the “homemade” promotional pieces were “false or misleading because they contain misrepresentations of safety information, broaden Duragesic’s indication, contain unsubstantiated claims, and lack fair balance.”³⁴⁹

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The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence.”³⁵¹ Specifically, the FDA stated that Janssen was marketing Duragesic for indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was approved:

- You present the claim, “It’s not just for end stage cancer anymore!” This claim suggests that Duragesic can be used for any type of pain management. However, the PI for Duragesic states, “Duragesic (fentanyl transdermal system) is indicated in the

³⁴⁸ *Id.* at 3 (emphasis in original).

³⁴⁹ NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

³⁵⁰ *Id.*

³⁵¹ *Id.*

management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means” Therefore, the suggestion that Duragesic can be used for any type of pain management promotes Duragesic[] for a much broader use than is recommended in the PI, and thus, is misleading. In addition, the suggestion that Duragesic can be used to treat any kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI states,

BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED:

- In the management of acute or post-operative pain, including use in outpatient surgeries³⁵²

526. The March 30, 2000 letter also stated Janssen failed to adequately present “contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product”:

Although this piece contains numerous claims for the efficacy and safety of Duragesic, you have not presented any risk information concerning the boxed warnings, contraindications, warnings, precautions, or side effects associated with Duragesic’s use Therefore, this promotional piece is lacking in fair balance, or otherwise misleading, because it fails to address important risks and restrictions associated with Duragesic therapy.³⁵³

527. On September 2, 2004, the U.S. Department of Health and Human Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to “false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic,” including, specifically, “suggesting that Duragesic has a lower potential for abuse compared to other opioid products.”

528. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network (“DAWN”) as compared to other opioids. The letter stated that the claim was false or misleading because the

³⁵² *Id.* at 2-3.

³⁵³ *Id.* at 3 (emphasis in original).

claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic's lower frequency of use compared to other opioids listed in DAWN:

The file card presents the prominent claim, "Low reported rate of mentions in DAWN data," along with Drug Abuse Warning Network (DAWN) data comparing the number of mentions for Fentanyl/combinations (710 mentions) to other listed opioid products, including Hydrocodone/combinations (21,567 mentions), Oxycodone/combinations (18,409 mentions), and Methadone (10,725 mentions). The file card thus suggests that Duragesic is less abused than other opioid drugs.

This is false or misleading for two reasons. First, we are not aware of substantial evidence or substantial clinical experience to support this comparative claim. The DAWN data cannot provide the basis for a valid comparison among these products. As you know, DAWN is not a clinical trial database. Instead, it is a national public health surveillance system that monitors drug-related emergency department visits and deaths. If you have other data demonstrating that Duragesic is less abused, please submit them.

Second, Duragesic is not as widely prescribed as other opioid products. As a result, the relatively lower number of mentions could be attributed to the lower frequency of use, and not to a lower incidence of abuse. The file card fails to disclose this information.³⁵⁴

529. The September 2, 2004 letter also detailed a series of unsubstantiated false or misleading claims regarding Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported, including:

- "“Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep.””
- "“All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain.””
- "“Significantly reduced nighttime awakenings.””
- "“Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index.””

³⁵⁴ Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc. (Sept. 2, 2004), https://www.pharmamedtechbi.com/~media/Images/Publications/Archive/The%20Pink%20Sheet/66/038/00660380018/040920_duragesic_letter.pdf at 2.

- ““Significant improvement in physical functioning summary score.””
- ““Significant improvement in social functioning.””³⁵⁵

530. In addition, the September 2, 2004 letter identified “outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic.” The claims include ““1,360 loaves . . . and counting,’ ‘[w]ork, uninterrupted,’ ‘[l]ife, uninterrupted,’ ‘[g]ame, uninterrupted,’ ‘[c]hronic pain relief that supports functionality,’ ‘[h]elps patients think less about their pain,’ and ‘[i]mprove[s] . . . physical and social functioning.”” The September 2, 2004 letter stated: “Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims.”³⁵⁶

531. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. Plaintiff is informed and believes that the advisory noted that the FDA had been ““examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch”” and noted the possibility “that patients and physicians might be unaware of the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.”³⁵⁷

532. Finally, Cephalon has been the subject of investigations and enforcement actions for its misrepresentations concerning Actiq. For example:

533. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States. The FDA explicitly stated that Actiq

³⁵⁵ *Id.* at 2-3.

³⁵⁶ *Id.* at 3.

³⁵⁷ *New Fentanyl Warnings: More Needed to Protect Patients*, Institute for Safe Medication Practices, August 11, 2005, <https://www.ismp.org/newsletters/acutecare/articles/20050811.asp>

“**must not** be used in opioid non-tolerant patients,” was contraindicated for the management of acute or postoperative pain, could be deadly to children, and was “intended to be used only in the care of opioid-tolerant 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.”³⁵⁸ The FDA also required that Actiq be provided only in compliance with a strict risk management program that explicitly limited the drug’s direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses and office staff.³⁵⁹

534. Cephalon purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA approval to sell this faster-acting version of Actiq; but once again, concerned about the power and risks inherent to fentanyl, the FDA limited Fentora’s approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

535. Due to the FDA’s restrictions, Actiq’s consumer base was limited, as was its potential for growing revenue. In order to increase its revenue and market share, Cephalon needed to find a broader audience and thus began marketing its lollipop to treat headaches, back pain, sports injuries and other chronic non-cancer pain, targeting non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and indirect contravention of the FDA’s strict

³⁵⁸ *Id.*

³⁵⁹ See John Carreyrou, *Narcotic “Lollipop” Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), <https://www.opiates.com/media/narcotic-lollipop-becomes-big-seller-despite-fdacurbs/>.

instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

536. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil).

537. According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses. Specifically, the DOJ stated:

From 2001 through at least 2006, Cephalon was allegedly promoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results.³⁶⁰

538. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Cephalon's unlawful practices:

"This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved."³⁶¹

539. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its

³⁶⁰ Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay \$425 Million For Off-Label Drug Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf>.

³⁶¹ *Id.*

sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- a. Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons;
- b. Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches;
- c. Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward recreational use;
- d. Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication;
- e. Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl; and
- f. Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid-tolerant.³⁶²

540. The FDA's letters and safety alerts, the DOJ and state investigations, and the massive settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

541. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid-tolerant had been

³⁶² John Carreyrou, Cephalon Used Improper Tactics to Sell Drug, Probe Finds, Wall St. J., Nov. 21, 2006, at B1 (hereinafter "Carreyrou, Cephalon Used Improper Tactics").

prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.”³⁶³

542. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of non-cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that the drug’s safety for such use had never been clinically evaluated.³⁶⁴ An FDA advisory committee noted that Fentora’s existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora’s label and medication guide to add strengthened warnings.

543. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

544. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora (“Warning Letter”). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden “the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case.”³⁶⁵ Rather, Fentora was only indicated for those who were already

³⁶³ Press Release, U.S. Food & Drug Administration, Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

³⁶⁴ *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee*, U.S. Food & Drug Administration (May 6, 2008), <https://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-03-Cephalon.pdf>.

³⁶⁵ Letter from Michael Sauer, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, to Carole S. Marchione, Senior Director and Group Leader, Regulatory Affairs (March 26, 2009)

opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

545. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

546. The misrepresentations disseminated by members of the Opioid Marketing Enterprise, and the RICO Marketing Defendants, caused Plaintiff and Georgia consumers to pay for excessive opioid prescriptions, suffer injuries and losses, and to incur costs associated with the opioid epidemic caused by the Opioid Marketing Enterprise.

547. The RICO Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the RICO Defendants themselves. Without these misrepresentations, the Opioid Marketing Enterprise could not have achieved its common purpose.

548. The impact of the Opioid Marketing Enterprise's scheme is still in place – i.e., the opioids continue to be prescribed and used for chronic pain throughout the State of Georgia, and the epidemic continues to injure Plaintiff, and consume the resources of Plaintiff's and Georgia's health care and law enforcement systems.

549. The foregoing evidences that the RICO Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

B. CONDUCT OF THE OPIOID MARKETING ENTERPRISE.

550. During time period described in this Complaint, from approximately the late 1990s to the present, the RICO Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. Creating a body of deceptive, 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 thus more likely to be relied upon by physicians, patients, and payors;
- b. Creating a body of deceptive, misleading and unsupported electronic and print advertisements 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 thus more likely to be relied upon by physicians, patients, and payors;
- c. Creating a body of deceptive, misleading and unsupported sales and promotional training materials 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 thus more likely to be relied upon by physicians, patients, and payors;
- d. Creating a body of deceptive, misleading and unsupported CMEs and speaker presentations 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 thus more likely to be relied upon by physicians, patients, and payors;
- e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the RICO Defendants' messages about the use of opioids for chronic pain;
- f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- g. Paying KOLs to serve as consultants or on the RICO Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;
- h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Defendants' messages about the use of opioids for chronic pain;
- i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Defendants suggested or chose (and paid for),

with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

- j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;
- k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;
- l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;
- o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Defendants, such as veterans and the elderly, and then funded that distribution;
- p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and
- q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

551. The Front Groups also participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. The Front Groups promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages;
- b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

- d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

552. The RICO Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The RICO Marketing Defendants' larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."³⁶⁶ "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."³⁶⁷

553. The KOLs also participated, on information and belief, in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages themselves;
- b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;
- d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

³⁶⁶ *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 <https://www.hsdl.org/?abstract&did=808171> ("*Fueling an Epidemic*"), at 1.

³⁶⁷ *Id.* 2.

- e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The KOLs concealed their connections to the Front Groups and the RICO Defendants, and their sponsorship by the RICO Marketing Defendants.

554. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

C. PATTERN OF RACKETEERING ACTIVITY

555. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

556. The RICO Marketing Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Marketing Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing Defendants participated in the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

557. The pattern of racketeering activity described herein used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including virtually uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the RICO Marketing Defendants' misrepresentations.

558. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which Defendants, the Front Groups and the KOLs defrauded and intended to defraud Georgia consumers, the State, and other intended victims.

559. In devising and executing the illegal scheme, the RICO Marketing Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. For the purpose of executing the illegal scheme, the RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance their illegal scheme.

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

- a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

561. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Georgia consumers, prescribers, regulators and Plaintiff. The RICO Marketing Defendants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

562. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, and then subsequently failing to disclose such practices to Georgia consumers, prescribers, regulators and Plaintiff. Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

563. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Georgia consumers, prescribers, regulators and Plaintiff. Each separate use

of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Georgia consumers, prescribers, regulators and Plaintiff. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

564. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

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

566. Many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiff has described the occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to Georgia consumers, prescribers, regulators and Plaintiff, and how those acts were in furtherance of the scheme, and do so further below.

567. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

- a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;
- b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;
- e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;
- f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities – the wrongful proceeds of the scheme.

568. In addition to the above-referenced predicate acts, it was foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

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

570. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and Plaintiff: (1) the fraudulent nature of the RICO Marketing Defendants' marketing scheme; (2) the fraudulent nature of statements made by the RICO Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (3) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

571. The RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

572. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of the RICO Marketing Defendants had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

573. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money

and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

574. The RICO Marketing Defendants predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

575. The RICO Marketing Defendants' predicate acts and pattern of racketeering activity were a substantial and foreseeable cause of Plaintiff's injury and the relationship between the RICO Marketing Defendants' conduct and Plaintiff's injury is logical and not speculative. It was foreseeable to the RICO Marketing Defendants that when they fraudulently marketed highly-addictive and dangerous drugs, that were approved for very limited and specific uses by the FDA, as non-addictive and safe for off-label uses such as moderate pain, non-cancer pain, and long-term chronic pain, that the RICO Marketing Defendants would create an opioid-addiction epidemic that logically, substantially and foreseeably harmed Plaintiff.

576. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. DAMAGES.

1. Impact of the Opioid Marketing Enterprise.

577. Georgia has been especially ravaged by the national opioid crisis.

578. The opioid scourge has visited devastating harm upon this State. At the 2017 University of Georgia College of Public Health's "State of the Public's Health" conference, experts explained that the deepening opioid epidemic is hitting Georgia harder than most states, and that from 2009 to 2014, Georgia's rate of increase in the number of opioid-related patient encounters led the nation.³⁶⁸

579. Georgia is among the top 11 states in terms of the most prescription opioid overdose deaths.³⁶⁹ Almost as many Georgians die of drug overdoses as in car accidents.³⁷⁰ Georgia suffered 1,394 overdose deaths in 2016,³⁷¹ 1,302 deaths in 2015,³⁷² and 1,206 deaths in 2014.³⁷³

580. Of the over 1,300 drug overdose deaths in 2015, 900 of them – or 68 percent – were due to opioid overdoses, including heroin.³⁷⁴ Overdose deaths tripled in Georgia from 1999 to 2013. Prescription opioid overdose deaths grew tenfold between 1999 and 2014 to 549 deaths, or a rate of 5.5 deaths per 100,000 people.³⁷⁵

³⁶⁸ *Experts: Opioid crisis is hitting Georgia*, The Augusta Chronicle (Oct. 21, 2017), available at <http://chronicle.augusta.com/news/2017-10-21/experts-opioid-crisis-hitting-georgia>.

³⁶⁹ Substance Abuse Research Alliance (SARA), Georgia Prevention Project, *Prescription Opioids and Heroin Epidemic in Georgia – a White Paper*, 2017, at 2, available at <http://www.senate.ga.gov/sro/Documents/StudyCommRpts/OpioidsAppendix.pdf> (last visited January 29, 2018).

³⁷⁰ *Id.* at 5.

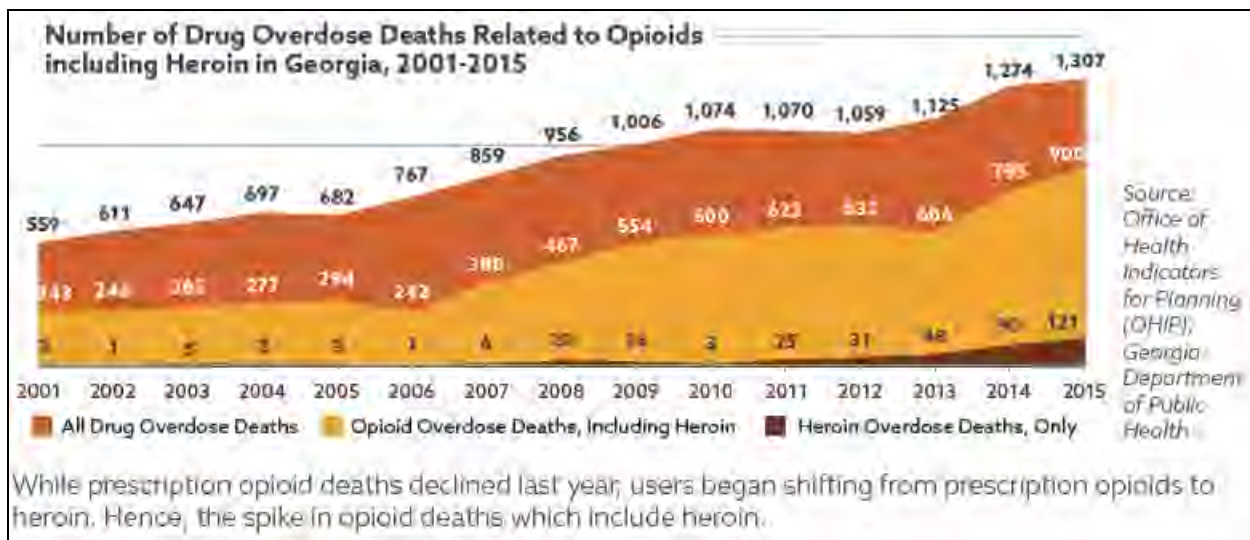
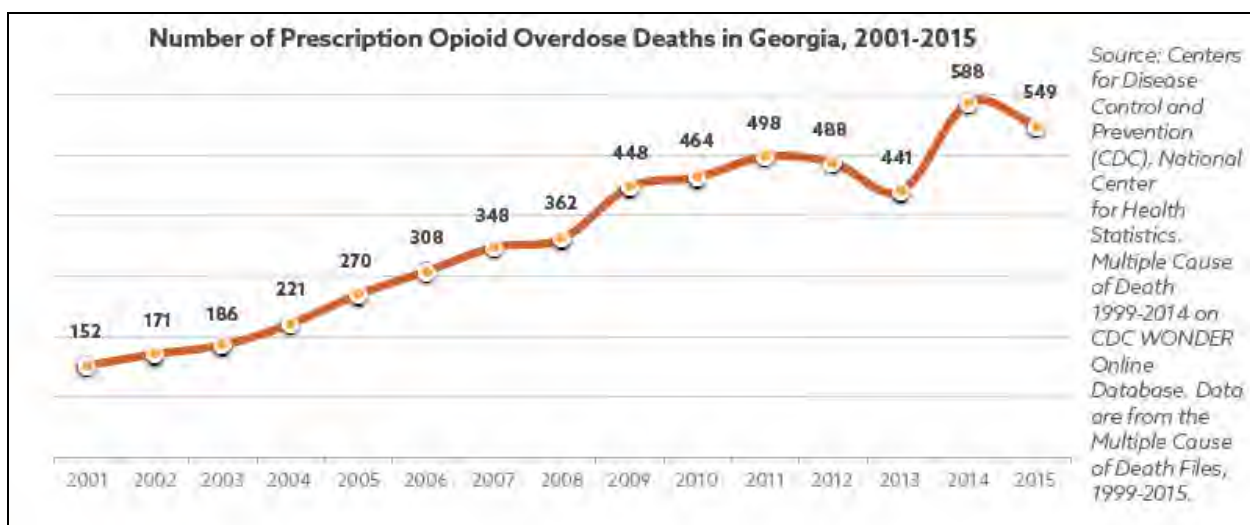
³⁷¹ CDC, Drug Overdose Death Data, available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> ("2016 Deaths" tab) (last visited January 19, 2018).

³⁷² *Id.* at "2015 Deaths" tab, (last visited January 19, 2018).

³⁷³ *Id.* at "2014 Deaths" tab, (last visited January 19, 2018).

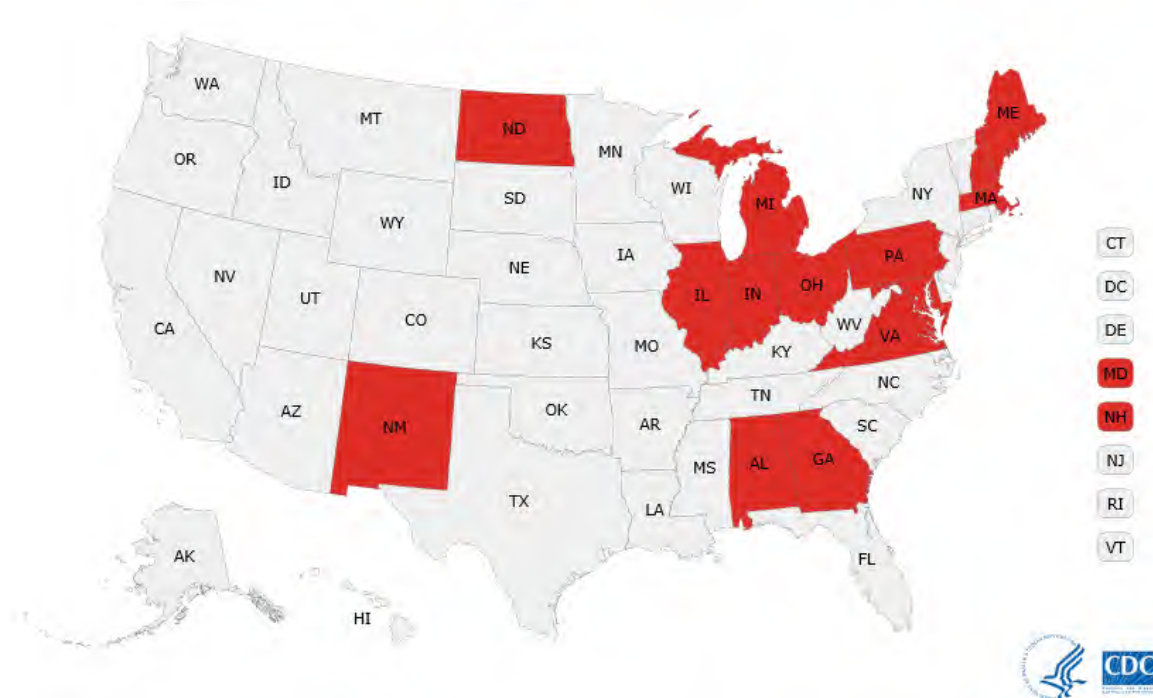
³⁷⁴ Substance Abuse Research Alliance (SARA), *supra*, at 5.

³⁷⁵ *Id.*



581. According to the Centers for Disease Control and Prevention (“CDC”), Georgia was among the States to experience a statistically significant (10.2 percent) increase in drug overdose death rates in 2014 as compared to 2013.³⁷⁶

³⁷⁶ See Substance Abuse Research Alliance (SARA), *supra*, at 14.



582. Hospitalizations due to opioid abuse in Georgia have soared from about 302,000 in 2002 to around 520,000 in 2012.³⁷⁷ During this time, the cost of this inpatient care related to opioid use more than doubled in Georgia, reaching \$15 billion in 2012.³⁷⁸

583. From 2009 to 2014, Georgia had the highest percent change in the rate of opioid-related inpatient stays of any state, at 99.8 percent.³⁷⁹ Georgia also had the third highest cumulative percent increase (85.2 percent) in the rate of opioid-related emergency department visits.³⁸⁰

³⁷⁷ *Id.* at 7.

³⁷⁸ *Id.*

³⁷⁹ Audrey J. Weiss, Ann Elixhauser, Marguerite L. Barrett, Claudia A. Steiner, Molly K. Bailey and Lauren O'Malley, *Opioid-Related Inpatient Stays and Emergency Department visits by State, 2009-2014*, December 2016, Revised January 2017, Healthcare Cost and Utilization Project (HCUP), available at <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.jsp> (last visited Jan. 29, 2018).

³⁸⁰ *Id.*

584. Georgia is also seeing an increase in cases of newborns with NAS, a collection of symptoms babies experience in withdrawing from opioid medications taken by the mother.³⁸¹ NAS is closely associated with opioid use.

585. Opioid addiction is part of the reason the number of children in Georgia state custody has almost doubled in the last three years.³⁸²

586. The opioid epidemic is particularly devastating in Plaintiff's Community.

587. In 2017, the coroner for Dougherty County, where Albany is located, saw seventeen deaths related to overdoses, up from five in 2015. Additionally, the County's EMS director reported around 90 overdose cases in 2017, with 2018 predicted to see at least 95 cases.

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588. The opioid epidemic has placed increased budgetary constraints upon inter alia the public health and medical care expenditures of the State and Plaintiff's Community. Opioid addiction is one of the primary reasons citizens of the State and Plaintiff's Community seek substance abuse treatment.

2. Relief Sought.

589. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiff's injuries, as described below, were not

³⁸¹ Substance Abuse Research Alliance (SARA), *supra*, at 30.

³⁸² WRDW, *News 12 Investigates: Children of Opioids*, Oct. 9, 2017, available at <http://www.wrdw.com/content/news/Children-of-Opioids-450115313.html> (last visited January 29, 2018).

³⁸³ WFXL, *Dougherty County coroner hosts opioid epidemic reenactment to educate students*, April 17, 2018, available at <https://wfxl.com/news/local/dougherty-county-coroner-hosts-opioid-epidemic-re-enactment-to-educate-students> (last visited September 21, 2018).

unexpected, unforeseen or independent.³⁸⁴ Rather, as Plaintiff alleges, the RICO Marketing Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.³⁸⁵ Nevertheless, the RICO Marketing Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products.

590. It was foreseeable and expected that a massive marketing campaign utilized by the RICO Marketing Defendants that misrepresented the non-addictive and effective use of prescription opioids for purposes for which they are not suited and not approved by the FDA would lead to a nationwide opioid epidemic.³⁸⁶ It was also foreseeable and expected that the RICO Marketing Defendants' marketing campaign would lead to increased opioid addiction and overdose.³⁸⁷ Plaintiff's injuries were logically, foreseeable, and substantially caused by the opioid epidemic that the RICO Marketing Defendants created.

591. Specifically, the RICO Marketing Defendants' predicate acts and pattern of racketeering activity caused the opioid epidemic which has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

- a. Losses caused by purchasing and/or paying reimbursements for the RICO Marketing Defendants' prescription opioids, that Plaintiff would not have paid for or purchased but for the RICO Marketing Defendants' conduct;

³⁸⁴ *Traveler's Property Casualty Company of America v. Actavis, Inc.*, 22 Cal. Rptr. 3d 5, 19 (Cal. Ct. App. 2017).

³⁸⁵ *Id.*

³⁸⁶ *Id.*

³⁸⁷ *Id.*

- b. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
- c. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
- d. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
- e. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- f. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;
- g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;
- i. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;
- j. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;
- k. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- l. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's Community;
- m. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

- n. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

592. Plaintiff's injuries were proximately caused by the RICO Marketing Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic created by the RICO Marketing Defendants' conduct, Plaintiff would not have lost money or property.

593. Plaintiff's injuries were directly caused by the RICO Marketing Defendants' pattern of racketeering activities.

594. Plaintiff is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

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

COUNT III
RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1961, et seq.
(Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal,
and AmerisourceBergen)

(The "Opioid Diversion Enterprise")

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

597. Plaintiff brings this Claim against the following Defendants, as defined above: Purdue, Cephalon, Endo, Mallinckrodt, Actavis (the "Manufacturer Defendants"), McKesson, Cardinal, and AmerisourceBergen (the "Distributor Defendants") (collectively, for purposes of this Claim, the "RICO Diversion Defendants").

598. The RICO Diversion Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise as defined in 18 U.S.C. § 1961(4). Alternatively, the RICO Diversion Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4). Specifically, each of the RICO Diversion Defendants was a member of the Healthcare Distribution Alliance (the “HDA”)³⁸⁸ which is a distinct legal entity that satisfies the definition of a RICO enterprise because it is a non-profit corporation and, therefore, and “enterprise” within the definition set out in 18 U.S.C. § 1961(4). On information and belief, each of the RICO Diversion Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to this cause of action. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

599. For over a decade, the RICO Diversion Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Diversion Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. As “registrants” under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the “CSA”), the RICO Diversion Defendants operated and continue to operate within a “closed-system.” The CSA restricts the RICO Diversion Defendants’ ability to manufacture or distribute Schedule II substances like opioids by: (1) requiring them to make sales within a limited quota set by the DEA for the overall production of

³⁸⁸ Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

Schedule II substances like opioids; (2) register to manufacture or distribute opioids; (3) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; and (4) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

600. The closed-system created by the CSA, and the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from “legitimate channels of trade” to the illicit market by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances].”³⁸⁹

601. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (defined below) engaged in the common purpose of fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids. The RICO Diversion Defendants formed and pursued their common purpose through the many personal interactions that they had, confidentially, in organizations like the Pain Care Forum and the Healthcare Distribution Alliance.

602. The RICO Diversion Defendants’ common purpose and fraudulent scheme to unlawfully increase the DEA quotas violated the RICO Act in two ways. First, the RICO Diversion Defendants violated the RICO Act because they engaged in the felonious manufacture, buying selling, or otherwise dealing in controlled substances that are punishable by law in the United States. Specifically, the RICO Diversion Defendants “furnish[ed] false or fraudulent material information in, or omit[t]ed material information from, applications, reports, records, and other document required to be made, kept, and filed under 21 U.S.C. §§ 801, et seq.”, in violation of 21 U.S.C. § 843(b), which is a felony. Second, the RICO Diversion Defendants

³⁸⁹ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

violated the RICO Act by engaging in mail and wire fraud. The RICO Diversion Defendants common purpose and fraudulent scheme was intended to, and did, utilize interstate mail and wire facilities for the commission of their fraud in violation 18 U.S.C. §§ 1341 (mail fraud) and 1343 (wire fraud).

603. The RICO Diversion Defendants' fraudulent scheme arises at the intersection between the quotas governing the RICO Diversion Defendants' prescription opioids and the RICO Diversion Defendants' duty to identify, report, and halt suspicious orders of controlled substances. The RICO Diversion Defendants' formed an enterprise with the intent to fraudulently increase the quotas for prescription opioids by refusing to identify, report and halt suspicious orders, thereby omitting both the fact and the RICO Diversion Defendants' knowledge of widespread diversion of prescription opioids into illegitimate channels.

604. The RICO Diversion Defendants engaged in systematic and fraudulent acts as part of the Opioid Diversion Enterprise, that furnished false or fraudulent material information in, and omitted material information from their applications, reports, records and other documents that the RICO Defendants were required to make, keep and/or file. Furthermore, the RICO Diversion Defendants engaged in systematic and fraudulent acts as part of the Opioid Diversion Enterprise that were intended to and actually did utilize the mail and wire facilities of the United States and Georgia, including refusing to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.³⁹⁰

605. Through the RICO Diversion Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly requested increases of the quotas governing the manufacture,

³⁹⁰ 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

sale and distribution of prescription opioids, misrepresented that they were complying with their duties under the CSA, furnished false or fraudulent material information in, and omitted material information from their applications, reports, records and other documents, engaged in unlawful sales of painkillers that resulted in diversion of controlled substances through suspicious orders, and refused to identify or report suspicious orders of controlled substances sales to the DEA.³⁹¹ Defendants' refusal to report suspicious orders resulted in artificial and illegal increases in the annual production quotas for opioids allowed by the DEA. The end result of the RICO Diversion Defendants' fraudulent scheme and common purpose was continually increasing quotas that generated obscene profits and, in turn, fueled an opioid epidemic.

606. The RICO Diversion Defendants' illegal scheme was hatched by an enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Diversion Defendants were associated with, and conducted or participated in, the affairs of the Opioid Diversion Enterprise, whose common purpose was fraudulently increase the quotas governing the manufacture and sale of prescription opioids.

607. The success of the RICO Diversion Defendants' scheme allowed them to unlawfully increase and/or maintain high production quotas and, as a direct result, allowed them to make billions from the unlawful sale and diversion of opioids.

608. Simultaneously, the opioid epidemic created by the RICO Diversion Defendants' actions caused Plaintiff's multi-million dollar injuries. Plaintiff's injuries were and are a reasonably foreseeable consequence of the prescription opioid addiction epidemic that the RICO Diversion Defendants created by fraudulently increasing quotas, misrepresenting their

³⁹¹ 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

compliance with their duties under the CSA, and allowing the widespread diversion of legally produced prescription opioids into the illicit market. As explained in detail below, the RICO Diversion Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

A. THE OPIOID DIVERSION ENTERPRISE.

609. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.³⁹² The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.³⁹³ Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.³⁹⁴ Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.”³⁹⁵ Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.³⁹⁶ All registrants -- manufacturers and distributors alike -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to

³⁹² Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

³⁹³ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

³⁹⁴ *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20); 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

³⁹⁵ See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

³⁹⁶ See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at <https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf>).

identify or prevent diversion.³⁹⁷ When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.³⁹⁸ The result is the scourge of addiction that has occurred.

610. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.”³⁹⁹ When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of disposal of the basic class;
- d. An applicant’s production cycle and current inventory position;
- e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.⁴⁰⁰

³⁹⁷ *Id.*

³⁹⁸ Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

³⁹⁹ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

⁴⁰⁰ *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

611. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.⁴⁰¹

612. At all relevant times, the RICO Diversion Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Diversion Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas. The RICO Diversion Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

613. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.⁴⁰² On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.⁴⁰³

⁴⁰¹ *Id.* (citing 21 U.S.C. 842(b)).

⁴⁰² Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. *Am J Public Health.* 2014;104(2):e52-9.

⁴⁰³ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>.

614. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. However, it was not until recently that federal and state regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

615. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Diversion Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Diversion Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Diversion Defendants; (d) was characterized by interpersonal relationships among the RICO Diversion Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

616. The Opioid Diversion Enterprise also engaged in efforts to constrain the DEA's authority to hold the RICO Diversion Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. To this end, the Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.⁴⁰⁴ The HDA and other members of the Pain Care Forum contributed

⁴⁰⁴ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017,

substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Upon information and belief, the Pain Care Forum and its members and HDA, poured millions into such efforts.

617. The RICO Diversion Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent scheme to profit from the unlawful sale of prescription opioids by increasing the quotas governing the manufacture and sale of these controlled substances. In order to achieve that goal, the RICO Diversion Defendants knowingly allowed suspicious orders of controlled substances to occur unhindered while millions of opioid doses diverted into illegal markets. The end result of this strategy was exactly as the RICO Diversion Defendants intended – artificially increased quotas for the manufacture and distribution of opioids, all of which resulted in a National opioid epidemic.

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

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

https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

620. Each of the RICO Diversion Defendants had systematic links to each other through joint participation in trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Diversion Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Diversion Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

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

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

623. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”⁴⁰⁵ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.⁴⁰⁶

⁴⁰⁵ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

⁴⁰⁶ *Id.*

624. Not surprisingly, each of the RICO Diversion Defendants who stood to profit from expanded prescription opioid use is a member of and/or participant in the PCF.⁴⁰⁷ In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Actavis (i.e., Allergan), and Teva (the parent company of Cephalon).⁴⁰⁸ Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.⁴⁰⁹ Upon information and belief, the Distributor Defendants participated directly in the PCF as well.

625. Additionally, the HDA -- or Healthcare Distribution Alliance -- led to the formation of interpersonal relationships and an organization between the RICO Diversion Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (i.e., Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.⁴¹⁰ Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating for the many benefits of members, including “strengthening . . . alliances.”⁴¹¹

⁴⁰⁷ PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>

⁴⁰⁸ *Id.* Upon information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.

⁴⁰⁹ *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/executive-committee>.

⁴¹⁰ Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/membership/manufacturer>.

⁴¹¹ Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en>.

626. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”⁴¹² Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Manufacturers and Defendants.

627. The application for manufacturer membership in the HDA further indicates the level of connection between the RICO Defendants and the level of insight that they had into each other’s businesses.⁴¹³ For example, the manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

628. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information.

629. And, Manufacturer Members were asked to identify their “most recent year end net sales” through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Cardinal Health, and McKesson and their subsidiaries.

630. The closed meetings of the HDA’s councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work

⁴¹² *Id.*

⁴¹³ Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en>.

closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

631. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”⁴¹⁴ The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”⁴¹⁵ The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.⁴¹⁶

632. Third, the RICO Diversion Defendants maintained their interpersonal relationships by working together, through contractual chargeback arrangements, to exchanging sales information and drive the unlawful sales of their opioids. To this end, the Manufacturer Defendants engaged in an industry-wide practice of paying rebates to the Distributor Defendants for sales of prescription opioids.⁴¹⁷

⁴¹⁴ Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers> (last accessed on September 14, 2017).

⁴¹⁵ *Id.*

⁴¹⁶ 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/events/2015-distribution-management-conference> (last accessed on September 14, 2017).

⁴¹⁷ Lenny Bernstein & Scott Higham, The government’s struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letters From Sen. Claire McCaskill, (March 28, 2017),

633. For example, the *Washington Post* reported that “[o]n Aug. 23, 2011, DEA supervisors met with Mallinckrodt executives at the agency’s headquarters in Arlington, Va., the day a rare 5.8-magnitude earthquake hit the Washington region. People involved in the case still call the gathering ‘the earthquake meeting.’ DEA officials showed the company the remarkable amounts of its oxycodone going to distributors and the number of arrests being made for oxycodone possession and distribution on the street, according to one participant in the meeting who also spoke on the condition of anonymity because the case is pending.”⁴¹⁸

634. “Three weeks after the Aug. 23 meeting, Mallinckrodt notified 43 of its distributors that they would no longer receive rebates from the company if they continued to supply certain pharmacies whose orders appeared to be suspicious.”⁴¹⁹

635. “On Nov. 30, 2011, the DEA served a subpoena on Mallinckrodt, demanding documents related to its suspicious-order-monitoring program, according to the company’s filings with the Securities and Exchange Commission. The subpoena brought a windfall of information. The DEA gained access to data from Mallinckrodt’s rebate or ‘chargeback’ program, an industry-wide practice that provides reimbursements to wholesale distributors. That information and other records showed where Mallinckrodt’s oxycodone was going — from the company to its network of distributors to retailers down the chain.”⁴²⁰

636. In addition, the Distributor Defendants and Manufacturer Defendants participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship

<https://www.mccaskill.senate.gov/opioid-investigation>; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), <http://www.purduepharma.com/payers/managed-markets/>.

⁴¹⁸ https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.f336835fd5da

⁴¹⁹ *Id.*

⁴²⁰ *Id.*

notices, and invoices.⁴²¹ For example, on April 27, 2011, the HDA offered a Webinar to “accurately and effectively exchange business transactions between distributors and manufacturers...”:

Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set



(Webinar held: April 27, 2011) Using EDI to accurately and efficiently exchange business transactions (i.e., purchase orders, acknowledgements, ship notices, invoices, etc.) between distributors and manufacturers in the healthcare supply chain is critical. The development and use of voluntary guidelines for specific EDI standards provide industry trading partners with a means to effectively convey the necessary information.

Hear updates on HDMA's Order-to-Cash Guidelines for Electronic Data Interchange (EDI) in the Healthcare Product Supply Chain, including the 810 Invoice; 850 Purchase Order; 855 Purchase Order Acknowledgement; and the 856 Ship Notice/Manifest.

637. On information and belief, the Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

638. And, through the HDA, Manufacturer Members were asked to identify their “most recent year end net sales” through wholesale distributors, including the Distributor Defendants as follows:

⁴²¹ Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/resources/webinar-leveraging-edi>.

Company	Most Recent Year End Net Sales
Henry Schein, Inc.	
Henry Schein Distribution Centers (7)	
Hospital Pharmaceutical Consulting (1)	
KeySource Medical, Inc. (1)	
Louisiana Wholesale Drug Co. Inc. (1)	
McKesson Corporation (71)	
McKesson Supply Solutions (25)	
McKesson Canada (12)	
McKesson Corporation (4)	
McKesson Specialty Health (1)	
McKesson Strategic Redistribution Center (1)	
McKesson Medical Surgical (1)	
Physician Sales & Service (PSS) (25)	
US Oncology (1)	
DeVictoria Healthcare, Inc. PR (1)	
Miami-Luken, Inc. (1)	
Morris & Dickson Co., LLC (1)	
Mutual Wholesale Drug Co. (1)	
PBA Health (1)	
Prescription Supply, Inc. (1)	
Prodigy Health Supplier Corporation (1)	
Quality Care Products, LLC (1)	
RDC (3)	
R&S Northeast LLC (2)	
Richie Pharmacal Co., LLC (1)	
Seacoast Medical LLC (1)	
Smith Drug Company, Div. JM Smith Corporation (4)	
Burlington Drug Company, Inc. (1)	
Smith Drug Company, Div. JM Smith Corporation (3)	
Top Rx (4)	
Value Drug Company (1)	
VaxServe (1)	
TOTAL SALES (millions)	\$ 0

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

640. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Diversion Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Diversion Defendants were in communication and cooperation.

641. Alternatively, the RICO Diversion Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Diversion Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. As alleged, the Healthcare Distribution Alliance (the “HDA”)⁴²² is a distinct legal entity that satisfies the definition of a RICO enterprise because it is a corporation formed under the laws of the District of Columbia, doing business in Virginia. As such, the HDA qualifies as an “enterprise” within the definition set out in 18 U.S.C. § 1961(4).

642. On information and belief, each of the RICO Diversion Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

643. Each of the RICO Diversion Defendants is a legal entity separate and distinct from the HDA. Additionally, the HDA serves the interests of distributors and manufacturers beyond

⁴²² Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

the RICO Diversion Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Diversion Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.

644. During the time period alleged in this Complaint, the RICO Diversion Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

645. Defendants disseminated false and misleading statements to state and federal regulators claiming that (1) the quotas for prescription opioids should be increased, (2) they were complying with their obligations to maintain effective controls against diversion of their prescription opioids, (3) they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids, (4) they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids and (5) they did not have the capability to identify suspicious orders of controlled substances despite their possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time, which the Defendants obtained 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”).

646. The RICO Diversion Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the “Ensuring Patient Access and Effective Drug Enforcement Act.”⁴²³

647. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the RICO Diversion Defendants identify suspicious orders or customers who were likely to divert prescription opioids.⁴²⁴ On information and belief, the “know your customer” questionnaires informed the RICO Diversion Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

648. The RICO Diversion Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing

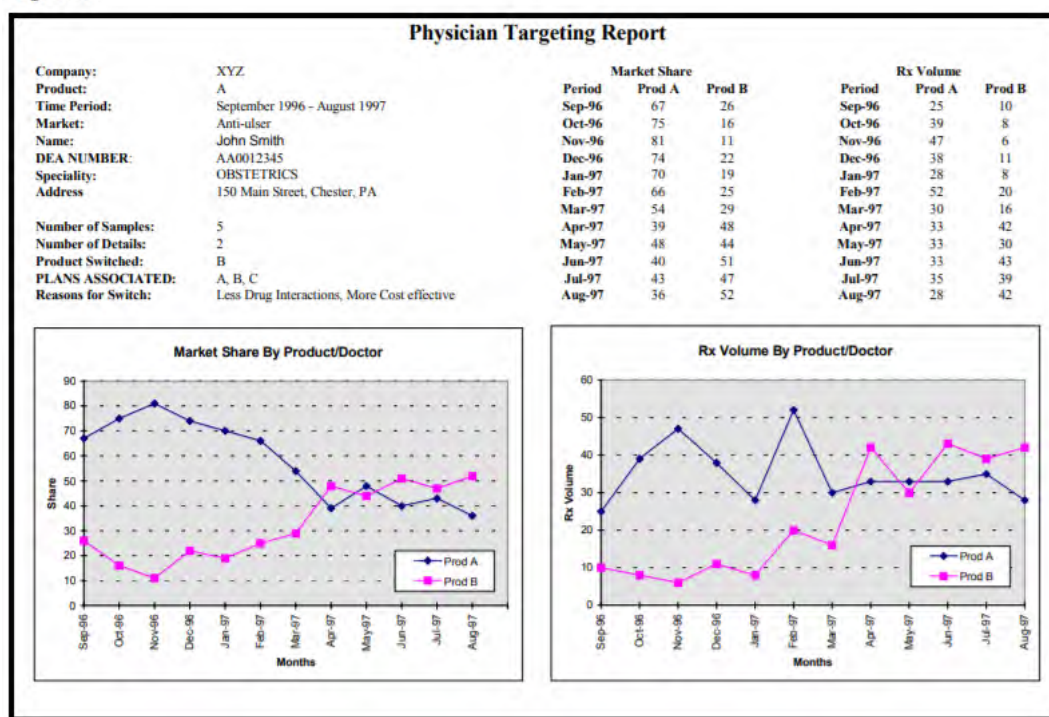
⁴²³ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had no Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

⁴²⁴ Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McGuireWoods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the RICO Diversion Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.⁴²⁵

649. IMS, for example, IMS provided the RICO Diversion Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.⁴²⁶

Figure 2:



650. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the RICO Defendants with charts analyzing the weekly prescribing patterns of multiple physicians,

⁴²⁵ A Verispan representative testified that the RICO Defendants use the prescribing information to “drive market share.” *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).

⁴²⁶ Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, (accessed on February 15, 2018), <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf>, Figure 2 at p.3.

organized by territory, regarding competing drugs, and analyzed the market share of those drugs.⁴²⁷

1. The Prescriber Roster shows Prescriber demographics, prescribing information and indicator arrows

Territory : 1102 Prescriber	Trend	Specialty	Product	Weekly Prescriber TR			
				WEEK Feb-03-06	WEEK Jan-27-06	WEEK Jan-20-06	WEEK Jan-13-06
Territory : 1102 – TOTAL			PRODUCT A	46	64	58	88
			PRODUCT B	292	253	247	278
			PRODUCT C	55	56	56	58
			PRODUCT D	36	28	34	33
			PRODUCT E	7	9	2	9
			PRODUCT F	1	3	5	0
Doctor A		IM	PRODUCT A	4	1	1	1
			PRODUCT B	2	2	2	3
			PRODUCT C	0	2	0	0
			PRODUCT D	0	0	0	0
			PRODUCT E	0	0	0	0
			PRODUCT F	0	0	0	0
Doctor B		GE	PRODUCT A	3	1	1	2
			PRODUCT B	5	4	7	2
			PRODUCT C	0	1	0	0
			PRODUCT D	0	0	0	0
			PRODUCT E	0	1	0	1
			PRODUCT F	0	0	0	0
Doctor C		GE	PRODUCT A	3	1	2	0
			PRODUCT B	4	5	0	3
			PRODUCT C	0	1	1	0
			PRODUCT D	0	1	0	2
			PRODUCT E	0	0	0	0
			PRODUCT F	0	0	0	0

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⁴²⁷ *Sorrell v. IMS Health Inc.*, 2011 WL 705207, *467-471 (Feb. 22, 2011).

3. Territory Summary Report shows Prescriber Roster information aggregated at a territory level

Territory Summary

Name	Spec	Zip	Product A NRX	Product A MM Share	Product A Rank	Market NRX	Market Rank
ABNEY, RAY C.	P	05302	6	10.7%	43	56	38
ALLISTER, ROBERT	P	03820	6	18.8%	43	32	63
ALTMAN, LEE S.	P	01655	34	14.0%	3	247	3
BALLARD, HARLOW	P	05801	0	0.0%	93	8	96
BARNEY, CHRISTINE A.	P	03766	6	26.1%	43	23	85
BARTON, GAIL	P	03755	13	32.5%	18	40	50
BERNSTEIN, RICHARD A.	P	05401	0	0.0%	93	14	94
BOHNERI, MICHAEL	P	03060	3	4.5%	73	66	29
BOSTIC, JEFFERY O.	CHP	03079	5	10.9%	55	45	44
BREITHOLTZ, TIMOTHY	P	03870	13	34.2%	18	38	52
BROWN, KENNETH	P	03941	4	10.0%	61	40	50
BUCHANAN, KEVIN	P	05701	5	16.1%	55	31	70
CARMAN, MEGAN W.	P	03246	10	12.3%	28	81	18
CARSEN, MARJORIA	P	05701	6	18.2%	43	33	59
CATPANO-FRIEDMAN, LISA	P	05201	5	8.6%	43	70	25
CLARKE-RUBIN, LORNA	P	12901	8	24.2%	32	33	59
COHEN, DEVRA H.	CHP	03060	3	6.5%	73	46	44
COLE, STEPHEN A.	P	05101	5	13.2%	55	38	52
COTTON, PAUL G.	P	05401	13	28.3%	18	46	44
CUSI, PRISCILLA M.	P	03104	17	7.9%	14	215	5
DAVISON, MARTHA F.	P	03110	14	11.3%	16	124	8
DEJONG, JACOB	P	03067	0	0.0%	93	21	87
DELFAUSSE, PETER O.	P	03301	6	35.3%	43	17	90
DENNETT, DOUGLAS E.	CHP	05401	0	0.0%	93	33	59
DEPPE, SUSAN L.	P	05401	1	0.3%	87	300	2
DEVENDERRAO, T.	P	03060	7	9.6%	37	73	21

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651. This information allowed the RICO Diversion Defendants to track and identify instances of, overprescribing.⁴²⁸ In fact, one of the Data Venders' experts testified that a manufacturer of "narcotic analgesics" used the Data Venders' information to track, identify, report and halt suspicious orders of controlled substances.⁴²⁹

⁴²⁸ See *Sorrell v. IMS Health Inc.*, 2011 WL 1449043, *37-38 (March 24, 2011) (arguing that data had been used to "identify overuse of antibiotics in children," and "whether there is a wide use of anthrax prophylactic medicines after the scares happened in 2001."). The Data Vender Respondents also cited evidence from the trial court proving that "because analysis of PI data makes it possible to 'identify overuse of a pharmaceutical in specific conditions, the government employs the data to monitor usage of controlled substances.'" *Id.*

⁴²⁹ *Id.* at *38. Eugene "Mick" Kolassa testified as an expert on behalf of the Data Vender stating that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.*; see also Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).

[455] Q. Besides marketing and promotion, are there any other uses for prescriber-identifiable data?

A. There's a number of other uses.

Q. And what are those?

A. The one that I was most impressed with was a firm that used it to identify – a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product and they would use that to notify the DEA and other authorities of potential problems.

652. The RICO Diversion Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

653. The RICO Diversion Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Diversion 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 2012⁴³⁰ and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six (76) actions involving orders to show cause and forty-one (41) actions involving immediate suspension orders – all for failure to report suspicious orders.⁴³¹

⁴³⁰ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

⁴³¹ *Id.*

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

655. The RICO Diversion Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

656. The RICO Diversion Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion. The RICO Diversion Defendants influenced the DEA production quotas in the following ways:

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

C. PATTERN OF RACKETEERING ACTIVITY.

658. The RICO Diversion Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(1)(D), including ; the felonious manufacture, importation, receiving, concealment buying

selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States; and 18 U.S.C. 1961(1)(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343).

1. The RICO Defendants Manufactured, Sold and/or Dealt in Controlled Substances and Their Actions Constitute Crimes Punishable as Felonies.

659. The RICO Diversion Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(1)(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

660. The RICO Diversion Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

661. Each of the RICO Diversion Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

662. The CSA and the Code of Federal Regulations, require the RICO Diversion Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as

required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

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

664. Upon information and belief, the foregoing examples reflect the RICO Diversion Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. The sheer volume of enforcement actions available in the public record against the Distributor Defendants supports this conclusion.⁴³² For example:

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

666. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone.

⁴³² Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

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

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

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

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

671. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”).

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

673. On May, 14, 2012, Cardinal Health entered into an Administrative Memorandum of Agreement with the DEA in which, among other things, Cardinal Health “admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate.”

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

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

676. In its Administrative Memorandum Agreement, McKesson acknowledged its wrongdoing and failure to comply with the obligations imposed by the CSA:

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to 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 about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

677. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis.

678. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA. The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. Documents published by the L.A. Times reveal that a Purdue sales manager spoke with company officials, asking:

679. Purdue was clearly aware of diversion. As a registrant, Purdue has the same obligation to report suspicious orders as a wholesale distributor. Although Purdue claimed that it was considering making a report to the DEA, it shirked its responsibility, claimed that it was the wholesaler's responsibility and then reserved the right to make the report:

680. Despite its knowledge of obvious diversion, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about [a pill mill] until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."

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

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

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

684. Many of the precise dates of the RICO Diversion Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to their books and records.

Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

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

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

687. The RICO Diversion Defendants' predicate acts and pattern of racketeering activity were a substantial and foreseeable cause of Plaintiff's injury and the relationship between the RICO Diversion Defendants' conduct and Plaintiff's injury are logical and not speculative. It was foreseeable to the RICO Diversion Defendants that when they refused to identify, report and halt suspicious orders as required by the CSA and Code of Federal Regulations, it would allow the wide-spread diversion of prescriptions opioids into the illicit market and create an opioid-addiction epidemic that logically, substantially, and foreseeably harmed Plaintiff.

688. The RICO Diversion Defendants' predicate acts and pattern of racketeering activity were a substantial and foreseeable cause of Plaintiff's injury and the relationship between the RICO Diversion Defendants' conduct and Plaintiff's injury is logical and not speculative. It was

foreseeable to the RICO Diversion Defendants that when they fraudulently marketed highly-addictive and dangerous drugs, that were approved for very limited and specific uses by the FDA, as non-addictive and safe for off-label uses such as moderate pain, non-cancer pain, and long-term chronic pain, that the RICO Diversion Defendants would create an opioid-addiction epidemic that logically, substantially and foreseeably harmed Plaintiff.

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

2. The RICO Diversion Defendants Engaged in Mail and Wire Fraud.

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

691. The RICO Diversion Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Diversion Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Diversion Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Diversion Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

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

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

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

- a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

695. The RICO Diversion Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers,

Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Diversion Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;
- d. Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated Defendants' DEA registrations;
- f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;
- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- l. Payments to Defendants' lobbyists through the PCF;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

696. On information and belief, the RICO Diversion Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or

received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

697.

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
Purdue	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Cephalon	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generec oxycontin	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. (<i>wholly-owned subsidiary of Endo</i>)	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II

Mallinckrodt	(1) Mallinckrodt PLC, (2) Mallinckrodt LLC (<i>wholly-owned subsidiary of Mallinckrodt PLC</i>)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
Allergan	(1) Allergan Plc, (2) Actavis LLC, (3) Actavis Pharma, Inc., (4) Actavis Plc, (5) Actavis, Inc., (6) Watson Pharmaceuticals, Inc., Watson Pharma, Inc.	Kadian	Morphine Sulfate	Schedule II
		Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II
		Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

698. Each of the RICO Diversion Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

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

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

701. Upon information and belief, the RICO Diversion Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

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

703. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators, the public and Plaintiff that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Diversion Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

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

705. The RICO Diversion Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Diversion Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Diversion Defendants.

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

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

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

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

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

711. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Diversion Defendants. The predicate acts were

committed or caused to be committed by the RICO Diversion Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

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

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

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

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

of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

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

717. It was foreseeable to Defendants that Plaintiff would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

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

D. DAMAGES.

1. Impact of the Opioid Diversion Enterprise.

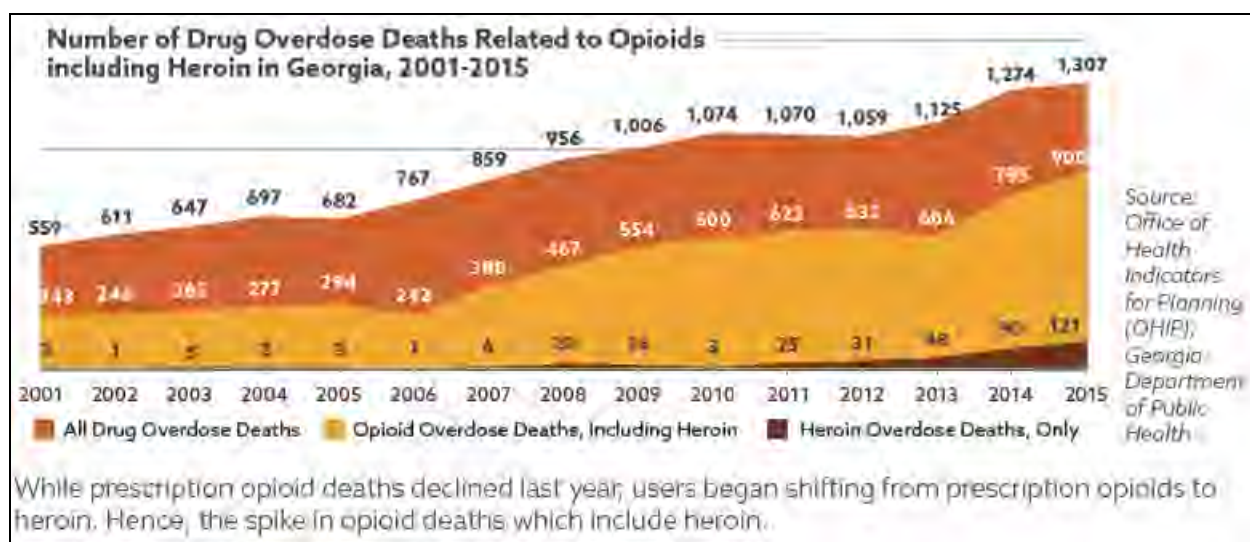
719. Georgia has been especially ravaged by the national opioid crisis.

720. The opioid scourge has visited devastating harm upon this State. At the 2017 University of Georgia College of Public Health's "State of the Public's Health" conference, experts explained that the deepening opioid epidemic is hitting Georgia harder than most states, and that from 2009 to 2014, Georgia's rate of increase in the number of opioid-related patient encounters led the nation.⁴³³

⁴³³ *Experts: Opioid crisis is hitting Georgia*, The Augusta Chronicle (Oct. 21, 2017), available at <http://chronicle.augusta.com/news/2017-10-21/experts-opioid-crisis-hitting-georgia>.

721. Georgia is among the top 11 states in terms of the most prescription opioid overdose deaths.⁴³⁴ Almost as many Georgians die of drug overdoses as in car accidents.⁴³⁵ Georgia suffered 1,394 overdose deaths in 2016,⁴³⁶ 1,302 deaths in 2015,⁴³⁷ and 1,206 deaths in 2014.⁴³⁸

722. Of the over 1,300 drug overdose deaths in 2015, 900 of them – or 68 percent – were due to opioid overdoses, including heroin.⁴³⁹ Overdose deaths tripled in Georgia from 1999 to 2013. Prescription opioid overdose deaths grew tenfold between 1999 and 2014 to 549 deaths, or a rate of 5.5 deaths per 100,000 people.⁴⁴⁰



⁴³⁴ Substance Abuse Research Alliance (SARA), Georgia Prevention Project, *Prescription Opioids and Heroin Epidemic in Georgia – a White Paper*, 2017, at 2, available at <http://www.senate.ga.gov/sro/Documents/StudyCommRpts/OpioidsAppendix.pdf> (last visited January 29, 2018).

⁴³⁵ *Id.* at 5.

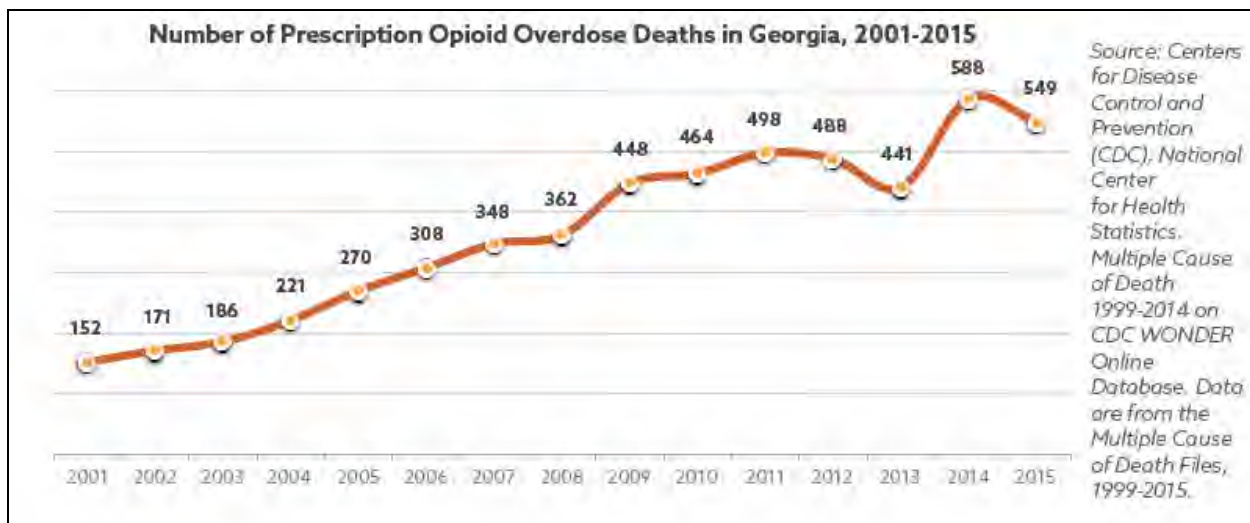
⁴³⁶ CDC, Drug Overdose Death Data, available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (“2016 Deaths” tab) (last visited January 19, 2018).

⁴³⁷ *Id.* at “2015 Deaths” tab, (last visited January 19, 2018).

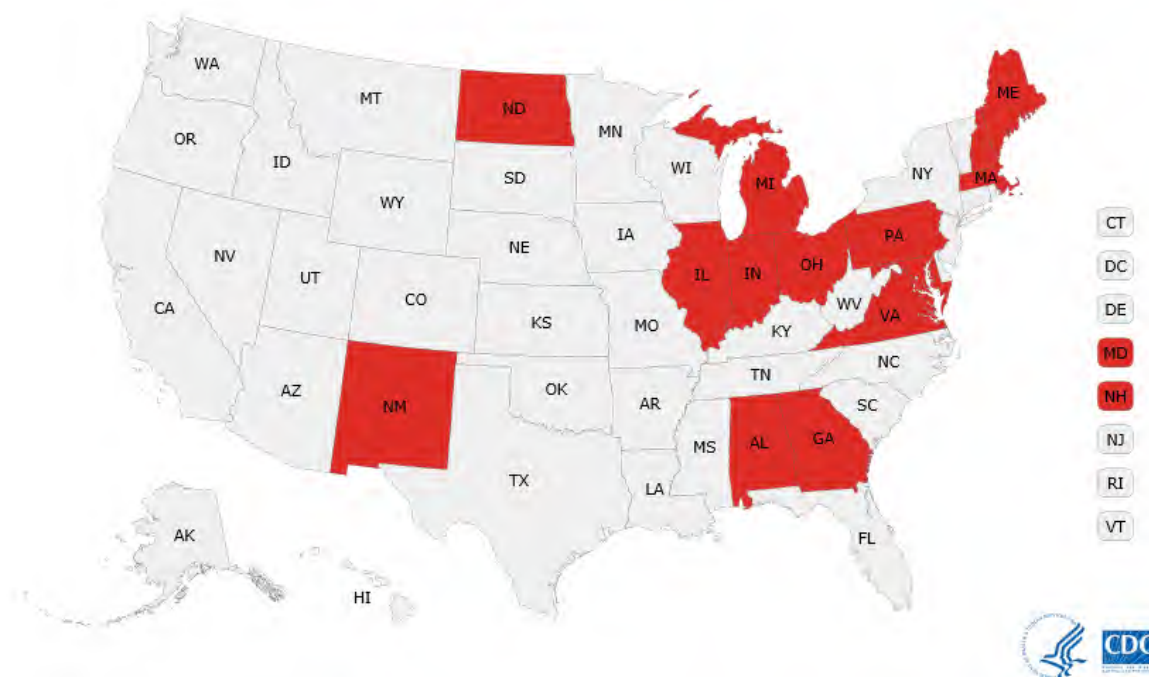
⁴³⁸ *Id.* at “2014 Deaths” tab, (last visited January 19, 2018).

⁴³⁹ Substance Abuse Research Alliance (SARA), *supra*, at 5.

⁴⁴⁰ *Id.*



723. According to the Centers for Disease Control and Prevention (“CDC”), Georgia was among the States to experience a statistically significant (10.2 percent) increase in drug overdose death rates in 2014 as compared to 2013:⁴⁴¹



⁴⁴¹ See Substance Abuse Research Alliance (SARA), *supra*, at 14.

724. Hospitalizations due to opioid abuse in Georgia have soared from about 302,000 in 2002 to around 520,000 in 2012.⁴⁴² During this time, the cost of this inpatient care related to opioid use more than doubled in Georgia, reaching \$15 billion in 2012.⁴⁴³

725. From 2009 to 2014, Georgia had the highest percent change in the rate of opioid-related inpatient stays of any state, at 99.8 percent.⁴⁴⁴ Georgia also had the third highest cumulative percent increase (85.2 percent) in the rate of opioid-related emergency department visits.⁴⁴⁵

726. Georgia is also seeing an increase in cases of newborns with NAS, a collection of symptoms babies experience in withdrawing from opioid medications taken by the mother.⁴⁴⁶ NAS is closely associated with opioid use.

727. Opioid addiction is part of the reason the number of children in Georgia state custody has almost doubled in the last three years.⁴⁴⁷

728. The opioid epidemic is particularly devastating in Plaintiff's Community.

729. In 2017, the coroner for Dougherty County, where Albany is located, saw seventeen deaths related to overdoses, up from five in 2015. Additionally, the County's EMS

⁴⁴² *Id.* at 7.

⁴⁴³ *Id.*

⁴⁴⁴ Audrey J. Weiss, Ann Elixhauser, Marguerite L. Barrett, Claudia A. Steiner, Molly K. Bailey and Lauren O'Malley, *Opioid-Related Inpatient Stays and Emergency Department visits by State, 2009-2014*, December 2016, Revised January 2017, Healthcare Cost and Utilization Project (HCUP), available at <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.jsp> (last visited Jan. 29, 2018).

⁴⁴⁵ *Id.*

⁴⁴⁶ Substance Abuse Research Alliance (SARA), *supra*, at 30.

⁴⁴⁷ WRDW, *News 12 Investigates: Children of Opioids*, Oct. 9, 2017, available at <http://www.wrdw.com/content/news/Children-of-Opioids-450115313.html> (last visited January 29, 2018).

director reported around 90 overdose cases in 2017, with 2018 predicted to see at least 95 cases.

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730. The opioid epidemic has placed increased budgetary constraints upon inter alia the public health and medical care expenditures of the State and Plaintiff's Community. Opioid addiction is one of the primary reasons citizens of the State and Plaintiff's Community seek substance abuse treatment.

2. The Relief Sought.

731. The RICO Diversion Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Diversion Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably cause an opioid epidemic. Plaintiff was injured by the RICO Diversion Defendants' pattern of racketeering activity and the opioid epidemic that they created.

732. As Plaintiff alleges, the RICO Diversion Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.⁴⁴⁹ Nevertheless, the RICO Diversion Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription

⁴⁴⁸ WFXL, *Dougherty County coroner hosts opioid epidemic reenactment to educate students*, April 17, 2018, available at <https://wfxl.com/news/local/dougherty-county-coroner-hosts-opioid-epidemic-re-enactment-to-educate-students> (last visited September 21, 2018).

⁴⁴⁹ *Traveler's Property Casualty Company of America v. Actavis, Inc.*, 22 Cal. Rptr. 3d 5, 19 (Cal. Ct. App. 2017).

opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.⁴⁵⁰

733. Here, as Plaintiff alleges, the link of causation generally breaks down into three very short steps: (1) the RICO Diversion Defendants' affirmative action to continue supplying prescription opioids through legal channels with knowledge that they were being diverted into the illicit market; (2) an opioid epidemic in the form of criminal drug trafficking, misuse and abuse; and (3) injuries to the Plaintiff.⁴⁵¹ Although not as direct as a car accident or a slip-and-fall case, this causal chain is still a "direct sequence" and a logical, substantial and foreseeable cause of Plaintiff's injury.⁴⁵²

734. Specifically, the RICO Diversion Defendants' predicate acts and pattern of racketeering activity caused the opioid epidemic which has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

- a. Losses caused by purchasing and/or paying reimbursements for the RICO Defendants' prescription opioids, that Plaintiff would not have paid for or purchased but for the RICO Diversion Defendants' conduct;
- b. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
- c. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
- d. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

⁴⁵⁰ *City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, *6 (W.D. Wash. Sept. 25, 2017).

⁴⁵¹ *Id.*

⁴⁵² *Id.*

- e. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- f. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;
- g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;
- i. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;
- j. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;
- k. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- l. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's Community;
- m. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and
- n. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

735. Plaintiff's injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic created by Defendants' conduct, Plaintiff would not have lost money or property.

736. Plaintiff's injuries were directly caused by the RICO Diversion Defendants' pattern of racketeering activities.

737. Plaintiff is most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

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

COUNT IV
GEORGIA RICO (RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS)
ACT, O.C.G.A. § 16-14-1 et seq.
(Against All Defendants)

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

740. Plaintiff has standing to bring this action as an "aggrieved person." O.C.G.A. § 16-14-6(b); *see also* O.C.G.A. § 16-1-3(12).

741. The Georgia RICO Act states that "[i]t shall be unlawful for any person, through a pattern of racketeering activity or proceeds derived therefrom, to acquire or maintain, directly or indirectly, any interest in or control of any enterprise, real property, or personal property of any nature, including money." O.C.G.A. § 16-14-4(a).

742. "'Racketeering activity' means to commit, to attempt to commit, or to solicit, coerce, or intimidate another person to commit any crime which is chargeable by indictment under the laws of this state involving:" *inter alia*, "The 'Georgia Controlled Substances Act' in violation of Article 2 of Chapter 13 of this title[.]" O.C.G.A. § 16-14-3(5)(A)(xxxiv).

743. "'Racketeering activity' shall also mean any act . . . involving . . . dealing in narcotic or dangerous drugs, ..." O.C.G.A. § 16-14-3(5)(B).

744. “‘Racketeering activity’ shall also mean any conduct defined as ‘racketeering activity’ under 18 U.S.C. Section 1961 (1), ...” O.C.G.A. § 16-14-3(5)(C).

745. The RICO Defendants violated the Georgia RICO Act by conspiring to, attempting and actually engaging in violations of the Georgia Controlled Substances Act, illegally dealing in narcotic or dangerous drugs, and violating 18 U.S.C. Section 1961(1), as described above in allegations expressly incorporated herein by reference.

746. Defendants violated the Georgia RICO Act by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as described above in allegations expressly incorporated herein by reference, in violation of Section 16-14-4(a). O.C.G.A. § 16-14-4(a).

747. The RICO Defendants’ Opioid Diversion Enterprise existed as an “enterprise” as defined in the Georgia RICO Act. O.C.G.A. § 16-14-3(3).

748. As described above and as fully incorporated herein, the violations set forth herein constitute “racketeering activity” within the meaning of section 16-14-3(5) with at least two such acts of racketeering activity having occurred within the past four years.

749. The RICO Defendants’ violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

750. Plaintiff’s injuries, and those of the citizens of Plaintiff’s Community, were proximately caused by the RICO Defendants’ racketeering activities. But for the RICO Defendants’ conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

751. Plaintiff's injuries and those of her citizens were directly caused by the RICO Defendants' racketeering activities.

752. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

753. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia actual damages, treble damages, punitive damages, equitable relief, attorney's fees and all costs and expenses of investigation and suit and pre- and post-judgment interest. O.C.G.A. § 16-14-6(b) & (c).

COUNT V
NEGLIGENCE AND NEGLIGENT MISREPRESENTATION
(Against All Defendants)

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

755. Plaintiff seeks economic damages that were the foreseeable result of Defendants' intentional and/or unlawful actions and omissions.

756. Under State law, to establish actionable negligence, one must show: the existence of a duty to conform to a standard of conduct raised by the law for the protection of others against unreasonable risks of harm, a breach of that duty, and injury resulting proximately therefrom and/or that was substantially caused thereby. All such essential elements exist here.

757. Georgia recognizes the "general duty ones owes to all the world not to subject them to an unreasonable risk of harm." *Bradley Ctr., Inc. v. Wessner*, 250 Ga. 199, 201, 296 S.E.2d 693, 695 (1982) (citing Restatement, Torts, 2d § 282). Each Defendant owed a duty to the Plaintiff and to the public health and safety in the Plaintiff's Community.

758. In Georgia, the imposition of a duty cannot be separated from foreseeability, such that "there must be evidence that the act (or omission to act) alleged to be negligent created a

foreseeable unreasonable risk of harm.” *Love v. Morehouse Coll., Inc.*, 287 Ga. App. 743, 745, 652 S.E.2d 624, 626 (2007) (citations and quotations omitted) (emphasis in original). For a party to be liable for negligence, “it is not necessary that he should have been able to anticipate the particular consequences which ensued. It is sufficient if, in ordinary prudence, he might have foreseen that some injury would result from his act or omission, and that consequences of a generally injurious nature might result.” *Freeman v. Wal-Mart Stores, Inc.*, 281 Ga. App. 132, 136, 635 S.E.2d 399, 402 (2006) (cit. om.).

759. Each Defendant owed a duty to the Plaintiff and to the public health and safety in the Plaintiff’s Community because the injury was foreseeable and, in fact, foreseen by the Defendants. If a course of action creates a foreseeable risk of injury, the individual engaged in that course of action has a duty to protect others from such injury. Each Defendant owed a duty to the Plaintiff and to the public in the Plaintiff’s Community, because the injury was foreseeable and, in fact, foreseen by the Defendants.

760. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, selling and distributing highly dangerous opioid drugs to the State and Plaintiff’s Community.

761. Each Defendant had an obligation to exercise due care in manufacturing, marketing, selling and distributing highly dangerous opioid drugs in the State and Plaintiff’s Community.

762. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and impose significant costs upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between

manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

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

764. Moreover, law enforcement repeatedly warned Defendants of the unlawfulness and consequences of their actions and omissions.

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

766. As described above in allegations expressly incorporated herein, Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

767. Under Georgia law, the elements for negligent misrepresentation include: 1) the negligent supply of false information to foreseeable persons, known or unknown; (2) such persons' reasonable reliance upon that false information; and (3) economic injury proximately

resulting from such reliance. *Futch v. Lowndes County*, 297 Ga. App. 308, 312, 676 S.E.2d 892 (2009); *Hardaway Co. v. Parsons, Brinckerhoff, Quade & Douglas, Inc.*, 267 Ga. 424, 479 S.E.2d 727, 729 (1997).

768. As described elsewhere in the Complaint in allegations expressly incorporated herein, Defendants supplied information to Plaintiff and Plaintiff's Community.

769. As described elsewhere in the Complaint in allegations expressly incorporated herein, Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiff's Community and destinations from which they knew opioids were likely to be diverted into Plaintiff's Community, in addition to other misrepresentations alleged and incorporated herein.

770. As described elsewhere in the Complaint in allegations expressly incorporated herein, Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable.

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

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

773. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive and/or fraudulent.

774. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. This reliance proximately caused Plaintiff's injuries.

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

776. As described above in allegations expressly incorporated herein, Defendants' breaches of duty and misrepresentations caused, bear a causal connection with and/or proximately resulted in the damages sought herein.

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

778. The Defendants failed to disclose the material facts that, inter alia, they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell opioids.

779. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed and sold had characteristics, uses or benefits that they do not have. The Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective when the Manufacturer Defendants knew, or should have known, such representations were untrue, false and misleading.

780. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value and in fact caused addiction and overdose deaths.

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

782. Defendants' unlawful and/or intentional actions create a rebuttable presumption of negligence and negligent misrepresentation under State law.

783. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' actions and omissions.

784. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, inter alia, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VI
NEGLIGENCE PER SE
(Against All Defendants)

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

786. "Georgia law allows the adoption of a statute as a standard of conduct so that its violation becomes negligence per se." *Brown v. Belinfante*, 252 Ga. App. 856, 861, 557 S.E.2d 399, 403 (2001) (cit. om.). "Where a statute provides a general rule of conduct, although only amounting to a requirement to exercise ordinary care, the violation thereof is negligence as a

matter of law, or negligence per se,” *Holbrook v. Exec. Conference Ctr., Inc.*, 219 Ga. App. 104, 107, 464 S.E.2d 398, 401 (1995) (cit. om.).

787. Violations of statutes and regulations support a cause of action for negligence per se where the plaintiff is within the class of persons the statute was designed to protect, and the harm sustained is the type sought to be prevented. *Goldstein, Garber & Salama, LLC v. J.B.*, 300 Ga. 840, 845, 797 S.E.2d 87, 92 (Ga. 2017) (cit. om.).

788. Georgia’s minimum requirements for controlled substance manufacture and wholesale drug distribution is that they must comply with “all applicable Federal, State, and local laws and regulations” and “all applicable State, Local and DEA regulations.” Ga. Comp. R. & Regs. 480-7-.03(10).

789. Each Defendant was required under Georgia law be licensed by the Georgia State Board of Pharmacy. *See* O.C.G.A. §§ 16-13-35; 26-4-115(a) and Ga. Comp. R. & Regs. 480-7-.03(1). To receive and maintain these licenses, each of the Defendants assumed a duty to comply with “all applicable Federal, State, and local laws and regulations” and “all applicable State, Local and DEA regulations.” Ga. Comp. R. & Regs. 480-7-.03(10).

790. The State Board of Pharmacy makes a determination of what is in the public interest when it decides whether to register manufacturers and distributors under the Georgia Controlled Substances Act. O.C.G.A. § 16-13-36(a).

791. The Georgia Board of Pharmacy may suspend or revoke a registration to manufacture or distribute a controlled substance if the registrant has “furnished false or fraudulent material information in any application” to receive or renew a registration. O.C.G.A. § 16-13-37(a)(1). *See also* O.C.G.A. § 16-13-36(a)(5) (furnishing false or fraudulent material in any application is factor considered in Board’s determination to grant registration); Ga. Comp. R.

& Regs. 480-7-.03(4) (minimum qualifications for “determining eligibility for licensure” to manufacture or distribute prescription drugs includes whether applicant has furnished “false or fraudulent material in any application made in connection with drug manufacturing or distribution”).

792. Federal and Georgia laws and regulations require Defendants to act as gatekeepers guarding against the diversion of the highly addictive, dangerous opioid drugs. See, e.g., O.C.G.A. § 16-13-37(a)(5); O.C.G.A. § 16-13-36(a)(1) and (4).

793. The federal mandates incorporated into Georgia law require that Defendants must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. §§ 823(a)(1), (b)(1). These federal regulations impose a non-delegable duty upon both manufacturers and distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor or manufacturer] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

794. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. See *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007); *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017). Regardless, all flagged orders must be reported. *Id.*

795. Defendants violated section 16-13-42 of the Georgia Controlled Substances Act, which provides that, “It is unlawful for any person: (2) Who is a registrant to manufacture a controlled substance not authorized by his registration or to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person[.]” O.C.G.A. § 16-13-42(a)(2).

796. Defendants violated section 16-13-30 of the Georgia Controlled Substances Act, which provides that, except as authorized by law, “[I]t is unlawful for any person to manufacture, deliver, distribute, dispense, administer, sell, or possess with intent to sell, any controlled substance.” O.C.G.A. § 16-13-30(b).

797. Defendants also violated section 16-13-33 of the Georgia Controlled Substances Act by attempting and conspiring to violate that Georgia Controlled Substances Act.

798. Defendants also violated section 26-4-115 of the Georgia Pharmacy Practice Act by failing to submit reports of excessive purchases of controlled substances. O.C.G.A. § 26-4-115(b)(2).

799. Defendants do not qualify for the “authorized by law” exceptions to the Georgia Controlled Substances Act violations because Defendants did not comply with the mandatory terms of the registrations issued to them by the Georgia State Board of Pharmacy or with federal requirements incorporated by reference, as further detailed in this Complaint.

800. Plaintiff is within the class intended to be protected by the public safety statutes and regulations concerning controlled substances.

801. Defendants’ violations of these public safety laws are prima facie evidence of negligence per se. Each Defendant had a duty under inter alia these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report

suspicious orders of opioids. Defendants' violations of the law constitute negligence per se. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

802. As described above in allegations expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes and regulations requiring that as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

803. As described above in allegations expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, is and was a substantial factor contributing to, and/or proximately resulted in, harm and damages to Plaintiff.

804. The injuries and damages sustained are those which the Georgia statutes and regulations were designed to prevent.

805. Defendants' violations of the Georgia statutes and public safety regulations cited herein were and are substantial factors in the injuries and damages sustained.

806. It was foreseeable that Defendants' breaches of statutory and regulatory duties described herein would result in the damages sustained.

807. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence per se. Plaintiff does not seek damages for physical, personal injury or any physical damage to property caused by Defendants' actions.

808. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including inter alia injunctive relief, restitution, disgorgement of profits,

compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VII
FRAUD AND FRAUDULENT MISREPRESENTATION
(Against All Defendants)

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

810. In Georgia, the tort of fraud has five elements: (1) a false representation or omission of a material fact; (2) scienter; (3) intention to induce the party claiming fraud to act or refrain from acting; (4) justifiable reliance; and (5) damages. *See, e.g., Home Depot U.S.A., Inc. v. Wabash Nat. Corp.*, 314 Ga. App. 360, 367, 724 S.E.2d 53, 60 (2012); *Fortson v. Freeman*, 313 Ga. App. 326, 328, 721 S.E.2d 607, 609 (2011). *See also* O.C.G.A., § 51-6-2 (“Willful misrepresentation of a material fact, made to induce another to act, upon which such person acts to his injury, will give him a right of action.”).

811. Defendants violated their general duty not to actively deceive, have made knowingly false statements and have omitted and/or concealed information that made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

812. As alleged herein, Defendants made false statements as to their compliance with state and federal law regarding their duties to prevent diversion and their duties to monitor, report and halt suspicious orders and/or concealed their noncompliance with these requirements.

813. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic, non-cancer pain.

814. As alleged herein, Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants

made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading Plaintiff, Plaintiff's Community, the public and persons on whom Plaintiff relied.

815. These false representations and concealments were reasonably calculated to deceive Plaintiff, Plaintiff's Community and the physicians who prescribed opioids for persons in Plaintiff's Community; were made with the intent to deceive; and did in fact deceive these persons, Plaintiff and Plaintiff's Community.

816. Plaintiff, Plaintiff's Community and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

817. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. This reliance proximately caused Plaintiff's injuries.

818. Defendants' fraudulent conduct was a direct and proximate cause of the injuries Plaintiff alleges herein.

819. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment.

820. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, inter alia, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

PUNITIVE DAMAGES

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

822. By engaging in the above-described intentional and/or unlawful acts or practices, Defendants acted with actual malice, wantonly and oppressively. Defendants acted with conscious disregard for the rights of others and/or in a reckless, wanton, willful or grossly negligent manner. Defendants acted with a prolonged reckless indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Defendants acted toward the Plaintiff with fraud, oppression and/or malice and/or were grossly negligent in failing to perform the duties and obligations imposed upon them under applicable federal and state statutes and common law.

823. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the State and Plaintiff's Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence and the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrence. Punitive damages should be awarded pursuant to the common law and all statutory grounds for recovery, including but not limited to section 51-12-5.1 of the Georgia Code.

824. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and gross negligence and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

RELIEF

WHEREFORE, the Plaintiff respectfully prays that this Court grant the following relief:

1. Enter a Judgment in favor of the Plaintiff in a final order against each of the Defendants;

2. Enjoin the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries and all other persons acting in concert or participation with them from engaging in unfair or deceptive practices in violation of law and ordering temporary, preliminary or permanent injunction;

3. Order that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

4. Order Defendants to fund an “abatement fund” for the purposes of abating the opioid nuisance;

5. Award actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorneys’ fees and all costs and expenses of suit pursuant to Plaintiff’s racketeering claims;

6. Award the Plaintiff the damages caused by the opioid epidemic, including (A) costs for providing medical care, additional therapeutic and prescription drug purchase, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services; (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (E) costs associated with law enforcement and public safety relating to the opioid epidemic;

7. Enter a judgment against the Defendants requiring Defendants to pay punitive damages;

8. Grant the Plaintiff:

- a. The costs of investigation, reasonable attorneys' fees, and all other costs and expenses;
- b. Pre-judgment and post-judgment interest; and
- c. All other relief as provided by law and/or as the Court deems appropriate and just.

Dated: November 20, 2018

RESPECTFULLY SUBMITTED:

/s/D. Bryant Chaffin

D. Bryant Chaffin, GA Bar No. 926074
Michael J. Fuller, Jr. (*Pro Hac Vice* pending)
McHUGH FULLER LAW GROUP, PLLC
97 Elias Whiddon Rd.
Hattiesburg, MS 39402
Tel.: 601-261-2220
Fax: 601-261-2481
mike@mchughfuller.com

Christina D. Crow
JINKS, CROW & DICKSON, P.C.
219 Prairie St. North
Union Springs, AL 36089
Tel.: 334-738-4225
ccrow@jinkslaw.com

Paul T. Farrell, Jr. (*Pro Hac Vice* pending)
**GREENE, KETCHUM, FARRELL,
BAILEY & TWEEL, LLP**
419 - 11th Street (25701)/ P.O. Box 2389
Huntington, West Virginia 25724-2389
Tel.: 800-479-0053 or 304-525-9115
Fax: 304-529-3284
paul@greeneketchum.com

James C. Peterson (*Pro Hac Vice* pending)
**HILL, PETERSON, CARPER,
BEE & DEITZLER, PLLC**
NorthGate Business Park
500 Tracy Way
Charleston, WV 25311
Tel.: 304-345-5667
Fax: 304-345-1519
jcpeterson@hpcbd.com

Peter J. Mougey (*Pro Hac Vice* pending)
**LEVIN, PAPANTONIO, THOMAS, MITCHELL,
RAFFERTY & PROCTOR, P.A.**
316 S. Baylen Street, Suite 600
Pensacola, FL 32502-5996
Tel.: 850-435-7068
Fax: 850-436-6068
pmougey@levinlaw.com

Derrell Dowdell
DERRELL DOWDELL & ASSOCIATES
922 Second Ave
Columbus, GA 31901
Tel.: 706-321-1130
dowdellderrell@gmail.com

J. Burton LeBlanc, IV (*Pro Hac Vice* pending)
BARON & BUDD, P.C.
3102 Oak Lawn Avenue, Suite 1100
Dallas, TX 75219
Tel.: 214-521-3605
Fax: 214-520-1181
bleblanc@baronbudd.com

Anthony J. Majestro (*Pro Hac Vice* pending)
POWELL & MAJESTRO, PLLC
405 Capitol Street, Suite P-1200
Charleston, WV 25301
Tel.: 304-346-2889
Fax: 304-346-2895
amajestro@powellmajestro.com

EXHIBIT 9

**IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION**

CITY OF PHILADELPHIA, MISSISSIPPI)

Plaintiff,)

v.)

CIVIL ACTION NO. 3:18-cv-143-LG-LRA

PURDUE PHARMA, L.P.; PURDUE PHARMA,)
INC.; THE PURDUE FREDERICK COMPANY;)
CEPHALON, INC.; TEVA PHARMACEUTICAL)
INDUSTRIES, LTD.; TEVA)
PHARMACEUTICALS USA, 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.; ENDO HEALTH)
SOLUTIONS INC.; ENDO PHARMACEUTICALS)
INC.; ALLERGAN PLC f/k/a ACTAVIS, PLC;)
WATSON PHARMACEUTICALS, INC. n/k/a)
ACTAVIS, INC.; WATSON LABORATORIES;)
INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC.)
f/k/a WATSON PHARMA, INC.; INSYS)
THERAPEUTICS, INC.; MALLINKRODT PLC;)
MALLINKRODT LLC;)
AMERISOURCEBERGEN DRUG)
CORPORATION; CARDINAL HEALTH, INC.;)
MCKESSON CORPORATION; and)
DOES 1 – 100, INCLUSIVE)

Defendants.)

COMPLAINT

Complaint for Public Nuisance;
Fraud; Negligence; Negligence *Per Se*;
Civil Conspiracy; Unjust Enrichment

JURY TRIAL DEMANDED

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff, the City of Philadelphia, Mississippi, by and through undersigned counsel (hereinafter “Plaintiff” or “City”), files this Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, 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., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Allergan PLC f/k/a Actavis PLC, Watson Pharmaceuticals, Inc. n/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, (“Manufacturer Defendants”), AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation (“Distributor Defendants”), and Does 1 – 100, inclusive. (collectively “Defendants”).

INTRODUCTION

1. Mississippi is facing an unprecedented opioid addiction epidemic. Presently, it is the fourth highest prescriber of opioids in the country.¹ Mississippi's opioid overdose death numbers show a 79 percent increase from 2016 to 2017. According to the State Bureau of Narcotics Director John Dowdy, “Mississippi is emerging on the brink of a super pandemic.”²

2. In 2016 alone, health care providers wrote more than 289 million prescriptions for opioids, enough for *every adult in the United States* to have more than one bottle of pills.³ In that same year, there were 3,574,662 prescriptions written and 201,224,298 dosage units dispensed for opioids in Mississippi. That equals to roughly 70 pills for every man, woman and child in

¹ CDC Annual Surveillance Report of Drug-Related Risks and Outcomes.

² www.clarionledger.com/story/news/2017/06/11/drug-overdose-deaths-reach-record-mississippi/349433001/

³ *Prevalence of Opioid Misuse*, BupPractice, <https://www.buppractice.com/node/15576> (Sept. 7, 2017).

Mississippi.

3 The City of Philadelphia is located in Neshoba County, Mississippi, which has an opioid prescribing rate of 147.1 prescriptions for every 100 residents of the county - nearly two and a half times the national average.⁴

4 Unfortunately, using opioids too often leads to misusing and abusing opioids. In 2014, almost 2 million Americans abused or were addicted to opioids.⁵ That same year, more people died from drug overdoses than in any other year, and most overdose deaths involved an opioid.

5 In fact, accidental drug overdose deaths, of which at least two-thirds are opioid overdoses, are the leading cause of death for Americans under the age of 50. Accidental drug overdose deaths, predominantly from opioids, exceed the number of deaths caused by cars or guns.

6 The economic burden caused by opioid abuse in the United States is approximately \$78.5⁶ billion, including lost productivity and increased social services, health insurance costs, increased criminal justice presence and strain on judicial resources, and substance abuse treatment and rehabilitation.

7 This epidemic did not occur by chance. Defendants manufacture, market, distribute, and sell prescription opioids, including, but not limited to, brand-name drugs like OxyContin, Vicodin, Opana, Percocet, Percodan, Roxicodone, Avinza, and generics like oxymorphone and hydrocodone, which are powerful narcotic painkillers. Other Defendants manufacture, market, distribute, and sell prescription opioids, including, but not limited to, brand-name drugs like Fentanyl, Fentora, Duragesic, Ultram, and Ultracet.

⁴ <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html>

⁵ Substance Abuse and Mental Health Services Administration, National Survey on Drug Use and Health, 2014.

⁶ CDC Foundation's New Business Pulse Focuses on Opioid Overdose Epidemic, Centers for Disease Control and Prevention (Mar. 15, 2017), <https://www.cdc.gov/media/releases/2017/a0315-business-pulse-opioids.html>.

8 Historically, opioids were considered too addictive and debilitating for treating chronic pain,⁷ such as back pain, migraines, and arthritis, and were used only to treat short-term acute pain or for palliative or end-of-life care.

9 By the late 1990s or early 2000s, however, each Defendant began a marketing scheme to persuade doctors and patients that opioids can and should be used for chronic pain. Each Defendant spent, and continues to spend, millions of dollars to promote the benefits of opioids for chronic pain while trivializing or even denying their risks.

10 Contrary to the language of their drugs' labels, Defendants falsely and misleadingly: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" thereby advocating that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

11 Defendants distributed these falsehoods through their sales representatives and physicians who supported Defendants' message. Sales representatives, working at Defendants' behest, promoted highly addictive opioids through souvenirs and toys, including but not limited to, opioid brand-bearing stuffed plush toys, dolls, coffee cups, fanny packs, water bottles, notepads, pens, refrigerator magnets, clocks, letter openers, rulers, daytime planners, bags, puzzles, posters, clipboards, highlighters, flashlights, key chains, clothing, reflex mallets, and mock-ups of the United States Constitution.

12 Defendants also used third parties they controlled by: (a) funding, assisting,

⁷ In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

encouraging, and directing doctors, known as “key opinion leaders” (“KOLs”) and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “FrontGroups”).

13. Defendants worked with KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly “neutral” guidance, such as treatment guidelines, Continuing Medical Education (“CME”) programs, medical conferences and seminars, and scientific articles. After their individual and concerted efforts, Defendants convinced doctors that instead of being addictive and unsafe for long-term use in most circumstances, opioids were *required* in the compassionate treatment of chronic pain.

14. The Distributor Defendants were not standing by idly while the Marketing Defendants were peddling their opioids to physicians and consumers. Cardinal, AmerisourceBergen, and McKesson (“Distributor Defendants”) are three of the largest opioid distributors in the United States. Distributor Defendants purchased opioids from Defendants herein and sold them to pharmacies throughout the City of Philadelphia.

15. Despite the alarming and suspicious rise in the ordering of opioids by retailers in the City of Philadelphia, Distributor Defendants did nothing.

16. Essentially each Defendant ignored science and consumer health for profits. Defendants’ efforts were so successful that opioids are now the most prescribed class of drugs generating \$11 billion in revenue for drug companies in 2014 alone.

17. As a direct and foreseeable consequence of Defendants’ misrepresentations regarding the safety and efficacy of using opioids Plaintiff, the City of Philadelphia, has been impacted by the scourge of opioid addiction. The City of Philadelphia, Mississippi, is being forced to expend City resources combatting the opioid epidemic and its cascading effects. As a direct

result of Defendants' corporate malfeasance, the City's medical professionals and first responders must now prioritize combatting drug overdoses, including opioid overdoses, and must now spend their time and resources combatting the multifaceted harms that drug addiction imposes on families, children, and infants. The City's law-enforcement officers are engaged in a battle against the heroin trade, and against criminal enterprises illegally trading in prescription opioids. The adverse effects of opioid addiction radiate across the City of Philadelphia. When workers in the City become addicted, it decreases their productivity and their earning power, and ultimately harms the local economy. When heads of households fall victim to the opioid epidemic, the children that rely on them fall victim as well—increasing the strain on social service providers. The opioid epidemic has, perhaps, its most pernicious effects in neighborhoods where drugs are sold. The illegal drug trade often invites violence and decimates the quality of life for innocent families living nearby. The opioid epidemic has contributed to the destabilization of communities and neighborhoods in the City of Philadelphia and elsewhere, and, in turn, has deprived the City of Philadelphia of tax revenue and increased the costs of delivering City services.

18. The City of Philadelphia spends significant funds each year to provide and pay for resources such as health care, law enforcement, social services, public assistance, pharmaceutical care and other necessary services on behalf of residents and City employees who are addicted to opioids, which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants. Also, as an employer, the City of Philadelphia is responsible for funding a medical insurance plan for its employees, and on behalf of its employees, the City paid for opioid prescriptions for chronic pain, suffered a loss of productivity as a result of opioid abuse and addiction, and therefore it has been damaged by Defendants' conduct.

19. Plaintiff, the City of Philadelphia, Mississippi, accordingly brings this civil action to eliminate or, at a minimum, reduce the imminent threat to public health and safety in the City of Philadelphia caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup municipal monies spent to address the harm that resulted from: (1) the false, deceptive and unfair marketing of prescription opioids by Defendants, and from (2) Defendants' failure to stop plainly suspicious orders of opioids, as defined below. The economic damages suffered by Plaintiff were caused by the use of opioid products that were foreseeable to Defendants and were sustained through Defendants' patterns of activity directly resulting from their reckless, intentional and unlawful acts and omissions.

VENUE AND JURISDICTION

20. Federal subject matter jurisdiction is based upon 28 U.S.C.A. § 1332, in that there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

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

22. Venue is further proper in this District pursuant to 28 U.S.C.A. § 1391 and 18 U.S.C.A. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C.A. §§ 1391(b); § 1965(a).

PARTIES

A. Plaintiff

23. Plaintiff, CITY OF PHILADELPHIA, MISSISSIPPI, is authorized to bring the causes of action set forth herein. MS Code § 11-45-25 (2013). (“A municipality may sue and be sued by its corporate name.”) Plaintiff is responsible for the public health, safety and welfare of its citizens. The City of Philadelphia is also an employer of a substantial number of individuals and is responsible for funding a medical insurance plan for its employees, and for maintaining worker’s compensation insurance. The City of Philadelphia has declared, *inter alia*, that opioid abuse, addiction, morbidity, and mortality have created a serious public health and safety crisis and are a public nuisance and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

24. Plaintiff has standing to bring all claims pled herein and to recover damages incurred as a result of Defendants’ actions and omissions.

B. Defendants

Manufacturer Defendants

25. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware.

26. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut.

27. THE PURDUE FREDERICK COMPANY, INC. is a Delaware corporation with its principal place of business in Stamford, Connecticut.

28. The Purdue Defendants (collectively “Purdue”) manufacture, promote, sell, and distribute opioids in the U.S. and the City of Philadelphia. Purdue’s opioid drug, OxyContin, is among the most addictive and abused prescription drugs in the history of America.

29. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids in the U.S. and in the City of Philadelphia.

30. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc.

31. TEVA PHARMACEUTICALS USA, INC. (“Teva USA”) is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

32. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in the City of Philadelphia, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in the City of Philadelphia, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon’s promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.’s logo. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceutical Industries, Ltd., Teva

Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as “Cephalon.”)

33. JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

34. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J).

35. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

36. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals’ drugs and Janssen’s profits inure to J&J’s benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as “Janssen.”)

37. Janssen manufactures, promotes, sells, and distributes opioids in the U.S. and in the City of Philadelphia.

38. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

39. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as “Endo.”)

40. Endo develops, markets, and sells opioid drugs in the U.S. and in the City of Philadelphia. Endo also manufactures and sells generic opioids in the U.S. and the City of Philadelphia.

41. ALLERGAN PLC formerly known as Actavis PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, Defendant, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to ACTAVIS, INC., then to ACTAVIS PLC in October 2013.

42. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

43. ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC.

44. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

45. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as “Actavis.”).

46. Actavis manufactures, promotes, sells, and distributes opioids in the U.S. and in the City of Philadelphia.

47. INSYS THERAPEUTICS, INC. (“Insys”) is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys manufactures opioids that are sold throughout the United States and in the City of Philadelphia.

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

Distributor Defendants

49. MCKESSON CORPORATION (“McKesson”) is a Delaware corporation with its principal place of business in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Mississippi and the City of Philadelphia. Upon information and belief, McKesson is a pharmaceutical distributor licensed to do business in Mississippi.

50. CARDINAL HEALTH, INC. (“Cardinal”) is an Ohio Corporation with its principal place of business in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Mississippi and the City of Philadelphia. Cardinal does substantial business in Mississippi and, upon information and belief, Cardinal is a pharmaceutical distributor licensed to do business in Mississippi.

51. AMERISOURCEBERGEN DRUG CORPORATION (“Amerisource”) is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Mississippi and the City of Philadelphia. Amerisource does

substantial business in Mississippi and, upon information and belief, Amerisource is a pharmaceutical distributor licensed to do business in Mississippi.

52 The City lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. The City will amend this Complaint to show their true names and capacities if and when they are ascertained. The City of Philadelphia is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE has engaged in conduct that contributed to cause events and occurrences alleged in this Complaint and, as such, shares liability for at least some part of the relief sought herein.

FACTUAL ALLEGATIONS

53 Before the 1990s, generally accepted standards of medical practice dictated that opioids should be used only for short-term acute pain – pain relating to recovery from surgery or for cancer or palliative (end-of-life) care. Using opioids for chronic pain was discouraged or even prohibited because there was a lack of evidence that opioid improved patients ability to overcome pain and function. Instead the evidence demonstrated that patients developed tolerance to opioids over time, which increased the risk of addiction and other side effects.

54 Defendants dramatically changed doctors' views regarding opioids through a well-funded deceptive marketing scheme. Each Defendant used direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use.

A. Defendants Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids.

55 Defendants spread their false and deceptive statements by (1) marketing their branded opioids directly to doctors and patients in the City of Philadelphia and (2) deploying so-

called unbiased and independent third parties to the City of Philadelphia.

1. Defendants Spread and Continue to Spread Their False and Deceptive Statements Through Direct Marketing of Their Branded Opioids.

56. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted advertising campaigns touting the purported benefits of their branded drugs. For example, Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001, including \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

57. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like a construction worker and chef, implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Pursuant to a settlement agreement, Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Mississippi.

58. Additionally, each Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. Defendants devoted massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing branded opioids to doctors, including \$108 million by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$10

million by Endo, and \$2 million by Actavis. This amount is twice as much as Defendants spent on detailing in 2000.

59. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

60. Defendants employed the same marketing plans, strategies, and messages in the City of Philadelphia, Mississippi as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

2. Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Deceptive Statements about the Risks and Benefits of Opioids.

61. Defendants also deceptively marketed opioids in the City of Philadelphia through unbranded advertising – *i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in

concert with them to falsely and misleadingly promote opioids for treating chronic pain.

62. Unbranded advertising also avoided regulatory scrutiny because Defendants did not have to submit it to the FDA, and therefore it was not reviewed by the FDA.

63. Defendants’ deceptive unbranded marketing often contradicted their branded materials reviewed by the FDA. For example, Endo’s unbranded advertising contradicted its concurrent, branded advertising for Opana ER.

Opana ER Advertisement (Branded)	Pain: Opioid Therapy (Unbranded)
<p>“All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use.”</p>	<p>“People who take opioids as prescribed usually do not become addicted.”</p>

a. Key Opinion Leaders (KOLs)

64. Defendants spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported using opioids to treat chronic pain. These doctors became known as “key opinion leaders” or “KOLs.”

65. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs’ professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

66. KOLs have written, consulted on, edited, and lent their names to books and articles,

and given speeches and CMEs supportive of chronic opioid therapy. Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

67. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage using opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exert control over each of these activities through their KOLs.

68. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

69. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

1. Russell Portenoy

70. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

71. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS")/American Academy of Pain

Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by Defendants.

72 Dr. Portenoy also made frequent media appearances promoting opioids. He appeared on *Good Morning America* in 2010 to discuss using opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Mississippi and across the country, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”⁸

73 Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.”⁹ These lectures falsely claimed that less than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”¹⁰ Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well...I guess I did.”¹¹

2. Lynn Webster

74 Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake County, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently

⁸ Good Morning America television broadcast, ABC News (Aug. 30, 2010).

⁹ Thomas Catan & Evan Perez, A Pain-Drug Champion Has Second Thoughts, WALL ST. J., Dec. 17, 2012.

¹⁰ *Id.*

¹¹ *Id.*

supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster authored numerous CMEs sponsored by Cephalon, Endo, and Purdue while he was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

75. In 2011, Dr. Webster presented a program via webinar sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended using risk screening tools, such as urine testing and patient agreements as a way to prevent “overuse of prescriptions” and “overdose deaths,” which was available to and was intended to reach the City’s doctors.

76. Dr. Webster also was a leading proponent of the concept of “pseudoaddiction,” the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster’s description, the only way to differentiate the two was to *increase* a patient’s dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.” Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”¹²

b. Front Groups

77. Defendants entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for treating chronic pain. Under Defendants’ direction and control, these “Front Groups” generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Defendants by

¹²John Fauber & Ellen Gabler, Networking Fuels Painkiller Boom, MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012).

responding to negative articles, by advocating against regulatory changes that would limit prescribing opioids in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

78. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure these Groups would generate only the messages Defendants wanted to distribute. Even so, the Front Groups held themselves out as independent and as serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

79. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), American Society of Pain Education (“ASPE”), National Pain Foundation (“NPF”) and Pain & Policy Studies Group (“PPSG”).

1. American Pain Foundation (“APF”)

80. The most prominent of Defendants’ Front Groups was APF, which received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next at \$1.7 million.

81. In 2009 and 2010, more than 80% of APF’s operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total

income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

82 PF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach patients and consumers in the City of Philadelphia.

2. American Academy of Pain Medicine (“AAPM”)

83 The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants’ deceptive marketing of chronic opioid therapy.

84 AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM’s marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an “exclusive venue” for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon, and

Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

85. AAPM is viewed internally by Endo as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM’s presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”¹³

86. AAPM’s staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

87. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed there was a low risk that patients would become addicted to opioids. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011, and was taken down from AAPM’s website only after a doctor complained, though it still lingers on the internet elsewhere.

88. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”) and continued to recommend using opioids to treat chronic pain. Fourteen of the 21 panel members

¹³Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), <http://www.medscape.org/viewarticle/500829>.

who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

89. The 2009 Guidelines promote opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. 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 he was concerned the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in the City of Philadelphia during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

B. Defendants’ Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

90. To convince doctors and patients in the City of Philadelphia that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and effective. Knowing they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by, or were contrary to, the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

C. Defendants Falsely Trivialized or Failed to Disclose the Known Risks of Long- Term Opioid Use.

91. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

92. **First**, Defendants falsely claimed the risk of addiction is low and unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. For example:

- a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 claiming opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond;
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online;
- c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted."

Another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them;”

- d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website, www.opana.com;
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain;”
- f. Janssen currently runs a website, Prescriberresponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated;”
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction.” This publication is still available online; and
- h. Detailers for Purdue, Endo, Janssen, and Cephalon in The City of Philadelphia minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for opioid abuse with purportedly abuse- deterrent formulations; and routinely did not correct the misrepresentations noted above.

93. These claims contradict longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).”¹⁴ The guideline points out that “[o]pioid pain medication use presents serious risks, including...opioid use disorder” and that “continuing opioid therapy for

¹⁴ CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016, Centers for Disease Control and Prevention (Mar. 18, 2016)

3 months substantially increases risk for opioid use disorder.”¹⁵

94. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA discussed the risks related to opioid use and that IR opioids are associated with “persistent abuse, addiction, overdose mortality, and risk of NOWS [neonatal opioid withdrawal syndrome].”¹⁶

95. According to the FDA, because of the risks associated with long-term opioid use, including “the serious risk of addiction, abuse, misuse, overdose, and death,”¹⁷ opioids should be “reserved for pain severe enough to require opioid treatment and for which alternative treatment options (e.g., non-opioid analgesics or opioid combination products, as appropriate) are inadequate or not tolerated.”¹⁸

96. The warnings on Defendants’ own FDA-approved drug labels caution that opioids “exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death”¹⁹ and that addiction “can occur in patients appropriately prescribed”²⁰ opioids.

97. **Second**, Defendants falsely instructed doctors and patients that signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon “pseudoaddiction” – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and claimed that pseudoaddiction is substantiated by scientific evidence. Foreexample:

¹⁵ *Id.*

¹⁶ *FDA Announcement of Enhanced Warnings for Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death*, Federal Drug Administration (Mar. 22, 2016)

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *See, e.g.*, OxyContin label and insert at OxyContin.com

²⁰ *Id.*

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition continues to teach that pseudoaddiction is real;
- b. Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management;”
- c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials;
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated;” and
- e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long- acting opioid.

98. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment...are unlikely to experience pain relief with longer-term use,”²¹ and

²¹ *CDC Guidelines for Prescribing Opioids for Chronic Pain*, *supra*.

that physicians should “reassess pain and function within 1 month”²² in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids”²³ because the patient is “not receiving a clear benefit.”²⁴

99. **Third**, Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher- risk patients. Defendants’ misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting opioid therapy for chronic pain. For example:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo’s speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts;
- a. Purdue sponsored a 2011 webinar, *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent “overuse of prescriptions” and “overdose deaths;” and
- b. As recently as 2015, Purdue has represented in scientific conferences that “bad apple” patients – and not opioids – are the source of the addiction crisis and that once those “bad apples” are identified, doctors can safely prescribe opioids without causing addiction.

100. Once again, the 2016 CDC Guideline confirms these representations are false.

The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies

²² *Id.*

²³ *Id.*

²⁴ *Id.*

– such as screening tools, patient contracts, urine drug testing, or pill counts, widely believed by doctors to detect and deter abuse, “for improving outcomes related to overdose, addiction, abuse, or misuse.”²⁵ As a result, the Guideline recognizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse”²⁶ and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”²⁷

101. **Fourth**, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem thereby failing to disclose the increased difficulty of stopping opioids after long-term use.

102. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days. And Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation.”

103. Defendants deceptively minimized the significant symptoms of opioid withdrawal, which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use.

²⁵ CDC Guidelines for Prescribing Opioids for Chronic Pain, *supra*.

²⁶ *Id.*

²⁷ *Id.*

104. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be limited to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,”²⁸ because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days.”²⁹ The Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence”³⁰ and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal”³¹ and pausing and restarting tapers depending on the patient’s response.

105. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”³²

106. **Fifth**, Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example:

- a. Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Upon information and belief, based on Actavis’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond;

²⁸ *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

- b. Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online;
- c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until “you are on the right dose of medication for your pain;”
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo’s website. 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;”
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of increased opioid dosages;
- f. Purdue’s In the Face of Pain website promotes the notion that if a patient’s doctor does not prescribe what, in the patient’s view, is a sufficient dosage of opioids, he or she should find another doctor who will;
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which taught that dosage escalations are “sometimes necessary,” even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online;
- h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages; and
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, “the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,” challenging the correlation between opioid dosage and overdose.

107. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic

pain are not established”³³ while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.”³⁴

108. More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.”³⁵ Similarly, there is an “increased risk for opioid use disorder, respiratory depression, and death at higher dosages.”³⁶ That is why the CDC advises doctors to avoid increasing dosages above 90 morphine milligram equivalents per day.

109. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged that available data suggested that increasing the opioid dosage likewise increased certain adverse events. For example, the FDA noted that studies suggest a positive association between high-dose opioid use and overdoses.

110. **Finally**, Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse.

111. More specifically, Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo’s advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant in a way that suggested it was more difficult to abuse. This claim was false.

112. The FDA warned in a 2013 letter that there was no evidence Endo’s design would provide a reduction in oral, intranasal or intravenous abuse.³⁷ Moreover, Endo’s own studies,

³³ CDC Guidelines for Prescribing Opioids for Chronic Pain, *supra*.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ See FDA Statement: Original Opana ER Relisting Determination (May 10, 2013).

which it failed to disclose, showed that Opana ER could still be ground and chewed.

113. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was designed to be or is crush resistant. The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER.

114. Similarly, the 2016 CDC Guideline states that no studies support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,”³⁸ noting that the technologies – even when they work – “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes.”³⁹

115. These numerous, long-standing misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

D. Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy.

116. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants had to persuade them that there was a significant benefit to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is “insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain.”⁴⁰

117. In fact, the CDC found no evidence showing “a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)”⁴¹ and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use.

³⁸ *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

118. In 2013, the FDA stated that it was unaware of any studies demonstrating the safety and efficacy of opioids for long-term use.⁴² Despite this lack of studies, Defendants falsely and misleadingly touted the benefits of long-term opioid use and suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today. For example:

- a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives;
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects;
- c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs;
- d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled “Pain vignettes,” which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients’ function;
- e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online;
- f. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids “give [pain patients] a quality of life we deserve.” The guide was available online until APF shut its doors in 2012;
- g. Endo’s NIPC website *painknowledge.com* claimed in 2009 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,

⁴² Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make misleading claims about function, and Endo closely tracked visits to the site;

- h. Endo was the sole sponsor, through NIPC, of a series of CMEs 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;
- i. Janssen sponsored, funded, and edited a website, *Let’s Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to “continue to function.” This video is still available today on YouTube;
- j. Purdue sponsored the development and distribution of 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.” The Policymaker’s Guide was originally published in 2011 and is still available online today;
- k. Abbott’s sales representatives were not only instructed to misrepresent the so-called benefits of OxyContin to doctors, such as it having a less euphoric effect than other opioids, but were being offered \$20,000.00 cash prizes and luxury vacations for doing so; and
- l. Purdue’s, Cephalon’s, Endo’s, and Janssen’s sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

119. These claims find no support in the scientific literature. Most recently, the 2016 CDC Guideline, approved by the FDA, concluded, “There is no good evidence that opioids improve pain or function with long-term use”⁴³ and “complete relief of pain is unlikely.”⁴⁴ (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

- a. “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . .”⁴⁵

⁴³ CDC Guidelines for Prescribing Opioids for Chronic Pain, *supra*

⁴⁴ *Id.*

⁴⁵ *Id.*

- b. “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy;”⁴⁶ and
- c. “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”⁴⁷

120. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.”⁴⁸ As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

121. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants’ claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that “[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience...results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”⁴⁹

122. Defendants also falsely emphasized or exaggerated the risks of competing products like NSAIDs so that doctors and patients would look to opioids first for treating chronic pain. Once again, Defendants’ misrepresentations contravene pronouncements by and guidance from the FDA

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/W arningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm>.

and CDC based on the scientific evidence.

123. Consequently, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should be used only as a last resort where alternative treatments like non-opioid drugs are inadequate. And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

124. In addition, Purdue misleadingly promoted OxyContin as unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action.

125. According to Purdue’s own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. The reason is that OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. Although the patient experiences a powerful initial response, there is little or no pain relief at the end of the dosing period because less medicine is released.

126. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a substantial number of chronic pain patients taking OxyContin experience it.

127. This “end of dose” failure not only renders Purdue’s promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

128. Purdue’s competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to “real” 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue’s sales

representatives continue to tell the City doctors that OxyContin lasts a full 12 hours.

E. Defendants also engaged in Other Unlawful, Unfair, and Fraudulent Misconduct.

129. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

130. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients.

131. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should be used only for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

132. Despite this advisory, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer, or non-cancer, related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online;

- b. Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and
- c. In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

133. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were safe and effective not only for treating chronic pain, but were also approved by the FDA for such uses.

134. Insys committed outright fraud in disseminating its drug, Subsys. Like Actiq and Fentora, Subsys was intended for breakthrough or cancer pain. Because the drug was so expensive, however, the insurance companies would pay for it only if there was prior authorization for the drug.

135. Insys developed an elaborate scam in which their own employees posed on the telephone as employees for prescribing physicians who then contacted the insurance companies to obtain prior authorization for Subsys. Insys' employees had a script to use in which they were instructed to use the words "breakthrough pain" and to avoid the word "cancer" thereby allowing the opioid to be prescribed for chronic pain.

136. Insys intended to deceive prescribing physicians into believing Subsys was safe and effective for chronic pain and deliberately lied to insurance companies to ensure payment for its drug.

137. Other Defendants herein participated in illicit and unlawful prescribing of its drugs.

For example, Purdue did not report illegal prescribing of OxyContin until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets. In doing so, Purdue protected its own profits at the expense of public health and safety.

138. The State of New York also found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

F. Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

139. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including the City of Philadelphia. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids.

140. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them.

141. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are “special risks of long-term opioid use for elderly patients” and recommends that doctors use “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-

anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

G. Although Defendants Knew That Their Marketing of Opioids Was False and Deceptive, They Fraudulently Concealed Their Misconduct.

142. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes.

143. Not only did the FDA and other regulators warn Defendants, but 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 that harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.

144. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

145. Moreover, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs.

146. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective

evidence when they were not.

147. Thus, Defendants successfully concealed from the medical community and patients facts sufficient to arouse suspicion of the claims the City of Philadelphia now asserts. The City did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

H. By Increasing Opioid Prescriptions and Use, Defendants' Deceptive Marketing Scheme Has Fueled the Opioid Epidemic and Damaged the City of Philadelphia.

148. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies reveal that many doctors and patients are unaware of or do not understand the risks or benefits of opioids. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.⁵⁰

149. Defendants' deceptive marketing scheme caused and continues to cause doctors in the City of Philadelphia to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids.

150. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

151. Defendants' deceptive marketing has caused and continues to cause the prescribing

⁵⁰ Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), available at <http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent-opioid-addiction>.

and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

152. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly increase in opioid addiction, overdose, and death throughout the U.S. and the City of Philadelphia.

153. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that prescribing opioids has quadrupled since 1999, which has resulted in a parallel increase in opioid overdoses.⁵¹ Indeed, there has been a two-third increase in overdose deaths from using opioids since 2000.⁵² For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic."⁵³

154. Defendants' deceptive marketing scheme has also detrimentally impacted children in the City of Philadelphia. Overprescribing opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household.

155. There was also an increase in the City's child protection services in the number of

⁵¹ CDC. National Vital Statistics System, Mortality. CDC WONDER. Atlanta, GA: US Department of Health and Human Services, CDC; 2016. <https://wonder.cdc.gov/>; Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016.

⁵² *National Vital Statistics System*, Mortality file and appearing *Center for Disease Control and Prevention* Morbidity and Mortality Weekly Report, January 1, 2006 / 64(50); 1378-82, Increases in Drug and Opioid Deaths – United States, 2000-2014.

⁵³ *CDC Guideline for Prescribing Opioids for Chronic Pain*, *supra*; see also Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016.

children in foster care driven by parental drug addiction. Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes these cases more expensive for cities like the City of Philadelphia.

156. Opioid addiction is one of the primary reasons that the City of Philadelphia residents seek substance abuse treatment. A significant number of admissions for drug abuse were associated with a primary diagnosis of opiate abuse or dependence.

157. Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed the City of Philadelphia's communities. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.⁵⁴

158. Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. This ongoing diversion of prescription narcotics creates a lucrative marketplace.

159. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. For example, heroin use has more than doubled in the

⁵⁴ Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care (Apr. 19 2013), at 5 ("The most common source of abused [opioids] is, directly or indirectly, by prescription."), *available at* <http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers>.

past decade among adults aged 18 to 25 years.⁵⁵ Moreover, heroin-related overdoses in the United States has more than quadrupled since 2010.⁵⁶

160. The costs and consequences of opioid addiction are staggering. For example, in 2007, the cost of healthcare due to opioid abuse, dependence, and misuse was estimated at 25 billion, the cost of criminal justice was estimated at 5.1 billion, and the cost of lost workplace productivity was estimated at 25.6 billion.

161. Consequently, prescription opioid misuse, abuse, and overdose have an enormous impact on the health and safety of individuals, as well as communities at large, because the consequences of this epidemic reach far beyond the addicted individual.

162. Some of the repercussions for residents of the City of Philadelphia include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration, which results in instability in communities often already in economic crisis and contributes to increased demand on community services provided by the City such as hospitals, courts, child services, treatment centers, and law enforcement.

163. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend substantial funds each year in its efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiff has incurred, and continues to incur, costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, law enforcement costs, substance abuse treatment costs, costs for treating overdose victims with drugs such as Narcan, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term

⁵⁵ Centers for Disease Control and Prevention. Vital Signs: Today's Heroin Epidemic – More People at Risk, Multiple Drugs Abused. (<http://www.cdc.gov/vitalsigns/heroin/index/html>). MMWR 2015.

⁵⁶ <https://www.cdc.gov/drugoverdose/data/heroin.html>.

opioid use proximately caused injury to Plaintiff and its residents.

164. Defendants' misrepresentations were material to, and influenced, the City's decisions to pay claims for opioids for chronic pain (and, therefore, to bear its consequential costs in treating overdose, addiction, and other side effects of opioid use). In the first instance, the City would not have been presented with, or paid, claims for opioids that would not have been written but for Defendants' fraudulent and deceptive marketing. Second, the City has demonstrated that Defendants' marketing is material by taking further steps to ensure that the opioids are only prescribed and covered when medically necessary or reasonably required.

165. As laid out above, Defendants' misrepresentations related to the City's requirement that medical treatments be medically necessary or reasonably required – a condition of payment for any medical treatment under the City's health plans and workers' compensation program. But for Defendants' fraudulent and deceptive marketing, prescribers would have accurately understood the risks and benefits of opioids and would not have prescribed opioids where not medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but the core of prescribers' decision-making.

166. It is the City's practice not to pay claims that are not medically necessary or reasonably required. However, the City would not have known whether a prescriber had made an informed judgment that a particular claim for opioids was medically necessary or reasonably required, or, conversely had acted under the influence of Defendants' fraudulent and deceptive marketing. It is not clear from the face of a claim whether: (1) the patient suffered from cancer or another terminal condition, for example, where long-term prescribing was medically necessary or

appropriate; or (2) the prescriber was exposed to Defendants' marketing materials, treatment guidelines, or education programs, or visited by a drug representative who engaged in affirmative misrepresentations or omissions, for example.

167. The City's spending on opioids rose along with Defendants' spending to promote opioids. That spending had a direct impact on opioid use (and its consequences in abuse, addiction, and overdose) in the City of Philadelphia, Mississippi.

168. Defendants knew and should have known about these harms that their deceptive marketing has caused. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding.

169. Defendants also had access to and carefully watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. Defendants not only knew, but intended that their misrepresentations would persuade doctors to prescribe and encourage patients to use their opioids for chronic pain. Defendants' actions are neither permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by, and guidance from, the FDA based on the medical evidence and their own labels.

170. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also hijacked what doctors wanted to believe – namely,

that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

I. Defendants' Fraudulent Marketing Has Led to Record Profits.

171. While using opioids has taken an enormous toll on the City and its residents, Defendants have realized blockbuster profits. Indeed, upon information and belief, each of the Defendants have experienced material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

CAUSES OF ACTION

**COUNT I
PUBLIC NUISANCE
(*Against All Defendants*)**

172. The City of Philadelphia re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

173. Defendants knowingly encouraged the City of Philadelphia doctors to prescribe, and residents to use, highly addictive opioids for chronic pain even though Defendants knew using opioids had a high risk of addiction and reduced quality of life.

174. By doing so, Defendants purposefully interfered with the City's public health, public safety, public peace, public comfort, and public convenience.

175. Defendants, individually and in concert with each other, have contributed to and/or assisted in creating and maintaining a condition that is harmful to the health and safety of the City's residents and/or unreasonably interferes with the peace and comfortable enjoyment of life in violation of Mississippi law.

176. The public nuisance created by Defendants' actions is substantial and unreasonable - it has caused and continues to cause significant harm to the community – and the harm inflicted

outweighs any offsetting benefit.

177. The staggering rates of opioid use resulting from Defendants' marketing efforts have caused, and continues to cause, harm to the community including, but not limited to:

- a. Upwards of 30% of all adults use opioids. These high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths;
- b. Children have been exposed to opioids prescribed to family members or others resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among the City's teenagers; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure causing severe withdrawal symptoms and lasting developmental impacts;
- c. Residents of the City of Philadelphia, who have never taken opioids, have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids;
- d. More broadly, opioid use and misuse have driven the City's residents' health care costs higher;
- e. Employers have lost the value of productive and healthy employees who have suffered from adverse consequences from opioid use;
- f. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them;
- g. This demand has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process;
- h. Diverting opioids into secondary, criminal markets and increasing the number of individuals who abuse or are addicted to opioids has increased the demands on emergency services and law enforcement in the City of Philadelphia;
- i. All of Defendants' actions have caused significant harm to the community – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and

broken families and homes;

- j. These harms have taxed the human, medical, public health, law enforcement, and financial resources of the City of Philadelphia; and
- k. Defendants' interference with the comfortable enjoyment of life of a substantial number of people is entirely unreasonable because there is limited social utility to opioid use and any potential value is outweighed by the gravity of harm inflicted by Defendants' actions.

178. Defendants knew, or should have known, that promoting opioid use would create a public nuisance in the following ways:

- a. Defendants have engaged in massive production, promotion, and distribution of opioids for use by the citizens of the City of Philadelphia;
- b. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management;
- c. Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs; and
- d. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences that the larger community would suffer as a result.

179. Defendants' actions were, at the least, a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain thereby causing opioids to become widely available and used in the City of Philadelphia.

180. Without Defendants' actions, opioid use would not have become so widespread and the enormous public health hazard of opioid overuse, abuse, and addiction not existing would have been averted.

181. The health and safety of the citizens of the City of Philadelphia, including those who use, have used, or will use opioids, as well as those affected by opioid users, is a matter of great public interest and legitimate concern to the City's citizens and residents.

182. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further reoccurrence of such harm and inconvenience can be prevented.

183. Defendants' conduct has affected, and continues to affect, a considerable number of people within the City of Philadelphia and is likely to continue to cause significant harm to patients who take opioids, their families, and the community at large.

184. Each Defendant created or assisted in creating the opioid epidemic, and each Defendant is jointly and severally liable for its abatement. Furthermore, each Defendant should be enjoined from continuing to create, perpetuate, or maintain said public nuisance in the City of Philadelphia.

185. The City of Philadelphia seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT II
FRAUD/FRAUDULENT MISREPRESENTATIONS
(Against All Defendants)

186. The City of Philadelphia re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

187. As alleged herein, Defendants engaged in false representations and concealments of material fact about using opioids for chronic pain.

188. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omission of material fact to physicians and residents in the City of Philadelphia to induce them to prescribe, administer, fill, purchase, and consume opioids as set forth herein.

189. Defendants knew that their representations and omissions were false.

190. Defendants intended that physicians and other residents of the City of Philadelphia would rely upon their misrepresentations and omissions.

191. The physicians and residents of the City of Philadelphia reasonably relied on Defendants' misrepresentations and omissions.

192. Defendants' intentionally failed to alter or correct the fraudulent information it had disseminated through the United States and the City of Philadelphia and acted willfully, wantonly, and maliciously.

193. Because of their reliance on Defendants' misrepresentations and omissions of material fact, the City of Philadelphia and its residents have been damaged.

194. The City of Philadelphia seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT III
NEGLIGENCE
(Against All Defendants)

195. The City of Philadelphia re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

196. Manufacturing Defendants have a duty to exercise reasonable care in marketing its opioids to the City's physicians and residents. Manufacturing Defendants have breached their duty by knowingly and fraudulently misrepresenting the benefits of, and downplaying the risks of, opioids for chronic pain.

197. Manufacturing Defendants have used deceitful marketing ploys, KOLs, Front

Groups, and other schemes to increase profits at the cost of public health causing an opioid epidemic. Manufacturing Defendants have acted willfully, wantonly, and maliciously.

198. Likewise, Distributor Defendants have a duty to exercise ordinary care in distributing opioids. Distributor Defendants have breached their duty by failing to prevent or reduce the distribution of opioids, or to report the increase in the distribution and/or sale of opioids.

199. Distributor Defendants have intentionally failed to prevent or reduce the distribution of opioids, or to report any increases in the sale of opioids, so that they could increase profits and receive rebates or kick-backs from Manufacturing Defendants. Distributor Defendants have acted willfully, wantonly, and maliciously.

200. As a proximate result, Manufacturing and Distributor Defendants and its agents have caused the City of Philadelphia to incur excessive costs to treat the opioid epidemic in its City, including but not limited to increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities.

201. The City of Philadelphia seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT IV
NEGLIGENCE *PER SE* VIOLATION OF MISS CODE ANN. § 97-23-3
(Against Manufacturing Defendants)

202. The City of Philadelphia incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

203. Mississippi law recognizes the doctrine of negligence per se, which provides that breach of a statute or ordinance may render the offender liable in tort without proof of lack of due

care. Violations of statutes and regulations support a cause of action for negligence per se where the plaintiff is within the class protected, the harm sustained is the type sought to be prevented, and that the violations proximately caused the plaintiff's injuries.

204. Miss. Code Ann. § 97-23-3 provides:

Any person who, with intent to sell or in any way dispose of merchandise, [...], or anything offered by such person, directly or indirectly, to the public for sale or distribution, or who, with intent to increase the consumption of or demand for such merchandise, [...] or other thing, or to induce the public in any manner to enter into any obligation relating thereto, or to acquire title thereto, or an interest therein, makes, publishes, disseminates, circulates or places before the public, or causes, directly or indirectly, to be made, published, disseminated, circulated or placed before the public within the state, in a newspaper or other publication, or in the form of a book, notice, handbill, poster, bill, circular, pamphlet or letter, or by a label affixed to the merchandise or its container, or in any other way, an advertisement of any sort regarding merchandise, [...] or anything so offered to the public, which advertisement contains any assertion, representation or statement of fact which is untrue, deceptive or misleading, [...], and which such person knew, or might on reasonable investigation have ascertained to be untrue, deceptive or misleading[.]shall be guilty of a crime.

Further, violators of Miss. Code Ann. § 97-23-3, “may be held civilly responsible in tort for damages to persons or property proximately resulting from a violation of this section.”

205. Defendants' marketing scheme to optimize profits by misrepresenting and falsely touting opioids as the panacea to chronic pain was done intentionally. Defendants violated Miss. Code Ann. § 97-23-3, because they acted knowingly, intentionally and/or unlawfully, by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of themselves or others, attempted to obtain or obtained payment from public funds for services or supplies furnished or purportedly furnished pursuant to § 97-23-3.

206. The Defendants engaged in false and misleading representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, by misrepresenting the

nature of the drugs, and by aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable. These false or misleading statements were made to the public, including to Plaintiff's Community.

207. The Plaintiff is within the class intended to be protected by the public safety statutes and regulations concerning advertising and controlled substances.

208. Defendants' violations of these public safety laws are *prima facie* evidence of negligence *per se*.

209. By reason of Defendants' violation of § 97-23-3, Plaintiff has been damaged.

210. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence *per se*. Plaintiff does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

211. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

212. At every stage, Defendants knew or should have known that their conduct would create an unreasonable risk of physical harm to others, including the City of Philadelphia and its residents. The City of Philadelphia seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT V
NEGLIGENCE *PER SE*
(*Against All Defendants*)

213. The City of Philadelphia incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

214. Federal mandates require that Defendants must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. §§ 823(a)(1), (b)(1). These federal regulations impose a non-delegable duty upon both manufacturers and distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor or manufacturer] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

215. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. Indeed, all flagged orders must be reported.

216. Each Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. Each Defendant is a “registrant” as a wholesale distributor and/or manufacturer in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. By the acts as set forth hereinabove Defendants violated the federal Controlled Substances Act.

217. Defendants violated § 41-29-141 of the Mississippi Uniform Controlled Substances

Law, which provides that, “It is unlawful for any person: (2) Who is a registrant under Section 41-29-125 to manufacture a controlled substance not authorized by his registration, or to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person[.]” MS Code § 41-29-141 (2013).

218. Defendants violated § 41-29-139 of the Mississippi Uniform Controlled Substances Law, which provides that, except as authorized by law, “[I]t is unlawful for any person knowingly or intentionally: (1) To sell, barter, transfer, manufacture, distribute, dispense or possess with intent to sell, barter, transfer, manufacture, distribute or dispense, a controlled substance[.]” MS Code § 41-29-139 (2013).

219. Defendants do not qualify for the “authorized by law” exceptions to the Mississippi Uniform Controlled Substances Law violations because Defendants did not comply with the mandatory terms of the licenses issued to them by the Mississippi Board of Pharmacy or with federal requirements incorporated by reference, as further detailed in this Complaint.

220. Defendants violated MS Code § 97-1-1, by their conspiracy to commit acts injurious to the public health and to accomplish any unlawful purpose, or a lawful purpose by any unlawful means.

221. The City of Philadelphia is within the class intended to be protected by the public safety statutes and regulations concerning controlled substances.

222. Defendants’ violations of these public safety laws are *prima facie* evidence of negligence *per se*. Each Defendant had a duty under, *inter alia*, these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

223. As described above in allegations expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes and regulations requiring that as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

224. As described above in allegations expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, is and was a substantial factor contributing to, and/or proximately resulted in, harm and damages to Plaintiff.

225. The injuries and damages sustained are those which the statutes and regulations were designed to prevent.

226. Defendants' violations of the Mississippi statutes and public safety regulations cited herein were and are substantial factors in the injuries and damages sustained.

227. It was foreseeable that Defendants' breaches of statutory and regulatory duties described herein would result in the damages sustained.

228. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VI
CIVIL CONSPIRACY
(Against All Defendants)

229. The City of Philadelphia re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

230. Defendants engaged in a civil conspiracy with each other and with the co-

conspirators identified above who are not parties to this action. Defendants and their non-Defendant co-conspirators combined to accomplish an unlawful end, or alternatively to accomplish a lawful end by unlawful means.

231. As set forth herein, Defendants engaged in a civil conspiracy to create a public nuisance in conjunction with their unlawful marketing, sale, distribution and/or diversion of opioids into the State and into the City of Philadelphia.

232. As set forth herein, Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful distribution and diversion of opioids into the State and into the City of Philadelphia.

233. As set forth herein, Defendants engaged in a civil conspiracy to unlawfully divert opioids and create opioid dependence and abuse in the State and into the City of Philadelphia.

234. Distributor and Manufacturer Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report and prevent suspicious orders of opioids.

235. The Manufacturer Defendants further unlawfully marketed opioids in the State and in the City of Philadelphia in furtherance of that conspiracy.

236. Defendants acted tortiously in concert with each other and/or in pursuit of a common design, and/or Defendants knew each other's conduct constituted a breach of their legal duties and provided substantial assistance and/or encouragement in the conduct.

237. Defendants' conspiracy is a continuing conspiracy, and the overt acts performed in compliance with the conspiracy's objective(s) are ongoing.

238. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the injuries alleged herein.

239. Defendants acted with malice, purposely, intentionally, unlawfully and without a reasonable or lawful excuse.

240. The City of Philadelphia has been damaged as a direct and proximate result of this civil conspiracy Defendants' conspiracy and Defendants' actions and omissions in furtherance thereof proximately caused and/or substantially contributed to the direct and foreseeable losses alleged herein.

241. The City of Philadelphia seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, *inter alia*, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VII
UNJUST ENRICHMENT
(Against All Defendants)

242. The City of Philadelphia re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

243. The City of Philadelphia re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

244. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the City and its residents.

245. When the City of Philadelphia and its residents purchased opioids, they expected that Defendants had provided necessary and accurate information regarding those risks. Instead, Defendants had misrepresented the material facts regarding the risks and benefits of opioids.

246. Defendants have been unjustly enriched at the expense of the City of Philadelphia.

The City of Philadelphia seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the City of Philadelphia, Mississippi respectfully prays:

247. That the acts alleged herein be adjudged and decreed to be unlawful and that the Court enter a judgment declaring them to be so;

248. That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Mississippi law;

249. That Plaintiff recover all measures of damages, past, present and future, including disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants and that judgment be entered against Defendants in favor of Plaintiff;

250. That Plaintiff recover restitution on behalf of the City of Philadelphia and its consumers who paid for opioids for chronic pain;

251. That Plaintiff recover restitution and damages on behalf of the losses due to the City of Philadelphia, as an employer, who has paid for opioids and opioid-related health issues of its employees;

252. That Plaintiff recover the costs and expenses of suit, pre- and post- judgment interest, and reasonable attorneys' fees as provided by law; and

253. That Defendants be ordered to abate the public nuisance that they created in violation of Mississippi law.

This the 7th day of March, 2018.

Respectfully submitted,

THE CITY OF PHILADELPHIA, MISSISSIPPI

By: /s/ Sheila M. Bossier
Sheila M. Bossier (MSB # 10618)
Cecily L. Ethridge (MSB # 105494)
BOSSIER & ASSOCIATES, PLLC
1520 N. State Street
Jackson, MS 39202
Telephone: (601) 352-5450
Facsimile: (601) 352-5452
Email: sbossier@bossier-law.com
Email: cethridge@bossier-law.com

OF COUNSEL:

Daniel F. Mars (MSB # 1872)
James M. Mars, II (MSB # 1873)
MARS, MARS & MARS, P.A.
Post Office Box 612
Philadelphia, MS 39350
Telephone : (601) 656-2152
Facsimile : (601) 656-1186
Email : danmars@mmclaw.net
Email: jmm2@mmclaw.net

EXHIBIT 10

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
COUNTY OF CUYAHOGA**

CUYAHOGA COUNTY, OH; ASHTABULA COUNTY, OH; HARRISON COUNTY, OH; JEFFERSON COUNTY, OH; LORAIN COUNTY, OH; SANDUSKY COUNTY, OH; CITY OF BROADVIEW HEIGHTS, OH; CITY OF DAYTON, OH; CITY OF EUCLID, OH; CITY OF FINDLAY, OH; CITY OF GARFIELD HEIGHTS, OH; CITY OF LORAIN, OH; CITY OF NORTH OLMSTED, OH; CITY OF NORTH RIDGEVILLE, OH; CITY OF OLMSTED FALLS, OH; CITY OF PARMA, OH; CITY OF PARMA HEIGHTS, OH; CITY OF SEVEN HILLS, OH; CITY OF STRONGSVILLE, OH; CITY OF TOLEDO, OH; CITY OF WARREN, OH; CITY OF WARRENSVILLE HEIGHTS, OH; PAINESVILLE TOWNSHIP, OH

Plaintiffs,

-against-

MYLAN PHARMACEUTICALS, INC.; SANDOZ, INC.; NOVARTIS AG; WESTWARD PHARMACEUTICALS CORP. N/K/A HIKMA PHARMACEUTICALS, INC.; AMNEAL PHARMACEUTICALS, INC.; AMNEAL PHARMACEUTICALS LLC; KVK-TECH, INC.; INDIVIOR INC. F/K/A RECKITT BENCKISER PHARMACEUTICALS, INC.; ASSERTIO THERAPEUTICS F/K/A DEPOMED, INC.; ZYDUS PHARMACEUTICALS (USA) INC.; ABBOTT LABORATORIES, INC.; SUN PHARMACEUTICAL INDUSTRIES, INC.; COLLEGIUM PHARMACEUTICAL, INC.; KEYSOURCE MEDICAL, INC.; QUEST PHARMACEUTICALS, INC.; ASSOCIATED PHARMACIES, INC.; HENRY SCHEIN, INC.; HENRY SCHEIN MEDICAL SYSTEMS, INC.; SMITH DRUG COMPANY; THE KROGER CO.; COSTCO

MDL No. 2804

Case No.:

COMPLAINT

**PLAINTIFFS DEMAND A TRIAL BY
JURY**

WHOLESALE CORPORATION; TARGET CORPORATION; EXPRESS SCRIPTS HOLDING COMPANY; EXPRESS SCRIPTS, INC.; UNITEDHEALTH GROUP INCORPORATED; MEDCO HEALTH SOLUTIONS, INC.; MERCK-MEDCO; OPTUM, INC.; OPTUMRX INC.; NAVITUS HOLDINGS, LLC; AND NAVITUS HEALTH SOLUTIONS, LLC

Defendants.

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Plaintiffs, Cuyahoga County, OH; Ashtabula County, OH; Harrison County, OH; Jefferson County, OH; Lorain County, OH; Sandusky County, OH; the City of Broadview Heights, OH; the City of Dayton, OH; the City of Euclid, OH; the City of Findlay, OH; the City of Garfield Heights, OH; the City of Lorain, OH; the City of North Olmsted, OH; the City of North Ridgeville, OH; the City of Olmsted Falls, OH; the City of Parma, OH; the City of Parma Heights, OH; the City of Seven Hills, OH; the City of Strongsville, OH; the City of Toledo, OH; the City of Warren, OH; the City of Warrensville Heights, OH; Painesville Township, OH (“Plaintiffs”), by and through their attorneys, against Defendants Mylan Pharmaceuticals, Inc.; Sandoz, Inc.; Novartis AG; West-Ward Pharmaceuticals Corp. n/k/a Hikma Pharmaceuticals, Inc.; Amneal Pharmaceuticals, Inc.; Amneal Pharmaceuticals LLC; KVK-Tech, Inc.; Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals, Inc.; Assertio Therapeutics f/k/a Depomed, Inc.; Assertio Distribution, LLC; Abbott Laboratories, Inc.; Sun Pharmaceutical Industries, Inc.; Collegium Pharmaceutical, Inc.; Zydus Pharmaceuticals (USA) Inc. (Collectively, “Manufacturers,” “Manufacturer Defendants,” or “Defendants”); KeySource Medical, Inc.; Quest Pharmaceuticals, Inc.; Smith Drug Company; Henry Schein, Inc.; Henry Schein Medical Systems, Inc.; (Collectively, “Distributors,” “Distributor Defendants,” or “Defendants”); Associated Pharmacies, Inc.; The Kroger Co; Costco Wholesale Corporation; Target Corporation (Collectively, “Distributors,” or “Pharmacies,” or “Defendants”); Express Scripts Holding Company; Express Scripts, Inc.; UnitedHealth Group Incorporated; Medco Health Solutions, Inc.; Merck-Medco; Optum, Inc.; OptumRx Inc.; Navitus Holdings, LLC; Navitus Health Solutions, LLC (collectively, “PBM Defendants” or “Defendants”); (Collectively, “Defendants”) alleges as follows:

INTRODUCTION

1. This case is about one thing: corporate greed. Defendants put their desire for profits above the health and well-being of consumers in Plaintiffs' geographic area at the cost of Plaintiffs.

2. Plaintiffs each spend millions of dollars each year to provide and pay for health care, services, pharmaceutical care and other necessary services and programs on behalf of residents of its Counties and Cities who are indigent or otherwise eligible for services, including payments through services such as Medicaid for prescription opium painkillers ("opioids") which are manufactured, marketed, promoted, sold, distributed, processed, and/or dispensed by the Defendants.

3. Plaintiffs also provide a wide range of other services to its residents, including law enforcement, services for families and children, and public assistance.

4. In recent years, Plaintiffs have been forced to expend exorbitant amounts of money, described further below, due to what is commonly referred to as the "opioid epidemic" and as a direct result of the actions of Defendants.

5. Plaintiffs are also responsible for either partially or fully funding a medical insurance plan for their employees, including the costs of prescription drugs, including opioids.

6. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction.¹ Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder spectrum.

7. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. Yet they also knew—and had known

¹ Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

for years—that opioids were addictive and subject to abuse, particularly when used long-term for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as “chronic pain”), and should there not be used except as a last-resort.

8. Defendants knew that, barring exceptional circumstances, opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer.

9. Defendants further knew—and had known for years—that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly increasing the risk of significant side effects and addiction.^{2, 3}

10. Defendants also knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (*e.g.*, hospitals), where the risk of addiction and other adverse outcomes was much less significant.

11. Indeed, the U.S. Food and Drug Administration (“FDA”) has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.⁴

12. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled

² See, *e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994).

³ The authoritative *Diagnostic and Statistical Manual of Mental Disorders*, (5th ed. 2013) (“DSM-V”) classifies addiction as a spectrum of “substance use disorders” that ranges from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on the substance use disorder continuum. Throughout this Complaint, “addiction” refers to this range of substance use disorders.

⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

substances.⁵ Like heroin, prescription opioids work by binding to receptors on the spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and death.

13. In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a sea of change in the medical and public perception that would permit the use of opioids not just for acute and palliative care, but also for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches.

14. Defendants, through a sophisticated and highly deceptive and unfair marketing campaign that began in the late 1990s, deepened around 2006, and continues to the present, set out to, and did, reverse the popular and medical understanding of opioids. Chronic opioid therapy—the prescribing of opioids to treat chronic pain long-term—is now commonplace.

15. To accomplish this reversal, Defendants spent hundreds of millions of dollars: (a) developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids long-term use to treat

⁵ Since passage of the Controlled Substances Act (“CSA”) in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription from a doctor, which may not be refilled, and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin), fentanyl (Duragesic, Actiq, Fentora), methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dilaudid, Palladone). Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. Schedule III drugs may not be dispensed without a written or oral prescription, which may not be filled or refilled more than six months after the date of the prescription or be refilled more than five times. 21 U.S.C. § 829. Some opioids had been categorized as Schedule III drugs, including forms of hydrocodone and codeine combined with other drugs, like acetaminophen. However, in October 2013, the FDA, following the recommendation of its advisory panel, reclassified all medications that contain hydrocodone from Schedule III to Schedule II. *See* 21 C.F.R. § 1308.

chronic pain (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids (c) recruiting prescribing physicians as paid speakers as a means to secure those physicians' future "brand loyalty" and extend their reach to all physicians; (d) funding, assisting, encouraging, and directing certain doctors, known as "key opinion leaders" ("KOLs"), not only to deliver scripted talks, but also to draft misleading studies, present continuing medical education programs ("CMEs") that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; and (e) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups") that developed educational materials and treatment guidelines that were then distributed by Defendants, which urged doctors to prescribe, and patients to use, opioids long-term to treat chronic pain.

16. These efforts, executed, developed, supported, and directed by Defendants, were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors, patients and others that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be used safely by most patients. Defendants and the third parties whom they recruited and supported, all profited handsomely through their dissemination of the deceptive information. KOLs and Front Groups saw their stature in the medical community elevated dramatically due to Defendants' funding, and Defendants saw an equally dramatic rise in their revenues.

17. Working individually, with, and through these Front Groups and KOLs, Defendants pioneered a new and far broader market for their potent and highly addictive drugs—the chronic pain market. Defendants persuaded doctors, patients and others that what they had long

understood—that opioids are addictive drugs and unsafe in most circumstances for long-term use—was untrue, and to the contrary, that the compassionate treatment of pain *required* opioids. Ignoring the limitations and cautions in their own drugs’ labels, Defendants: (a) overstated the benefits of chronic opioid therapy, promised improvement in patients’ function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized or obscured their serious risks and adverse outcomes, including the risk of addiction, overdose, and death; (c) overstated their superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. There was, and is, no reliable scientific evidence to support Defendants’ marketing claims, and there was, and is, a wealth of scientific evidence that these claims are simply false. Defendants also deceptively and unfairly marketed the drugs for indications and benefits that were outside of the drugs’ labels and not supported by substantial evidence.

18. Even Defendants’ KOLs initially were very cautious about whether opioids were appropriate to treat chronic pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants’ marketing went too far. Yet despite the voices of renowned pain specialists, researchers, and physicians who have sounded the alarm on the overprescribing of opioids to treat chronic pain, Defendants continue to disseminate their misleading and unfair marketing claims to this day.

19. Defendants’ efforts were wildly successful in expanding opioid abuse. The United States is now awash in opioids. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers— enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors’ visits in 2010 resulted in the prescription of an opioid, nearly double

the rate in 2000. Opioids—once a niche drug—are now the most prescribed class of drugs—more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world’s population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.

20. Together, opioids generated \$8 billion in revenue for drug companies in 2012. Of that amount, \$3.1 billion went to Purdue for its OxyContin sales. By 2015, sales of opioids grew further to approximately \$9.6 billion.⁶

21. It was Defendants’ marketing—and not any medical breakthrough—that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

22. Indeed, the National Institutes of Health “NIH” not only recognizes the opioid abuse problem, but also identifies Defendants’ “aggressive marketing” as a major cause: “Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies.*”⁷ As shown herein, the “drastic increases in the number of prescriptions written and dispensed” and the “greater social acceptability for using medications for different purposes” are not really independent causative factors but are in fact the direct result of “the aggressive marketing by pharmaceutical companies.”

⁶ D. Crow, *Drugmakers hooked on \$10bn opioid habit*, Financial Times (August 10, 2016).

⁷ America’s Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed August 18, 2017) (emphasis added).

23. According to the U.S. Centers for Disease Control and Prevention (“CDC”), the nation has been swept up in an opioid-induced “public health epidemic.”⁸ According to the CDC, prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012.

24. From 1999 through 2016, more than 350,000 people died from an overdose involving any opioids. Well over half of those deaths—over 200,000 people—involved opioids prescribed by doctors to treat pain. These opioids include brand-name prescription medications like OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

25. Plaintiffs have taken steps and will foreseeably continue to take steps in efforts to combat the opioid epidemic which has been caused by the actions of the Defendants. These government efforts create an increased cost and spending.

26. Due to the continued rise of the opioid epidemic and deaths, Plaintiffs have taken steps and will continue to take steps to fight the use of opioids and save lives.

27. The commission of criminal acts to obtain opioids is an inevitable consequence of opioid addiction.

28. But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

29. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors. When turned down by one physician, many of these addicts deploy increasingly desperate tactics—including doctor-shopping, use of aliases, and criminal means—to satisfy their cravings.

⁸ CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), <http://www.cdc.gov/washington/testimony/2014/t20140429.htm> (accessed May 30, 2017).

30. Efforts by doctors to reverse course for a chronic pain patient already on opioids long-term include managing the physical suffering and psychological distress a patient endures while withdrawing from the drugs. This process is often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that is diverted to supply them. Even though they never would have prescribed opioids in the first place, many doctors feel compelled to continue prescribing opioids to patients who have become dependent on them.

31. According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in 2010, and adolescents are abusing opioids in alarming numbers.⁹

32. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on Plaintiffs and local agencies that address heroin use and addiction. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002-2004 to 45.2% in 2011-2013. Heroin produces a very similar high to prescription opioids but is often cheaper. While a single opioid pill may cost \$10-\$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person who started on prescription opioids for a back injury to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

33. Dr. Robert DuPont, former director of the National Institute on Drug Abuse, opines that opioids are more destructive than crack cocaine:

[Opioid abuse] is building more slowly, but it's much larger. And the potential for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine,

⁹ CDC, *Prescription Painkiller Overdoses in the US* (Nov. 2011), <https://www.cdc.gov/vitalsigns/painkilleroverdoses/> (accessed May 30, 2017).

a one-day dose can be sold on the black market for \$100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.¹⁰

34. Countless Plaintiff residents suffer from chronic pain, which takes an enormous toll on their health, their lives, and their families. These residents deserve both appropriate care and the ability to make decisions based on accurate and complete information about treatment risks and benefits. But Defendants' deceptive and unfair marketing practices deprived residents and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

35. Defendants' actions are not permitted or excused by the fact that their labels may have allowed, or did not exclude, the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids. Indeed, what makes Defendants' efforts particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances. Defendants deceptively and unfairly engaged a patient base that—physically and psychologically—could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

¹⁰ Transcript, *Use and Abuse of Prescription Painkillers*, The Diane Rehm Show (Apr. 21, 2011), <http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript> (accessed May 30, 2017).

36. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians (PCPs), nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements. Defendants were also able to callously manipulate what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

37. By 2014, nearly two million Americans were either abusing opioid medications or were dependent on opioids.¹¹ According to the CDC, opioids have created a “public health epidemic” as of 2016.¹²

38. Defendants' marketing campaign has been extremely harmful and has cost American lives – including lives of residents of Plaintiffs. Deaths from prescription opioids have quadrupled since 1999. From 2000 to 2014 nearly 500,000 people died from such overdoses; seventy-eight Americans die every day from opioid overdoses.¹³

39. It is estimated that, in 2012, 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.¹⁴

40. The rising numbers of persons addicted to opioids have led not only to an increase in health care costs to Plaintiffs, but also a major increase in issues such as drug abuse, diversion,¹⁵

¹¹ CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids, Addiction and Overdose. Available at <http://www.cdc.gov/drugoverdose/opioids/prescribed.html> (accessed May 30, 2017).

¹² CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, (Apr. 29, 2014), <http://www.cdc.gov/washington/testimony/2014/ts0140429.htm> (accessed May 30, 2017).

¹³ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic.

¹⁴ Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

and crimes related to obtaining opioid medications. Plaintiffs have been severely and negatively impacted due to the fraudulent misrepresentations and omissions by Defendants regarding the use and risk related to opioids. In fact, upon information and belief, Defendants have been and continue to be aware of the high levels of diversion of their product.

41. The actions of Defendants have created an environment where select physicians have sought to profit at the expense of their patients who become addicted to opioid pain medications, often accepting cash payments and ordering unnecessary medical tests, again at the expense of Plaintiffs.

42. Prescription drug manufacturers, wholesalers/distributors, pharmacies, and pharmacy benefit managers (“PBMs”) have created this epidemic. The manufacturers make the opioids and lie about their efficacy and addictive properties. The wholesalers distribute the opioids from the point of manufacture to the point of delivery to the patient. The pharmacies distribute and dispense opioids. And the PBMs control, through their formularies, which drugs go where and how they are paid for.

43. PBMs are a necessary party to any discussion of opioid-related misconduct committed by pharmaceutical supply chain actors, and its ramifications. Neither courts nor the governmental entities left to clean up the opioid crisis can address the flow of opioids or the costs of abatement without including the parties that are in fact capable of controlling that flow, across all manufacturers and distributors, i.e. the PBMs.

44. PBMs are the gatekeepers to the vast majority of opioid prescriptions filled in the United States. Caremark, Express Scripts, and OptumRx (all named Defendants here) manage the drug benefits for approximately ninety-five percent (95%) of the United States’ population or 253

¹⁵ The CDC defines using or obtaining opioids illegally as “diversion.”

million American lives.¹⁶ PBMs control drug formularies which set the criteria and terms under which pharmaceutical drugs are reimbursed. In this way, PBMs control prescription drug utilization overall.

45. PBMs' complicity in the overall fraudulent scheme is purposeful given the nature of the financial arrangements between PBMs and drug manufacturers and others in the supply chain. Drug manufacturers compete for PBM formulary placement (preferred placement results in greater utilization and greater profits) and pay PBMs incentives to avoid pre-authorization requirements that would slow down flow.

46. PBMs require, and receive, incentives from Manufacturer Defendants to keep certain drugs on and off formularies. These incentives include the payment of rebates by Manufacturers Defendants to PBMs based on utilization, bonuses for moving product and hitting volume targets, and the payment of lucrative administrative fees to maximize PBM profits. Much of this activity is not transparent to anyone, including those who in good faith hire PBMs to manage their benefits.

47. PBMs are the middlemen between the manufacture and the availability of opioids. The PBM formularies determine what drugs (a) will be available (or not available) to patients; (b) for what diagnosis, efficacious or otherwise; (c) in what quantities; (d) at what co-pay; (e) what level of authorization will be required; and (f) what beneficial drugs will not be available. PBMs collude with Manufacturers who pay fees in the form of rebates, administrative fees and other, in order to ensure good placement on the formulary to the financial benefit of the PBMs. This leads to more prescriptions and more pills available to the general public, many of which find their way to

¹⁶ Brittany Hoffman-Eubanks, The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1, PHARMACY TIMES, Nov. 14, 2017, <http://www.pharmacytimes.com/news/the-role-of-pharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-perspectives-part-1>

the black market. PBMs have in their exclusive power the ability to limit the number of pills available for legitimate and illegitimate consumption. Even though PBMs were well aware of the effect of their decisions about formulary placement, they chose to make decisions purely for their own financial gain.

48. PBMs not only control the majority of this country's prescriptions through their formularies, they generate massive profits from that work. "[N]early one third of all expenditures on branded drugs in 2015 were eventually rebated back. And most of these rebates directly benefited the PBM."¹⁷

49. PBMs can extract rebates and other incentives from Manufacturer Defendants because of the PBMs' market power. Today, PBMs have leveraged their position as the middlemen and now impact almost every aspect of the prescription drug marketplace.

50. "The position of the three major PBMs at the center of the drug distribution system appears to be unassailable for now. Last year CalPERS, California's public employee benefits system, awarded OptumRx a five-year, \$4.9-billion contract to manage prescriptions for nearly 500,000 members and their families enrolled in non-HMO health plans. The only other finalists in the bidding were CVS Caremark and Express Scripts,"¹⁸ all Defendants here.

51. The power of the PBMs has evolved over time. Originally mere claims processors, PBMs now play a major role in managing pharmaceutical spending and enhancing health benefits for end-users.¹⁹

¹⁷ Wayne Winegarden, To Improve Pharmaceutical Pricing, Reform PBMs And Fix Health Care's Systemic Problems, FORBES, Apr. 4, 2017, <https://www.forbes.com/sites/econostats/2017/04/04/to-improve-pharmaceutical-pricingreform-pbms-and-fix-health-cares-systemic-problems/#4da58c5a3322>

¹⁸ Michael Hiltzik, How 'price cutting' middlemen are making crucial drugs vastly more expensive, LOS ANGELES TIMES, Jun. 9, 2017, <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html>

¹⁹ Zacks Equity Research, PBM Industry Shows Strength: 3 Stocks in Focus, NASDAQ, Dec. 13, 2017, <http://www.nasdaq.com/article/pbm-industry-shows-strength-3-stocks-in-focus-cm891506>

52. PBMs quietly became an integral part of the pharmaceutical supply chain—that is, the path a drug takes from the manufacturing facility to a bathroom medicine cabinet—following the passage of the Medicare Modernization Act in 2003.²⁰

53. Because PBMs are the intermediary between drug manufacturers, pharmacies, and ultimately patients, these companies control everything from pharmacy reimbursements to what drugs are covered under formularies.²¹ In these ways, the PBMs control which drugs enter the marketplace. Their fingerprints are on nearly every opioid prescription filled and they profit in myriad ways on every pill.

54. The harm caused by the PBMs is not just monetary: “[t]he PBMs and insurers are harming the health of patients with chronic and rare diseases by limiting access and charging them retail for drugs they buy at deep discounts.”²²

55. MedPageToday, a source for clinical and policy coverage that directly affects the lives and practices of health care professionals, describes the PBMs’ complicity in the opioid crisis this way:

If you are looking for someone to blame for the opioid epidemic, you can certainly blame physicians. You can blame pharmaceutical companies. But while you are at it, don't forget to include payers [PBMs]. This conclusion should not be surprising. We live in a world where payers -- not physicians -- determine what drugs and treatments patients receive. If patients have a life-threatening condition, it is not unusual for a payer to demand that a physician first prescribe a cheaper and less effective alternative. Physicians know that the drugs they are allowed to use may not work very well, but frequently, payers demand that they be tried first anyway.

²⁰ Jessica Wapner, Understanding the Hidden Villain of Big Pharma: Pharmacy Benefit Managers, NEWSWEEK, Mar. 17, 2017, <http://www.newsweek.com/big-pharma-villain-pbm-569980>

²¹ Matthew Kandrach, PBM stranglehold on prescription drug market demands reform, THE HILL, May 2, 2017, <http://thehill.com/blogs/pundits-blog/healthcare/331601-pbm-stranglehold-on-prescription-drug-market-demandsreform>

²² Jonathan Wilcox, PBMs Must Put Patients First, HUFFINGTON POST, Feb. 28, 2017, https://www.huffingtonpost.com/entry/pbms-must-put-patients-first_us_58b60bd8e4b02f3f81e44dcc

What happens if the patient doesn't respond to the cheap drug? Often, the physician continues to prescribe it, because -- to gain access to the more effective drug -- physicians need to go through a painful process of preauthorization. For many practitioners, it isn't worth it. So we spend more for healthcare than any other country in the world, but Americans do not get the care they need. There is a simple reason. Treatment decisions are not being driven based on a physician's knowledge or judgment. They are being driven by what payers are willing to pay for.²³

56. As one news outlet described it, “[o]ne overlooked culprit worsening the epidemic, however, comes straight from our health care system: pharmacy benefit managers, or PBMs. To improve their bottom line, they’re blocking access to prescriptions that can help prevent overdoses.”²⁴

57. As a direct and foreseeable consequence of Defendants’ wrongful conduct, Plaintiffs have each been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Defendants’ deceptive marketing campaign. Plaintiffs have incurred and continue to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants’ misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiffs and its residents.

58. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis and perpetuate the public nuisance.

²³ Milton Packer MD, Are Payers the Leading Cause of Death in the United States?, MEDPAGETODAY, Nov. 1, 2017, <https://www.medpagetoday.com/blogs/revolutionand revelation/68935>

²⁴ Peter J. Pitts, Pharmacy benefit managers are driving the opioid epidemic, SW NEWS MEDIA, Nov. 21, 2017, http://www.swnewsmedia.com/shakopee_valley_news/news/opinion/guest_columns/pharmacy-benefit-managersare-driving-the-opioid-epidemic/article_2f6be2a1-c7a3-5f8d-9f3e-, 61d29d25c84b.html

59. Plaintiffs bring this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused.

JURISDICTION AND VENUE

60. This Court has subject-matter jurisdiction of this action pursuant to 28 U.S.C. § 1331 because the Plaintiffs' claims involve Defendants' duties under federal law, including the Controlled Substance Act.

61. This Court has personal jurisdiction over the Defendants under R.C. 2307.382 because the causes of action alleged in this Complaint arise out of the Defendants transacting business in Ohio, contracting to supply services or goods in this state, causing tortious injury by an act or omission in this state, and because the Defendants regularly do or solicit business or engage in a persistent course of conduct or derive substantial revenue from goods used or consumed or services rendered in this state. The Defendants have purposefully directed their actions towards Ohio and/or have the requisite minimum contacts with Ohio to satisfy any statutory or constitutional requirements for personal jurisdiction.

62. Defendants derived substantial revenue as the result of the opioids which were distributed to Ohio physicians, patients, and others and later consumed by persons then residing in Ohio. Defendants' intentional and tortious conduct is continuing and presently existing, arose out of or is incidental to each Defendants' interstate, intrastate and international business ventures conducted in the United States, including Ohio, and proximately caused the Plaintiffs to sustain losses and damages in the State of Ohio. Accordingly, the Defendants have the requisite minimum contacts with Ohio necessary to constitutionally permit this Court to exercise jurisdiction because:

- a. The Defendants' contacts with Ohio, including, but not limited to, their manufacture, sale, distribution, dispensing and/or promotion of highly

addictive prescription opioid drugs, are directly related to and gave rise to this Complaint;

- b. Defendants' purposefully availed themselves of the privilege of conducting business in the State of Ohio by selling, distributing and/or promoting the use of highly addictive prescription opioid drugs to doctors, hospitals, patients, health insurers and other individuals throughout the State of Ohio, including, but not limited to, Cuyahoga County, OH; Ashtabula County, OH; Harrison County, OH; Jefferson County, OH; Lorain County, OH; Sandusky County, OH; the City of Broadview Heights, OH; the City of Dayton, OH; the City of Euclid, OH; the City of Findlay, OH; the City of Garfield Heights, OH; the City of Lorain, OH; the City of North Olmsted, OH; the City of North Ridgeville, OH; the City of Olmsted Falls, OH; the City of Parma, OH; the City of Parma Heights, OH; the City of Seven Hills, OH; the City of Strongsville, OH; the City of Toledo, OH; the City of Warren, OH; the City of Warrensville Heights, OH; Painesville Township, OH; and
- c. Defendants' fraudulent and deceptive marketing campaign and intentional misconduct was such that the Defendants should have reasonably anticipated being hauled into court in Ohio. See § 2307.382, Ohio Revised Code.

63. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) in that a substantial part of the events or omissions giving rise to the claim occurred in the Northern District of Ohio. Venue is also proper under 18 U.S.C. § 1965(a) because the Defendants, are found, have agents, or transact their affairs in this district.

PARTIES

A. Plaintiffs.

64. Plaintiff Cuyahoga County is a county within the State of Ohio, with a population of approximately 1,260,227 residents.

65. Plaintiff Ashtabula County is a county within the State of Ohio, with a population of approximately 96,398 residents.

66. Plaintiff Harrison County is a county within the State of Ohio, with a population of approximately 14,069 residents.

67. Plaintiff Jefferson County is a county within the State of Ohio, with a population of approximately 63,911 residents.

68. Plaintiff Lorain County is a county within the State of Ohio, with a population of approximately 316,447 residents.

69. Plaintiff Sandusky County is a county within the State of Ohio, with a population of approximately 58,281 residents.

70. Plaintiff City of Broadview Heights is a city within the State of Ohio, with a population of approximately 20,098 residents.

71. Plaintiff City of Dayton is a city within the State of Ohio, with a population of approximately 136,480 residents.

72. Plaintiff City of Euclid is a city within the State of Ohio, with a population of approximately 49,923 residents.

73. Plaintiff City of Findlay is a city within the State of Ohio, with a population of approximately 40,046 residents.

74. Plaintiff City of Garfield Heights is a city within the State of Ohio, with a population of approximately 30,060 residents.

75. Plaintiff City of Lorain is a city within the State of Ohio, with a population of approximately 65,544 residents.

76. Plaintiff City of North Olmsted is a city within the State of Ohio, with a population of approximately 32,358 residents.

77. Plaintiff City of North Ridgeville is a city within the State of Ohio, with a population of approximately 37,026 residents.

78. Plaintiff City of Olmsted Falls is a city within the State of Ohio, with a population of approximately 8,450 residents.

79. Plaintiff City of Parma is a city within the State of Ohio, with a population of approximately 81,008 residents.

80. Plaintiff City of Parma Heights is a city within the State of Ohio, with a population of approximately 20,905 residents.

81. Plaintiff City of Seven Hills is a city within the State of Ohio, with a population of approximately 11,696 residents.

82. Plaintiff City of Strongsville is a city within the State of Ohio, with a population of approximately 47,013 residents.

83. Plaintiff City of Toledo is a city within the State of Ohio, with a population of approximately 265,969 residents.

84. Plaintiff City of Warren is a city within the State of Ohio, with a population of approximately 38,493 residents.

85. Plaintiff City of Warrensville Heights is a city within the State of Ohio, with a population of approximately 13,864 residents.

86. Plaintiff Painesville Township is a township within the State of Ohio, with a population of 20,450 residents.

87. Plaintiffs provide a wide range of services on behalf of their residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

B. Defendants.²⁵

1. Mylan

88. Defendant Mylan Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business located in Canonsburg, Pennsylvania. It manufactures, promotes, markets, distributes and sells opioids in Plaintiffs' geographical area and throughout the nation. This includes many Schedule II controlled substances such as Oxycodone and Propoxy-N. Mylan conducts its pharmaceutical business operations through various entities, including Mylan Specialty, L.P. and Mylan Pharms, Inc. (collectively "Mylan".) At all relevant times, Mylan manufactured, marketed, and sold generic opioids, including fentanyl and oxycodone products, throughout the United States and Plaintiffs' geographic area. Mylan manufactured, marketed, and sold opioids throughout Plaintiffs' geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs' injuries.

89. As a generic manufacturer, Mylan failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users. Mylan could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare

²⁵ Plaintiffs have made its best efforts, based on the information available, to identify all of the corporate entities with responsibilities related to the sale and distribution of opioids in or affecting Plaintiffs. If information that becomes available to Plaintiffs alters its understanding or discloses additional entities, Plaintiffs reserve the right to seek to join any such entities as Defendants. Furthermore, the County recognizes that corporate entities affiliated with the Defendants may possess discoverable information relevant to Plaintiffs' claims, even though those entities have not been named as Defendants. Plaintiffs reserve the right to seek all information relevant to these claims.

provider letters. However, Mylan had a financial incentive not to communicate these warning and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Mylan failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

2. Sandoz

90. Defendant Sandoz, Inc. is a Colorado corporation with its principal place of business located in Princeton, New Jersey. Sandoz, Inc. is a subsidiary of Defendant Novartis AG.

91. Sandoz manufactures, promotes, markets, distributes and sells opioids in Plaintiffs' geographical area and throughout the nation. At all times relevant, Sandoz, Inc. manufactured, marketed, and sold opioids, including fentanyl and oxycodone products, throughout the United States and Plaintiffs' geographic area. Sandoz manufactured, marketed, and sold opioids throughout Plaintiffs' geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs' injuries.

92. As a generic manufacturer, Sandoz failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users. Sandoz could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Sandoz had a financial incentive not to communicate these warnings and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Sandoz

failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

3. Novartis

93. Defendant Novartis AG a/k/a Novartis Inc. and Novartis Pharmaceuticals Corporation (collectively “Novartis”) is a Delaware corporation and is located at One Health Plaza, East Hanover, New Jersey, 07936-1080.

94. Novartis manufactures, promotes, markets, distributes and sells opioids in Plaintiffs’ geographical area and throughout the nation. At all times relevant, Novartis manufactured, marketed, and sold opioids, including fentanyl and oxycodone products, throughout the United States and Plaintiffs’ geographic area. Novartis manufactured, marketed, and sold opioids throughout Plaintiffs’ geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs’ injuries.

95. As a generic manufacturer, Novartis failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users Novartis could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Novartis had a financial incentive not to communicate these warning and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Novartis failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a)

4. West-Ward n/k/a Hikma Pharmaceuticals

96. Defendant West-Ward Pharmaceuticals Corp. n/k/a Hikma Pharmaceuticals, Inc. (“Hikma”) is a Delaware corporation with its principal place of business located in Eatontown, New Jersey. It manufactures, promotes, markets, distributes and sells opioids in Plaintiffs’ geographical area and throughout the nation. At all times relevant, Hikma manufactured, marketed, and sold opioids, including hydromorphone, oxymorphone, and methadone products, throughout the United States and Plaintiffs’ geographic area. Hikma manufactured, marketed, and sold opioids throughout Plaintiffs’ geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs’ injuries.

97. As a generic manufacturer, Hikma failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users. Hikma could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Hikma had a financial incentive not to communicate these warning and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Hikma failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

5. Amneal

98. Defendant Amneal Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located in New Jersey. Upon information and belief, Amneal Pharmaceuticals, Inc. is a subsidiary of Amneal Pharmaceuticals LLC.

99. Defendant Amneal Pharmaceuticals, LLC is a foreign limited liability company organized under the laws of Delaware with its principal place of business in Bridgewater, New Jersey.

100. Defendant Amneal Pharmaceuticals, Inc. and Defendant Amneal Pharmaceuticals, LLC are collectively referred to as “Amneal”.

101. Amneal manufactures, promotes, markets, distributes and sells opioids in Plaintiffs’ geographical area and throughout the nation.

102. At all times relevant, Amneal manufactured, marketed, and sold opioids, including generic oxycodone and hydrocodone, throughout the United States and Plaintiffs’ geographic area. Amneal manufactured, marketed, and sold opioids throughout Plaintiffs’ geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs’ injuries.

103. As a generic manufacturer, Amneal failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users. Amneal could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Amneal had a financial incentive not to communicate these warning and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Amneal failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

6. KVK-Tech

104. Defendant KVK-Tech, Inc. is a privately held Pennsylvania corporation with its principal place of business in Pennsylvania. KVK-Tech, Inc. is a manufacturer of generic prescription opioids, including many Schedule II controlled substances such as Oxycodone and Hydrocodone. KVK-Tech, Inc. manufactures, markets, sells and/or distributes pharmaceutical drugs nationally and in Plaintiffs' geographic area. KVK-Tech, Inc. is registered to conduct business and/or conducts business in Plaintiffs' geographic areas as a licensed wholesale pharmaceutical manufacturer.

7. Indivior

105. Defendant Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals, Inc. ("Indivior") is a Delaware corporation with its principal place of business located at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235.

106. At all times relevant to this Complaint, Indivior Inc. manufactured, marketed, sold, and distributed prescription opioids nationally, including in Plaintiffs' geographic area, including many opioid medications such as Sublocade (buprenorphine), Subutex tablet (buprenorphine), Suboxone tablet (buprenorphine/naloxone), and Suboxone film (buprenorphine/naloxone).

107. In April 2019, the U.S. Department of Justice announced that Indivior Inc. was indicted for fraudulently marketing their Suboxone film opioid as safer, less divertible, and less abusable than other opioid-addiction treatment drugs. Indivior was alleged to have sought to boost profits by using a "Here to Help" program to connect opioid-addicted patients to doctors the company knew were prescribing opioids at high rates and in a clinically unwarranted manner.

108. According to the indictment, Indivior promoted the film version of Suboxone (Suboxone film) to physicians, pharmacists, Medicaid administrators, and others across the country

as less-divertible and less-abusable and safer around children, families, and communities than other buprenorphine drugs, even though such claims have never been established.

109. The indictment also alleges that, to further its scheme, Indivior announced a “discontinuance” of its tablet form of Suboxone based on supposed “concerns regarding pediatric exposure” to tablets, despite Indivior executives’ knowledge that the primary reason for the discontinuance was to delay the Food and Drug Administration’s approval of generic tablet forms of the drug.

110. In July 2019, the U.S. Department of Justice and Indivior negotiated a \$1.4 billion settlement of the issues presented by the indictment.

111. Indivior Solutions, a subsidiary of Indivior Inc., was sentenced to pay \$289 million in criminal penalties in connection with a previous guilty plea related to the marketing of the opioid-addiction treatment drug Suboxone. Together with Indivior’s civil penalties, it will pay \$600 million to resolve its civil and criminal liability.

112. Altogether, the investigation and prosecution of Indivior Solutions and its parent companies, Indivior Inc. and Indivior plc, and two former Indivior executives (its CEO and Medical Director) and a resolution with Indivior’s former parent, Reckitt Benckiser Group plc, resulted in recoveries of more than \$2 billion.

113. Indivior Solutions pleaded guilty on July 24, 2020, to a one-count felony criminal information charging false statements relating to health care matters. Indivior Inc. agreed to terms complementing the Indivior Solutions guilty plea and agreed to implement prospective measures that include permanently disbanding Indivior Inc.’s Suboxone sales force and taking steps to prevent promoting Suboxone to health care providers at a high risk of inappropriate prescribing.

8. Assertio

114. Defendant Assertio Therapeutics, Inc. f/k/a Depomed, Inc. (“Assertio” or “Depomed”) is a Delaware corporation with its principal place of business in Lake Forrest, Illinois. Depomed acquired Nucynta (tapentadol immediate-release oral tablets) and Nucynta ER (tapentadol extended-release tablets) from J&J in April of 2015 and began to manufacture, market, sell and distribute Nucynta® in the U.S., including in Plaintiffs’ geographic areas. Depomed also manufactures, markets, sells, and distributes Lazanda (fentanyl).

115. On information and belief, Depomed entered a Commercialization Agreement with Collegium Pharmaceutical, Inc. (Collegium) in January of 2018 that granted Collegium the right to commercialize Nucynta and Nucynta ER in the U.S. Collegium assumed all commercialization responsibilities for Nucynta effective January 9, 2018, including sales and marketing. Pursuant to the Commercialization Agreement, Depomed will receive a royalty on all Nucynta and Nucynta ER revenues based on certain net sales thresholds, with a minimum royalty of \$135 million per year during the first four years of the agreement. Additionally, Depomed retained certain rights to co-promote Nucynta products.

116. Depomed actively promoted and continues to promote the sale and use of its opioid products throughout the U.S., including Plaintiffs’ geographic areas. In 2015, Depomed paid over \$2.11 million to physicians and hospitals across the U.S. to promote widespread prescribing, sales and use of Nucynta and Nucynta ER. On information and belief, from 2013 through 2015, Depomed paid \$1.07 million to physicians and hospitals across the U.S. to promote the sale and use of Lazanda. Additionally, from 2012 to 2017, Depomed paid \$1,071,000 to non-profit patient advocacy groups and medical societies to promote opioid prescribing and enhance the acceptance of opioids for non-cancer pain. Specifically, Depomed made payments to several industry front

groups, including the Academy of Integrative Pain Management (\$43,491.95), American Academy of Pain Medicine (\$332,100.00), AAPM Foundation (\$304,605.00), American Chronic Pain Association (\$54,670.00), American Pain Society (\$288,750.00), American Society of Pain Management Nursing (\$25,500.00), and U.S. Pain Foundation (\$22,000.00).

117. Depomed established a training module called the “Depomed Pain Medicine Education Program” with the American Academy of Pain Medicine, which can be found at the American Academy of Pain Medicine (AAPM) Education Center. The training module appears on the AAPM webpage and “was designed to further sales specialists' knowledge of the fundamentals of pain medicine and gain confidence and credibility when interacting with health care clinicians.” The Pain Medicine Education Program promotes use of opioids for chronic pain in older adults and has modules entitled: “Strategies for Success with Chronic Opioid Therapy,” “Pain Management with Older Adults,” and “Pain and Pathways: Understanding Chronic Low Back Pain.”

9. Abbott

118. Abbott Laboratories, Inc. is a domestic BCA organized under the laws of Illinois. Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois, and Abbott Laboratories, Inc. is a Illinois corporation with its principal place of business in Abbott Park, Illinois (collectively, “Abbott”).

119. Abbott was primarily engaged in the promotion, and distribution of opioids nationally, in Plaintiffs’ geographic area, due to a co-promotional agreement with Defendant Purdue. Pursuant to that agreement between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products.

120. With Abbott's help, sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

121. Abbott, as part of the co-promotional agreement, helped make OxyContin into the largest-selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received 25 to 30 percent of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996 to 2002, following which Abbott continued to receive a residual payment of 6 percent of net sales up through at least 2006.

122. Abbott heavily incentivized its sales staff to push OxyContin, offering \$20,000 cash prizes and luxury vacations to top performers. The company used Middle Age Crusade terminology: Sales reps were called “Crusaders” in the “Royal Court of OxyContin,” executives referred to in memos as the “Wizard of OxyContin”, “Supreme Sovereign of Pain Management” and the “Empress of Analgesia”. The head of pain care sales, Jerry Eichorn, was the “King of Pain” and signed memos simply “King.”

123. In one particular memo to Sales Reps, two Abbott Reps received high accolades from “The Kingdom of Abbott Pain Management” for a “particularly outstanding Crusader success story.”

124. In this same memo, the “Empress of Analgesia” pushed Sales Reps to hone their focus on 50 key surgeons and anesthesiologists, more specifically to “target those who have the potential to widely prescribe OxyContin and Vicoprofen on a consistent basis each month.” The “King of Pain” encouraged sales representatives to use emotion in their sales tactics, and then supplied examples, both based on vague science:

Did Doctor X have disruptive callbacks from Patient Y today, unhappy with his bread-through pain levels on Percocet? Explain how OxyContin smooth, sustained blood level throughout 12 hours should alleviate this problem by keeping patients comfortable. Is Surgeon A concerned about the euphoria Patient B is experiencing from Vicodin? Tell your doctor that, with its longer half life, OxyContin has fewer such effects.

125. Abbott and Purdue sales representatives wooed doctors with food, gifts, and influence peddling, techniques which netted them both a huge portion of profits from opioid sales in Plaintiffs' geographic area, and nationwide. The sales forces of Abbott and Purdue worked in tandem, holding regular strategy sessions.

10. Sun Pharmaceutical

126. Defendant Sun Pharmaceuticals is a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd. It manufactures, markets, and distributes drugs, including opioids, in the United States, including in Plaintiffs' geographic area.

11. Collegium

127. Defendant Collegium Pharmaceutical, Inc. ("Collegium") is a Virginia corporation with its principal place of business in Canton, Massachusetts.

128. Collegium manufactures, promotes, sells, and distributes opioids nationally and in Plaintiffs' geographic area, including the following opioids, as well as their generic versions:

Drug Name	Chemical Name	Form
Xtampza ER	Oxycodone	Tablet extended release

129. As of January 10, 2018, Collegium has signed a commercialization agreement with Depomed, Inc., which allows Collegium to market the opioid products Nucynta and Nucynta ER.

130. Collegium Vice President, Steven Passik, has proudly identified Dr. Portenoy as one of his mentors, stating that Dr. Portenoy, among others, “taught me everything I know about pain and encouraged and supported me long before I had any idea of what I was talking about.”

131. In September 2016, the FDA's Office of Prescription Drug Promotion (“OPDP”) sent advisory comments to Collegium regarding the company's presentations for Xtampza ER. In these advisory comments, OPDP recommended that Collegium revise its proposed presentations so that they did not misrepresent the approved indication or omit important context; misrepresent or omit important risk information; or omit other material information. In those comments, the OPDP also cautioned Collegium about failing to present risk information for Xtampza ER with a prominence and readability reasonably comparable to the presentation of benefits.

132. On February 9, 2018, the FDA sent a warning letter to Collegium regarding Collegium's exhibit booth advertisement of Xtampza ER at the American Society Health-System Pharmacists (ASHP) Summer Meetings 8c Exhibition, which was held on June 3-7, 2017. The warning letter referenced its September 2016 advisory comments to Collegium and voiced “concern[] that Collegium is promoting Xtampza ER in a manner that fails to adequately present the very serious risks of the drug, despite this direction from OPDP.” The warning letter stated that Collegium's exhibit booth “failed to adequately provide material information about the drug's limitations of use and the serious and life-threatening consequences that may result from the use of the drug, thereby creating a misleading impression about the drug's safety.” The warning letter further stated that “the exhibit booth presentation included a principal display panel that prominently presented benefit claims about the abuse-deterrent properties of Xtampza ER, but failed to include any information with respect to the drug's limitations of use, which state that due to the risks of addiction, abuse, misuse, overdose and death, Xtampza ER should only be used in

patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Nor did the principal display panel include any information with respect to the indication or serious and life-threatening risks...”

133. Collegium falsely stated in their presentation at the 2014 Jefferies Global Healthcare Conference that “prescription opioids remain the primary treatment for chronic pain[,]” although this was not (and is not) the case. Collegium repeated this false information in its March 2018 Form 10-K SEC filing.

134. On December 16, 2021, the Massachusetts Attorney General and Collegium entered into an assurance of discontinuance. “According to the AG’s Office, Collegium sales representatives misled doctors about the potential risks of the drug by marketing it as a safe and responsible alternative to other opioids, even though Xtampza has the same active ingredient (oxycodone) as other drugs like Oxycontin.”²⁶

12. Zydus

135. Defendant Zydus Pharmaceuticals (USA) Inc. is a company located in New Jersey.

136. At all relevant times, Zydus manufactured, marketed, and sold generic opioids throughout the United States and Plaintiffs’ geographic area. Zydus manufactured, marketed, and sold opioids throughout Plaintiffs’ geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs’ injuries.

137. As a generic manufacturer, Zydus failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users. Zydus could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Zydus had a financial incentive not to communicate these warning and

²⁶ <https://www.mass.gov/news/drug-company-ends-face-to-face-marketing-for-its-opioid-product-to-massachusetts-doctors-in-ag-settlement>

risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Zydus failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

13. Quest

138. Quest Pharmaceuticals, Inc. (“Quest”) is a privately held company incorporated under the laws of Kentucky with its principal place of business in Kentucky.

139. Quest distributes prescription opioids to providers and retailers, including in Plaintiffs’ geographic area.

140. At all times relevant to this Complaint, Quest distributed prescription opioids throughout the United States, including in and around Plaintiffs’ geographic area.

141. The only Plaintiffs in this case bringing causes of actions against Defendant Quest are Plaintiffs Cuyahoga County, Jefferson County, City of Strongsville, City of North Olmsted, City of Euclid, City of Garfield Heights, City of Olmstead Falls, City of Parma Heights, City of Seven Hills, City of Warrensville Heights, City of Warren, City of Broadview Heights, and City of Parma. The other Plaintiffs are not bringing any claims against Defendant Quest.

14. KeySource

142. Defendant KeySource Medical, Inc. is a corporation organized under the laws of Ohio with its principal place of business at 7820 Palace Drive Cincinnati, Ohio 45249.

143. KeySource is a distributor of brand, generic, and specialty pharmaceuticals, including opioids, nationwide and in Plaintiffs’ geographic area. Its principal place of business is Cincinnati, Ohio.

144. At all times relevant to this Complaint, KeySource distributed prescription opioids in and around Plaintiffs' geographic area.

145. According to the Washington Post, "In May 2008, as the opioid epidemic was raging in America, a representative of the nation's largest manufacturer of opioid pain pills sent an email to a client at a wholesale drug distributor in Ohio. Victor Borelli, a national account manager for Mallinckrodt, told Steve Cochrane, the vice president of sales for KeySource Medical, to check his inventories and "[i]f you are low, order more. If you are okay, order a little more, Capesce?" Then Borelli joked, "destroy this email... Is that really possible? Oh Well..."²⁷

146. Additionally, the Washington Post wrote, "DEA investigators also noticed that another wholesale drug company, KeySource Medical, operating out of Cincinnati, was pouring massive amounts of oxycodone into Florida. In 2010, it sent 41 million tablets of Mallinckrodt-made oxycodone to the state — nearly 2.5 pills for every man, woman and child. The DEA eventually revoked the registrations of Sunrise and KeySource, barring them from distributing controlled substances."²⁸

147. On June 10, 2011, the DEA published a press release that provides, "Robert L. Corso, Special Agent in Charge of the Detroit Field Division, Drug Enforcement (DEA) announced today the immediate suspension of the federal controlled substance Registration of KeySource Medical, a wholesale supplier of pharmaceuticals. KeySource Medical, based in Cincinnati, Ohio, has been the subject of a DEA investigation that alleges the company was selling large quantities of controlled substances to pharmacies, primarily in Florida. The investigation has revealed that several of KeySource Medical's largest purchasers of oxycodone were engaged in schemes to

²⁷ https://www.washingtonpost.com/investigations/internal-drug-company-emails-show-indifference-to-opioid-epidemic-ship-ship-ship/2019/07/19/003d58f6-a993-11e9-a3a6-ab670962db05_story.html.

²⁸ <https://www.washingtonpost.com/investigations/interactive/2022/mallinckrodt-documents-doctors-sales/>

dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. The investigation revealed that Keystone Medical distributed approximately 48 million dosage units of oxycodone products to customers in Florida over a two year time between November of 2008 and November of 2010.”²⁹

148. The only Plaintiffs in this case bringing causes of actions against Defendant KeySource are Plaintiffs Ashtabula County, Cuyahoga County, Lorain County, Jefferson County, City of Strongsville, City of North Olmsted, City of Broadview Heights, City of Euclid, City of Garfield Heights, City of Olmstead Falls, City of Parma Heights, City of Seven Hills, City of Warrensville Heights, City of Lorain, City of North Ridgeville, Painesville Township, City of Warren, and City of Parma. The other Plaintiffs are not bringing any claims against Defendant KeySource.

15. Associated Pharmacies

149. Defendant Associated Pharmacies, Inc. (“Associated”), is an Alabama corporation with its principal place of business in Alabama. It distributed prescription opioids in the United States, including in Plaintiffs’ geographic area.

150. At all times relevant to this Complaint, Associated distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in and around Plaintiffs’ geographic area.

151. The only Plaintiffs in this case bringing causes of actions against Defendant Associated are Plaintiffs Jefferson County, and City of Warren. The other Plaintiffs are not bringing any claims against Defendant Associated.

²⁹ <https://www.dea.gov/press-releases/2011/06/10/cincinnati-pharmaceutical-suppliers-dea-license-suspended>

16. Costco

152. Defendant Costco Wholesale Corporation (“Costco”) is a Washington corporation with its principal place of business in Washington. At all times relevant to this Complaint, Costco dispensed prescription opioids and engaged in the retail sale of opioids throughout the United States, including in and near Plaintiffs’ geographic area.

153. On January 19, 2017, the Department of Justice issue a press release titled, “Costco Wholesale to Pay \$11.75 Million to Settle Allegations of Lax Pharmacy Controls - Costco Pharmacies Filled Prescriptions that Were Improper or Incomplete.”³⁰ Additionally, it provides, “Costco Wholesale will pay \$11.75 million to settle allegations that its pharmacies violated the Controlled Substances Act when they improperly filled prescriptions for controlled substances. The settlement resolves allegations that Costco pharmacies filled prescriptions that were incomplete, lacked valid Drug Enforcement Administration (DEA) numbers or were for substances beyond various doctors’ scope of practice. Additionally, the settlement resolves allegations that Costco failed to keep and maintain accurate records for controlled substances at its pharmacies and centralized fill locations.”³¹ Further, it provides, “Under the settlement reached Jan. 18, 2017, Costco acknowledges that between Jan. 1, 2012 and Dec. 31, 2015, certain Costco Pharmacies dispensed controlled substances inconsistent with their compliance obligations under the Controlled Substances Act (CSA) and its implementing regulations. The violations include filling prescriptions from practitioners who did not have a valid DEA number; incorrectly recording the practitioner’s DEA number; filling prescriptions outside the scope of a practitioner’s DEA registration; filling prescriptions that did not contain all the required information; failing to

³⁰ <https://www.justice.gov/opa/pr/costco-wholesale-pay-1175-million-settle-allegations-lax-pharmacy-controls>

³¹ *Id.*

maintain accurate dispensing records; and failing to maintain records for their central fill locations in Sacramento, California, and Everett, Washington.”³²

154. The only Plaintiffs in this case bringing causes of actions against Defendant Costco are Plaintiffs Cuyahoga County, Lorain County, City of Broadview Heights, City of Euclid, City of Garfield Heights, City of North Olmstead, City of Olmstead Falls, City of Parma Heights, City of Parma, City of Seven Hills, City of Warrensville Heights, City of Lorain, City of North Ridgeville, and City of Strongsville. The other Plaintiffs are not bringing any claims against Defendant Costco.

17. Target

155. Defendant Target Corporation (“Target”) is a Minnesota corporation with its principal place of business in Minneapolis, Minnesota.

156. At all times relevant to this Complaint, Target dispensed prescription opioids and engaged in the retail sale of opioids throughout the United States, including in and near Plaintiffs’ geographic area.

157. The only Plaintiffs in this case bringing causes of actions against Defendant Target are Plaintiffs Cuyahoga County, Lorain County, City of Broadview Heights, City of Euclid, City of Garfield Heights, City of Olmstead Falls, City of Parma Heights, City of Seven Hills, City of Warrensville Heights, City of Strongsville, City of Dayton, City of Toledo, City of North Olmsted, City of Lorain, City of North Ridgeville, Painesville Township, City of Warren, and City of Parma. The other Plaintiffs are not bringing any claims against Defendant Target.

18. Smith Drug

³² *Id.*

158. Defendant Smith Drug Company is a South Carolina corporation with its principal place of business in South Carolina. Smith Drug, and through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor.

159. Smith Drug Company is a division of J M Smith Corporation responsible for operating JM Smith Corporation's pharmaceutical distribution business. J M Smith Corporation and Smith Drug Company are referred to as “Smith Drug” throughout this Complaint.

160. Smith Drug is a wholesale pharmaceutical distributor primarily serving the eastern United States. At all relevant times, Smith Drug operated as a licensed pharmacy wholesaler in Florida and delivered substantial amounts of opioid drugs to buyers in Plaintiffs’ geographic area. Smith Drug operates a distribution center in Valdosta, Georgia.

161. At all times relevant to this Complaint, Smith Drug distributed prescription opioids throughout the United States, including in and around Plaintiffs’ geographic area.

162. The only Plaintiffs in this case bringing causes of actions against Defendant Smith Drug are Plaintiffs Cuyahoga County, City of Broadview Heights, City of Euclid, City of Garfield Heights, City of North Olmstead, City of Olmstead Falls, City of Parma Heights, City of Parma, City of Seven Hills, City of Warrensville Heights, and City of Strongsville. The other Plaintiffs are not bringing any claims against Defendant Smith Drug.

19. Kroger

163. Defendant The Kroger Co. (“Kroger”) is an Ohio corporation with headquarters in Cincinnati, OH. At all times relevant to this Complaint, Kroger distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in and around Plaintiffs’ geographic area.

164. Kroger operates approximately 2,200 pharmacies across the country.³³

165. At all relevant times, Kroger dispensed prescription opioids in Plaintiffs' geographic area. Until at least 2014, Kroger self-distributed certain drugs, including one of the most widely diverted opioids, hydrocodone, in Plaintiffs' geographic area.

166. The only Plaintiffs in this case bringing causes of actions against Defendant Kroger are Plaintiffs Jefferson County, Sandusky County, City of Dayton, City of Findlay, and City of Toledo. The other Plaintiffs are not bringing any claims against Defendant Kroger.

167. Although Kroger had access to significant information about red flags due to its vertical integration with its stores, it failed to use this information in order to more effectively prevent diversion.

a. Kroger Failed to Maintain Effective Controls Against Diversion of Opioids It Distributed, Instead Oversupplying Its Stores.

168. Kroger failed to implement an effective suspicious order monitoring program.

169. Kroger funneled far more opioids into Plaintiffs' geographic area than could have been expected to serve legitimate medical use and ignored other indicia of suspicious orders. This information, along with the information known only to distributors such as Kroger (especially with its pharmacy dispensing data), would have alerted Kroger to potential diversion of opioids. Yet, upon information and belief, Kroger did not report a single suspicious order in Plaintiffs' geographic area between 2007 and 2014.

170. Kroger appears to have assigned responsibility for reviewing "unusual orders" to the Pharmacy Manager, who had the ability to release the order. Kroger had computer-assisted ordering systems aiming to ensure it had enough supply of controlled substances and other drugs

³³ <https://www.reuters.com/companies/KR>

on hand. “Excessive purchase” information about individual pharmacies was forwarded to a “Pharmacy Coordinator” who would either file a report internally or alert the Division Merchandiser to start an internal investigation.

171. It is unclear when Kroger developed “computerized statistical information” for purposes of “pending” orders for evaluation, but it contracted with an outside consultant in 2013. Even with that system in place, however, it still appears to allow release of orders based simply on contacting the pharmacy coordinator and obtaining a reason such as “[n]ew customers” to clear an order. This occurred even though Kroger understood that its “SOM system will fail if individuals clear orders without adequate investigation.” As of October 2013, an internal document described “rolling out the SOM program to all” distribution centers and acknowledged it currently lacked any system to prevent a pharmacy from going to Kroger’s outside vendor, Cardinal Health, to order items “pended” by the SOM program.

172. A Suspicious Order Monitoring Training Material notes the ability of analysts to review “Business Objects” reports with sales trends and purchase history, and to clear orders based on that history.

173. Upon information and belief, Kroger by virtue of the data available to it, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug “cocktails,” known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Kroger ignored these obvious red flags.

174. Kroger, therefore, was aware of the suspicious orders that flowed from its distribution facilities. Kroger refused to identify, investigate, and report suspicious orders despite

its actual knowledge of drug diversion. Rather, Kroger failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into Plaintiffs' geographic area.

175. Upon information and belief, Kroger failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

176. Kroger was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

177. Given Kroger's retail pharmacy operations, in addition to its role as a wholesale distributor, Kroger knew or reasonably should have known about the disproportionate flow of opioids into Plaintiffs' geographic area and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

b. Kroger Failed to Implement Effective Policies and Procedures to Prevent Diversion from Its Pharmacy Stores.

178. Before 2005, the inadequacy of Kroger's policies and procedures was particularly glaring. DEA began investigating King Soopers and City Market, part of the "Kroger Co. Family of Stores" in response to information concerning potential diversion. Audits at seven Colorado pharmacies revealed "a pattern of non-compliance" with the CSA and federal regulations. Because of record-keeping and security problems, the DEA could not determine from the audit "how many

drugs had been lost or diverted,” but could tell that “many of the CSA violations were the result of systemic weaknesses present in all King Soopers and City Market pharmacies.”

179. Ultimately, the parent corporation, Kroger Co., agreed in October 2005 to a then-record \$7 million settlement for the “systemic violations of the Controlled Substances Act (CSA) by the company’s pharmacies.” Kroger also “agreed to implement a pharmacy compliance program estimated to cost over \$6 million dollars in all 1,900 of its pharmacies nationwide.” The changes included the Kroger stores in the County. Upon information and belief, Kroger promised national reforms because it imposed its procedures at a national level across its “family” of stores, such that the same systemic failures also existed in Plaintiffs’ geographic area.

180. A DEA press release concerning the settlement highlighted the trust Americans place in “corporations like Kroger” to “ensure that controlled substances aren’t diverted to the illicit market.” Kroger understood the vital importance of its role as the last line of defense. “As the last person that has the opportunity to speak with a patient or caregiver prior to handing over a medication that has been known to end the lives of so many when diverted or misused, no one can overestimate the responsibility of the pharmacist.” Kroger also recognized the “legislative and social intent of regulating controlled substances” as consistent with its mission in “serving the public good.”

181. Yet systemic failures persisted even after the 2005 settlement. Kroger created SOPs as a “single source” of information for its pharmacies concerning CSA requirements. A member of Kroger’s Law Department issued powers of attorney to Division Merchandisers/Directors of Pharmacy to make applications for federal and state-controlled substances registrations or licenses, using a “group renewal” process if desired. Kroger assigned that employee receiving the power of attorney responsibility for its compliance obligations.

182. Kroger was also slow to incorporate certain red flags into its training materials. For example, a May 2006 Standard Operating Procedures, applicable across all Kroger stores, fails to identify red flags such as pattern prescribing, including red flags it would later ask its pharmacists to confirm they understood in 2012.

183. Kroger stores obtained opioids not only through Kroger's self-distribution, but also outside supplier Cardinal Health. As a valued customer, Kroger received a "75% percent report" from Cardinal, ensuring it had the opportunity to avoid orders being flagged and to consider threshold increases.

184. At least as of 2016, Kroger had the benefit of a program called NARxCHECK. It is "an analytics tool that provides prescription drug use information and scoring at-a-glance for three different classes of drugs: narcotics, sedatives, and stimulants. . . . [It] is designed to help prescribers and dispensers identify potential drug therapy problems in conjunction with controlled substances, such as abuse and misuse." It also communicates, through a vendor (Apriss) a patient's PDMP information.

185. Discovery will reveal that Kroger knew or should have known that its pharmacies in Plaintiffs' geographic area were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in

combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Kroger had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

186. Kroger welcomed Purdue's marketing into its stores. Following an NACDS conference, a Purdue employee described Kroger's Pharmacy Procurement Manager in attendance as "very positive as to what Purdue is doing" and "interested in doing programs . . . a regional level" and with Purdue's "various brochures included." He also described making another new contact at Kroger, who had agreed to send Purdue's brochure and letter out electronically. An "account contact report" from Purdue further described the results of communication with Purdue's Pharmacy Category Manager, who "was very supportive and understanding" about Purdue's "ongoing OxyContin media battle" in 2001. Not only would Purdue's "Pharmacy brochure and letter" be sent out to all Kroger Pharmacy Directors in each division and when Kroger's employee's "co-sign the letter" it would have "better impact." Purdue would also send out its continuing education ("CE") programs on pain management.

20. Henry Schein

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

188. At all times relevant to this Complaint, Henry Schein distributed prescription opioids throughout the United States, including in and around Plaintiffs' geographic area.

189. The only Plaintiffs in this case bringing causes of actions against Defendant Henry Schein are Plaintiffs Ashtabula County, Cuyahoga County, Lorain County, Jefferson County, City of Strongsville, City of North Olmsted, City of Strongsville, City of North Olmsted, City of Broadview Heights, City of Euclid, City of Garfield Heights, City of Olmstead Falls, City of Parma Heights, City of Seven Hills, City of Warrensville Heights, City of Lorain, City of North Ridgeville, Painesville Township, City of Warren, and City of Parma, and City of Parma. The other Plaintiffs are not bringing any claims against Defendant Henry Schein.

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

191. Henry Schein Medical Systems, Inc. ("Henry Schein Medical") is a subsidiary of Henry Schein, Inc., that provides practice management, electronic medical records, and document management for medical groups.

192. Henry Schein Medical Systems Inc. has been registered to do business with the State of Ohio since at least 1987. In November of 2014, Henry Schein Medical and Cardinal Health entered into a strategic partnership, which consolidated Cardinal Health's physician office sales organization into Henry Schein Medical. Henry Schein took responsibility for serving physician offices, and through its "symbiotic" arrangement with Cardinal Health, gained access to over

25,000 physical offices as customer locations.³⁴ As a result of this agreement, Henry Schein Medical added more than \$300 million in annual sales.

193. Henry Schein, Inc. and Henry Schein Medical Systems Inc. are referred to as “Henry Schein.” At all relevant times, Henry Schein was in the business of distributing, and redistributing, pharmaceutical products to consumers within Plaintiffs’ geographic area.

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

195. The Pharmacy Benefit Manager Defendants (“PBM Defendants”) are defined below. At all relevant times the PBM Defendants acted as the gatekeepers of prescription drugs including opioids. Pharmacy benefit managers (“PBMs”) negotiate with drug manufacturers to offer preferred drug formulary placement for the manufacturers’ drugs. PBMs establish reimbursement rates for the drugs dispensed. PBMs earn revenue from at least the following sources: fees from health plans and insurers, rebates and other incentives such as volume target bonuses negotiated with drug manufacturers, and fees from maintaining pharmacy networks.³⁵

21. Express Scripts

196. Defendant, Express Scripts Holding Company (“ESHC”), is a Delaware corporation with its principal place of business in St. Louis, Missouri.

³⁴ Raymond Davis, Henry Schein and Cardinal, The J. of Healthcare Contracting, Feb. 12, 2018, <http://www.jhconline.com/henry-schein-and-cardinal.html>.

³⁵ Health Policy Brief, On behalf of payers, pharmacy benefit managers negotiate rebates from drug makers in exchange for preferred formulary placement, HEALTH AFFAIRS, Sep. 14, 2017, <https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/>

197. Defendant, Express Scripts, Inc. (“ESI”), is incorporated in the State of Delaware with its principal place of business located in St. Louis, Missouri, is a pharmacy benefit management company, and is a wholly owned subsidiary of ESHC. ESI has been registered to do business in Ohio and may be served through its registered agent: C T Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio, 43219.

198. In 2012, ESI acquired its rival, Medco Health Solutions Inc., in a \$29.1 billion deal. As a result of the merger, ESHC was formed and became the largest PBM in the nation, filing a combined 1.4 billion prescriptions for employers and insurers.³⁶

199. According to the Pharmacy Benefit Management Institute, in 2015, Express Scripts was the top ranking PBM nationwide with twenty-six percent (26%) of the industry market share.³⁷

200. Express Scripts derives substantial revenue managing pharmacy benefits in Plaintiffs’ geographic area through the services it provides and the formulary it maintains in its relationships with health plans.

22. United Health

201. Defendant, UnitedHealth Group Incorporated (“UnitedHealth”), a Delaware corporation with its principal place of business located in Minnetonka, Minnesota, is a diversified managed health care company with two business platforms. UnitedHealth serves approximately 115 million individuals throughout the United States, including Plaintiffs’ geographic area. For 2016, UnitedHealth reported an operating income of \$12.9 billion.

³⁶ Peter Frost, Express Scripts closes \$29.1-billion purchase of Medco, LOS ANGELES TIMES (Apr. 3, 2012), <http://articles.latimes.com/2012/apr/03/business/la-fi-medco-20120403>

³⁷ PBM Market Share, by Total Prescription Claims, 2015, PHARMACY BENEFIT MANAGEMENT INSTITUTE, INDUSTRY RESEARCH, https://www.pbmi.com/PBMI/Research/Industry_Research/PBMI/Research/PBMI_Industry_Research.aspx?hkey=22023612-80c4-4ada-a17e-85e7dfcbc1f8

202. UnitedHealth derives substantial revenue managing pharmacy benefits in Plaintiffs' geographic area through the services it provides and the formulary it maintains in its relationships with health plans.

23. Medco

203. Express Scripts, Inc. acquired Defendant Medco Health Solutions Inc. in 2012 in a \$29.1 billion deal. As a result of the merger, Defendant Express Scripts Holding Company ("ESHC") was formed and became the largest PBM in the nation, filling a combined 1.4 billion prescriptions for employers and insurers. Defendant Express Scripts Holding Company is a Delaware corporation with its principal place of business in St. Louis Missouri. Medco Health Solutions, Inc. can be served at c/o The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

204. Defendant Merck-Medco was established in mid-2002 by Merck & Co as its pharmacy benefits management subsidiary, as a separate, publicly traded company.

205. According to its SEC filing, in August 2003, Merck & Co. approved a spin-off, called Medco Health Solutions, Inc., a "wholly owned subsidiary of Merck that provides pharmacy benefit management services to approximately 62 million members.'

206. Upon information and belief, Merck-Medco is the corporate predecessor of Medco Health Solutions Inc., collectively referred to herein as "Medco".

207. Medco derives substantial revenue managing pharmacy benefits in Plaintiffs' geographic area through the services it provides and the formulary it maintains in its relationships with health plans.

24. Optum

208. Defendant, Optum, Inc., is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth's pharmacy benefits, including OptumRX, Inc. On information and belief, Optum, Inc. is a subsidiary of UnitedHealth.

209. Defendant, Optum, Inc., is a Delaware corporation with its principal place of business located in Irvine, California. OptumRx operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of Optum, Inc. OptumRx operates as the PBM for UnitedHealth, collectively referred to herein as "Optum".

210. OptumRx is registered to do business in Ohio and may be served through its registered agent: C T Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio, 43219.

211. At all times relevant hereto, OptumRx derives substantial revenue providing pharmacy benefits in Plaintiffs' geographic area through several different means.

212. According to the Pharmacy Benefit Management Institute, OptumRx (UnitedHealth) was the third highest ranking PBM in 2015 with twenty-two (22%) of the industry market share.³⁸

213. In one case, OptumRx, which is owned by UnitedHealth, suggested that a member taking Butrans consider switching to a "lower cost alternative," such as OxyContin or extended-release morphine, according to a letter provided by the member. Mr. Wiggin, the UnitedHealthcare spokesman, said the company's rules and preferred drug list "are designed to ensure members have access to drugs they need for acute situations, such as post-surgical care or serious injury, or

³⁸ Pharmacy Benefit Management Institute, Industry Research, *supra* note 35.

ongoing cancer treatment and end of life care, as well as for long-term use after alternatives are tried.”³⁹

214. “UnitedHealthcare places morphine on its lowest-cost drug coverage tier with no prior permission required, while in many cases excluding Butrans. And it places Lyrica, a nonopioid, brand-name drug that treats nerve pain, on its most expensive tier, requiring patients to try other drugs first.”⁴⁰

215. Optum derives substantial revenue managing pharmacy benefits in Plaintiffs’ geographic area through the services it provides and the formulary it maintains in its relationships with health plans.

25. Navitus

216. Defendant, Navitus Holdings, LLC, is a limited liability company organized under the laws of Wisconsin with its principal place of business located in Madison Wisconsin. Navitus Holdings, LLC may be served through its registered agent: CT Corporation System, 301 South Bedford Street, Suite 1, Madison, Wisconsin 53703.

217. Defendant, Navitus Health Solutions, LLC, a pharmacy benefit manager, is a limited liability company organized under the laws of Wisconsin with its principal place of business located in Madison, Wisconsin and is a wholly owned subsidiary of Navitus Holdings, LLC.

218. Navitus Holdings, LLC and Navitus Health Solutions, LLC are collectively referred to as “Navitus.”

³⁹ Katie Thomas and Charles Ornstein, Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers, THE NEW YORK TIMES, Sep. 17, 2017, <https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurancecompanies.html?mwrs=Email>

⁴⁰ *Id.*

219. Navitus derives substantial revenue managing pharmacy benefits in Plaintiffs' geographic area through the services it provides and the formulary it maintains in its relationships with health plans.

220. The opioids at issue in this case were reimbursed by the PBM Defendants. Without the PBM Defendant reimbursement for the opioids at issue herein, the opioids would not have entered the marketplace and the entire scheme would have failed.

FACTS RELEVANT TO ALL CAUSES OF ACTION

A. Background on Pain Medicine.

1. Safe and Effective Treatment of Chronic Pain Centers on Informed Risk Management.

221. The practice of medicine centers on informed risk management. Prescribers must weigh the potential risks and benefits of each treatment option, as well as the risk of non-treatment.

222. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risks of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.

223. This bedrock principle of full disclosure is particularly important in the context of chronic opioid therapy because of the risk that patients will become physically and psychologically dependent on the drugs, finding it difficult to manage or terminate their use.

224. The FDA-approved drug labels on each of Defendants' opioids do not attempt to advise physicians how to maximize the benefits and minimize the risks for patients on long-term chronic opioid therapy. The labels contain no dosing cap above which it would be unsafe for any doctor to prescribe to any patient. Nor do any of the labels provide a duration limit, after which the

risks to a patient might increase. Thus, doctors and patients rely more heavily on educational materials such as treatment guidelines, CMEs, and scientific and patient education articles and websites to inform their treatment decisions.

2. Opioid Use Is Associated with Known and Substantial Risks.

225. Opium has been recognized as a tool to relieve pain for millennia; so has the magnitude of its potential for abuse, addiction and its dangers. Opioids are related to illegal drugs like opium and heroin. In fact, types of fentanyl, a widely-distributed opioid in the United States, have now been made illegal in China.

226. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain – particularly on the battlefield – and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants and beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States.⁴¹ Many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

227. Beginning in the late 20th century and continuing through today, the pharmaceutical industry acted to dramatically expand the marketplace for opioids. As set forth below, pharmaceutical actors facilitated this expansion in three ways. First, pharmaceutical manufacturers engaged in a misinformation campaign which altered public perception of opioids, and deceived doctors, federal regulators, and the general public about their addictive qualities. Second, PBMs ensured that opioids were widely available, regularly prescribed and reimbursed. Third, opioid manufacturers and wholesalers/distributors flouted their federally imposed requirements to report

⁴¹ Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

suspicious opioid orders to the DEA and state agencies. These facilitated an explosion in the illegitimate marketplace for prescription opioids.

228. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration (“DEA”) since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and “[s]erious, life-threatening, or fatal respiratory depression,” as the result of an excessive dose.

229. Studies and articles from the 1970s and 1980s also made the reasons to avoid opioids clear. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids’ mixed record in reducing pain long-term and failure to improve patients’ function; greater pain complaints as most patients developed tolerance to opioids; opioid patients’ diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, and even prohibited, the use of opioid therapy for chronic pain.

230. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the patient had been using opioids.

231. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he or she has become accustomed – up

to and including doses that are “frighteningly high.”⁴² At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

232. Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, has explained the effect of opioids as akin to “hijack[ing] the brain’s reward system,” which in turn convinces a user that “the drug is needed to stay alive.”⁴³ A patient’s fear of the unpleasant effects of discontinuing opioids combined with the negative reinforcement during a period of actual withdrawal can drive a patient to seek further opioid treatment—even where ineffective or detrimental to quality of life—simply to avoid the deeply unpleasant effects of withdrawal.

233. Patients that receive high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to an overdose even when opioids are taken as recommended.

234. Further, “a potential side effect from chronic use [of opioids] can be abuse and addiction . . . [i]n fact, correct use and abuse of these agents are not polar opposites—they are

⁴² M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

⁴³ David Montero, *Actor’s Death Sows Doubt Among O.C.’s Recovering Opioid Addicts*, The Orange Cnty. Reg. (Feb. 3, 2014), <http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html> (accessed May 30, 2017).

complex, inter-related phenomena.”⁴⁴ It is very difficult to tell whether a patient is physically dependent, psychologically dependent, or addicted. Drug-seeking behaviors, which are signs of addiction, will exist and emerge when opioids are suddenly not available, the dose is no longer effective, or tapering of a dose is undertaken too quickly.

235. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.⁴⁵

236. Each of these risks and adverse effects—dependence, tolerance, and addiction—is fully disclosed in the labels for each of Defendants’ opioids (though, as described below, not in Defendants’ marketing).⁴⁶ Prior to Defendants’ deceptive marketing scheme, each of these risks was well-recognized by doctors and seen as a reason to use opioids to treat chronic pain sparingly and only after other treatments had failed.

237. Opioids vary by duration. Long-acting opioids, such as Purdue’s OxyContin and MS Contin, Janssen’s Nucynta ER and Duragesic, Endo’s Opana ER, and Actavis’s Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon’s Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address “episodic pain” and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

⁴⁴ Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81(2) *Drug & Alcohol Dependence* 103, 106 (2006).

⁴⁵ Joseph A. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) *Addiction* 1776 (2010); Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3) *Journal of Addictive Diseases* 185 (2011).

⁴⁶ For example, Purdue’s OxyContin label (October 5, 2011) states: “Physical dependence and tolerance are not unusual during chronic opioid therapy.”

238. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them with short-acting, rapid-onset opioids for episodic pain.

239. While it was once thought that long-acting opioids would not be as susceptible to abuse and addiction as short-acting ones, this view has been discredited. OxyContin's label now states, as do all labels of Schedule II long-acting opioids, that the drug "exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." The FDA has required extended release and long-acting opioids to adopt "Risk Evaluation Mitigation Strateg[ies]" on the basis that they present "a serious public health crisis of addiction, overdose, and death."⁴⁷

In 2013, in response to a petition to restrict the labels of long-acting opioid products, the FDA noted the "grave risks" of opioids, "the most well-known of which include addiction, overdose, and even death."⁴⁸ The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death."⁴⁹ The FDA required that—going forward—opioid makers of long-acting formulations clearly communicate these risks in their labels. Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain—that the adverse outcomes from opioid use include "addiction, unintentional overdose, and death" and that long-acting or extended-release opioids "should be used ***only when alternative treatments are inadequate.***"⁵⁰

⁴⁷ FDA, *Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids* (last updated Oct. 9, 2014), <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm> (accessed May 30, 2017).

⁴⁸ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

⁴⁹ *Id.*

⁵⁰ *Id.* at 7 (emphasis in original).

240. Notably, in reaching its conclusion, the FDA did not rely on new or otherwise previously unavailable scientific studies regarding the properties or effects of opioids.

241. The FDA-approved labels on each of Defendants' opioids do not attempt to advise physicians on how to maximize the benefits and minimize the risks for patients on long term opioid therapy. The labels contain no dosage cap above which it would be unsafe to prescribe to any patient. Nor do they provide a duration limit. Doctors and patients rely heavily on education materials, such as treatment guidelines, CMEs, and scientific and patient education articles and websites, to inform their treatment decisions.

242. On July 25, 2012, the Physician For Responsible Opioid Prescribing ("PROP"), a non-profit organization made up of doctors and other health care professionals, petitioned the FDA to change the labeling of opioid medications. The petition was signed by thirty-seven physicians located nationwide. In its letter to the FDA, the group stated that "an increasing body of medical literature suggests that long term-use of opioids may be neither safe nor effective for many patients, especially when prescribed in high doses."⁵¹

243. In its petition, PROP also stated that "many clinicians are under the false impression that chronic opioid therapy (COT) is an evidence-based treatment for chronic non-cancer pain" and that "these misconceptions lead to overprescribing and high dose prescribing." It was also their opinion that "the current label on opioid analgesics does not comply with [FDA law]".

244. As the basis for its petition, PROP provided "Statements of Scientific Basis for Petition" which provided a list of detailed reports and studies proving the risks of opioid medications, the high risk of addiction, the exaggerated and false benefits, and further medically backed reasons to change the labelling of opioid medications to reduce prescribing.

⁵¹ July 25, 2012 letter from PROP to FDA, accessed at <http://www.citizen.org/documents/2048.pdf> on May 30, 2017.

245. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the “grave risks” of opioids, including “addiction, overdose, and even death.” The FDA further warned, “[e]ven proper use of opioids under medical supervision can result in life- threatening respiratory depression, coma, and death.” Because of those grave risks, the FDA said that long-acting or extended-release opioids “should be used only when alternative treatments are inadequate.”⁵² The FDA required that – going forward – opioid makers of long-acting formulations clearly communicate these risks on their labels.

246. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release for opioid pain medications as it had for extended-release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.⁵³

247. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants for many years since they began marketing these drugs.

3. Long-Term Opioid Use Benefits Are Unproven and Contradicted.

248. Despite the fact that opioids are now routinely prescribed, there has never been evidence of their safety and efficacy for long-term use.

249. Defendants have always been aware of these gaps in knowledge. While promoting opioids to treat chronic pain, Defendants have failed to disclose the lack of evidence to support

⁵² Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013) (emphasis in original).

⁵³ FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm> (accessed May 30, 2017).

their long-term use and have failed to disclose the contradictory evidence that chronic opioid therapy actually makes patients sicker.

250. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. The first random, placebo-controlled studies appeared in the 1990s, and revealed evidence only for short-term efficacy and only in a minority of patients.⁵⁴

251. A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and showed that, while opioids had short-term efficacy, the data was insufficient to establish long-term effectiveness. Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently note the lack of data to assess long-term outcomes. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain).

252. On the contrary, evidence exists to show that opioid drugs are not effective to treat chronic pain and may worsen patients' health. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."⁵⁵ Another review of evidence relating to the use of opioids for

⁵⁴ Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23(4) Clin J. Pain 303 (2007); Roger Chou et al., *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147 (2009).

⁵⁵ Andrea D. 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

chronic pain found that up to 22.9% of patients in opioid trials dropped out before the study began because of the intolerable effects of opioids, and that the evidence of pain relief over time was weak.

253. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

254. As a pain specialist noted in an article titled *Are We Making Pain Patients Worse?*, “[O]pioids 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.”⁵⁶

255. This is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients’ function. Conversely, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not help patients return to work or to physical activity. This is due partly to addiction and other side effects.

256. As many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to

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. Karen H. 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).

⁵⁶ Andrea Rubenstein, *Are we making pain patients worse?*, Sonoma Medicine (Fall 2009).

experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

257. The lack of evidence for the efficacy of opioid use long-term has been well-documented nationally in the context of workers' compensation claims, where some of the most detailed data exists. Claims involving workers who take opioids are almost four times as likely to reach costs of over \$100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, taking an opioid for more than seven days and receiving more than one opioid prescription increased the risk that the patient would be on work disability one year later. A prescription for opioids, as the first treatment for a workplace injury, doubled the average length of the claim.

4. Defendants' Impact on the Perception and Prescribing of Opioids.

258. Before Defendants began the marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance.

259. In 1986, the World Health Organization ("WHO") published an "analgesic ladder" for the treatment of cancer pain.⁵⁷ The WHO recommended treatment with over-the-counter or prescription acetaminophen or non-steroidal anti-inflammatory drugs ("NSAIDs") first, and then the use of unscheduled or combination opioids, and then stronger (Schedule II or III) opioids if pain persisted. The WHO ladder pertained only to the treatment of cancer pain and did not contemplate the use of narcotic opioids for chronic pain—because the use of opioids for chronic pain was not considered appropriate medical practice at the time.

⁵⁷ http://apps.who.int/iris/bitstream/10665/43944/1/9241561009_eng.pdf (accessed May 30, 2017)

260. Studies and articles from the 1970s and 1980s made the reasons to avoid opioids clear. Scientists observed negative outcomes from long-term opioid therapy in pain management programs: opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

261. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for drug companies, published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”⁵⁸

262. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

The traditional approach to chronic nonmalignant 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*

⁵⁸ Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).

*effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*⁵⁹

263. According to Portenoy, these 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.”⁶⁰

264. For the reasons outlined by Dr. Portenoy, and in the words of one researcher from the Harvard Medical School, “it did not enter [doctors’] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids.”⁶¹ Defendants changed that perception.

B. Defendants Promoted Their Branded Products Through Direct Marketing to Prescribers and Consumers.

265. Defendants’ direct marketing proceeded on two tracks, serving two related purposes. First, Defendants worked through branded and unbranded marketing to build confidence in long-term opioid use by overstating its benefits and downplaying its risks, thereby expanding the chronic pain market. In addition, Defendants worked through their own staffs of sales representatives, physician speakers whom those representatives recruited, and advertising in medical journals to claim their share of that broader market. Defendants directed all of this activity through carefully designed marketing plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

1. Defendants Relied Upon Branded Advertisements.

⁵⁹ Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994) (emphasis added).

⁶⁰ *Id.*

⁶¹ Igor Kissin, *Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?*, 6 J. Pain Research 513, 514 (2013) (quoting Loeser JD, *Five crises in pain management*, 20(1) Pain Clinical Updates 1-4 (2012)).

266. Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. 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*. Defendants' advertising budgets peaked in 2011, when they collectively spent more than \$14 million on the medical journal advertising of opioids, nearly triple what they spent in 2001.

267. A number of these branded advertisements deceptively portrayed the benefits of opioid therapy for chronic pain. As just one example, a 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "There Can Be Life With Relief." This depiction falsely implied that OxyContin provides both effective long-term pain relief and functional improvement, claims that, as described below, are unsubstantiated and contradicted in medical literature.

268. Defendants jumped on Purdue's bandwagon.

2. Defendants Relied Upon Their Sales Forces and Recruited Physician Speakers.

269. Defendants promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual physicians and their staff in their offices—and small group speaker programs. By establishing close relationships with doctors, Defendants' sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain. Representatives were trained on techniques to build these relationships.

270. Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health. This data allows them to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor, and monitor the impact of their appeals.

271. Defendants, in particular, relied upon “influence mapping,” *i.e.*, using decile rankings or similar breakdowns to identify the high-volume prescribers on whom detailing would have the greatest sales impact. Defendants also closely monitored doctors’ prescribing after a sales representative’s visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

272. Defendants’ sales representatives have visited hundreds of thousands of doctors, including thousands of visits to prescribers in Plaintiffs’ geographic area, and as described herein, spread misinformation regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. This misinformation includes deceptive and unfair claims regarding the risks of opioids for chronic pain, particularly the risks of addiction, withdrawal, and high doses, as well as the benefits.

273. Each Defendant carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of that company’s drugs specifically, and opioids in general. Pharmaceutical companies exactingly direct and monitor their sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and other means—to ensure that individual detailers actually deliver the desired messages and do not veer off-script. Pharmaceutical companies likewise require their detailers to deploy sales aids reviewed, approved, and supplied by the company and forbid them to use, in industry

parlance, “homemade bread”—*i.e.*, promotional materials not approved by the company’s marketing and compliance departments. Sales representatives’ adherence to their corporate training is typically included in their work agreements. Departing from their company’s approved messaging can, and does, lead to severe consequences including termination of employment.

274. Besides carefully training their sales representatives, Defendants used surveys of physicians—conducted by third-party research firms—to assess how well their core messages came across to prescribers.

275. In addition to making sales calls, Defendants’ detailers also identified doctors to serve, for payment, on Defendants’ speakers’ bureaus and to attend programs with speakers and meals paid for by Defendants. Defendants almost always selected physicians who were “product loyalists,” as they were sure to be asked whether they prescribe the drug themselves. Such invitations are lucrative to the physicians selected for these bureaus; honorarium rates range from \$800 to \$2,000 per program, depending on the type of event, speaker training is typically compensated at \$500 per hour.

276. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; a forum in which to further market to the speaker him or herself; and an opportunity to market to the speaker’s peers. Defendants grade their speakers and future opportunities are based on speaking performance, post-program sales, and product usage. Defendants also track the prescribing of event attendees. It would make little sense for Defendants to devote significant resources to programs that did not increase their sales.

277. Like the sales representatives who select them, speakers are expected to stay “on message”—indeed, they agree in writing to follow the slide decks provided to them. Endo’s

speaker rules, for example, provide that “all slides must be presented in their entirety and without alterations . . . and in sequence.” This is important because the FDA regards promotional talks as part of product labeling and requires their submission for review. Speakers thus give the appearance of providing independent, unbiased presentations on opioids, when in fact they are presenting a script prepared by Defendants’ marketing departments. Although these meal-based speaker events are more expensive to host, and typically have lower attendance than CMEs, they are subject to less professional scrutiny and thus afford Defendants greater freedom in the messages they present.

278. Defendants devoted massive resources to these direct sales contacts with prescribers.

279. Defendants have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that detailers’ sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors’ prescribing habits,⁶² and face-to-face detailing has the highest influence on intent to prescribe. Defendants could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers whom they targeted for detailing, and who responded by prescribing more of Defendants’ drugs.

3. Defendants Directed These Promotional Efforts Through Detailed Marketing Plans.

⁶² See, e.g., Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue’s sales force and trebling of annual sales calls).

280. Defendants guided their efforts to expand opioid prescribing through comprehensive marketing and business plans for each drug. These documents, based on the companies' extensive market research, laid out ambitious plans to bring in new prescribers and increase overall prescribing of Defendants' opioids.

a. Targeting categories of prescribers

281. Defendants targeted, by zip codes and other local boundaries, individual health care providers for detailing. Defendants chose their targets based on the potential for persuading a provider to prescribe, ease of in-person access, and the likelihood of higher numbers of prescriptions at higher doses, with no correlation to demonstrated need or demand for opioid therapy, or to risk of abuse.

282. Collectively, Defendants' marketing plans evince dual strategies, which often operated parallel to one another. Defendants' sales representatives continued to focus their detailing efforts on pain specialists and anesthesiologists, the highest-volume prescribers of opioids and, as a group, more educated than other practitioners about opioids' risks and benefits. Seeking to develop market share and expand sales, however, Defendants also targeted increasing numbers and types of prescribers for marketing.

283. This expanded market of prescribers was, as a group, less informed about opioids and, as market research concluded, more susceptible to Defendants' marketing messages.

284. The expanded market also included internists and general practitioners who were low- to mid-volume prescribers.

b. Increasing "direct to consumer" marketing

285. Defendants knew that physicians were more likely to prescribe their branded medications when patients asked for those medications. Defendants thus increasingly took their

opioid sales campaigns directly to consumers, including through patient-focused “education and support” materials. These took the form of pamphlets, videos, or other publications that patients could view in their physician’s office, as well as employer and workers’ compensation plan initiatives.

286. Defendants also knew that one of the largest obstacles to patients starting and remaining on their branded opioids—including by switching from a competitor’s drug—was out-of-pocket cost. They recognized they could overcome this obstacle by providing patients financial assistance with their insurance co-payments, and each of the Defendants did so through vouchers and coupons distributed during detailing visits with prescribers.

c. Differentiating each brand

287. Purdue’s OxyContin was the clear market leader in prescription opioid therapy, with 30% of the market for analgesic drugs in 2012. However, by 2010, Defendants had begun facing increasing pushback from the medical community and regulators based on the growing problems of opioid addiction and abuse. Both market conditions prompted Defendants to pursue product differentiation strategies—particularly an emphasis on their products being less subject to diversion, abuse, and addiction—as a means of grabbing market share from Purdue and other competitors.

d. Moving beyond office visits

288. Defendants sought to reach additional prescribers by expanding beyond traditional sales calls and speaker events to new channels for their messages. For their sales forces, these included marketing to prescribers through voice mail, postcards, and email—so-called “e-detailing.” Defendants also created new platforms for their speakers by implementing “peer to peer” programs such as teleconferences and webinars that were available to prescribers nationally.

These programs allowed Defendants to use this more seemingly credible vehicle to market to, among other hard-to-reach audiences, prescribers at hospitals, academic centers, and other locations that limit or prohibit in-person detailing. Employing these new approaches, each Defendant relied heavily on speakers to promote its drugs.

4. Defendants Marketed Opioids in Plaintiffs' Geographic Area Using the Same Strategies and Messages They Employed Nationwide.

289. Defendants employed the same marketing plans and strategies and deployed the same messages in Plaintiffs' geographic area as they did nationwide.

290. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

291. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors traveled with them periodically to check on both their performance and compliance.

292. As they did nationwide, Defendants extensively tracked the prescribing behavior of City-area health care providers and used that data to target their detailing and speaker- recruiting

efforts. Top prescribers were profiled at Plaintiffs' geographic area, region, zip code, and sometimes facility levels, with information about their specialty, prescribing patterns (including product and dose), product loyalty and refill history. Providers' prescribing volume was ranked and sorted into deciles.

293. As described herein, misrepresentations and deceptions regarding the risks, benefits, and superiority of opioid use to treat chronic pain were part and parcel of Defendants' marketing campaigns in Plaintiffs' geographic area.

C. Defendants Used "Unbranded" Marketing to Evade Regulations and Consumer Protection Laws.

294. In addition to their direct marketing efforts, Defendants used unbranded, third-party marketing, which they deployed as part of their national marketing strategies for their branded drugs. Each Defendant executed these strategies through a network of third-party KOLs and Front Groups, with which it acted in concert by funding, assisting, encouraging, and directing their efforts. At the same time, Defendants exercised substantial control over the content of the messages third parties generated and disseminated and distributed certain of those materials themselves. As with their other marketing strategies, Defendants' unbranded marketing created, and relied upon, an appearance of independence and credibility that was undeserved but central to its effectiveness. Unlike their direct promotional activities, Defendants' unbranded marketing allowed them to evade the oversight of federal regulators and gave them greater freedom to expand their deceptive messages.

1. Regulations Governing Branded Promotion Require that it Be Truthful, Balanced, and Supported by Substantial Evidence.

295. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. A drug 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 false or misleading statements or material omissions; and (c) fairly balance the drug’s benefits and risks.⁶³ The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

296. Further, the Federal Food, Drug, and Cosmetic Act (“FDCA”) prohibits the sale in interstate commerce of drugs that are “misbranded.” A drug is “misbranded” if it lacks “adequate directions for use” or if the label is false or misleading “in any particular.”⁶⁴ “Adequate directions for use” are directions “under which the layman can use a drug safely and for the purposes for which it is intended.”⁶⁵ “Labeling” includes more than the drug’s physical label; it also includes “all . . . other written, printed, or graphic matter . . . accompanying” the drug, including promotional material.⁶⁶ “The term “accompanying” is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.”⁶⁷ Thus, Defendants’ promotional materials are part of their drugs’ labels and are required to be accurate, balanced, and not misleading.

297. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product’s risks. “The most serious risks set forth in a product’s labeling

⁶³ 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

⁶⁴ 21 U.S.C. §§ 352.

⁶⁵ 21 C.F.R. § 201.5.

⁶⁶ 21 U.S.C. § 321(m).

⁶⁷ *See id.*

are generally material to **any** presentation of efficacy.” The FDA notes that “[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included.”⁶⁸ Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

298. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug’s safety or efficacy or present conclusions that “clearly cannot be supported by the results of the study.”⁶⁹ Further, drug companies must not make comparisons between their drugs and other drugs that represent or suggest that “a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.”⁷⁰

299. While the FDA must approve a drug’s label, it is the drug company’s responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information.⁷¹ Promotional materials also must be submitted to the FDA when they are first used or disseminated. The FDA does not have to approve these materials in advance; if, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address

⁶⁸ FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, May 2009, at 14.

⁶⁹ 21 C.F.R. § 99.101(a)(4).

⁷⁰ 21 C.F.R. § 202.1(e)(6)(ii).

⁷¹ See 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); see also *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6) (iii)(A-C) (allowing manufacturers to make changes that “strengthen . . . a warning, precaution, or adverse reaction” or “strengthen a statement about drug abuse, dependence, psychological effect, or overdose”).

promotions involving safety or health risks and indicate the FDA may take further enforcement action.

2. Defendants Deployed Front Groups and Doctors to Disseminate Unbranded Information on Their Behalf.

300. Drug companies market both directly and indirectly, using third party validators (such as scientists, physicians, patient or professional organizations) that appear to be independent and therefore more credible. The FDA has made clear that its promotional requirements apply to both forms of marketing:

FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf.

....

Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third-party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.⁷²

301. In addition to being carried out directly or through third parties, drug companies' promotional activity can be branded or unbranded; unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can sidestep the extensive regulatory framework governing branded communications.

302. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing

⁷² FDA, *Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, January 2014, at 1, 4, <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm381352.pdf> (accessed May 30, 2017).

materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Defendants, with their own knowledge of the risks, benefits, and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

303. Even where such unbranded messages were channeled through third-party vehicles, Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Unbranded brochures and other materials that are "disseminated by or on behalf of [the] manufacturer" constitute drug "labeling" that may not be false or misleading in any particular. *See* 21. C.F.R. 202.1(e)(7)(l)(2).⁷³ Defendants' sales representatives distributed third-party marketing material that was deceptive to Defendants' target audiences. Defendants are responsible for these materials.

304. Moreover, Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials,

⁷³ This regulation provides: "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and the references published . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling, as defined in section 201(m) of the act." As labeling, such third party-created content distributed by a drug company may not be misleading and must meet the accuracy, substantiation, and fair balance requirements in the FDCA.

Defendants exercised control over their deceptive messages and acted in concert⁷⁴ with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

305. For example, drug companies have been admonished for making functional claims in FDA-reviewed branded materials if there is no evidence for such claims. Thus, drug companies were put on notice that the FDA would not allow such claims in branded materials. Defendants instead created and disseminated these same unsupported claims—that opioids allow patients to sleep, return to work, or walk more easily—through *unbranded* marketing materials.

306. The third-party publications Defendants assisted in creating and distributing did not include the warnings and instructions mandated by their FDA-required drug labels and consistent with the risks and benefits known to Defendants. For example, these publications either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction.

307. By acting through third parties, Defendants were able to both avoid FDA scrutiny and give the false appearance that the messages reflected the views of independent third parties. Later, Defendants would cite to these sources as “independent” corroboration of their own statements. As one physician adviser to Defendants noted, third-party documents not only had greater credibility, but broader distribution as doctors did not “push back” at having materials from, for example, the non-profit American Pain Foundation (“APF”) on display in their offices, as they might with first party, drug company pieces. Nevertheless, the independence of these materials was a ruse—Defendants were in close contact with these third parties, paid for and were aware of the

⁷⁴ As used in this Complaint, the allegation that Defendants “acted in concert” with third parties is intended to mean *both* that they conspired with these third parties to achieve some end and that they aided and abetted these third parties in the commission of acts necessary to achieve it.

misleading information they were disseminating about the use of opioids to treat chronic pain, and regularly helped them to tailor and distribute their misleading, pro-opioid messaging.

308. As part of a strategic marketing scheme, Defendants spread and validated their deceptive messages through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

a. Defendants' Use of KOLs

309. Defendants cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid Defendants by touting the benefits of opioids to treat chronic pain.

310. Pro-opioid doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of pro-opioid advocacy groups and professional societies that develop,

select, and present CMEs. Defendants were able to exert control of each of these modalities through their KOLs.

311. In return, the KOLs' association with Defendants provided not only money, but prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community.

312. Although some KOLs initially may have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.⁷⁵ These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

313. Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy. Indeed, one prominent KOL sponsored by pharmaceutical companies, Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding.

314. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many

⁷⁵ Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

315. Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences.

316. These KOLs were carefully vetted to ensure that they were likely to remain on-message and supportive of a pharmaceutical industry agenda. One measure was a doctor's prior work for trusted Front Groups.

317. Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said—as they did with all their recruited speakers. The KOLs knew, or deliberately ignored, the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Defendants, all the while causing harm to prescribers and patients within Plaintiffs' geographic area.

b. “Research” That Lacked Supporting Evidence

318. Rather than find a way to actually test the safety and efficacy of opioids for long-term use, Defendants led people to believe that they already had. 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 thus more likely to shape the perceptions of prescribers, patients and payors. This literature was, in fact, marketing material focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

319. To accomplish this, Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals. Defendants’ internal documents reveal plans to submit research papers and “studies” to long lists of journals, including back-up options and last resort, “fast-track” application journals, that they could use if the pending paper was rejected everywhere else.

320. Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. The plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development or any other area that would have specialized knowledge about the drugs and their effects on patients, but in Defendants’ marketing departments and with Defendants’ marketing and public relations consultants. Defendants often relied on “data on file” or presented posters, neither of which are subject to peer review. They also published their articles not through a competitive process, but in paid journal supplements, which allowed Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

321. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study. Most notably, Purdue promoted a 1980 reference in the well-respected *New England Journal of Medicine*: J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (1980) (“Porter-Jick Letter”). It is cited 856 times in Google Scholar, and 86 times since 2010. It also appears as a reference in two CME programs in

2012 sponsored by Purdue and Endo.⁷⁶ Defendants and those acting on their behalf fail to reveal that this “article” is actually a letter-to-the-editor, not a peer-reviewed study (or any kind of study at all). The Porter-Jick Letter, reproduced in full below, describes a review of the charts of hospitalized patients who had received opioids. (Because it was a 1980 study, standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.)

**ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS**

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

**JANE PORTER
HERSHEL JICK, M.D.**
Boston Collaborative Drug
Surveillance Program
Boston University Medical Center

Waltham, MA 02154

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol*. 1978; 18:180-8.

322. The Porter-Jick Letter notes that, when these patients’ records were reviewed, it found almost no references to signs of addiction, though there is no indication that caregivers were instructed to assess or document signs of addiction. None of these serious limitations is disclosed when Defendants, or those acting on their behalf, cite the Porter-Jick Letter, typically as the sole scientific support for the proposition that opioids are rarely addictive, even when taken long-term. In fact, Dr. Jick later complained that his letter had been distorted and misused.

⁷⁶ AAPM, Safe Opioid Prescribing Course, February 25-26, 2012, sponsored by Purdue and Endo; “Chronic Pain Management and Opioid Use,” October 11, 2012, sponsored by Purdue. Each CME is available for online credit, including to prescribers in Genessee City.

323. Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Defendants—often with the help of third-party consultants—targeted a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

324. Defendants' strategies—first, to plant and promote supportive literature and then, to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicts those claims—are in dereliction of their legal obligations. The strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief resulting in distorted prescribing patterns.

c. Treatment Guidelines

325. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts, nor trained, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Furthermore, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

i. *FSMB*

326. 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.

327. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (“FSMB Guidelines”), which FSMB admitted was produced “in collaboration with pharmaceutical companies.”⁷⁷ The FSMB Guidelines taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and they discussed addiction only in the sense that “inadequate understandings” of addiction can lead to “inadequate pain control.”

328. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also make these same claims. These guidelines were posted online and were available to and intended to reach City physicians.

329. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies for bulk sales and distribution to sales representatives (for distribution to prescribing doctors).

330. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), and the FSMB benefitted by earning approximately \$250,000 in revenue and commissions from their sale. The FSMB website

⁷⁷ FSMB, “Position of the FSMB in Support of Adoption of Pain Management Guidelines” (1998).

describes the book as the “leading continuing medication education (CME) activity for prescribers of opioid medications.”

331. Drug companies relied on FSMB guidelines to convey the message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors’ fear of discipline on its head—doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

332. FSMB, more recently, has moderated its stance. Although the 2012 revision of *Responsible Opioid Prescribing* continued to teach that “pseudoaddiction” is real and that opioid addiction risk can be managed through risk screening, it no longer recommended chronic opioid therapy as a first choice after the failure of over-the-counter medication and has heightened its addiction and risk warnings.

ii. *AAPM/APS Guidelines*

333. AAPM and the APS are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013 (with AAPM receiving over \$2 million).

334. They issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.⁷⁸ The co-author of the statement, Dr. Haddox, was, at the time, a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM’s website until

⁷⁸ Consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), available at <http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf> (accessed May 30, 2017).

2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.⁷⁹

335. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines" or "Consensus Recommendations") and continued to recommend the use of opioids to treat chronic pain.⁸⁰ Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah.

336. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Plaintiffs' geographic area during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

337. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

iii. *American Geriatrics Society*

⁷⁹ *Id.*

⁸⁰ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) The Journal of Pain: Official Journal of the American Pain Society 113-130 (2009)

338. The American Geriatrics Society (“AGS”), a nonprofit organization serving health care professionals who work with the elderly, disseminated 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 “2009 AGS Guidelines”). The 2009 AGS Guidelines included the following recommendations: “All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation),” and “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.”⁸¹ These recommendations, which continue to appear on AGS’s website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

339. AGS contracted with Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. These Defendants were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were first published online on July 2, 2009. Internal AGS 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 the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed and allowing these companies to determine whether to provide support only after they had approved the message, AGS ceded significant control to these companies.

⁸¹ Pharmacological Management of Persistent Pain in Older Persons, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2009.00699.x/full> (accessed May 30, 2017).

340. According to one news report, AGS has received \$344,000 in funding from opioid makers since 2009.⁸² The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

iv. *Guidelines That Did Not Receive Defendants' Support*

341. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines—the authors of which did not accept drug company funding—reached very different conclusions. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, 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.” ASIPP’s 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.” ASIPP recommends long-acting opioids in high doses only “in specific circumstances with severe intractable pain” and only when coupled with “continuous adherence monitoring, in well- selected populations, in conjunction with

⁸² John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel, May 30, 2012.

or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects.”⁸³

342. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental 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,” while conceding there may be patients for whom opioid therapy is appropriate.⁸⁴

343. The *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the U.S. Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) in 2010, notes that their review:

revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps . . . include: lack of effectiveness studies on long-term benefits and harms of opioids . . . ; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification . . . ; lack of evidence on the utility of informed consent and opioid management plans . . . ; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse.⁸⁵

d. Continuing Medical Education

344. CMEs are ongoing professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional

⁸³ 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).

⁸⁴ *American College of Occupational and Environmental Medicine’s Guidelines for the Chronic Use of Opioids*, (2011), available at: <https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf> (accessed May 30, 2017).

⁸⁵ 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 http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf (accessed May 30, 2017).

organizations' conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs are typically delivered 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.

345. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

346. In all, 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.

347. The American Medical Association ("AMA") has recognized 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 urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."⁸⁶

⁸⁶ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011), available at http://eo2.commpartners.com/users/ama/downloads/120328_Opinion_E-9_0115.pdf (accessed May 30, 2017).

348. Dozens of CMEs that were available to and attended or reviewed by doctors within Plaintiffs' geographical area during the relevant time period did not live up to the AMA's standards.

349. The influence of Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non-industry-funded CME mentioned the risks of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.⁸⁷

350. By sponsoring CME programs presented by Front Groups like APF, AAPM, and others, Defendants could expect messages to be favorable to them, as these organizations were otherwise dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and 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.

⁸⁷ Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010), available at pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf.

e. Unbranded Patient Education

351. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in “increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats.”⁸⁸ Evidence also demonstrates that physicians are willing to acquiesce to patient demands for a particular drug— even for opioids and for conditions for which they are not generally recommended.⁸⁹ An Actavis marketing plan, for example, noted that “[d]irect-to-consumer marketing affects prescribing decisions.” Recognizing this fact, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

352. The drug companies expect that they will recoup their investment in direct-to-consumer advertisements by capturing at least some of any additional prescriptions that result from patients “asking their doctor” about drugs that can treat their pain. Doctors also may review direct-to-consumer materials sales representatives give them to distribute to patients.

f. Defendants’ Use of Front Groups

353. As noted above, Cephalon, Endo, Janssen, and Purdue entered into arrangements with numerous organizations to promote opioids. These organizations depend upon Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Defendants’ marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They

⁸⁸ Kanika Johar, *An Insider’s Perspective: Defense of the Pharmaceutical Industry’s Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

⁸⁹ Prescribers often accede 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. 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).

developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

354. Several representative examples of such Front Groups are highlighted below, but there are others, too, such as APS, AGS, FSMB, American Chronic Pain Association (“ACPA”), AAPM, American Society of Pain Educators (“ASPE”), NPF, and PPSG.

i. *American Pain Foundation*

355. The most prominent of Front Groups was APF, which received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

356. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach residents.

357. In addition to Perry Fine, Russell Portenoy, and Scott Fishman, who served on APF’s Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

358. In 2009 and 2010, more than 80% of APF’s operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received

about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies out of total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from pharmaceutical companies to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

359. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide “patient representatives” for Defendants’ promotional activities, including Purdue’s *Partners Against Pain* and Janssen’s *Let’s Talk Pain*. As laid out below, APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in nonprofit organizations that share [its] business interests.”

360. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications APF could pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

361. APF assisted in other marketing projects for drug companies. One project funded by another drug company—*APF Reporter’s Guide: Covering Pain and Its Management* (2008)⁹⁰—recycled text that was originally created as part of the company’s training document.

⁹⁰ <https://assets.documentcloud.org/documents/277606/apf-reporters-guide.pdf> (accessed May 30, 2017).

362. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, “I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?”

363. The close relationship between APF and the drug company was not unique. APF’s clear lack of independence—in its finances, management, and mission—and its willingness to allow Defendants to control its activities and messages, support an inference that each Defendant that worked with APF was able to exercise editorial control over its publications.

364. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF’s credibility as an objective and neutral third party and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF’s board voted to dissolve the organization “due to irreparable economic circumstances.” APF “cease[d] to exist, effective immediately.”⁹¹

ii. *The American Academy of Pain Medicine*

365. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants’ deceptive marketing of chronic opioid therapy.

366. AAPM has received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintains a corporate relations council, whose members pay \$25,000 per

⁹¹ <http://www.painfoundation.org> (last visited May 30, 2017).

year (on top of other funding) to participate. The benefits include allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an “exclusive venue” for offering education programs to doctors.

367. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings.

368. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”⁹²

369. AAPM's staff understood that they and their industry funders were engaged in a common practice. Defendants were able to influence AAPM through both their significant and regular funding, and the leadership of pro-opioid KOLs within the organization.

3. Defendants Acted in Concert with KOLs and Front Groups in the Creation, Promotion, and Control of Unbranded Marketing.

370. Like cigarette manufacturers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively present the risks, benefits, and superiority of opioids to treat chronic pain.

⁹² Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), <http://www.medscape.org/viewarticle/500829> (accessed May 30, 2017).

371. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages. These KOLs have worked reciprocally with Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated to prescribers and patients in Plaintiffs' geographic area.

372. One vehicle for their collective collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and to "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the Forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

373. PCF is comprised of representatives from opioid manufacturers and distributors; doctors and nurses in the field of pain care; professional organizations (*e.g.*, American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other like-minded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendants.

374. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.⁹³ This was critical as a REMS that went too far in narrowing the uses or benefits, or highlighting the risks of chronic opioid therapy, would deflate Defendants' marketing efforts. The recommendations—drafted by

⁹³ The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

Will Rowe of APF—claimed that opioids were “essential” to the management of pain, and that the REMS “should acknowledge the importance of opioids in the management of pain and should not introduce new barriers.”⁹⁴ Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

4. Defendants Targeted Vulnerable and Lucrative Populations.

a. The Elderly

375. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which, as Defendants acknowledge in their labels (but not in their marketing), occurs more frequently in elderly patients. A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs. Defendants’ targeted marketing to the elderly and the absence of cautionary language in their promotional materials flies in the face of scientific evidence and their own labels and creates a heightened risk of serious injury to elderly patients.

376. Defendants also promoted the notion—also without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids.

377. Defendants’ efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

b. Veterans

⁹⁴ Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

378. Veterans, too, are suffering greatly from the effects of Defendants' targeted marketing. A 2008 survey showed that prescription drug abuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001. Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days. Although many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment. Among former service members receiving VA services nationally in a single year (2005), 1,013 had died of accidental drug overdoses—double the rate of the civilian population.

379. Plaintiffs have a substantial population of veterans who must cope with the consequences of overprescribing opioids.

380. Opioids are particularly dangerous to veterans. According to a study published in the 2013 *Journal of American Medicine*, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death. According to a VA Office of Inspector General Report, despite the risks, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines.⁹⁵ Again, as with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids pose to them.

⁹⁵ <https://www.va.gov/oig/pubs/VAOIG-14-00895-163.pdf> (accessed May 30, 2017).

381. *Exit Wounds*, a 2009 publication sponsored by Purdue, distributed by APF with grants from Janssen and Endo, and written as a personal narrative of one veteran, describes opioids as “underused” and the “gold standard of pain medications” and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications “increase a person’s level of functioning” and that “[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications.” The book also asserts that “[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards.” As laid out above, the FSMB itself received support from Defendants during the time it created and published its guidelines.

382. *Exit Wounds* minimizes the risks of chronic opioid therapy and does not disclose the risk that opioids may have fatal interactions with benzodiazepines, which were taken by a significant number of veterans.⁹⁶ It is not the unbiased narrative of a returning war veteran. The American Pain Foundation’s name is prominently marked on the book’s spine. Dr. Scott Fishman, then-chair of the APF, wrote the book’s preface, which touted the APF as “an organization that raises public awareness, provides education, promotes research, and advocates for improved access to effective pain management – answering the unmet needs of our active military and veterans in pain.”

383. The deceptive nature of *Exit Wounds* is obvious in comparing it to guidance on opioids published by the VA and DOD in 2010 and 2011. The VA’s *Taking Opioids Responsibly* describes opioids as “dangerous.” It cautions against taking extra doses and mentions the risk of

⁹⁶ FDA guidance states that materials designed to target a particular audience should disclose risks particular to that audience. See FDA Notice, Guidance for Industry, “Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs,” August 6, 2015.

overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death—none of which is disclosed in *Exit Wounds*.

D. Why Defendants' Marketing Messages Are Misleading and Unfair.

384. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The Defendants and their allies had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.

385. Defendants' marketing of opioids for long-term use to treat chronic pain, both directly and with and through third parties, included information that was false, misleading, contrary to credible scientific evidence and their own labels, and lacked balance and substantiation. Their marketing materials omitted material information about the risks of opioids and overstated their benefits. Moreover, Defendants inaccurately suggested that chronic opioid therapy was supported by evidence and failed to disclose the lack of evidence in support of treating chronic pain with opioids.

386. There are seven primary misleading and unfounded representations. Defendants and the third parties with which they teamed:

- misrepresented that opioids improve function;
- concealed the link between long-term use of opioids and addiction;
- misrepresented that addiction risk can be managed;
- masked the signs of addiction by calling them “pseudoaddiction”;

- falsely claimed withdrawal is easily managed;
- misrepresented or omitted the greater dangers from higher doses of opioids; and
- deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

387. Exacerbating each of these misrepresentations and deceptions was the collective effort of Defendants and third parties to hide from the medical community the fact that the FDA “is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks.”⁹⁷

1. Defendants and Their Third-Party Allies Misrepresented that Opioids Improve Function.

388. Each of the following materials was created with the expectation that, by instructing patients and prescribers that opioids would improve patients’ function and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy in the belief that failure to improve pain, function, or quality of life, could be overcome by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

389. However, not only is there no evidence of improvement in long-term functioning, a 2006 study-of-studies found that “[f]or functional outcomes . . . other analgesics were significantly more effective than were opioids.”⁹⁸ Studies of the use of opioids in chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients’ function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to

⁹⁷ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

⁹⁸ Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass’n J. 1589-1594 (2006). This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

return to work or physical activity.⁹⁹ Indeed, one Defendant's own internal marketing plans characterized functional improvement claims as "aspirational." Another acknowledged in 2012 that "[s]ignificant investment in clinical data [was] needed" to establish opioids' effect on mitigating quality of life issues, like social isolation.

390. The long-term use of opioids carries a host of serious side effects, including addiction, mental clouding and confusion, sleepiness, hyperalgesia, and immune-system and hormonal dysfunction that degrade, rather than improve, patients' ability to function. Defendants often omitted these adverse effects as well as certain risks of drug interactions from their publications.

2. Defendants and Their Third-Party Allies Concealed the Truth About the Risk of Addiction from Long-Term Opioid Use.

391. The fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. To reach chronic pain patients Defendants, and the Front Groups and KOLs that they directed, assisted, and collaborated with, had to overcome doctors' legitimate fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk—condemning patients to, among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. But for Defendants' campaign to convince doctors otherwise, finding benefits from opioid use for common chronic pain conditions sufficient to justify that risk would have, and previously had, posed a nearly insurmountable challenge.

⁹⁹ Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. They also were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

392. Through their well-funded, comprehensive marketing efforts, Defendants and their KOLs and Front Groups were able to change prescriber perceptions despite the well-settled historical understanding and clear evidence that opioids taken long-term are often addictive. Defendants and their third-party partners: (a) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (b) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk—and Defendants’ own labels—compelled disclosure.

393. Further, in addition to falsely claiming opioids had low addiction risk or omitting disclosure of the risk of addiction altogether, Defendants employed language that conveyed to prescribers that the drugs had lower potential for abuse and addiction. Further, in addition to making outright misrepresentations about the risk of addiction, or failing to disclose that serious risk at all, Defendants used code words that conveyed to prescribers that their opioid was less prone to abuse and addiction.

394. Each of the following was created with the expectation that, by instructing patients and prescribers that addiction rates are low, and that addiction is unlikely when opioids are prescribed for pain, doctors would prescribe opioids to more patients. For example, one publication sponsored exclusively by Purdue—APF’s 2011 *A Policymaker’s Guide to Understanding Pain & Its Management*—claimed that opioids are not prescribed often enough because of “misconceptions about opioid addiction.”¹⁰⁰

395. Acting directly or with and through third parties, each of the Defendants claimed that the potential for addiction from its drugs was relatively small, or non-existent, even though there was no scientific evidence to support those claims, and the available research contradicted

¹⁰⁰ <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (accessed May 30, 2017).

them. A recent literature survey found that while ranges of “problematic use” of opioids ranged from <1% to 81%,¹⁰¹ abuse averages between 21% and 29% and addiction between 8% and 12%.¹⁰² These estimates are well in line with Purdue’s own studies, showing that between 8% and 13% of OxyContin patients became addicted, but on which Purdue chose not to rely, instead citing the Porter-Jick letter.

396. The FDA has found that 20% of opioid patients use two or more pharmacies, 26% obtain opioids from two or more prescribers, and 16.5% seek early refills—all potential “red flags” for abuse or addiction.¹⁰³ The FDA in fact has ordered manufacturers of long-acting opioids to “[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain,” in recognition of the fact that it found “high rates of addiction” in the medical literature.¹⁰⁴

397. Of course, the significant (and growing) incidence of abuse, misuse, and addiction to opioids is also powerful evidence that Defendants’ statements regarding the low risk of addiction were, and are, untrue. This was well-known to Defendants who had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

¹⁰¹ Cited for the low end of that range was the 1980 Porter-Jick letter in the *New England Journal of Medicine*.

¹⁰² Kevin Vowels et al., *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, 156 PAIN 569-76 (April 2015).

¹⁰³ Len Paulozzi, M.D., “Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse,” available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM233244.pdf> (accessed May 30, 2017).

¹⁰⁴ September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics, available at <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf> (accessed May 30, 2017).; Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

398. Acting directly or through and with third parties, each of the Defendants claimed that the potential for addiction even from long-term use of its drugs was relatively small, or non-existent, despite the fact that the contention was false and there was no scientific evidence to support it. In addition to denying or minimizing the risk of addiction and abuse generally, Defendants also falsely claimed that their particular drugs were safer, less addictive, and less likely to be abused or diverted than their competitors' or predecessor drugs. In making these claims, Defendants said or implied that because their drug had a "steady-state" and did not produce peaks and valleys, which cause drug-seeking behavior—either to obtain the high or avoid the low—it was less likely to be abused or addicting. Defendants had no evidence to support any of these claims, which, by FDA regulation, must be based on head-to-head trials;¹⁰⁵ the claims also were false and misleading in that they misrepresented the risks of both the particular drug and opioids as a class.

399. Further, rather than honestly disclose the risk of addiction, Defendants, and the third parties they directed and assisted and whose materials they distributed, attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables; it was doctors who fail to treat their patients' chronic pains with opioids—not doctors who cause their patients to become addicted to opioids—who are failing their patients (and subject to discipline). Defendants and their third-party allies claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. This mantra of under-treated pain and under-used drugs reinforced Defendants' messages that the risks of addiction and abuse were not significant and were overblown.

¹⁰⁵ See *Guidance for Industry*, "Abuse-Deterrent Opioids—Evaluation and Labeling," April 2015 (describing requirements for premarket and postmarket studies).

3. Defendants and Their Third-Party Allies Misrepresented that Addiction Risk Can Be Avoided or Managed.

400. To this day, Defendants each continue to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted. Presumably only to explain why doctors encounter so many patients addicted to opioids, Defendants and their third-party allies have come to admit that some patients could become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

401. There are three fundamental flaws in these assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction. Second, there is no reliable scientific evidence that high-risk or addicted patients can take opioids long-term without triggering addiction, even with enhanced monitoring and precautions. Third, there is no reliable scientific evidence that patients without these red flags are necessarily free of addiction risk.

402. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. A recent Evidence Report by the Agency for Healthcare Research and Quality (“AHRQ”), which “systematically review[ed] the current evidence on long-term opioid therapy for chronic pain” identified “[n]o study” that had “evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse- deterrent formulations on

outcomes related to overdose, addiction, abuse or misuse.”¹⁰⁶ Furthermore, attempts to treat high-risk patients, such as those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening are not proven to work in the real world, if busy doctors even in fact attempt them.

403. Most disturbingly, despite the widespread use of screening tools, patients with past substance use disorders—which every tool rates as a risk factor—receive, on average, higher doses of opioids.

4. Defendants and Their Third-Party Allies Created Confusion By Promoting the Misleading Term “Pseudoaddiction.”

404. Defendants and their third-party allies developed and disseminated each of the following misrepresentations with the intent and expectation that, by instructing patients and prescribers that signs of addiction are actually the product of untreated pain, doctors would prescribe opioids to more patients and continue to prescribe them, and patients would continue to use opioids despite signs that the patient was addicted. The concept of “pseudoaddiction” was coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, who consulted for Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants’ treatment of this issue, highlighting the contrast between “undertreated pain” and “true addiction,” as if patients could not experience both. As KOL Dr. Lynn Webster wrote: “[Pseudoaddiction] obviously became too much of an excuse to give patients more medication... It lead us down a path that caused harm. It is already something we are debunking as a concept.”¹⁰⁷

5. Defendants and Their Third-Party Allies Claimed Withdrawal is Simply Managed.

¹⁰⁶ *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, Agency for Healthcare Res. & Quality (September 19, 2014).

¹⁰⁷ John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb.19, 2012).

405. Defendants and their third-party allies promoted the false and misleading messages below with the intent and expectation that, by misrepresenting the difficulty of withdrawing from opioids, prescribers and patients would be more likely to start chronic opioid therapy and would fail to recognize the actual risk of addiction.

406. In an effort to underplay the risk and impact of addiction, Defendants and their third-party allies frequently claim that, while patients become “physically” dependent on opioids, physical dependence can be addressed by gradually tapering patients’ doses to avoid the adverse effects of withdrawal. They fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs.

407. In reality, withdrawal is prevalent in patients after more than a few weeks of therapy. Common symptoms of withdrawal include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

6. Defendants and Their Third-Party Allies Misrepresented that Increased Doses Pose No Significant Additional Risks.

408. Each of the following misrepresentations was created with the intent and expectation that, by misrepresenting and failing to disclose the known risks of high dose opioids, prescribers and patients would be more likely to continue to prescribe and use opioids, even when they were not effective in reducing patients’ pain, and not to discontinue opioids even when tolerance required them to reach even higher doses.

409. Defendants and their third-party allies 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. Each of Defendants’ claims also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

410. These claims are false. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The FDA has itself acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—the signs of addiction.

7. Defendants and Their Third-Party Allies Deceptively Omitted or Minimized Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment.

411. Each of the following misrepresentations was created with the intent and expectation that, by omitting the known, serious risks of chronic opioid therapy, including the risks of addiction, abuse, overdose, and death, and emphasizing or exaggerating risks of competing products, prescribers and patients would be more likely to choose opioids. Defendants and their third-party allies routinely ignored the risks of chronic opioid therapy. These include (beyond the

risks associated with misuse, abuse, and addiction): hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;”¹⁰⁸ 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 withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions).¹⁰⁹

412. Despite these serious risks, Defendants asserted, or implied, that opioids were appropriate first-line treatments and safer than alternative treatments, including NSAIDs such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal, renal, and cardiac risks, particularly for elderly patients, Defendants’ exaggerated descriptions of those risks were deceptive in themselves, and also made their omissions regarding the risks of opioids all the more striking and misleading. Defendants and their third-party allies described over-the-counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000-20,000 deaths annually (more than opioids), when in reality the number is closer to 3,200. This description of NSAIDs starkly contrasted with their representation of opioids, for which the listed risks were nausea, constipation, and sleepiness (but not addiction, overdose, or death). Compared with NSAIDs, opioids are responsible for roughly four times as many fatalities annually.

¹⁰⁸ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

¹⁰⁹ Several of these risks do appear in the FDA-mandated warnings. *See, e.g.*, the August 13, 2015 OxyContin Label, Section 6.2, identifying adverse reactions including: “abuse, addiction ... death, ... hyperalgesia, hypogonadism ... mood altered ... overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria [hives].”

413. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.

E. Each Defendant Engaged in Deceptive Marketing, Both Branded and Unbranded, that Targeted and Reached City prescribers.

414. Defendants—and the Front Groups and KOLs who depended on and worked alongside them—were able to affect a sea change in medical opinion in favor of accepting opioids as a medically necessary long-term treatment for chronic pain. As set forth below, each Defendant contributed to that result through a combination of both direct marketing efforts and third-party marketing efforts over which that Defendants exercised editorial control. These deceptive and misleading statements were directed to, and reached, prescribers and patients in Plaintiffs' geographic area, with the intent of distorting their views on the risks, benefits, and superiority of opioids for treatment of chronic pain.

415. Defendants engaged in their deceptive marketing campaign, both nationwide and in Plaintiffs' geographic area, using a number of strategies. Defendants trained their sales forces and recruited physician speakers to deliver these deceptive messages and omissions, and they in turn conveyed them to prescribers. Defendants also broadly disseminated promotional messages and materials, both by delivering them personally to doctors during detailing visits and by mailing deceptive advertisements directly to prescribers. Because they are disseminated by Defendant drug manufacturers and relate to Defendants' drugs, these materials are considered "labeling" within the meaning of 21 C.F.R. § 1.3(a), which means Defendants are liable for their content.

416. Each of the misrepresentations received by these doctors constitutes an integral piece of a centrally directed marketing strategy to change medical perceptions regarding the use of opioids to treat chronic pain. Defendants were aware of each of these misrepresentations, and Defendants approved of them and oversaw their dissemination at the national, corporate level.

F. The Result of Defendants' Fraudulent Scheme.

417. Through their direct promotional efforts, along with those of the third-party Front Groups and KOLs they assisted and controlled, and whose seemingly objective materials they distributed, Defendants accomplished exactly what they set out to do: change the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain. As a result, doctors in Plaintiffs' geographic area began prescribing opioids long-term to treat chronic pain—something most would never have considered prior to Defendants' campaign.

418. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

1. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Plaintiffs.

419. In the first instance, Plaintiffs were damaged directly, through its payments of false claims for chronic opioid therapy by (a) partially funding a medical insurance plan for its employees and (b) its workers' compensation program.

420. Defendants' marketing of opioids caused health care providers to prescribe, and Plaintiffs' geographic area, through partially funding a medical insurance plan for its employees and its workers' compensation program, to pay for prescriptions of opioids to treat chronic pain.

Because of Defendants' unbranded marketing, health care providers wrote and Plaintiffs paid for prescriptions of opioids for chronic pain that were filled not only with their drugs, but with opioids sold by other manufacturers. All of these prescriptions were caused by Defendants' fraudulent marketing and therefore all of them constitute false claims. Because, as laid out below, Plaintiffs are obligated to cover medically necessary and reasonably required care, it had no choice but to pay for these false and fraudulent claims.

421. The fact that Plaintiffs would pay for these ineligible prescriptions was both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, and government payors such as Plaintiffs, to pay for long-term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

a. Increase in Opioid Prescribing Nationally

422. Defendants' scheme to change the medical consensus regarding opioid therapy for chronic pain was greatly successful. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide, rising to 257 million in 2009.¹¹⁰

423. Opioid prescriptions increased even as the percentage of patients visiting doctors for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that

¹¹⁰ Office of National Drug Control Policy, *2011 Prescription Drug Abuse Prevention Plan*, Whitehouse.gov, (no longer available on whitehouse.gov), <https://obamawhitehouse.archives.gov/ondcp/prescription-drug-abuse1> (accessed May 30, 2017).

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 of NSAID use.¹¹¹

424. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids. Indeed, “[o]pioids are the most common means of treatment for chronic pain.”¹¹² From 1980 to 2000, opioid prescriptions for chronic pain visits doubled. This resulted not from an epidemic of pain, but an epidemic of prescribing. A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010—even though the number of office visits in which patients complained of pain did not change and prescribing of non-opioid pain medications **decreased**. For back pain alone—one of the most common chronic pain conditions—the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady—and climbing.

425. This increase corresponds with, and was caused by, Defendants’ massive marketing push.

426. Defendants’ opioid detailing visits to individual doctors made up the largest component of this spending, with total detailing expenditures more than doubling between 2000 and 2014 to \$168 million annually.

b. Plaintiffs’ Increased Spending on Opioids

427. As a direct and foreseeable consequence of Defendants’ wrongful conduct, Plaintiffs have been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Defendants’ deceptive marketing campaign. Plaintiffs have incurred,

¹¹¹ Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care 870 (2013).

¹¹² Deborah Grady et al., *Opioids for Chronic Pain*, 171(16) Arch. Intern. Med. 1426 (2011).

and continues to incur, costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiffs and its residents.

i. *Defendants' Misrepresentations Were Material*

428. Defendants' misrepresentations were material to, and influenced, Plaintiffs' decisions to pay claims for opioids for chronic pain (and, therefore, to bear its consequential costs in treating overdose, addiction, and other side effects of opioid use). In the first instance, Plaintiffs would not have been presented with, or paid, claims for opioids that would not have been written but for Defendants' fraudulent and deceptive marketing. Second, Plaintiffs have demonstrated that Defendants' marketing is material by taking further steps to ensure that the opioids are only prescribed and covered when medically necessary or reasonably required.

429. As laid out above, Defendants' misrepresentations related to Plaintiffs' requirement that medical treatments be medically necessary or reasonably required – a condition of payment for any medical treatment under Plaintiffs' health plans and workers' compensation program. But for Defendants' fraudulent and deceptive marketing, prescribers would have accurately understood the risks and benefits of opioids and would not have prescribed opioids where not medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but the core of prescribers' decision-making.

430. It is Plaintiffs' practice not to pay claims that are not medically necessary or reasonably required. However, Plaintiffs would not have known whether a prescriber had made an

informed judgment that a particular claim for opioids was medically necessary or reasonably required, or, conversely had acted under the influence of Defendants' fraudulent and deceptive marketing. It is not clear from the face of a claim whether: (1) the patient suffered from cancer or another terminal condition, for example, where long-term prescribing was medically necessary or appropriate; or (2) the prescriber was exposed to Defendants' marketing materials, treatment guidelines, or education programs, or visited by a drug representative who engaged in affirmative misrepresentations or omissions, for example.

ii. *Plaintiffs' Increased Costs Correlate with Defendants' Promotion*

431. Plaintiffs' spending in connection with opioids rose along with Defendants' spending to promote opioids. That spending was directly impacted by opioid use (and its consequences in abuse, addiction, and overdose) in Plaintiffs' geographic area.

432. It is also distressing (and a sign of further problems ahead) that the drop in opioid prescribing beginning in 2014 has been accompanied by a corresponding increase in Defendants' promotional spending, which is headed towards a new high, despite evidence of the grave toll that opioids are taking on law enforcement, public health, and individual lives.

2. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Consumers in Plaintiffs' Geographic Area.

a. Increased Opioid Use Has Led to an Increase in Opioid Abuse, Addiction, and Death

433. Nationally, the sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and opioid abuse. "Deaths from opioid overdose have risen steadily since 1990 in parallel with

increasing prescription of these drugs.”¹¹³ Prescription opioid use contributed to 16,917 overdose deaths nationally in 2011—more than twice as many deaths as heroin and cocaine combined; drug poisonings now exceed motor vehicle accidents as a cause of death. More Americans have died from opioid overdoses than from participation in the Vietnam War.

434. Contrary to Defendants’ misrepresentations, most of the illicit use stems from *prescribed* opioids; in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet. According to the CDC, the 80% of opioid patients who take low-dose opioids from a single prescriber (in other words, who are not illicit users or “doctor-shoppers”) account for 20% of all prescription drug overdoses.

435. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).

436. Emergency room visits tied to opioid use likewise have sharply increased in Plaintiffs’ geographic area.

437. Widespread opioid use and abuse in Plaintiffs’ geographic area are problems even when they do not result in injury or death. Opioid addiction is affecting residents of all ages, ethnicities, and socio-economic backgrounds in Plaintiffs’ geographic area. Many addicts start with a legal opioid prescription—chronic back pain, fibromyalgia, or even dental pain—and do not realize they are addicted until they cannot stop taking the drugs.

¹¹³ Deborah Grady et al., *Opioids for Chronic Pain*, 171(16) Arch. Intern. Med. 1426 (2011).

438. These glaring omissions, described consistently by counselors and patients, mirror, and confirm Defendants’ drug representatives’ own widespread practice, as described above, of omitting any discussion of addiction from their sales presentations to physicians or in their “educational” materials.

b. Increased Opioid Use Has Increased Costs Related to Addiction Treatment

439. Plaintiffs have opioid treatment programs within their geographic areas, Substance Alternative Clinics, that provide a comprehensive treatment program for persons addicted to heroin or other opioids.

440. In addition to intense counseling, many treatment programs prescribe additional drugs to treat opioid addiction. Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction—buprenorphine/naloxone and naltrexone—were written and paid for. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payors to be \$72.5 billion.

c. Increased Opioid Use Has Fueled An Illegal Secondary Market for Narcotics and the Criminals Who Support It

441. Defendants’ success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants’ scheme supplies both ends of the secondary market for opioids—producing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that a “substantial increase in the nonmedical use of opioids is a predictable adverse

effect of substantial increases in the extent of prescriptive use.”¹¹⁴ It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors’ prescriptions.

442. A significant black market in prescription opioids also has arisen, not only creating and supplying additional addicts, but fueling other criminal activities.

443. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals. In 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006. Nearly 80% of those who used heroin in the past year had previously abused prescription opioids. Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street. In the words of one federal DEA official, “Who would have ever thought in this country it would be cheaper to buy heroin than pills . . . [t]hat is the reality we’re facing.”¹¹⁵

444. That reality holds true in Plaintiffs’ geographic area. According to addiction programs, a typical course sees addicts requesting more and more opioids from their doctors, who eventually cut them off. Many addicts then doctor-shop for additional prescriptions, and when that source runs out, turn to the streets to buy opioids illicitly. A significant number become heroin addicts. Addiction treatment programs, whose patient populations vary, reported rates of patients who had switched from prescription opioids to heroin ranging from half to 95%. Those addicts who do reach treatment centers often do so when their health, jobs, families and relationships reach the

¹¹⁴ G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308(18) JAMA 1865 (2012).

¹¹⁵ Matt Pearce & Tina Susman, *Philip Seymour Hoffman’s death calls attention to rise in heroin use*, L.A. Times, Feb. 3, 2014, <http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204> (accessed May 30, 2017).

breaking point, or after turning to criminal activity such as prostitution and theft to sustain their addiction. Unfortunately, few are successful in getting and staying clean; repeated relapse is common.

3. Defendants' Fraudulent Marketing Has Led to Record Profits.

445. While the use of opioids has taken an enormous toll on Plaintiffs and their residents, Defendants have gained blockbuster profits. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers nationally¹¹⁶—roughly one prescription per American adult. Opioids generated \$8 billion in revenue for drug companies just in 2010.

446. Financial information—where available—indicates that Defendants each experienced a material increase in sales, revenue, and profits from the fraudulent, misleading, and unfair market activities laid out above.

4. Defendants Fraudulently Concealed Their Misrepresentations.

447. At all times relevant to this Complaint, Defendants took steps to avoid detection of, and fraudulently conceal, their deceptive marketing and conspiratorial behavior.

448. First, and most prominently, Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Defendants purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

449. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and exerting final approval over

¹¹⁶ Press Release, Center for Disease Control, Opioid painkiller prescribing varies widely among states: Where you live makes a difference (July 1, 2014), <https://www.cdc.gov/media/releases/2014/p0701-opioid-painkiller.html> (accessed May 30, 2017).

their content. Defendants exerted their considerable influence on these promotional and “educational” materials.

450. 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 if they were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions they did not actually support. The true lack of support for Defendants’ deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by Plaintiffs.

451. Thus, while the opioid epidemic was evident, Defendants, in furtherance of their respective marketing strategies, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that Plaintiffs now assert. Plaintiffs were not alerted to the existence and scope of Defendants industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

452. Through their public statements, marketing, and advertising, Defendants’ deceptions deprived Plaintiffs of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

G. Defendants Entered into and Engaged in a Civil Conspiracy.

453. Defendants entered into a conspiracy to engage in the wrongful conduct complained of herein and intended to benefit both independently and jointly from their conspiratorial enterprise.

454. Each of the Defendants either actively participated and/or aided and abetted in the pursuance of this common purpose. Each of the participants in the opioid promotion enterprise described herein received substantial revenue from the scheme, in the form of sales for Manufacturer Defendants, sales and kickbacks for Distributor Defendants and Pharmacy Defendants who reached particular monthly goals, and rebates or other financial incentives for PBM Defendants who placed opioids in a preferred place on a formulary or otherwise made opioids available for improper use—all in an effort to maximize profits.

455. Defendants reached an agreement between themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, and others through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

456. At all relevant times, each Defendants was aware of the enterprise's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales, distributions, and prescriptions of opioids. In fact, Distributor and Pharmacy Defendants received kickbacks from Manufacturer Defendants if they reached particular monthly goals and PBM Defendants received rebates and other financial incentives to promote the Manufacturer Defendants' drugs to ensure they were widely sold.

457. This network is interconnected, interrelated and relied upon Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded collectively by Defendants, and Defendants relied upon the materials to intentionally mislead consumers and medical providers of the appropriate uses, risks and safety of opioids.

458. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Defendants committed overt acts in furtherance of their conspiracy.

H. Pharmacy Defendants Flooded the Market.

459. The Pharmacies earned enormous profits by flooding the country with prescription opioids.

460. The Pharmacies are all engaged in the business of selling opioids at retail locations. The failure of the Pharmacies to effectively monitor and report suspicious orders of prescription opioids at the retail level and to implement measures to prevent diversion through improper prescriptions greatly contributed to the vast increase in opioid overdose and addiction.

461. The Pharmacies' conduct directly caused a public health and law-enforcement crisis across this country, including in Plaintiffs' geographic area.

462. Each of the Pharmacies do substantial business throughout the United States. This business includes the distribution and retail sales of prescription opioids.

463. The Pharmacies distributed and sold at retail substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in Plaintiffs' geographic area. In addition, they distributed and sold at retail substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Plaintiffs' geographic area. The Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it and contributed substantially to the diversion problem.

464. Each participant in the supply chain of opioid distribution, including the Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity.

465. As sellers of substances known to be dangerous and addictive, the Pharmacies owe a common law duty to act with care in selling at retail these dangerous drugs. In particular, because the risks to public health of uncontrolled distribution of these substances are well-known, the Pharmacies are obliged to use reasonable care to prevent diversion of dangerous drugs.

466. Defendants' common-law duties parallel their obligations under state and federal law, which inform, and provide the standard of care for, these common law duties.

467. The Pharmacies, like manufacturers and wholesale distributors, are registrants under the federal Controlled Substances Act ("CSA"). 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

468. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

469. 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.

470. Additional types of suspicious orders 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.

471. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

472. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the Pharmacies 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.

473. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

474. Despite their legal obligations under the common law (and under the CSA), the Pharmacies failed to meet their obligations and allowed widespread diversion to occur—and they did so knowingly.

475. The Pharmacies’ failure 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.

476. The Pharmacies 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 crisis.

477. The Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

478. The Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

479. The Pharmacies 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.

480. The Pharmacies were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and

retail sellers. Yet, instead of taking any meaningful action to stem the flow of opioids into communities and prevent diversion, they continued to participate in the oversupply and profit from it.

481. The Pharmacies developed and maintained extensive data on opioids they distributed and sold in their retail stores. Through this data, Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Plaintiffs' geographic area. They used the data to evaluate their own sales activities and workforce. The Pharmacies also provided other Defendants with data regarding, inter alia, individual doctors in exchange for rebates or other forms of consideration. The Pharmacies' data is a valuable resource that they could have used to help stop diversion but failed to do so.

482. Performance metrics and prescription quotas adopted by the Pharmacies for their retail stores contributed to their failure to perform their duties.

483. The performance metric systems rate the pharmacist employees at the stores operated by Pharmacies based solely on productivity. These requirements place significant and unrealistic time pressures on the pharmacists.

484. The Pharmacies measure how many and how quickly prescriptions are filled daily based on store volume. Many of the Pharmacies' 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 retail Defendants' profits.

485. In addition to the pharmacist's other duties, Pharmacies required their employee pharmacists to fill more than 600 prescriptions per work shift.

486. At the same time that Pharmacies increased demands for productivity, they cut the hours of pharmacy technicians, leaving pharmacists severely understaffed and unable to provide all necessary services.

487. Pharmacies' 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.

488. 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.

489. Further, the National Association of Boards of Pharmacy found that performance metrics, which measure the speed and efficiency of prescription workflow—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.

490. The practices 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.

491. The Pharmacies' productivity policies are directly at odds with their performance of 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.

492. The Pharmacies 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.

493. The Pharmacies failed to adequately train their pharmacists and pharmacy techs 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 phone, false, forged, or otherwise illegal.

494. The Pharmacies failed to instruct their pharmacists and pharmacy techs on how to address situations in which they are forced to decline filling a prescription for a customer who submitted a prescription which a pharmacist has identified as suspicious.

495. The Pharmacies have failed to train their pharmacists and pharmacy techs on how to properly exercise their judgment with respect to determinations about whether a prescription is one that should be filled, or whether, under the law, the pharmacists should refuse to fill it.

496. The Pharmacies failed to adequately use data available to them to identify doctors that were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids.

497. The Pharmacies failed to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that contributed to the opioid crisis. The Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to

the population of the pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

498. The Pharmacies failed to conduct internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly.

499. The Pharmacies failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

500. The Pharmacies violated the Controlled Substances Act by failing to have in place policies and procedures to avoid the diversion of opioids.

501. The Pharmacies failed to speak with prescribing physicians prior to dispensing opioids.

502. The Pharmacies failed to take steps such as investigating whether a prescription was written within a prescriber's scope of practice.

503. The Pharmacies failed to investigate whether an opioid prescription was appropriate for the diagnosis.

504. The Pharmacies failed to investigate whether a therapeutic regimen is within the standard of care.

505. The Pharmacies failed to investigate and consider the length of an opioid prescription prior to dispensing.

506. The Pharmacies failed to review State Prescription Drug Monitoring databases prior to dispensing.

507. The Pharmacies failed to abide by internal company policies in the dispensing of opioids.

508. The Pharmacies 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. Indeed, several of the Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Pharmacies.

509. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

510. The litany of state and federal actions against the Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violate their legal obligations that govern the distribution and dispensing of prescription opioids.

511. Throughout the country and in Plaintiffs' geographic area in particular, the Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

512. From the vantage point of their retail pharmacy operations, the Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into Plaintiffs' geographic area and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion.

Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

513. The Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in Plaintiffs' community.

514. Because of (among other sources of information) regulatory and other actions taken against the Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

515. The Pharmacies' actions and omission 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.

516. The Pharmacies' failure to control the supply chain and prevent diversion adversely affected communities throughout the United States. Once diverted opioids do not stay put. Rather, diverted opioids move from areas of high supply to areas of high demand, traveling across state lines in a variety of ways.

517. First, prescriptions written in one state may, under some circumstances, be filled in a different state. But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them in another. When authorities in some states cracked down on opioid suppliers, suppliers in other states filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created fertile ground for pill mills. Residents of other states would

simply drive to Florida, stock up on pills from a pill mill, and transport them back home to sell. The practice became so common that authorities dubbed these individuals “prescription tourists.”

518. Thus, once diverted into the illegal market in one location, prescription opioids could then flow freely into Plaintiffs’ geographic area and elsewhere.

519. For this reason, the Pharmacies’ negligence in failing to prevent diversion in Ohio and throughout the United States, substantially contributed to the opioid crisis in Plaintiffs’ geographic area.

I. PBMs Ensured that Opioids Were Regularly Prescribed and Flooded the Market.

520. PBMs are brokers between payers (representing patients), drug manufacturers, and retailers and they influence which drug products are used most frequently and set prices for pharmacies.

521. The big three PBMs manage the drug benefits for nearly 95% of the population.¹¹⁷ They control what drugs are covered by virtually all health insurance providers for over 260 million people. PBMs made almost \$260 billion last year.¹¹⁸ In 2015 they covered most of the 4 billion retail prescriptions that were covered in the United States.¹¹⁹ They are key participants and play a crucial role in the administration of prescription drugs.¹²⁰

522. PBM influence is notable especially considering the lack of competition in the PBM space. Market concentration is an important indicator of a company’s ability to earn extraordinary

¹¹⁷ Brittany Hoffman-Eubanks, The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1, PHARMACY TIMES, Nov. 14, 2017, <http://www.pharmacytimes.com/news/the-role-of-pharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-perspectives-part-1>

¹¹⁸ John Breslin, Health care experts call for more transparency into PBMs, PATIENTDAILY, Dec. 20, 2017, <https://patientdaily.com/stories/511298841-health-care-experts-call-for-more-transparency-into-pbms>

¹¹⁹ Lydia Ramsey and Skye Gould, A huge pharma middleman just lost its biggest customer — and it shows how drug pricing really works, BUSINESS INSIDER, Apr. 25, 2017, <http://www.businessinsider.com/express-scripts-esrx-anthemnot-renewing-pbm-2017-4>

¹²⁰ Health Policy Brief, supra note 33.

returns, and several segments in the United States pharmaceutical distribution system are highly concentrated.¹²¹

523. With this kind of monopolistic structure, the top three PBMs have almost exclusive control over the dissemination of opioids. In concert with drug manufacturers who give them rebates as an incentive,¹²² they choose which drugs will be on a health insurance company's formulary, thus determining which drugs will be covered. If an insurance plan does not cover a drug, that drug will not enter the marketplace to be abused.

524. People with chronic pain are at the mercy of PBMs, yet PBMs make it more difficult to get pain medication that is less addictive and easier to get opioids, because opioids are generally cheaper than non-opioid alternatives. According to a study by the New York Times and ProPublica of 35.7 million people on Medicare prescription drug plans, in the second quarter of 2017 only one-third of them had access to pain medication less addictive than opioids.¹²³

525. The Manufacturer and PBM Defendants and their co-conspirators engaged in a conspiracy to increase the use of the least expensive, most addictive opioid by controlling the drugs' placement on the formulary. The PBM formularies are a critical piece of the enterprise described herein. The enterprise would not have succeeded absent the opioids' placement on the formulary. The formulary controlled which opioids were paid for, reimbursed, and covered by public and private pharmacy benefit plans.

526. The PBM and Manufacturer Defendants coordinated to ensure that the PBM Defendants got the maximum profit at the expense of patients.

¹²¹ Neeraj Sood, Tiffany Shih, Karen Van Nuys, Dana Goldman, Follow the Money: The Flow of Funds In the Pharmaceutical Distribution System, HEALTH AFFAIRS, Jun. 13, 2017, <https://www.healthaffairs.org/doi/10.1377/hblog20170613.060557/full/>

¹²² Health Policy Brief, *supra* note 33.

¹²³ Thomas and Ornstein, *supra* note 45.

527. Even when they were asked to limit accessibility to opioids, PBMs refused. The seeds of the opioid epidemic were sown with early overprescription of OxyContin. In 2001, when officials in the West Virginia state employee health plan tried to get Purdue, which manufactured OxyContin, to require pre-authorization, Purdue refused.¹²⁴ Using the financial quid pro quo it had with the state's PBM, it paid Merck Medco (now Express Scripts) to prevent insurers from limiting access to the drug:

The strategy to pay Merck Medco extended to other big pharmacy benefit managers and to many other states, according to a former Purdue official responsible for ensuring favorable treatment for OxyContin. The payments were in the form of "rebates" paid by Purdue to the companies. In return, the pharmacy benefit managers agreed to make the drug available without prior authorization and with low copayments.

"That was a national contract," Bernadette Katsur, the former Purdue official, who negotiated contracts with pharmacy benefit managers, said in an interview. "We would negotiate a certain rebate percentage for keeping it on a certain tier related to copay or whether it has prior authorization. We like to keep prior authorization off of any drug."¹²⁵

528. PBMs are "driving patients to opioids, away from abuse-deterrent form (ADF) and less addictive forms of opiates through formulary and pricing strategies."¹²⁶

529. Not only do PBMs place roadblocks in the way of limiting excessive opioid prescriptions, but they also make it more difficult to obtain Abuse Deterrent Formula (ADF) opioids. These pills are more difficult to physically alter (crushing to snort or dissolving to inject)

¹²⁴ David Armstrong, Drug maker thwarted plan to limit OxyContin prescriptions at dawn of opioid epidemic, STAT, Oct. 26, 2016, <https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/>

¹²⁵ *Id.*

¹²⁶ Charles L. Bennett MD PhD MPP, Do you have pain, cancer, or diabetes? Your PBM may now be your doctor for these illnesses, COLLABRX, Dec. 27, 2017, <http://www.collabrx.com/pain-cancer-diabetes-pbm-may-now-doctorillnesses/>

and therefore are less prone to abuse.¹²⁷ The three major PBMs carry at most 3 of the 10 FDA approved ADF opioids.¹²⁸ A study by Tufts CSSD found that ninety-six percent (96%) of all prescription opioids were non-ADF in 2015.¹²⁹

530. This denial was endorsed by the Institute for Clinical and Economic Review, a private organization funded in part by some of the largest health plans and PBMs, that claimed that ADF opioids provided neither financial or societal benefits, even though they were given data showing that ADF OxyContin could prevent 4,300 cases of abuse and save \$300 million over a five-year period.¹³⁰

ICER ignored research that demonstrated abuse deterrent Oxy reduced abuse by 20 percent and reduced the average daily dose of OxyContin from 80mg to 60mg. Perhaps even more important, it reduced sharing and selling of the drug for getting high (“diversion”) by nearly 90 percent. The diversion of generic painkillers is responsible for as many as 63 percent of fatal prescription drug overdoses. ICER consciously decided to ignore the human cost of this deadly behavior.

What the ICER report ignores entirely is that one of the factors driving abuse and addiction is the inappropriate use of generic opioids for conditions that have non-opioid, on-label options. Fifty-two percent of patients diagnosed with osteoarthritis receive an opioid pain medicine as first-line treatment, as do 43 percent of patients diagnosed with fibromyalgia and 42 percent of patients with diabetic peripheral neuropathy.¹³¹

531. What is inconceivable is that PBMs, while making it easy to obtain generic highly addictive opioids, make it harder to obtain treatment. The NY Times/ProPublica study found that

¹²⁷ Peter J. Pitts, Pharmacy benefit managers are driving the opioid epidemic, SW NEWS MEDIA, Nov. 21, 2017, http://www.swnnewsmedia.com/shakopee_valley_news/news/opinion/guest_columns/pharmacy-benefit-managersare-driving-the-opioid-epidemic/article_2f6be2a1-c7a3-5f8d-9f3e-,61d29d25c84b.html

¹²⁸ Charles L. Bennett MD PhD MPP, Do you have pain, cancer, or diabetes? Your PBM may now be your doctor for these illnesses, COLLABRX, Dec. 27, 2017, <http://www.collabrx.com/pain-cancer-diabetes-pbm-may-now-doctorillnesses/>

¹²⁹ Pitts, *supra* note 214.

¹³⁰ Robert Goldberg & Peter Pitts, ICER Perpetuates the Opioid Crisis, Morning Consult, MORNING CONSULT, May 11, 2017, <https://morningconsult.com/opinions/icer-perpetuates-opioid-crisis/>

¹³¹ *Id.*

insurers have erected more hurdles to approving addiction treatments than for the addictive substances themselves.¹³² Only after being subject to much public pressure and congressional investigations did some insurers remove the barriers to addiction treatment.

532. A 2008 study by the Mayo Clinic¹³³ found that patients who were weaned off opioids and followed a non-drug treatment experienced less pain than when they were on opioids and had improved functioning. Some plans cover these costs but other do not.¹³⁴

533. PBM Defendants fraudulently hid their financial relationship with Manufacturer, Distributor, and Pharmacy Defendants, making it impossible for Plaintiffs to discover the PBM Defendants' role in promoting opioids through reasonable diligence.

534. The Manufacturer Defendants knowingly and intentionally financially incentivized the PBM Defendants to place their opioids on the PBMs formularies irrespective of medical necessity, resulting in widespread and unnecessary overuse.

535. The PBM Defendants knowingly and intentionally chose to include opioids on their formularies that were more addictive to users because they generated greater profits. This failure led directly to the increased likelihood of addiction.

536. The PBM Defendants knowingly and intentionally chose to include opioids that were easier to misuse (for example, by crushing them into powder and mixing them with liquid in order to inject them) instead of Abuse Deterrent Formulations ("ADFs") which tended to be more expensive. This choice directly led to the ease with which the pills could be misused.

¹³² Thomas and Ornstein, *supra* note 45.

¹³³ Available at <https://www.ncbi.nlm.nih.gov/pubmed/18804915>

¹³⁴ Barry Meier and Abby Goodnough, New Ways To Treat Pain Meet Resistance, THE NEW YORK TIMES, Jun. 22, 2016, <https://www.nytimes.com/2016/06/23/business/new-ways-to-treat-pain-without-opioids-meet-resistance.html?mcubz=1>.

537. The PBM Defendants knowingly and intentionally made it more expensive or more difficult to obtain knowingly efficacious non-opioid medications for pain. This led directly to the increased sale and use of opioids.

538. The PBM Defendants knowingly and intentionally chose not to include certain medications that would prevent overdoses or made them more difficult or expensive to obtain.

539. The PBM Defendants chose not to cover or provide less coverage for drug treatment.

540. The PBM Defendants knowingly and intentionally created their formularies to ensure that an excessive number of pills were made available to users for use and abuse.

541. The PBM Defendants made deceptive representations about using opioids to treat chronic pain and/or omitting or concealing material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each PBM Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

542. The efforts to artificially increase the number of opioid prescriptions implemented by PBMs directly and predictably caused a corresponding increase in opioid abuse. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and **has increased in parallel with [opioid] overdoses.**”¹³⁵ Many abusers start with legitimate prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “[t]o reverse the epidemic of opioid drug overdose deaths and

¹³⁵ 3 Rose A Rudd, et al., Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014, MORBIDITY AND MORTALITY WKLY REP., Jan. 1, 2016, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (emphasis added)

prevent opioid-related morbidity.”¹³⁶ The PBMs’ role in increasing prescriptions played an enormous role in the current opioid epidemic.

543. The PBM Defendants also had the power to shut off the supply of illicit opioids into Plaintiffs’ geographic area.

544. The PBM Defendants had the power to minimize the sale and use of less effective, more addictive and more divertible opioids. They could have prohibited doctors from prescribing opioids for non-chronic pain when other non-opioid options were available. They could have responded favorably to direct requests from governmental payors attempting to control opioid flow. They could have made it easier for patients to access less addictive, less dangerous drugs.

545. There are steps the PBMs could take. They could make it easier to access other nonaddictive forms of pain relief. They could require doctors to start treating pain first with non-opioid pain medications as recommended by the CDC and turn to opioids as a last resort. They could cover alternative, non-medication treatments for pain. They could make addiction treatment more accessible. They could make their pricing more transparent so everyone could see if they were being improperly influenced by manufacturers to make choices for financial, not medical, reasons. No single actor is to blame for this epidemic, but PBMs have a unique role to play.

J. Defendants Flooded Plaintiffs’ Geographic Area with Suspiciously Large Amounts of Opioids.

546. The Distributor and Pharmacy Defendants are opioid distributors in Plaintiffs’ geographic area.

¹³⁶ *Id.*

547. The Distributor and Pharmacy Defendants purchased opioids from manufacturers, such as the named Defendants herein, and sold them to pharmacies throughout Plaintiffs' geographic area.

548. The Distributor and Pharmacy Defendants played an integral role in the chain of opioids being distributed throughout Plaintiffs' geographic area.

549. The Defendants were each on notice that the controlled substances they manufactured and distributed were the kinds that were susceptible to diversion for illegal purposes, abused, overused, and otherwise sought for illegal, unhealthy, and problematic purposes.

550. The Defendants were each on notice that there was an alarming and suspicious rise in manufacturing and distributing opioids to retailers within the Plaintiffs' geographic area during this time period.

551. As entities involved in the manufacture and distribution of opioid medications, Defendants were engaged in abnormally and/or inherently dangerous activity and had a duty of care under State and Federal Law.

552. The Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies including the DEA and State agencies.

553. The Defendants knew or should have known that they were supplying vast amounts of dangerous drugs to Plaintiffs that were already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

554. The Defendants failed in their duty to take any action to prevent or reduce the distribution of these drugs.

555. The Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the manufacture and flow of these drugs to Plaintiffs.

556. The Defendants, in the interest of their own massive profits, intentionally failed in this duty.

557. The Defendants have displayed a continuing pattern of failing to submit suspicious order reports.

558. Despite the charges, fines, and penalties brought against the Distributor and Pharmacy Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids, including into Plaintiffs' geographic area.

559. The Healthcare Distribution Management Association ("HDMA") created "Industry Compliance Guidelines" which stressed the critical role of each member of the supply chain in distributing controlled substances. The HDMA guidelines provided that "[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

560. Between the years in question, including 2006 through 2016, the Distributor and Pharmacy Defendants have shipped millions of doses of highly addictive controlled opioid pain killers into Plaintiffs' geographic area.

561. Many of these orders should have been stopped, or at the very least, investigated as potential suspicious orders.

562. The sheer volume of the increase in opioid pain medications, including OxyCodone, being distributed to retailers, should have put the Defendants on notice to investigate and report such orders.

563. The Defendants manufactured and delivered an excessive and unreasonable amount of opioid pain medications to retailers in Plaintiffs' geographic area.

564. Upon information and belief, the Defendants did not refuse to manufacture, ship, or supply any opioid medications to any pharmacy in Plaintiffs' geographic area from 2006 to the present.

565. The Defendants knew or should have known that they were manufacturing and distributing levels of opioid medications that far exceeded the legitimate needs of Plaintiffs.

566. The Defendants also paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications within Plaintiffs' geographic area.

567. The Defendants made substantial profits from the opioids sold in Plaintiffs' geographic area.

568. The Defendants violated State and Federal rules and regulations for manufacturers and distributors by failing to properly report suspicious orders.

569. By the actions and inactions described above, the Defendants showed a reckless disregard for the safety of the residents of Plaintiffs.

570. By the actions and inactions described above, the Defendants caused great harm to Plaintiffs.

571. On December 27, 2007, the U.S. Department of Justice, Drug Enforcement Administration, sent a letter to Defendants stating, "This letter is being sent to every entity in the United States registered with the Drug Enforcement Agency (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b)."

572. The DEA has provided briefings to each of the Defendants and conducted a variety of conferences regarding their duties under federal law.

573. The DEA sent a letter to each of the Defendants on September 26, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.” The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

574. The DEA sent a second letter to each of the Defendants on December 27, 2007. This letter reminded the Defendant Distributors of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious

depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the pattern throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

575. As a result of the decade-long refusal by the Defendants to abide by federal law, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 177 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. The Drug Enforcement

Administration's Adjudication of Registrant Actions, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014). The public record reveals many of these actions.

576. Rather than abide by these public safety statutes, the Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.¹³⁷

FIRST CAUSE OF ACTION

PUBLIC NUISANCE (AGAINST ALL DEFENDANTS)

577. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

578. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable

¹³⁷ See Lenny Bernstein and Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.d84d374ef062; Lenny Bernstein and Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.b44410552cde.

number of persons in Plaintiffs' geographic area by their production, promotion, and marketing of opioids for use by residents of Plaintiffs' geographic area.

579. Defendants' conduct and subsequent sale of its opioid products is not only unlawful and unreasonable but has also resulted in substantial and unreasonable interference with the public health, and the public's enjoyment of its right not to be defrauded or negligently injured.

580. The public nuisance is an absolute public nuisance because the Defendants' nuisance-creating conduct was intentional and unreasonable and/or violated statutes, such as 21 C.F.R. 1301.71(a), O.A.C. §§ 4729:5-1-01, 4729:5-2-01 et. seq., 4729:5-3-01 et. seq., 4729:5-4-01, 4729:5-8-01 et. seq., and O.R.C. §§ 4729.55, which established specific legal requirements for the protection of others.

581. Defendants have created and maintained an absolute public nuisance through their ongoing conduct of facilitating and encouraging the use of dangerously addictive opioids by colluding with manufacturers to place opioid drugs on formularies with preferred status, declining to impose limits on their approval for use in exchange for payments and fees from manufacturers, assisting in promoting but failing to disclose the real risks and appropriate limits on the use of opioids, and failing to use the wealth of data available to them to identify and address signs of over-prescribing, illegitimate and dangerous use of opioids, misuse, abuse, and diversion. Their conduct caused prescriptions and sales of opioids to skyrocket and failed to limit their use even as evidence of the epidemic mounted, including in Plaintiffs' geographic area, flooding Plaintiffs with opioids and facilitating and encouraging the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiffs and the residents of Plaintiffs' Communities.

582. Defendants' conduct is not insubstantial or fleeting. In fact, Defendants' unlawful conduct has so severely impacted public health on every geographic and demographic level that the public nuisance perpetrated by Defendants' conduct is commonly referred to as a "crisis" or an "epidemic." It has caused deaths, serious injuries, and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

583. Defendants' conduct constitutes a public nuisance.

584. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimate societal interest in the Manufacturer Defendants' dissemination of false "scientific" facts and advice in their pursuit of increased profits. There is no legitimate societal interest in the Distributor Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in the PBM Defendants promoting and reimbursing for pills that are more addictive and easier to divert purely for financial reasons by giving such drugs prime position on their formularies.

585. Defendants' conduct directly and proximately caused injury to Plaintiffs and its residents.

586. Plaintiffs and its residents suffered special injuries distinguishable from those suffered by the general public.

587. Defendants created and maintained a public nuisance which proximately caused injury to Plaintiff.

588. A public nuisance is an unreasonable interference with a right common to the general public.

589. PBM Defendants have created and maintained a public nuisance by colluding with manufacturers to make opioids more available, by ignoring evidence of addiction and misuse found in their own claims data, and by failing to maintain effective controls against diversion, leading to the oversupply of opioids in Plaintiffs' geographic area.

590. Defendants' actions unreasonably interfere with the public health, welfare, and safety in Plaintiffs' geographic area, and Plaintiffs and its residents have a common right to be free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person or property.

591. Defendants knew, or should have known, that their intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiffs and their residents.

592. The interference is unreasonable because Defendants' nuisance-creating conduct:

- a. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;
- b. At all relevant times was and is proscribed by state and federal laws and regulations; and/or
- c. Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

593. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

- a. The creation and fostering of an illegal, secondary market for prescription opioids;
- b. Easy access to prescription opioids by children and teenagers;
- c. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;
- d. Infants being born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;
- e. Employers have lost the value of productive and healthy employees; and
- f. Increased costs and expenses for Plaintiff relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

594. Defendants intentionally and unreasonably and/or unlawfully pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiffs' geographic area, a higher level of fear, discomfort and inconvenience to the residents of Plaintiffs, and direct costs to Plaintiffs and their residents.

595. Defendants are liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of the Defendants were a substantial factor in producing the public nuisance and harm to Plaintiffs.

596. At all times relevant to this Complaint, Defendants knew that increasing the availability of opioids would increase the number of opioids that would be abused, misused, and

diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

597. At all times relevant to this Complaint, Defendants knew that opioids were dangerous because these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

598. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Plaintiffs and the harm inflicted outweighs any offsetting benefit.

599. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiffs have suffered and will continue to suffer stigma damage, property damage, and damage to its proprietary interests.

600. The nuisance created by Defendants' conduct is abatable.

601. Defendants' misconduct alleged in this case is ongoing and persistent, as is the nuisance to which they substantially contributed.

602. Plaintiffs have incurred expenditures for special programs over and above Plaintiff's ordinary public services.

603. Plaintiffs assert this Cause of Action as a common law tort claim for absolute public nuisance and not as a "product liability claim" as defined in R.C. § 2307.71. In this claim, Plaintiffs does not seek damages for death, physical injury to person, emotional distress, or physical damages to property, as defined under the Ohio Product Liability Act.

604. Plaintiffs seeks all legal and equitable relief as allowed by law, including inter alia injunctive relief, abatement, restitution, disgorgement of profits, attorneys' fees and costs, pre and post-judgment interest, and such other relief as this Court deems appropriate.

605. Plaintiffs are entitled to recover its damages caused by Defendants' creation of this public nuisance in an amount to be determined at trial, plus costs and attorneys' fees.

SECOND CAUSE OF ACTION

**NEGLIGENCE
(AGAINST ALL DEFENDANTS)**

606. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

607. Defendants have a duty to exercise reasonable care in the marketing, distribution, and dispensing of opioids.

608. Defendants owed Plaintiff a duty to not expose Plaintiff to an unreasonable risk of harm.

609. Defendants had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling and/or distributing opioids.

610. Defendants had a duty not to breach the standard of care established under Ohio law and the federal Controlled Substances Act ("CSA") and its implementing regulations, which require Defendants to report suspicious orders and to maintain systems to detect and report such activity.

611. Defendants' duties were preexisting.

612. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in marketing, distributing, and selling 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.

613. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

614. Defendants breached their duty to Plaintiffs by, inter alia:

- a. Distribution and dispensing by Defendants and sales by manufacturers of opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distribution and dispensing by Defendants and sales by manufacturers of opioids without maintaining effective controls against the diversion of opioids;
- c. Choosing not to effectively monitor for suspicious orders;
- d. Choosing not to investigate suspicious orders;
- e. Choosing not to report suspicious orders;
- f. Choosing not to stop or suspend shipments of suspicious orders; and
- g. Distributing, dispensing, and selling by Defendants of opioids prescribed by “pill mills” when Defendants knew or should have known the opioids were being prescribed by “pill mills.”
- h. PBM Defendants have created and maintained a public nuisance by colluding with manufacturers to make opioids more available, by ignoring evidence of addiction and misuse found in their own claims data, and by failing to maintain effective controls against diversion, leading to the oversupply of opioids in Plaintiffs’ geographic area.

615. Defendants breached their duty to Plaintiff by deceptively marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

616. Plaintiffs does not allege that Defendants were negligent for failure to protect from harm. Rather, Defendants engaged in conduct the foreseeable result of which was to cause harm to Plaintiffs.

617. Defendants have engaged in affirmative acts of creating an illegal, secondary prescription opioid market by failing to exercise adequate control over the marketing, distribution, dispensing and sale of their prescription opioids.

618. Defendants were negligent by marketing, distributing, dispensing, and selling opioids in a way that created and fostered an illegal, secondary prescription opioid market that resulted in a foreseeable and unreasonable risk of harm to Plaintiffs.

619. The method by which Defendants created this market was by marketing, distributing, dispensing, and selling opioids without regard to the likelihood that the opioids would be placed in the hands of criminals, addicts, juveniles, and others not permitted to use or possess prescription opioids.

620. A reasonably prudent opioid manufacturer, pharmacy, PBM and distributor should have anticipated an injury to Plaintiffs as a probable result of marketing, distributing, dispensing, and selling prescription opioids in this manner.

621. It was reasonably foreseeable that Defendants' actions and omissions would result in the harm to Plaintiffs as described herein.

622. Defendants had control over their conduct in Plaintiffs' Communities. 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. 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 process 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.

623. Because of the Defendants' deceptive marketing of opioids and each of the Defendants' special positions within the closed system of opioid distribution and dispensing, 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.

624. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious orders. 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.

625. Defendants are in the business of manufacturing, marketing, dispensing and/or distributing prescription drugs, including 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.

626. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiffs – exactly as would be expected when medical grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

627. Reasonably prudent manufacturers, distributors, dispensers, and PBMs of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of R.C. § 4729.35 and Ohio Administrative Code §§ 4729-9-12, 4729-9-16, and 4729-9-28 for distributors (including Defendants registered as distributors) and a violation of R.C. § 4729.35, 21 U.S.C. § 823, and 21 C.F.R. § 1301.74 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.

628. 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. The 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 Plaintiff, physicians, patients, and the public.

629. Defendants conduct was negligence per se in that Defendants violated federal law, including, but not limited to, 21 U.S.C. §§ 823 and 827(d)(1); 21 C.F.R. §§ 1301.74, 1304.21, 1304.22, and 1304.33(e); and Ohio law, including, but not limited to, R.C. § 2925.02(A); and § 4729.01(F) and O.A.C. §§ 4729-9-12, 4729-9-16, and 4729-9-28. Plaintiffs were a party intended to be protected by such laws and whose injuries said laws were designed to prevent. Defendants' violations of said laws proximately caused injury to Plaintiffs.

630. Defendants also violated federal and Ohio statutes and regulations, including the controlled substances laws, by, inter alia:

- a. Distribution and dispensing by Defendants and sales by manufacturers of opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distribution and dispensing by Defendants and sales by manufacturers of opioids without maintaining effective controls against the diversion of opioids;
- c. Choosing not to effectively monitor for suspicious orders;
- d. Choosing not to investigate suspicious orders;
- e. Choosing not to report suspicious orders;
- f. Choosing not to stop or suspend shipments of suspicious orders; and
- g. Distributing, dispensing, and selling by Defendants of opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."
- h. PBM Defendants have created and maintained a public nuisance by colluding with manufacturers to make opioids more available, by ignoring

evidence of addiction and misuse found in their own claims data, and by failing to maintain effective controls against diversion, leading to the oversupply of opioids in Plaintiffs' geographic area.

631. 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.

632. 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 its proprietary interests.

633. 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.

634. Defendants' misconduct alleged in this case is ongoing and persistent.

635. 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 existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

636. Plaintiffs have incurred expenditures for special programs over and above Plaintiffs' ordinary public services.

637. Plaintiffs have suffered an indivisible injury as a result of the tortious conduct of Defendants.

638. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiffs.

639. 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.

640. Plaintiffs seek all legal and equitable relief as allowed by law, including inter alia injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, as to the FIRST and SECOND Causes of Action, awarding Plaintiffs in amounts that exceed the jurisdiction of all lower Courts:

- i. abatement of the nuisance;
- ii. compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages;
- iii. treble damages, penalties, and costs;
- iv. punitive damages;
- v. attorneys' fees;
- vi. interest, costs and disbursements; and
- vii. such further relief, including injunctive relief, as this Court may deem just and proper.

Dated: March 17, 2023

/s/ Frank L. Gallucci III

Frank L. Gallucci
fgallucci@pglawyer.com
Plevin & Gallucci
55 Public Square, Suite 2222
Cleveland, Ohio 44113
Telephone: (216) 861-0804
Facsimile: (216) 771-1632

/s Hunter J. Shkolnik

Hunter J. Shkolnik (admitted *pro hac vice*)
Paul J. Napoli
1302 Avenida Ponce de Leon
Santurce, Puerto Rico 00907
hunter@nspirlaw.com

Napoli Shkolnik PLLC

Salvatore C. Badala (admitted *pro hac vice*)
Shayna E. Sacks (admitted *pro hac vice*)
360 Lexington Avenue
New York, New York 10017
sbadala@napolilaw.com
ssacks@napolilaw.com
Phone: (212) 397-1000

Attorneys for Plaintiffs