COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT
C.A. NO.

THE CITY OF BOSTON, THE BOSTON PUBLIC HEALTH COMMISSION, THE BOSTON HOUSING AUTHORITY.

Plaintiffs,

v.

PURDUE PHARMA L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

PURDUE PHARMA, INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

THE PURDUE FREDERICK COMPANY INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

TEVA PHARMACEUTICALS USA, INC.
190 Horsham Road
North Wales, PA 19454

CEPHALON, INC.
41 Moores Road
Frazer, PA 19355

JOHNSON & JOHNSON
CT Corporation System
101 Federal Street
Boston, MA 02110

JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;

COMPLAINT

(Jury Trial Demanded)

JANSSEN PHARMACEUTICA, INC.
n/k/a JANSSEN PHARMACEUTICALS, INC.
c/o CT Corporation System
600 N 2nd Street, Suite 401
Harrisburg, Pennsylvania 17101-1071

ENDO HEALTH SOLUTIONS INC.
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110

ENDO PHARMACEUTICALS, INC.
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110

INSYS THERAPEUTICS
133 S Spectrum Blvd #100
Chandler, AZ 85286

CARDINAL HEALTH INC.
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110

MALLINCKRODT LLC
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110

MALLINCKRODT PLC
675 McDonnell Blvd.
St. Louis, MO 63042

SPECGX LLC
385 Marshall Avenue
Webster Groves, MO
63119

MCKESSON CORPORATION
c/o Corporation Service Company
84 State St.
Boston, MA 02109

AMERISOURCEBERGEN DRUG

CORPORATION
c/o CT Corporation System
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110

WALGREENS BOOTS ALLIANCE
d/b/a WALGREEN CO
d/b/a Walgreens of Massachusetts, LLC
c/o Corporation Service Company
84 State Street
Boston, MA 02109

Dr. Fathallah Mashali
NEW ENGLAND WELLNESS & PAIN MANAGEMENT, P.C., a/k/a NEW ENGLAND PAIN ASSOCIATES, P.C. OF MASSACHUSETTS AND RHODE ISLAND, a/k/a GREYSTONE PAIN MANAGEMENT, INC., a/k/a NEW ENGLAND PAIN INSTITUTE, P.C.
160 Dedham St.
Dover, MA 02030
c/o David W. Krumsiek
101 Arch St.
Boston, MA 02110

AND

JANE DOES 1 – 50

Defendants.

TABLE OF CONTENTS

I. PRELIMINARY STATEMENT

1. Plaintiffs, the City of Boston, Massachusetts, and the Boston Public Health Commission ("the Plaintiffs"), like many other jurisdictions and agencies across the country, are struggling with an opioid crisis. Unlike the crack cocaine and crystal methamphetamine epidemics that preceded it, this drug crisis began with a corporate business plan. It started with a decision by Purdue Pharma L.P., and its corporate family (collectively, "Purdue"), to promote opioids deceptively and illegally in order to significantly increase sales and generate billions of dollars in revenue for Purdue's private owners, the Sackler family. Unfortunately, Purdue's strategies were quickly joined by Endo Pharmaceuticals Inc., Endo Health Solutions 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., Teva Pharmaceuticals USA, Inc, Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC (collectively with Purdue, "Manufacturing Defendants"), all of whom, along with Insys Therapeutics, Inc., used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.[1] In addition, the Manufacturing Defendants, along with McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and Walgreens Boots Alliance d/b/a Walgreen Co. (collectively, "Distributor Defendants") failed to maintain effective controls, and to investigate, report, and take steps to terminate suspicious orders. As a direct consequence, the rampant use, overuse, and abuse of opioids has overwhelmed much of the country, including Boston and its residents.

[1] Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

2. Boston, Massachusetts and the Boston Public Health Commission bring this action to redress these Defendants' campaign of unfairly, deceptively, and fraudulently marketing, promoting, and distributing opioids.

3. Manufacturing Defendants manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Subsys, Xartemis XR, Exalgo, Nucynta/Nucynta ER, and Duragesic, and generic drugs such as oxycodone.

4. Distributor Defendants McKesson Corporation d/b/a McKesson Drug Company, AmerisourceBergen Drug Corporation, Walgreens Boots Alliance d/b/a Walgreens Co., and Cardinal Health, Inc. distribute opioid medications, including the medications listed above, to pharmacies, pain clinics and other dispensaries across the country and in Boston.

5. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—which are often prolonged, if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

6. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited

the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care.[2] Consequently, the market for prescription opioids was sharply constrained.

7. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Purdue, joined by Teva, Janssen, Endo, Mallinckrodt, and, more recently, Insys, began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, these Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

8. From the day they made the opioids to the day the medicines were consumed in our communities, the Manufacturing Defendants and Defendant Insys had control over the information that they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring them into prescribing their products by arguing, among other things, that no one should be in pain, the Manufacturing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the Manufacturing Defendants caused their profits to soar as more and more people became dependent on opioids.

9. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers and distributors, (together, "Defendants"), who failed to maintain effective controls over the distribution of prescription opioids, and who instead

[2] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

10. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care setting struggles with addiction. In 2014, almost 2 million Americas were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than 1999.

11. As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

12. As a direct and foreseeable result of Defendants' conduct, cities and counties across the nation, including Plaintiffs, are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent

health crisis."[3] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire or simply could not afford prescription opioids.

13. Thus, rather than compassionately helping patients, this explosion in opioid use and the concurrent explosion in Defendants' profits, has come at the expense of patients and has caused ongoing harm and damages to Plaintiffs. As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.[4]

14. Defendants' conduct was designed to increase their profits by vastly expanding the market for opioids and flooding communities with these dangerous drugs. Their conduct has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. A substantial amount of the associated costs are borne by governmental entities. The necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care, among others.

15. The burdens imposed on the Plaintiffs are not the normal or typical burdens of government programs and services. Rather, they are extraordinary costs and losses that are related directly to Defendants' illegal actions. The Defendants' conduct has created a public nuisance and

---

[3] CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at http://www,cdc,give.washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at http://turnthetiderx.org.

[4] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

a blight. Governmental entities, and the services they provide their citizens, have been strained by this public health crisis.

16. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis. Within the next hour, six Americans will die from opioid overdoses; two babies will be born addicted to opioids and begin to go through withdrawal; and drug manufacturers and distributors will earn millions from the sale of opioids.

17. Defendants' misrepresentations and omissions constitute unfair and deceptive trade practices in violation of Massachusetts General Laws Chapter 93A, Sections 2 and 11. Additionally, Defendants' conduct was negligent, grossly negligent, fraudulent, has created a public nuisance, and has resulted in the Defendants' unjust enrichment.

18. Accordingly, the Plaintiffs bring this action to hold Defendants accountable for their conduct and seek past and future costs and damages, injunctive relief including abatement, and any other relief within this Court's powers, to redress and halt these unfair, deceptive, and unlawful practices. The relief sought by Plaintiffs includes but is not limited to the past and future costs of providing medical care and treatment for those who suffer from opioid addiction and their loved ones, supplying emergency responders and others with Naloxone, providing ongoing medical care for babies born with Neonatal Abstinence Syndrome, and providing programs that promote safe storage and disposal of unused opioids.

II. PARTIES

A. Plaintiffs

19. The City of Boston ("the City") is located in Suffolk County, Massachusetts. Boston is the capitol of the Commonwealth and is the most populous municipality within the Commonwealth with a population of 685,094 residents. Pursuant to M.G.L.A. 40 §§ 1 and 2, it has the authority to prosecute suits on behalf of the City.

20. The City provides services to its citizens such as police and fire department services, public school services, and youth and family services; and also funds two out of three of its own health insurance programs for its employees and their dependents, and a workers' compensation program.

21. The Boston Public Health Commission is a legal entity located in the City of Boston. The Boston Public Health Commission oversees several programs and departments which work to combat the opioid epidemic, including Emergency Medical Services, and the Office of Recovery Services. Pursuant to M.G.L.A. 111 App. §2-7(11), it has the authority to prosecute suits on behalf of the Department.

22. The Boston Housing Authority is a body politic located in the City of Boston. The Boston Housing Authority provides public housing to residents of Boston. Pursuant to M.G.L.A. 121B. §11(a), the Boston Housing Authority has the authority to prosecute suits on behalf of the Department. Collectively, the City of Boston, the Boston Public Health Commission, and the Boston Housing Authority are referred to as "Plaintiffs."

B. Defendants

23. Purdue Pharma, L.P. ("Purdue") 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. The Purdue Frederick Company Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing opioids.

24. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, and Hysingla ER in the United States and in

Boston.[5] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

25. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States, including Boston. Teva USA also sells generic opioids throughout the United States and Boston, including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd., Teva USA's parent company based in Israel, acquired in August 2016. These parties are collectively referred to herein as "Teva."

26. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill, throughout the United States and in Boston. Actiq and Fentora have been approved by the U.S. Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

[5] Purdue also obtained approval to market Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) in 2014, but it has not actively marketed it.

27. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. 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. These parties are collectively referred to as "Janssen."

28. J&J imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. Thus, the code governs all forms of marketing at issue in this case.

29. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Boston, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual

sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

30. 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. These parties are collectively referred to as "Endo."

31. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and in Boston. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Boston, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the company announced that it would stop marketing and selling a reformulated version of Opana ER that it had marketed as abuse-deterrent.

32. 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 with its principal place of business in St. Louis, Missouri. Mallinckrodt, LLC is licensed to do business in Massachusetts. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC was a wholly-owned subsidiary of Covidien plc. Defendant SpecGx LLC is a Delaware limited liability company with its

headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. SpecGX currently manufactures and sells certain opioids which were previously manufactured by Mallinckrodt LLC. Mallinckrodt, plc, Mallinckrodt, LLC, and SpecGx LLC are referred to as "Mallinckrodt."

33. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc. acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

34. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. In 2015, Mallinckrodt estimated, based on IMS Health data, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.[6] In 2017, Mallinckrodt paid a $35 million fine to the Department of Justice for its failure to report suspicious orders of its opioids.[7]

---

[6] https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/mnk10-k93016.htm

[7] *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.

35. Collectively, Purdue, Teva, Janssen, Endo, and Mallinckrodt are referred to herein as "Manufacturing Defendants."

36. Insys Therapeutics, Inc. ("Defendant Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys' principal product and source of revenue is Subsys, a transmucosal immediate-release formulation ("TIRF") of fentanyl, contained in a single-dose spray device intended for oral sublingual administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain. Insys promotes, sells, and distributes Subsys throughout the United States and in the City of Boston.

37. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the country, including in Boston. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

38. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Boston. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

39. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Boston. It has a distribution center in Mansfield, Massachusetts. AmerisourceBergen is the eleventh largest

company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

40. Collectively Cardinal, McKesson and AmerisourceBergen are, at times, referred to herein as "The Big Three."

41. Walgreens Boots Alliance d/b/a Walgreen Co ("Walgreens") includes a captive distributor that supplies pharmaceutical drugs and opioids to Walgreens pharmacies in Boston and throughout the country. Walgreens is headquartered in Deerfield, Illinois, and has distribution centers across the country which distribute medications, including opioids, to various states, including Massachusetts. Walgreens is registered to do business in Massachusetts under the name Walgreens of Massachusetts, LLC.

42. Collectively Cardinal, McKesson, AmerisourceBergen, and Walgreens are at times referred to herein as "Distributor Defendants."

43. The Distributor Defendants dominate the wholesale distribution market, including in Boston. In order to increase their revenue, increase their profits, and grow their share of the prescription painkiller market they each distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling their fundamental duty under Massachusetts and federal statutes, and Massachusetts common law, to detect, report, and refuse to ship suspicious orders of opioids in order to prevent diversion of these dangerous drugs for non-medical purposes. Each have been cited and fined by the DEA and/or DOJ for failing to maintain effective controls against diversion. This unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Boston.. Defendant Dr. Fathallah Mashali operated three pain clinics in the Boston area which operated as "pill mills." The pain clinics were known

as New England Wellness & Pain Management, P.C., a/k/a New England Pain Associates P.C. of Massachusetts and Rhode Island, a/k/a Greystone Pain Management, Incl. a/k/a New England Pain Institute. (collectively referred to herein as "Mashali Defendants") For example, Defendant Mashali prescribed over 1,000 oxycodone prescriptions in one month—more than some of the Commonwealth's largest hospitals. In February 2014, a criminal complaint was filed against Defendant Mashali in Massachusetts Federal District Court alleging that the doctor committed healthcare fraud. In March 2017, Defendant Mashali plead guilty to 44 counts of health care fraud, conspiracy to commit mail fraud, and money laundering. Defendant Mashali also directly benefited from the City. From January 2012 until August 2013, Defendant Mashali benefited from the City as its health plan spent funds on opioid prescriptions written by the Defendant.

44. For Defendant Jane Does 1 – 50, Plaintiffs lack sufficient information to specifically identify the true names or capacities, whether individual, corporate, or otherwise, of these Defendants. The Plaintiffs will amend this Complaint to show their true names when they are ascertained.

III. JURISDICTION AND VENUE

45. This Court has subject matter jurisdiction over this action pursuant to Mass. Gen. Laws Ann. ch. 212, § 3 (West). This court has personal jurisdiction over Defendants because they carry on a continuous and systematic part of their general businesses within Boston, have transacted substantial business with Boston and its residents, and have caused grave harm in Boston as a result.

46. Venue as to each Defendant is proper in this court because a substantial part of the events and omissions giving rise to the claim occurred in Boston.

IV. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

47. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. For the last two decades, Manufacturing Defendants have sought to successfully turn that consensus on its head, primarily by covering up the risk of addiction and overstating the benefits of using opioids long-term.

48. Through marketing that was as pervasive as it was deceptive, Manufacturing Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. Purdue's sales representatives, in particular, promoted the concept that pain was undertreated, that opioids could not be abused, that the rate of addiction to opioids was less than 1%, that "old views" of opioid addiction were untrue, and that "appropriate patients" would not become addicted. These themes were repeated by sales representatives from other Manufacturing Defendants.

49. These Defendants blanketed the medical community with their misleading and deceptive misinformation campaign in order to change the narrative regarding the appropriate use of opioid medications and increase their profits. They enlisted trusted doctors, professional associations, and patient groups to disseminate their misrepresentations overstating the benefits of opioid use for chronic pain conditions and downplaying the risks of such use. As is discussed more fully below, these doctors and groups appeared to be independent, but were funded and controlled by the Manufacturing Defendants in order to distort the public's and medical communities' perception of the risks, benefits, efficacy, and superiority of opioids to treat chronic pain. Misleading and deceptive messages were disseminated through seminars, physician

Continuing Medical Education programs, speaker programs, websites, patient guides, and "scientific" and other publications given to doctors and stacked in patient waiting rooms.

50. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Manufacturing Defendants not only marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants),[8] who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Defendants' marketing claims.

51. Manufacturing Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

A. Manufacturing Defendants and Defendant Insys Falsely Trivialized, Mischaracterized, And Failed To Disclose The Known, Serious Risk Of Addiction

52. Manufacturing Defendants, and Defendant Insys rely heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. These visits frequently coincide with payments to the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." Purdue's former Vice President of Marketing, Russ Gasdia, acknowledged the utility of a Purdue sales representative as "someone [prescribers] can look to for the information they need to make prescribing decisions." Not surprisingly, all of the Manufacturing Defendants' and Defendant

[8] For example, in 2013, Purdue sought to identify Key Opinion Leaders ("KOLs") to reach non-physician prescribers, including for a program to educate nurses about opioids. By 2015, nurse practitioners and physician assistants were responsible for over 800 million prescriptions and constituted Purdue's largest growth area.

Insys' sales representatives visited prescribers in Boston. Publicly available data shows that these Defendants visited Boston prescribers at least 305 times between the third quarter of 2013 and the end of 2016. However, this number understates the amount of "detailing" by each of the Manufacturing Defendants' and Defendant Insys' sales representatives, as it only reflects visits in which some sort of payment was provided to the prescriber.

53. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report which noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[9] The Report quotes ProPublica findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

54. To ensure that sales representatives delivered the desired messages to prescribers, Manufacturing Defendants and Defendant Insys, directed and monitored their respective sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit. These Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies and forbade them to use promotional materials not approved by the company's marketing and compliance departments. They further ensured marketing consistency nationwide through national and regional sales representative training. Thus, upon information and belief,[10]

---

[9] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*.

[10] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Boston in the same manner as elsewhere.

their sales forces in Massachusetts and Boston carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

55. Manufacturing Defendants and Defendant Insys were aware of the strength of its in-person marketing. The effects of sales calls on prescribers' behavior is well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling its sales calls. A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[11] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization.[12] An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.[13]

56. Manufacturing Defendants also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided

---

[11] Ian Larkin et al., Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing, 317 J. Am. Med. Ass'n 1785 (2017).

[12] Berdent ER, et al. Information, marketing and pricing in the US antiulcer drug market. Amer Econ Rev 1995, 85:101-105.

[13] Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA 2000,283:373-80.

information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from these Defendants, and the CMEs were often sponsored by Manufacturing Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."[14]

57. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Manufacturing Defendants exerted influence over these groups by providing major funding directly to them, as well. These "front groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Manufacturing Defendants distributed these publications to prescribers or posted them on their websites.

58. The FDA does not regulate all of the conduct in which the Manufacturing Defendants and Defendant Insys engaged. For example, drug labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia, three conditions for which opioids are ineffective, but for which Purdue and, upon information and belief, the other Manufacturing Defendants and Defendant Insys, marketed their drugs. The FDA

[14] Catan, Thomas, and Perez Evan, "A Pain-Drug Champion Has Second Thoughts," The Wall Street Journal, December 17, 2017, available at https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

also does not regulate unbranded advertising. Likewise, the FDA does not regulate marketing funneled through third-parties.

59. Neither these third-party unbranded materials, nor the marketing messages or scripts relied on by Manufacturing Defendants' and Defendant Insys' sales representatives, were reviewed or approved by the U.S. Food & Drug Administration ("FDA"). Upon information and belief, all of the messages described below were disseminated to Boston prescribers and patients through sales representative visits, medical education programs, marketing materials, websites, and other sources.

1. Minimizing or mischaracterizing the risk of addiction

60. To convince prescribers and patients that opioids are safe and increase the market for and sales of opioids, Manufacturing Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, (3) all other patients could safely be prescribed opioids, and (4) even high risk patients could be prescribed opioids if closely managed.

61. Upon information and belief, sales representatives regularly omitted from their sales conversations with prescribers in Boston any discussion of the risk of addiction from long-term use of opioids. These omissions rendered other arguably truthful statements about opioids false and misleading, and they both reinforced and failed to correct their prior misrepresentations regarding the risk of addiction.

62. Manufacturing Defendants also deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients. According to these Defendants, doctors can screen patients to identify those who are likely to

become addicted, and therefore could safely prescribe to everyone else. Manufacturing Defendants discounted general concerns or warnings regarding addiction by reassuring doctors that their patients would not become addicted. One former Purdue sales representative in another region confirmed Purdue's message that opioids were appropriate and safely prescribed to legitimate patients with actual pain; upon information and belief, based on the uniformity of Purdue's practices, the same message was delivered to prescribers in Boston.. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction. In addition, upon information and belief, Manufacturing Defendants' sales representatives also failed to disclose to prescribers in Boston the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This difficulty in terminating use is a material risk, which can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

63. Manufacturing Defendants falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." Purdue knew that opioid addicts who resort to these extremes are uncommon; they far more typically become dependent and addicted through oral use. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time.

64. These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. Purdue

made *Providing Relief, Preventing Abuse* available to sales representatives to show to or leave with prescribers, including, on information and belief, to prescribers in Boston.

65. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"). Purdue was APF's second-biggest donor. Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby for its interests on Capitol Hill.

66. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction. Purdue provided funding in the form of a $26,000 grant to APF and closely collaborated with APF in creating *A Policymaker's Guide*. On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*.

67. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain* that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. Although it included the Purdue copyright at the bottom of each page, the site did not refer to any specific Purdue products and cultivated the "impression that it [was] neutral and unbiased."[15]

[15] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151 (August 19, 2015).

68. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.

69. 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."

70. 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.

71. 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." This guide is still available online.

72. Janssen currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated."

73. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."[16]

74. The FAQs section of pain-topics.org contained misleading information about pseudoaddiction, discussed further in subsection 2. Specifically, the website described pseudoaddiction as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'" [17]

75. Among its content, the website contained a handout titled *Oxycodone Safety for Patients,* which advised doctors that "[p]atients' fears of opioid addiction should be expelled."[18] The handout stated the following misleading information regarding the risk of addiction:

Will you become dependent on or addicted to oxycodone?

- After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.

This handout is still available to prescribers and patients today.

---

[16] https://web.archive.org/web/20070701065905/http://www.pain-topics.org:80/contacts_aboutus/index.php, (Last visited March 2, 2018.)

[17] https://web.archive.org/web/20071026152321/http://pain-topics.org/faqs/index1.php#tolerance (Last visited March 2, 2018.)

[18] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

76. In 2010, according to a Mallinckrodt Policy Statement, Mallinckrodt launched the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt further states: "Through the C.A.R.E.S. Alliance website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take." By 2012, the C.A.R.E.S. Alliance and Mallinckrodt were promoting a book titled *Defeat Chronic Pain Now!*..The false claims and misrepresentations in this book include the following statements:

a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

b. "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."

c. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."

d. "[P]hysical dependence . . . is a normal bodily reaction that happens with lots of different types of medications, including medications not used for pain, and is easily remedied."

e. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

f. "[I]n our experience, the issue of tolerance is overblown."

g. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

h. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

i. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

j. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

This book is still available online in Boston and elsewhere.

77. Manufacturing Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk [] of. . . addiction"—"even at recommended doses"—of all opioids."[19] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[20] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[21] An additional study showed that nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.

2. Manufacturing Defendants Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids

78. Manufacturing Defendants deceptively advised doctors to ignore signs of addiction

---

[19] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[20] CDC Guideline at 2.

[21] *Id.* at 21.

as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction was a concept invented to foster the misconception that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel. By disseminating misleading information regarding pseudoaddiction, Defendants acted with the sole purpose of increasing their profits at the expense of patients.

79. Purdue, through its unbranded imprint *Partners Against Pain*[22], promoted pseudoaddiction through at least 2013 on its website.

80. The Federation of State Medical Boards ("FSMB"), a trade organization representing Massachusetts state medical board as well as others, finances opioid- and pain-specific programs through grants from Manufacturing Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of "pseudoaddiction."

81. *Responsible Opioid Prescribing* was sponsored by Manufacturing Defendants. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally, including, upon information and belief, in Boston.

---

[22] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

82. 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." This website was accessible online until May 2012.

83. 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.

84. Manufacturing Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Manufacturing Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

85. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]patients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[23] and that physicians should "reassess [] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[24]

3. Overstating the efficacy of screening tools

---

[23] CDC Guideline at 13.

[24] *Id.* at 25.

86. Manufacturing Defendants falsely instructed prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies will mitigate addiction risk. By using screening tools, these Defendants, advised that doctors could identify those who are likely to become addicted and could safely prescribe to everyone else. Thus, Manufacturing Defendants undermined general concerns or warnings regarding addiction in drug labels and elsewhere by reassuring doctors that, despite the general warnings about addiction, their patients would not become addicted.

87. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Purdue aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations reassured doctors that opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients.

88. Upon information and belief, these Defendants conveyed these safe prescribing messages through their in-person sales calls to doctors in Boston.

89. On information and belief, based on their use elsewhere, Purdue sales representatives in Boston also shared the *Partners Against Pain* "Pain Management Kit," which contained several "drug abuse screening tools." These included the "Opioid Risk Tool," which is a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease," ignoring

the sensitivity of the topic and the nature of addiction, which make it unlikely that many patients can be counted on to share this information.

90. Manufacturing Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which likely were attended by and were available to Boston prescribers.

91. For example, Purdue sponsored a 2011 CME program titled *Managing Patients' Opioid Use: Balancing the Need and Risk.* This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

92. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids.

93. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented an outsized number of talks—with very different messages from non-Purdue talks—at each CPDD conference. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the addiction crisis, and that once those patients are identified doctors can safely prescribe opioids without addicting patients. Hundreds of addiction treatment specialists from across the country and, upon information and belief, prescribers from Boston, attended these conferences.

94. 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.

95. A 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

96. Manufacturing Defendants' efforts to convince doctors that they could confidently prescribe to pain patients who did not intend to become addicted or abuse drugs were misleading. As these Defendants knew or should have known, sales to patients who doctor-shop (or visit multiple doctors to hide illicit use or overuse) constitute approximately only 1% of opioid volume.

97. Further, the 2016 CDC Guideline confirms the falsity of Manufacturing Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[25]

[25] CDC Guideline at 28 (emphasis added).

B. Manufacturing Defendants Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use In Order to Increase their Profits

1. Mischaracterizing the benefits and evidence for long-term use

98. To convince prescribers and patients that opioids should be used to treat chronic pain in order to increase the number of opioid prescriptions and their profits, Manufacturing Defendants had to persuade the medical community of a significant upside to long-term opioid use. Assessing existing evidence, the 2016 CDC Guideline found that there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[26] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[27] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[28] The FDA also determined that opioid use disorder and overdose risk are present when opioids are taken as prescribed. As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

99. Upon information and belief, Manufacturing Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

---

[26] *Id.* at 10.

[27] *Id.* at 9.

[28] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

100. Two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Manufacturing Defendants. Upon information and belief, Manufacturing Defendants exercised considerable influence over their work on opioids. Both organizations 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. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

101. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Manufacturing Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain, but who frequently treat patients who suffer from chronic pain, such as the elderly. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

102. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the

panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva made to the sponsoring organizations and committee members.

103. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

104. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

105. Manufacturing Defendants also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results… should be confirmed in trials of longer duration to confirm the

role of opioids in a chronic condition such as OA [osteoarthritis]."[29] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[30] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

106. Teva 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.

107. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. 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.

108. Despite this, Teva 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

---

[29] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).

[30] *Id.*

not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing[31] by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

109. For example: Teva paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

110. Teva'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.

111. In December 2011, Teva 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. The FDA does not regulate or approve journal publications sponsored by drug manufacturers, such as the Special Report.

[31] Pharmaceutical detailing is a one-on-one marketing technique utilized by pharmaceutical companies to educate a physician about a vendor's products in hopes that the physician will prescribe the company's products more often.

112. Teva'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.

113. In December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl ("TIRF"). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not totally comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

2. Overstating opioids' effect on patients' function and quality of life

114. Upon information and belief, Manufacturing Defendants also claimed to Boston doctors—without evidence—that long-term opioid use would help patients resume their lives and jobs.

115. Manufacturing Defendants' and Defendant-sponsored materials that, upon information and belief, were distributed or made available in Boston, reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

116. Similarly, since at least May 21, 2011, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

117. Defendant Mallinckrodt's website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[32] Additional illustrative examples are described below:

- 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 and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

- 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.

- Responsible Opioid Prescribing (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

- Purdue and Teva 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 May 2012.

- 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, 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

[32] Mallinckrodt Pharmaceuticals, Responsible Use, www.mallinckrodt.com/corporate-responsibility/responsible-use.

approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

- 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.

118. Likewise, Manufacturing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

119. One pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[33] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures.[34] Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over

---

[33] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

[34] *Id.*

$100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later. [35]

120. The CDC Guideline notes that "there is no good evidence that opioids improve pain or function with long-term use."[36] The FDA and other federal agencies have made this clear for years. [37] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[38] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[39] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[40]

---

[35] Jeffrey A. White, et al., The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan, 54(8) J. of Occupational & Environ. Med. 948-953 (2012).

[36] CDC Guidelines. at 20.

[37] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[38] CDC Guideline at 2.

[39] *Id* at 18.

[40] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

121. In materials Manufacturing Defendants produced, sponsored, or controlled, Manufacturing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

3. Omitting or mischaracterizing adverse effects of opioids

122. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Manufacturing Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[41] in which the patient becomes more sensitive to pain over time, hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally 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 (often among veterans, for example, post-traumatic stress disorder and anxiety also can accompany chronic pain symptoms).

123. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids).[42] This publication also warned that risks of

[41] *See* n. **Error! Bookmark not defined.**, *supra*.

[42] The higher figure reflects deaths from all causes.

NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

124. Purdue also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

125. Purdue sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.\

126. Manufacturing Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

127. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable

effects" of opioids.[43] Again, Manufacturing Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%.[44] Another study of an estimated 440 million visits for back pain over a period from 1999 to 2010 found that the use of NSAIDs fell from 36.9% to 24.5%, while use of narcotics increased from 19.3% to 29.1.%.[45] The CDC reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.[46]

C. Manufacturing Defendants Continued to Tell Doctors that Opioids Could Be Taken in Ever Higher Doses Without Disclosing Their Greater Risks

128. Manufacturing Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice a day, despite knowing that OxyContin frequently did not provide 12 hours of relief to ensure the doctors maintained patients on the drugs even at the high doses that became necessary.

129. Purdue-sponsored publications and CMEs available, upon information and belief, in Boston also misleadingly suggested that higher opioid doses carried no added risk.

---

[43] Meredith Noble M, *et al.*, *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010.).

[44] John N. Mafi et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

[45] *Id.*

[46] Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015, available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm.

130. Though at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

131. *A Policymaker's Guide*, the 2011 publication on which, upon information and belief Purdue collaborated with APF, taught that dose escalations are "sometimes necessary" but did not disclose the risks from high dose opioids.

132. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses. 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."

133. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 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."

134. 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. This guide is still available online.

135. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. 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 opioids' 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 CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[47] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[48]

D. Purdue Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief When Purdue Knew That, For Many Patients, It did Not

136. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

137. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below. Purdue conveyed to prescribers that the solution to end of dose failure is not more frequent dosing but higher doses—which pose greater risks.

138. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. It was Purdue's decision to submit OxyContin for approval with 12-hour

---

[47] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[48] CDC Guideline at 16.

rather than 8-hour dosing. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar.

139. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.,* little or no pain relief at the end of the dosing period.

140. Moreover, Purdue itself long has known, dating to its development of OxyContin that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.[49]

141. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason,

---

[49] Harriet Ryan, "' *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[50] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

142. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours) because 12-hour dosing was "a significant competitive advantage," among other reasons.[51] Purdue also falsely promoted OxyContin as providing "steady state" relief, less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse—a misrepresentation made upon information and belief, in Boston.

143. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to prescribers what it knew about OxyContin's actual duration, and not to promote more dangerous higher dosing, rather than increased frequency of use, regardless of any marketing advantage.

144. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was

---

[50] *Id.*

[51] *Id.*; http://documents.latimes.com/purdue-response-fda-2004/.

to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[52]

E. Purdue and Endo Overstated the Efficacy of Abuse-Deterrent Opioid Formulations

145. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of its ADF opioids preserved and expanded its sales and enabled prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids— thereby further exacerbating the opioid epidemic in Boston and elsewhere.

1. Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER

146. Reformulated, ADF OxyContin was approved by the FDA in April 2010. However, the FDA noted that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When

[52] CDC Guideline at 16.

Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties.

147. It is unlikely to be a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

148. Upon information and belief, Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis to prescribers in Boston.

149. Ironically, Purdue sales representatives also regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue detailers:

a. claimed that Purdue's ADF opioids *prevent* tampering and that its ADF products could not be crushed or snorted.

b. claimed that Purdue's ADF opioids *reduce* opioid abuse and diversion.

c. asserted or suggested that Purdue's ADF opioids are "safer" than other opioids.

d. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

150. These statements and omissions by Purdue are false and misleading and are inconsistent with the FDA-approved labels for Purdue's ADF opioids—which indicate that abusers seek them because of their high likeability when snorted, that their abuse deterrent properties can

be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and which do *not* indicate that ADF opioids prevent or reduce abuse, misuse, or diversion.

151. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[53] and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, also report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected[54].

152. Further, *one-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, those addicts simply shifted to other drugs such as heroin.

153. A 2013 article presented by Purdue employees based on review of data from poison control centers, while concluding that ADF OxyContin can reduce abuse, ignored important negative findings. The study reveals that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article emphasized the advantages and ignored disadvantages of ADF OxyContin.

---

[53] *In re OxyContin*, 1:04-md-01603-SHS, Docket No 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10.

[54] PMRS Citizens Petition.

154. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[55] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."[56]

155. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[57] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

156. Yet despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not

---

[55] CDC Guideline at 22. (emphasis added).

[56] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.

[57] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

show that Purdue's ADF opioids are being abused in large numbers.[58]

2. Endo's deceptive marketing of reformulated Opana ER

157. In a strategy that closely resembled Purdue's, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced in abuse-deterrent formulations, also made abuse deterrence a key to its marketing strategy and its ability to maintain and increase profits from Opana ER.

158. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it would not be permitted to market Opana ER, even after the reformulation, as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

159. In August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana

[58] Jacobs, Harrison, There is a big problem with the government's plan to stop the drug-overdose epidemic, Business Insider, March 16, 2016, available at https://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3.

ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug, and also help preserve the market for branded Opana ER, which could be sold at non-competitive prices.

160. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed its true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare," would be lost.[59] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[60]

161. Meanwhile, despite Endo's purported concern with public safety, court filings indicate that not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[61]

---

[59] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936 Doc. 23 at 20 (D.D.C. Dec.14, 2012).

[60] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936 Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[61] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

162. In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

163. Over time, evidence confirmed that injection was becoming the preferred means of abusing Opana ER, which made Opana ER *less safe* than the original formulation. This occurred both because injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura ("TTP"), which can cause kidney failure.[62] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500% according to data gathered in 2017.

164. Nevertheless, Endo continued to market the drug as tamper-resistant and deterring abuse. Indeed, upon information and belief, detailers for Endo have informed doctors in Massachusetts that Opana ER was abuse-deterrent. In addition, upon information and belief, Endo sales representatives did not disclose evidence that Opana was easier to abuse intravenously and,

[62] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

if pressed by prescribers, claimed that while some outlying patients might find a way to abuse the drug, most would be protected.

165. Likewise, a review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant, even after the May 2013 denial of Endo's Citizen Petition. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

166. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[63] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[64] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[65]

167. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on

---

[63] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[64] *Id.*

[65] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

an Endo press release, described Opana ER as "crush-resistant." This article was posted on the Pain Medicine News website, which was accessible to patients and prescribers nationally.

168. In a 2016 settlement with Endo, the New York Attorney General ("NY AG") found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

F. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys

169. Insys' 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").

170. 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 Teva'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."[66] Prescribers must enroll in TIRF REMS before writing a prescription for Subsys.

[66] Press Release, FDA, FDA Approves Shared System REMS for TIRF Products, December 29, 2011.

171. Since its launch, Subsys has been an extremely expensive medication, and Insys has increased its prices every year. Depending on a patient's dosage and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

172. 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 . . . meaning no reimbursement would be due."[67]

173. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims.[68] In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center (IRC) to obtain approval for Subsys reimbursements.[69] This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients,

---

[67] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.*

[68] Lopez, German, *Want to understand how big pharma helped create the opioid epidemic? Read this report*, Vox, September 6, 2017, available at https://www.vox.com/policy-and-politics/2017/9/6/16262456/claire-mccaskill-insys-opioid-epidemic.

[69] *Id.*

falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.[70]

174. 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%.[71]

175. Since its launch in 2012, Insys has aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics. 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 conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers programs in exchange for prescribing Subsys. And it defrauded insurance providers and health benefit payors into paying for improper prescriptions of Subsys. These fraudulent and misleading schemes had the effect of pushing Insys' highly potent and dangerous opioid onto patients who did not need it, further exacerbating the opioid epidemic.

176. In addition, 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.[72] The compensation structure was heavily weighed on commissions, and rewarded reps more for selling higher (and more expensive)

---

[70] *Id.*

[71] *Id.*

[72] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller, New York Times,* May 13, 2014.

doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.[73]

177. The Insys "speakers program" was perhaps its most widespread and damaging scheme. According to a report by the Southern Investigative Reporting Foundation ("SIRF") 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."[74]

178. Insys' 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.

179. 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 May of 2017, one of the doctors was sentenced to 20 years in prison.

180. In June of 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, plead 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 a rate of approximately $1,000 per event;

---

[73] *Id.*

[74] Roddy Boyd, *Insys Therapeutics and the New 'Killing It'"*, Southern Investigative Reporting Foundation, The Investigator, April 24, 2015.

however, she did not give any presentations. In her guilty plea, the nurse admitted that she was receiving the speaker fees in exchange for writing prescriptions for Subsys.

181. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General, alleging that Insys paid doctors "speaking fees" to increase prescriptions of Subsys, among other allegations. 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 employing an unconscionable scheme, including "speaking fees," whereby payments that were intended to be kickbacks were made to doctors to incentivize the doctor to prescribe Subsys. [75]

182. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of the Alabama prescribers discussed above 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.

183. In August of 2016 the State of Illinois sued Insys for its 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 complaint explains that Insys categorized prescribers into deciles (D1-D10) according to the number of rapid onset opioids (ROOs) prescribed. The sales reps were instructed to call on the highest volume ROO prescribers more frequently than the low volume ROO prescribers, and encouraged to obtain the majority of their sales from one or two high volume prescribers.

---

[75] In The Matter of Insys Therapeutics, Inc., Notice of Unlawful Trade Practices and Proposed Resolution, July 10, 2015.

184. 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 a speaker "honorarium" ranging from $700 – $5,100 in addition to their meal. The prescribers 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 rep.

185. In December of 2016, six Insys executives and managers were indicted by the United States Attorney's Office for the District of Massachusetts. The indictment alleged that the former Insys employees conspired to bribe prescribers, many of whom operated pain clinics, in order to induce them to prescribe Subsys. In exchange for bribes and kickbacks, the indictment states, the prescribers wrote large numbers of prescriptions for the patients, though most of them were not diagnosed with cancer. In announcing the indictments, the Special Agent in charge of the Boston Division of the FBI noted that this scheme "contributed to the growing opioid epidemic and placed profit before patient safety."[76]

186. Insys' misleading marketing of Subsys as appropriate for non-cancer pain occurred in Boston. Publicly available data shows that between the third quarter of 2013 and 2016 Insys sales representatives visited Boston providers approximately 88 times and spent $30,753 on these prescribers. Of the prescribers detailed, the majority of the doctors were not oncologists. In addition, upon information and belief, Insys employed its fraudulent prior authorization scheme to seek approval of Boston area doctors' prescriptions of Subsys.

---

[76] *Press Release, United States Attorney's Office District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme, December 8, 2016.*

G. Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report and Terminate Suspicious Orders

187. The Manufacturing Defendants and Defendant Insys created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to terminate orders that they knew or should have known were suspicious breached both their statutory and common law duties.

188. For over a decade, as the Manufacturing Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

1. All Defendants Have a Duty to Report Suspicious Orders and Terminate those Orders Unless Due Diligence Disproves Their Suspicions.

189. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

190. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By supplying Boston with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm to Boston.

191. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion of prescription opioids, to speak accurately and truthfully.

192. Third, Defendants violated their statutory obligations under Massachusetts law and federal law. Defendants are all required to register as either manufacturers or distributors pursuant to Massachusetts law (*e.g.* § M.G.L.A. 94C § 7(a)), and federal law (21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74). Federal regulations issued under the CSA are incorporated into Massachusetts law pursuant to § M.G.L.A. 94C § 12(a)(1) and (2).

193. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants – which includes all manufacturers and distributors of controlled substances -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

194. The CSA requires manufacturers and distributors of Schedule II substances like

opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

195. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs." When evaluating production quotas, the DEA was instructed to consider information including trends and rates of net disposal, an applicant's production cycle and current inventory position, total actual or estimated inventories of the class of drug and all substances manufactured from the class, trends in inventory accumulation, and other factors such as changes in the currently accepted medical use of substances, the economic and physical availability of raw materials, yield and sustainability issues, potential disruptions to production, and unforeseen emergencies.

196. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

197. To ensure that even drugs produced within quota are not diverted, Federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to passively process orders of controlled substances, counting their profits along the way. Rather, they "shall inform the Field

Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

198. 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 distributor or manufacturer 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 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 customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

199. These requirements are adopted by and incorporated into Massachusetts law. As manufacturers and wholesale drug distributors of controlled substances, Defendants were required to register with the Massachusetts Commissioner of Public Health. § M.G.L.A. 94C § 7(a). The Massachusetts Controlled Substances Act requires an applicant's registration to be "consistent with the public interest," which includes the applicant's "maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels," and "compliance with applicable federal, state, and local law." § M.G.L.A. 94C § 12(a)(1) and (2).

200. Thus, Massachusetts regulations mandate that suspicious orders, defined as unusual

in size ***or*** frequency ***or*** deviation from buying patterns, be reported to the requisite authority. Any of the red flags identified by law trigger a duty to report; however, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines, also should alert Defendants to potential problems.

201. Distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply– can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders, or an order that is unusual given the customer's history or its comparison to other customers in the area.

202. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

203. Massachusetts and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together,

these laws and industry guidelines make clear that Defendants possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

204. Further, these laws and industry guidelines make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

205. The FTC has recognized the unique role of Defendants McKesson, Cardinal, and AmerisourceBergen (the "Big Three"). Since their inception, the Big Three have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, the Big Three also offer their pharmacy, or dispensing, customers a broad range of added services. For example, they offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory-carrying costs. The Big Three are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, the Big Three have a unique insight into

the ordering patterns and activities of their dispensing customers.

206. Like the Big Three, Walgreens is also uniquely positioned to know the ordering patterns and activities of its dispensing customers due to its role as both a distributor and a national retail pharmacy. As a national retail pharmacy, Walgreens had a vertically integrated model, which placed it in a unique role, as it had both specific obligations under the CSA and a particular ability to spot, report, and stop filling suspicious orders. National retail pharmacies, like 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. These federal pharmacy regulations are also incorporated into Massachusetts law pursuant to § M.G.L.A. 94C § 12(a)(1) and (2).

207. 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.

208. 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.

209. 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 as compared to most written prescriptions; (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.

2. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

210. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by Walgreens itself. That data allows it 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. Indeed, this data is sufficiently valuable in identifying "high prescribers" for purposes of marketing efforts, that companies such as IMS Health, Dendrite, Verispan, and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies.[77] The majority of pharmacies sell these records.[78]

211. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

---

[77] Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *388-89 (Feb. 22, 2011) (Fugh-Berman A, Ahari S (2007) Following the Script: How Drug Reps Make Friends and Influence Doctors. PLoS Med 4(4): e150. doi:10.1371/journal.pmed.0040150).

[78] *Id.* at 389.

212. Manufacturing Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS. Their extensive boots-on-the-ground through their sales force, allows Manufacturing Defendants to observe the signs of suspicious prescribing, such as lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturing Defendants regularly mined data, including, upon information, chargeback data, that allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing that would have alerted them independent of their sales representatives, to suspicious prescribing. These information points gave Manufacturing Defendants insight into prescribing and dispensing conduct that enabled them to play a valuable role in the preventing diversion and fulfilling their obligations under Massachusetts and federal law.

213. Defendants breached these duties by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

3. Defendants Understood the Importance of Their Reporting Obligations

214. All Defendants were well aware that they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

215. Recently, Defendant Mallinckrodt admitted in a settlement with DEA that "[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."[79] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

216. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association to which the Big Three (and Manufacturing Defendants) belong, and the National Association of Chain Drug Stores ("NACDS"), where Walgreens sits on the Board of Directors, have long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."[80] Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain. . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[81]

---

[79] https://www.justice.gov/usao-edmi/press-release/file/986026/download

[80] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

[81] 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

217. The DEA also repeatedly reminded the Defendants of their obligations under federal law, mirrored in and incorporated by Massachusetts law, to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes.[82] The Big Three Distributor Defendants have each attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

218. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they 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

---

(App'x B at 1).

[82] Drug Enf't Admin., *Distributor Conferences*: https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin., *Manufacturer Conferences*, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; Drug Enf't Admin., *National Conference on Pharmaceutical and Chemical Diversion*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Drug Enf't Admin., *Diversion Awareness Conferences*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

American people."[83] The DEA's September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have 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."[84] The same letter reminds distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[85]

219. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, 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."[86] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the 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

---

[83] *See* 2006 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.").

[84] *See id.*

[85] *See id.*

[86] *See* 2007 Rannazzisi Letter.

report suspicious orders and "some criteria to use when determining whether an order is suspicious."[87]

4. Despite Repeated Admonitions, Defendants Have Repeatedly Violated their Obligations

220. Distributor Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

221. Governmental agencies and regulators have confirmed (and in some cases Distributor Defendants have admitted) that Distributor Defendants did not meet their obligations, and have uncovered especially blatant wrongdoing.

222. 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. These included a number of actions against AmerisourceBergen, Cardinal, McKesson, and Walgreens:

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;

[87] *See* id.

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* 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 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On September 30, 2009, the DEA issued an Order to Show Cause against the Walgreens retail facility in San Diego, California.

i. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement ("2011 Walgreens MOA") with the DEA in relation to its San Diego facility. The MOA provided that "Walgreens agrees to maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act ("CSA") and applicable DEA regulations.

j. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;

k. On September 14, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Walgreens' Distribution Center in Jupiter, Florida.

l. On June 11, 2013, Walgreens agreed to pay $80 million in civil penalties to resolve the DEA's investigations. It also entered into another Memorandum of Agreement with the DEA in which it acknowledged that its distribution and dispensing practices were not fully consistent with its obligations under the CSA.

m. 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.

223. More recently, Defendant McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into 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."[88] For example, at its Methuen, Massachusetts distribution center, "McKesson processed thousands of oxycodone and hydrocodone orders that were more than 10 times the average size of a pharmacy order from May 2008 through April 2013, but McKesson never reported to the DEA that any of those orders was suspicious."[89]

224. Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should

[88] 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."), available at https://www.justice.gov/opa/press-release/file/928471/download.

[89] United States Attorney's Office, District of Massachusetts, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs" (January 17, 2017) https://www.justice.gov/usao-ma/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

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)."[90] 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". These failures were direct violations of the 2008 McKesson MOA with the DEA. *See supra* ¶ 222(f).

225. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities.[91] A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[92]

226. Even the far lessor-than recommended civil penalty against McKesson, a $150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in four different states. Though this penalty too, was far less severe than investigators had recommended, as the

---

[90] *Id.*

[91] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017).

[92] *Id.*

DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[93]

227. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted.[94] Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'"[95] According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings."[96] "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[97]

228. Further, in a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Wholesaler Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die. "[98] He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

---

[93] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs," (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[94] *Id.* (alteration in original).

[95] *Id.* (quoting a March 30, 2015 DEA memo).

[96] *Id.*

[97] *Id.*

[98] Bill Whitaker, Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress

> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. Thats exactly what they did.99

229. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[100] He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[101]

230. At a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, the chief executives of McKesson and Cardinal, among others, testified regarding their anti-diversion programs and their roles in the opioid epidemic. The Chairman of Miami-Luken alone acknowledged, in response to questions, that his company failed in the past to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. Despite the frequent prior enforcement actions described above, neither McKesson nor Cardinal admitted any deficiencies in their compliance. In fact, both executives' answers confirmed gaps and breakdowns in past and current practices.

231. For example, Cardinal's former Executive Chairman, George Barrett, denied that "volume in relation to size of population" is a "determining factor" in identifying potentially suspicious orders. Despite regulatory and agency direction to identify, report, and halt suspicious *orders*, Cardinal focused on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. Despite a Cardinal employee flagging an especially prolific pharmacy as a

---

[99] *Id.*

[100] *Id.*

[101] *Id.*

potential pill mill in 2008, the Subcommittee found no evidence that Cardinal took any action in response. In addition, Cardinal increased another pharmacy's threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds.

232. According to records produced to the Subcommittee, McKesson's due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids consisted of only two pages. Despite McKesson's claim that it (a) reviewed every single customer for high volume orders of certain drugs; (b) set a threshold of 8,000 pills per month; and (c) examined and documented every order over that threshold, the company still shipped 36 times the monthly threshold to one pharmacy—more than 9,500 pills *per day*.

233. Further, as referenced above, Walgreens has also been repeatedly penalized for its 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 Walgreens.

234. 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.

235. 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.[102]

236. 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.

237. 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.[103]

238. 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 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. [104]

239. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for

---

[102] 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.

[103] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

[104] *Id.*

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.[105]

240. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

241. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[106]

242. Manufacturers had knowledge of diversion as well and have failed to comply with their obligations to report and decline suspicious orders. Sales representatives learned that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences—so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some

[105] *Id.*

[106] *Id.*

> kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

243. Moreover, Manufacturing Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[107]

244. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[108] She wrote, "This

---

[107] Meier, *Pain Killer*.

[108] 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/

is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[109] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

245. As discussed in more detail below, Mallinckrodt also failed to report suspicious prescribing. A former Mallinckrodt sales representative regularly visited Boston area criminally indicted doctor, Defendant Fathallah Mashali, over the course of 5 years. During those visits the Mallinckrodt representative saw the doctor's office overflowing with patients, some of whom waited for up to 8 hours to see the doctor, and heard them bragging about earning $70,000 from selling prescriptions written by the doctor. Despite having around 300 doctors on his call list, the former sales representative's supervisor at Mallinckrodt instructed the sales representative to spend half of his time with the doctor because of the sales potential due to the doctor's prescribing. Though the sales representative and his supervisor acknowledged not wanting Mallinckrodt to be connected to the doctor, they decided not to report the doctor because his sales were very high and they made a lot of money from his prescribing.

246. These examples demonstrate how Manufacturing Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. The goal of the marketing strategy was to increase these Defendants' profits by convincing more doctors to prescribe opioids in higher and higher doses for long term use. Thus, these Defendants did identify doctors who were their most prolific prescribers, but not to determine if their prescribing was suspicious and,

[109] *Id.*

if so, report them. Defendants identified these prescribers in order to market to them and ensure they continued to prescribe more and more of Defendants' opioids.

247. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Manufacturing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[110]

248. But given the closeness with which these Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

H. Defendants Worked Together To Sustain Their Market and Boost Their Profits

249. The Big Three, as leading wholesale distributors, had close financial relationships with both manufacturers and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their

[110] Meier, *Pain Killer*, at 179.

downstream customers who ultimately dispense the drugs and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers also offer marketing programs, patient services, and other software to assist their dispensing customers.

250. Distributor Defendants had financial incentives from manufacturers to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits. Of course, increased sales volumes have also resulted in the oversupply of opioids and concurrent increases in addiction, overdose, and criminal diversion across the nation and in Boston.

251. Upon information and belief, each of the Distributor Defendants also worked together, and with Manufacturing Defendants, through trade or other organizations, such as the HDA, the National Association of Chain Drugstores, and the Pain Care Forum ("PCF"), to

safeguard the market for opioids and the distribution of opioids.[111]

252. Although the entire HDA membership directory is private, the HDA website confirms that Defendants AmerisourceBergen, Cardinal, and McKesson, were members.[112] All of the Manufacturing Defendants were members as well.[113]

253. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Big Three with the opportunity to work closely with each other and with opioid manufacturers, confidentially, to develop and further their common purpose and interests.

254. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributors advertise these conferences 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."[114] The conferences also gave the Distributors and Manufacturing Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[115] The HDA and its conferences were significant opportunities for the Big Three to interact at a high level of leadership.

255. HDA members were eligible to participate on councils, committees, task forces and working groups, including:

---

[111] https://www.documentcloud.org/documents/3108980-PAIN-CARE-FORUM-Directory-04-2012.html (2012 document showing defendants or parents/affiliates)

[112] https://www.healthcaredistribution.org/about/membership/distributor (H.D. Smith would have been represented by Smith Drug Company, Div. J M Smith Corporation.)

[113] https://www.healthcaredistribution.org/about/membership/manufacturer

[114] *Business and Leadership Conference—Information for Manufacturers*, Healthcare Distribution Alliance, *available at* https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers (last accessed on Sept. 14, 2017).

[115] *Id.*

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

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. 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.

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

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.[116]

256. The Distributor Defendants and Manufacturing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…" Upon information and belief, the Manufacturing Defendants used this information to gather high-level

[116] Councils and Committees, Healthcare Distribution Alliance, (accessed on December 11, 2017), available at https://www.healthcaredistribution.org/about/councils-and-committees

data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

257. The Big Three also coordinated with each other and opioid manufacturers in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include, upon information and belief, the HDA—has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade."[117] This coordination in their lobbying further supports an inference that Defendants worked together in other ways, as is described in this Complaint.

258. Distributor Defendants also worked together through HDA and National Association of Chain Drugstores ("NACDS"). The respective CEOs of the HDA and NACDS have spoken with one voice, with respect to portraying their members as committed to safeguarding the integrity of the supply chain when opposing efforts to promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These statements support the inference that Distributor Defendants worked together in other ways as well to mislead the public regarding their commitment to complying with their legal obligations and safeguarding against diversion.

259. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were

---

[117] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011) (showing Covidien, Mallinckrodt LLC's parent company until mid-2013, as a member in 2012), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

260. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

261. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

262. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Manufacturing and Distributor Defendants did this through their participation in the PCF, HDA, and the NACDS.

263. Upon information and belief, the 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.

I. Defendants Ignored Red Flags Of Abuse and Diversion

264. 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.[118] The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants and Manufacturing Defendants, but has not been disclosed to the public.

265. Yet, publicly available information confirms that Defendants funneled far more opioids into Boston than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting Boston.

266. The Plaintiffs' information and belief rests upon the following facts:

(a) distributors have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

(b) The Big Three, Manufacturing Defendants, and Defendant Insys regularly visit pharmacies and/or doctors to promote and provide their products and services, which allows them to observe red flags of diversion. Similarly, Walgreens has direct access to the transaction data of its chain of retail pharmacies.

(c) The Big Three together may account for more than 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the

[118] *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area;

(d) Walgreens has been relatedly penalized for their illegal prescription opioid practices, and the wide-spread nature of these violations suggests they are the product of national policies and practices;

(e) Performance metrics and prescription quotas adopted by the national retail pharmacies such as Walgreens for their retail stores contributed to their failure. 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.

267. At all relevant times, Defendants were in possession of data or information that allowed them to track prescribing patterns over time. Walgreens, for example, had direct access to the prescription rates of its retail pharmacies.

268. Distributors have a duty to know their customers and the communities they serve. Wholesale distributors, such as the Big Three, developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help distributors identify suspicious orders or customers who were likely to divert prescription opioids.[119] The "know your customer" questionnaires informed distributors of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, 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.

---

[119] *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).

269. According to testimony by a Cardinal former Executive Chairman of the Board at a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, a distributor has the ability to request drug dispensing reports, which include all drugs dispensed by a pharmacy, not only those by Cardinal, and had requested such reports in the past. Upon information and belief, other wholesale distributors could request similar reports, and, as explained above, Walgreens would have had this information from their own pharmacies.

270. Given this, and the additional red flags described below, Defendants should have been on notice that the diversion of opioids was likely occurring in and around Boston, should have investigated, terminated suspicious orders, and reported potential diversion to law enforcement.

271. Publically available data suggest that distribution of opioids in and around Boston exceeded reasonable medical use and that opioids were likely diverted into Boston. For example, between 2010 and 2016, an average of 457.04 mg of oxycodone were dispersed per Boston resident, which is double the state average and nearly three times the national average.[120]

272. In addition, there has been a dramatic rise in fatal drug overdoses in Boston. Many of these deaths are attributable to prescription opioids, and increasingly, to illicit opiates, to which people who have become addicted to prescription opioids often transition. In 2012, opioid-related deaths claimed 70 lives in Boston. In 2015 this number increased to 146 opioid-related deaths—more than double the number of deaths from 2012. By 2016, there were 193 people in Boston who died due to opioid overdoses. The CDC estimates that for every opioid-related death, there

[120] Public ARCOS data.

are 733 individuals who take opioids for non-medical reasons. Defendants thus had every reason to believe that an overall oversupply and/or illegal diversion was occurring in Boston.

273. Moreover, in 2016, Suffolk County, the County in which Boston is located, was one of seven Massachusetts counties to be labeled as a "high intensity drug trafficking area" ("HIDTA"), which means the area is a critical drug trafficking region of the United States.

274. Based upon all of these red flags, it can be fairly inferred that Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in Boston.

J. Defendant Fathallah Mashali Operated Pill Mills that Directly Contributed to the Opioid Epidemic in Boston

275. In February 2014, a criminal complaint was filed against Dr. Mashali in Massachusetts Federal District Court alleging that the doctor committed healthcare fraud. According to an affidavit submitted to FBI special agent Clayton Phelps, Dr. Mashali operated three pain clinics in Massachusetts under the banner New England Wellness & Pain Management, P.C., a/k/a New England Pain Associates P.C. of Massachusetts and Rhode Island, a/k/a Greystone Pain Management, Incl. a/k/a New England Pain Institute. Four former employees of the Mashali Defendants stated that the doctor prescribed high doses of narcotics to patients who were drug-seekers, fraudulently billed for physical examinations that did not take place, and/or billed for examinations at a higher rate than what was appropriate. In March 2017, Dr. Mashali plead guilty to 44 counts of health care fraud, conspiracy to commit mail fraud, and money laundering.

276. According to federal prosecutors, Dr. Mashali prescribed oxycodone at alarming rates, writing more than 1,100 oxycodone prescriptions in one month - more than some of the largest hospitals in the Commonwealth. Dr. Mashali's pain management clinics were reported to be so packed that patients sat on the floor, leaned against the walls, and spilled out into the hallways

while waiting to be seen. Dr. Mashali saw more than 100 patients a day and, according to a former medical assistant, only 5% of these patients had legitimate medical conditions.[121] Former employees have noted that Dr. Mashali spent a maximum of 10 minutes with each patient – not enough time to perform physical examinations. Other former employees of the Mashali Defendants stated that Defendant Mashali prescribed high doses of drugs to patients with addictions and frequently billed for tests that he never performed. A former doctor who worked at one of Dr. Mashali's clinics estimated that 30% of his patients should have been discharged from his practice because they did not need pain medication. When the doctor left the practice he told a co-worker, "you guys pushed it [controlled substances] on [the patients.]"

277. The former Mallinckrodt sales representative who visited Dr. Mashali's offices noted that patients "booed" the sales representative when he left the office because the doctor spent time with him instead of writing prescriptions for the patients. Patients openly discussed selling opioids prescribed by Dr. Mashali on the street. At one point, Dr. Mashali posted a sign that he would no longer write prescriptions for "oxy" and his patients were very distressed by their loss of income. The former sales representative also recalled that several pharmacies refused to dispense medications for the doctor due to his over-prescribing.

278. The Mashali Defendants enabled patients who were addicted to opioids or who were seeking opioids for purposes of diversion to obtain opioid prescriptions easily and without significant scrutiny. Defendant Mashali's excessive, illicit prescribing exacerbated the opioid epidemic in the City of Boston and endangered the health and welfare of Boston residents. Defendant Mashali also directly benefited from the City. From January 2012 until August 2013,

---

121 https://www.boston.com/news/crime/2017/03/15/pain-doctor-accused-of-overprescribing-opioids-pleads-guilty

Defendant Mashali benefited from the City as its health plan spent funds on opioid prescriptions written by the Defendant.

279. In addition, this prescriber and others like him, and the pharmacies at which their patients filled prescriptions for opioids, would have yielded orders of unusual size, frequency, or deviation, or raised other warning signs that should have alerted Defendants not only to an overall oversupply in the Boston area, but to specific instances of diversion. Defendant Mallinckrodt, who had first-hand knowledge of Dr. Mashali's suspicious prescribing, failed to report him. Based on publicly available data, sales representatives from Janssen and Teva also visited Defendant Mashali, but, there is no indication that these Defendants reported him, or other Boston area doctors or pharmacies, to law enforcement or medical or pharmacy boards.

K. Defendants Hid Their Lack Of Cooperation With Law Enforcement and Falsely Claimed To Be Actively Working To Prevent Diversion

280. When a wholesaler or manufacturer does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action – or may not know to take action at all.

281. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

282. More generally, the Defendants publically portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone."[122] Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria."[123] Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse.[124] A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[125]

283. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at

---

[122] Cardinal website, Ethics and Governance, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance.html.

[123] Cardinal website, Archives, Cardinal Health Values Statement, available at http://cardinalhealth.mediaroom.com/valuestatement.

[124] Cardinal website, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/community-relations/population-health/rx-drug-misuse-and-abuse.html.

[125] Lenny Bernstein et al., How Drugs Intended for Patients Ended up in the Hands of Illegal Users: 'No one was doing their job', The Washington Post (Oct. 22,2016), http://wapo.st/2vCRGLt.

every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion.[126] Defendant McKesson has also 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."[127]

284. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." [128] A company spokeswoman, Lauren Moyer, also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."[129]

285. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade associations, the HDMA and the NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[130]

> "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."

---

[126] McKesson website, Pharmaceutical Distribution for Manufacturers, available at http://www.mckesson.com/manufacturers/pharmaceutical-distribution/.

[127] 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, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

[128] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

[129] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

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

"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."

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

287. These public statements created the false and misleading impression that the Distributor Defendants rigorously carried out their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

288. Manufacturing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[131]

289. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has

---

[131] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

290. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[132] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[133] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[134]

291. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

---

[132] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/.

[133] Purdue website, *Opioids Corporate Responsibility*, available at http://www.purduepharma.com/news-media/opioids-corporate-responsibility/.

[134] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

292. Mallinckrodt made misrepresentations regarding its efforts to fight opioid addiction. Mallinckrodt claims on its website to be "committed both to helping health care providers treat patients in pain and to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . ."[135] The truth, of course, is that Mallinckrodt failed to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continued to fill suspicious orders, which supplied far more opioids than were justified and led to diversion of opioids in Boston and other cities and states.

293. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

L. By Increasing Opioid Prescriptions and Use, Defendants Collectively Fueled The Opioid Epidemic And Significantly Harmed Boston and its Residents

294. Manufacturing Defendants' and Defendant Insys' misrepresentations prompted Boston health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, Manufacturing Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and

---

[135] Mallinckrodt website, Our Programs, http://www2.mallinckrodt.com/Responsibility/Responsible_Use/Our_Programs/

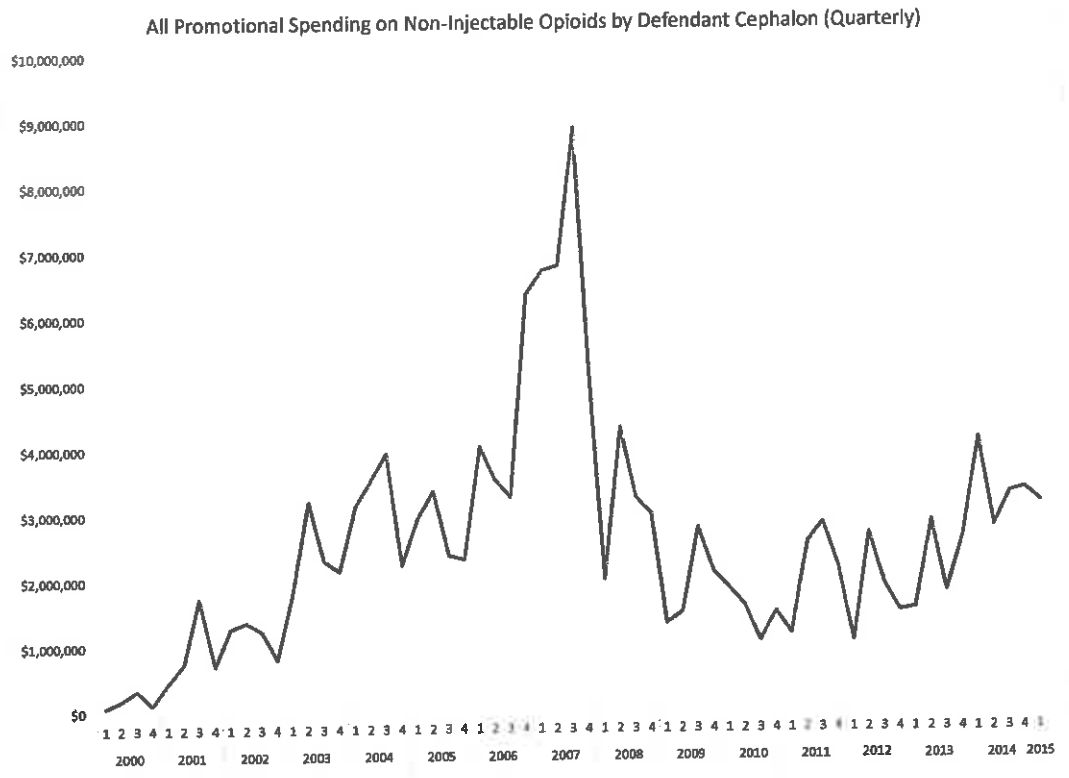
benefits of long-term opioid use. The Distributor Defendants recklessly distributed opioids and failed to meet their regulatory obligations in Massachusetts.

295. Defendants' deceptive marketing and illegal distribution practices substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain. Since 2016, 20% of office visits have included the prescription of an opioid.

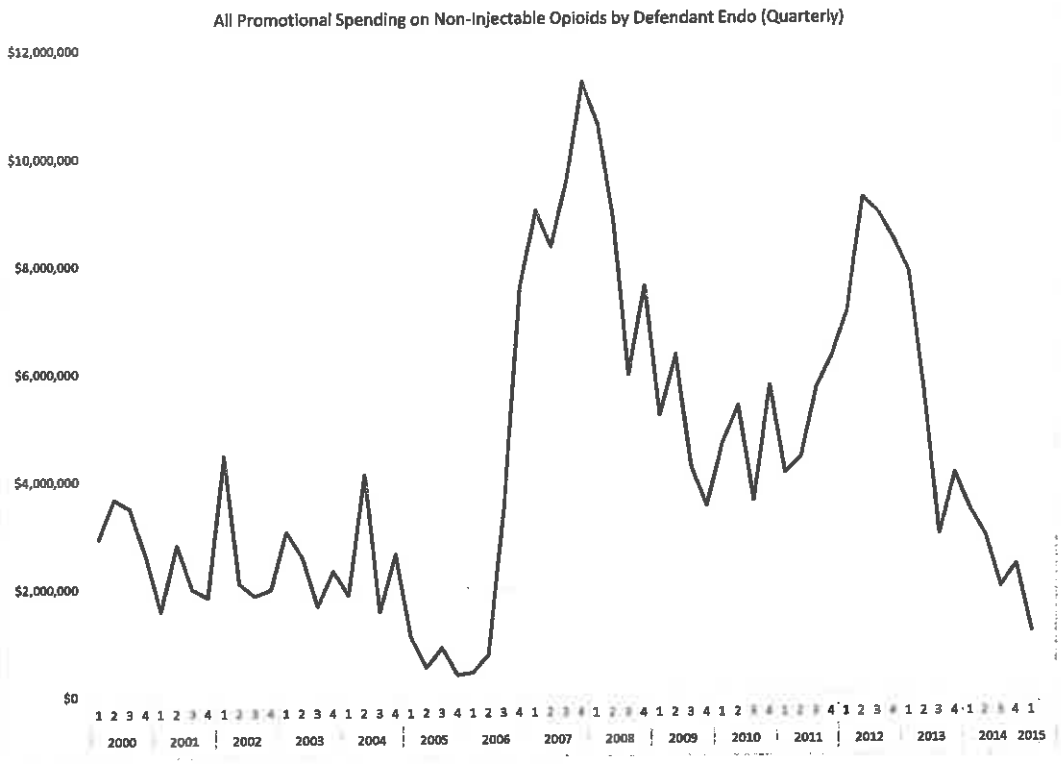
296. Overall sales of opioids in Massachusetts have increased over the past decade, and Boston is no exception. Between January 1, 2012 and April 30, 2018, the City's self-funded health plans spent over $9.5 million on opioid prescriptions. Additionally, during this time period the City's health plan spent over $1.3 million on in-patient treatment for opioid-use disorder. The City's workers' compensation program has also incurred a significant expense due to opioids. From July 2012 until August 1, 2018, the City's workers' compensation program spent over $100,000 on opioid medications for those in the program.

297. Manufacturing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

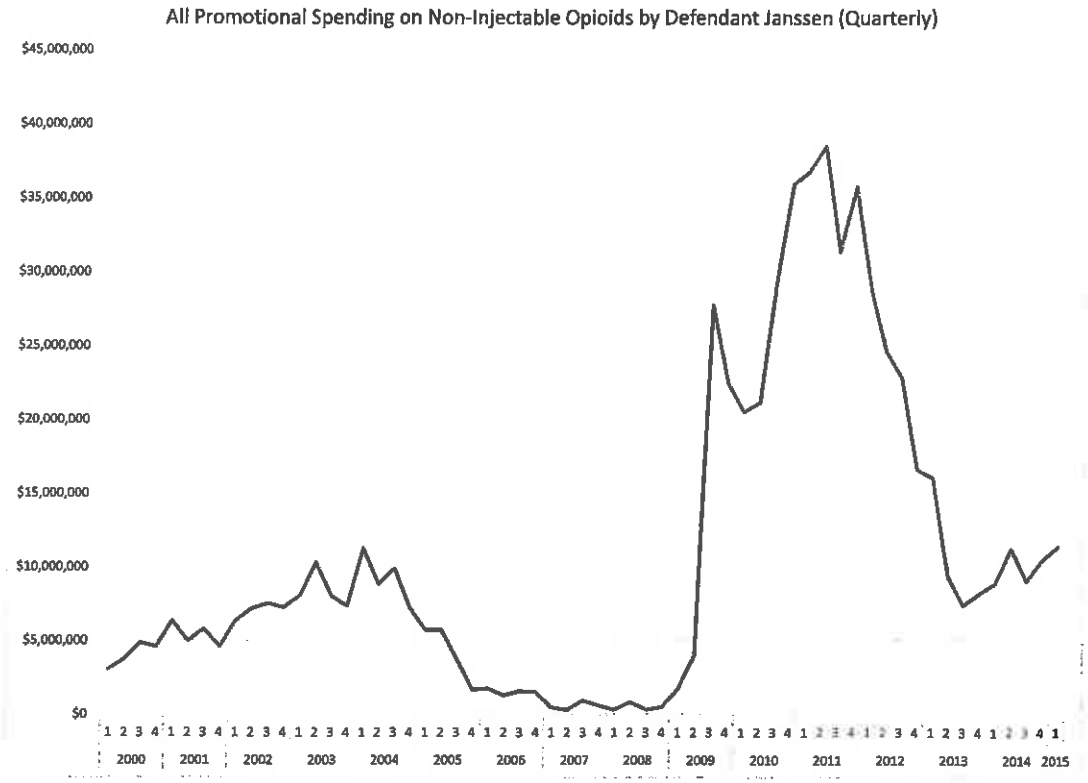
298. Teva's quarterly national spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:


All Promotional Spending on Non-Injectable Opioids by Defendant Cephalon (Quarterly)
$10,000,000
$9,000,000
$8,000,000
$7,000,000
$6,000,000
$5,000,000
$4,000,000
$3,000,000
$2,000,000
$1,000,000
$0
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015

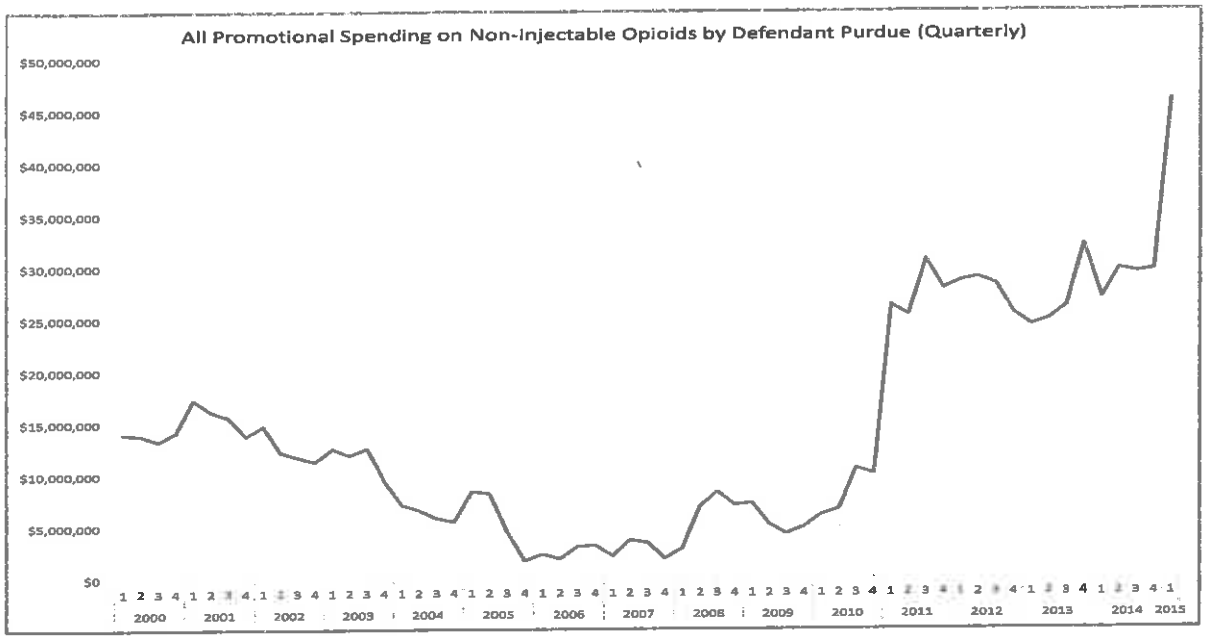
299. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



300. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



301. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continued to rise through at least 2015, as shown below:



302. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in Boston. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[136]

303. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking

[136] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing before the Senate Caucus on Int'l Narcotics Control*, May 14, 2014 Hr'g Testimony of Dr. Nora Volkow, available at http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[137]

304. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

305. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[138]

---

[137] *See* Murthy, *supra* note 2.

[138] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *Increases in drug and opioid overdose deaths—United States, 2000–2014*, Am. J. of Transplantation 16.4 (2016): 1323-1327.

306. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[139]

307. 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."[140] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[141]

308. Boston has experienced a surge of prescription opioids into its communities. Between 2010 and 2016, an average of 457 mg of oxycodone were dispersed per Boston resident, which is twice as high as the state average and nearly three times as high as the national average.

309. The number of individuals in Boston seeking treatment for opioid addiction reflects these statistics. As of May 2015, Boston had 152 treatment beds per 100,000 residents, which is the largest amount in the Commonwealth. Due to the location of Boston, at any given time, treatment beds based in Boston may be filled by individuals who live outside of Boston.

310. Thousands of Boston residents have experienced opioid-related overdoses, and the number of overdoses has only increased in the last few years. In 2014, the Boston Fire Department administered Narcan--the antidote to opioid overdose - 401 times. In 2015, this number nearly doubled to 777 overdoses involving the administration of Narcan. This number increased again in

---

[139] Theodore J. Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

[140] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).

[141] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse,* New Engl. J. Med. (Apr. 14, 2016).

2016, to 983 overdoses treated with Narcan, and increased again in 2017 to 1,182 overdoses where Narcan was administered – nearly triple the amount in just three years. As a result, the Boston Fire Department has spent a large amount of money on Narcan. From 2014 to 2018, the Department spent over $1.1 million on Narcan-related costs approximately $140,000 on Narcan itself, and protective masks and gloves which were purchased specifically for Narcan response incidents, which cost approximately $786,000. In total, the amount of Narcan and Narcan related costs was approximately $2,000,000 during this time.

311. Many of the City's first responders have been impacted by the opioid epidemic in the City. In recent years, the City's Fire Department has faced a high turn-over rate due to "burn-out" from constantly responding to overdoses. The Fire Department is now working in approximately 3 to 6 month rotations, and have has seen an uptick in transfers in and out of fire companies in neighborhoods which are impacted by the opioid crisis, including the neighborhood in which it is the headquarters is located, in order to combat fatigue and the emotional toll of the drug crisis in Boston.

312. There has recently been a surge in narcotic- related transports by the Emergency Medical Services ("EMS"), which is under the Boston Public Health Commission. According to Boston's EMS, there has been a steady increase in calls due to narcotic-related illnesses. In 2012, EMS responded to 1,381 narcotic-related illness calls. In 2014 this number increased to 2,037, and increased again in 2016 to 2,879 narcotic-related illness calls. In 2017, EMS responded to 3,604 narcotic-related illness calls, nearly three times the amount of narcotic-related illness calls than five years earlier. From January 1, 2018 until August 26, 2018, EMS responded to 2,336 narcotic-related illness calls, compared to 2,172 in the same time period in 2017. Additionally, the amount of Narcan administered by EMS has increased. In 2012, EMS administered Narcan

431 times. In 2014, this number nearly doubled to 809 administrations of Narcan. In 2017, EMS administered Narcan a total of 1,954 times. From January 1, 2018 until August 26, 2018, EMS administered Narcan to Boston residents 1,266 times, which is higher than the doses administered during the same time frame in 2017, which was 1,132 doses. The Director of the emergency department of Massachusetts General Hospital in Boston has suggested that residents buy and train on the use of Narcan, in order to save a loved one's, or stranger's, life.

313. Nationwide, opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 194,000 people died in the United States from prescription-related overdoses. Boston has experienced a steady-increase in opioid-related deaths. In 2012, opioid-related deaths claimed 70 lives in Boston in just one year. In 2015 this number increased to 146 opioid-related deaths for the year—more than double the number of deaths from 2012. In 2016, there were 193 people in Boston who died due to opioid overdoses in a single year. Additionally, the number of deaths that Boston's Emergency Medical Services, ("EMS") reported to the medical examiner increased by 50% from 2016 to 2017. This increase was attributed to opioid overdoses.

314. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive. Because the addictive pull of opioids is so strong, relapse is more common than with other drugs.

315. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25%

of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

316. The abuse of opioids has caused additional medical conditions that have injured residents in Boston. A growing number of people need medications aimed at treating secondary effects of opioids—including not only addiction and overdose, but also side effects like constipation and sedation. According to a recent analysis by the *Washington Post*, working-age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effect medications—essentially, drugs to treat the effects of opioids—generated at least $4.6 billion in spending nationally in 2015, on top of $9.57 billion in spending on opioids themselves.

317. The deceptive marketing and overprescribing of opioids also had a significant detrimental impact on children. Prescription opioid use before high school graduation is related to a 33% increase in the risk of later opioid misuse.[142] Additionally, the adolescent misuse of opioid medications greatly predicts the later use of heroin.[143] However, according to the CDC Guidelines, there has been a significant increase in the prescribing of opioids to adolescents and children for headaches and injuries.[144] Boston is no exception. According to a report regarding

[142] U.S. Pharmacist, Legitimate Opioid Use Prior to High School Graduation Increase Abuse Risk, available at https://www.uspharmacist.com/article/legitimate-opioid-use-prior-to-high-school-graduation-increases-abuse-risk.

[143] National Institute of Health, *Prescription Opioid Use is a Risk Factor for Heroin Use,* available at *https*://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use.

[144] CDC Guidelines.

substance abuse amongst Boston youth, from 2010 to 2015, 2.1% of hospital visits for Boston residents, ages 12-17, involved opioids.

318. Additionally, according to a 2015 survey conducted on students in Boston public high schools and vocational schools, 8% stated that they used prescription drugs, and 1% have admitted to using heroin. According to a survey conducted of Boston Public Middle School students, 7% of 10,691 students have admitted to using prescription pain medications without a prescription. Additionally, several school nurses within Boston Public Schools have asked that the schools carry Narcan, as they are concerned about overdoses within their schools. However, School officials are concerned that the costs associated with Narcan, which include training on Narcan administration and the hiring of additional nurses, will detract from other needs, such as asthma and diabetes medications.

319. City and Boston Public Health Commission resources have been diverted from specific programs, including the gang-outreach task force, to fight the opioid epidemic. The Boston Public Health Commission's outreach workers have recently had to devote time and efforts to children and families who struggle with opioid addiction, instead of to at-risk children susceptible to gangs. Additionally, children in Boston have been exposed to overdoses and drug paraphernalia in public buildings.

320. According to an employee of the Boston Public Libraries, overdoses occur and drug paraphernalia is found in the public libraries' bathroom stalls, which children often use. There have also been numerous fatal and non-fatal overdoses within the Boston Public Library system. From July 1, 2016 until June 30, 2017, 3 fatal overdoses and 12 non-fatal overdoses occurred in the City's libraries. From July 1, 2017, until June 30, 2018, there were 6 non-fatal overdoses that

occurred in the City's libraries. Additionally, the library system has experienced an increase in drug related incident reports.

321. The opioid epidemic is affecting other public areas in Boston, as areas such as public parks with playgrounds have become dangerous due to needles and drug paraphernalia being left in the parks. There are 276 parks within the City of Boston Park System, and 146 of these parks have active play features, which include tot lots, ball fields, and ball courts. According to a City employee, a park in the Roxbury neighborhood has become "infested" with needles, as people often use drugs at the park, and leave their needles behind. From 2013 until August 15, 2018, there were 219 calls to constituent services due to needles being found in parks. The disposal of needles and drug paraphernalia in the parks has created a safety concern for Boston residents, as children play in the playgrounds and bleachers. Additionally, several Boston day care centers utilize the parks for children to play. From 2014 until August 15, 2018, the Boston Fire Department has administered Narcan in the City parks due to overdoses 37 times. During this time period the Boston Fire Department responded to 10 calls in City parks due to overdoses in which Narcan was not administered. Additionally, Emergency Medical Services responded to 128 narcotic-related illness calls at the City's parks during this time.

322. Residential neighborhoods are also becoming areas for drug use. According to the Department of Inspection Services, an abandoned park which is located in the middle of a residential neighborhood, has a tree cluster, which is often utilized for drug use. In one day, the Boston Public Health Commission cleaned up over 400 used needles in the tree cluster.

323. Additionally, children and families in Boston witness first-hand the devastation of the opioid crisis in Boston public housing. According to the Boston Housing Authority, there are currently 6,491 children, ages 17 and under, who reside in the Boston Housing Authority's public

housing buildings. Additionally, according to the Boston Housing Authority, several individuals who are addicted to opioids and other drugs now live in the hallways of the public housing provided by the Boston Housing Authority, and mothers and children frequently step over individuals who are unconscious due to taking drugs, such as opioids. Furthermore, there have been several fatal and non-fatal overdoses in the public housing buildings. In order to combat drug dealing and violent crimes, the Boston Housing Authority has installed several security cameras to prevent and document drug dealing within the buildings. According to the head of the residents' board at one of the Boston Housing Authority's complexes, many individuals who are addicted to drugs have broken into the buildings and live in the hallways and stairwells. Children and families frequently come across needles in the building. Although the Boston Housing Authority cleans the building, the day after the cleaning the complex returns to a terrible condition, with needles, urine, and feces found in the hallways and stairwells.

324. Children attending summer camps have also been affected by the opioid crisis. According to the City's Department of Property Management, several children attend summer camps in buildings owned by the City. Children have been unable to use certain bathrooms in these buildings due to drug use and overdoses that have occurred in the bathrooms, and needles being found in the toilet. The Department has had to find other bathrooms in the buildings for their use. In the last 18 months, a Department employee has found two individuals who have overdosed in the City buildings' bathrooms, with needles still in their arms.

325. Many children in Boston have gone without meals due to their parents' drug addiction. There are several public buildings in Boston which provide breakfast, lunch, and dinner to Boston residents. Many of the residents who come for the meals are children whose parents have spent money on drugs, including opioids, as opposed to food. Additionally, members of the

Boston Fire Department frequently witness people injecting drugs in broad daylight on Boston's streets, around the perimeter of the Fire Department headquarters.

326. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

327. NAS rates in Boston have steadily increased during the past few years. In 2010, there were 6.2 babies born with NAS for every 1,000 live births in Boston. In 2013, this number increased to 7.4 babies born with NAS for every 1,000 live births, and jumped again in 2015 to 8.5 babies for every 1,000 live births in Boston. At Boston Medical Center, the average cost of a hospital stay for a baby with NAS is just under $20,000. According to the Boston Public Health Commission, from 2012 to 2015, 168 pregnant women in the City received treatment for opioid use disorder.

328. Additionally, according to Boston Public School officials, school principals have noticed that more children as young as ages 3 to 5-years old have been demonstrating intensive behavioral problems. These principals suspect that these children may have been born with NAS

and are continuing to suffer from the effects of this painful disease. Additionally, according to the Director of the Boston Public Schools Health Services, the schools' psychological services numbers have increased, mostly due deaths in the family, and many of these deaths are related to opioid addiction.

329. An increasing number of children in Boston have been placed in foster care because their parents or caregivers are addicted to opioids. As of June 30, 2016, 9,655 children in Massachusetts were in foster care, and the majority of these children were removed from their homes due to opioid addiction. Upon information and belief, many of these children lived in Boston, and many of these children were newborns. Several grandparents in Boston are now raising their grandchildren and are becoming the custodial grandparent due to their children's substance abuse disorder. The Boston Public School system has noted that many of its children have been removed from their homes due to parental opioid addiction. According to the Boston Public Schools system, many children are displaced and entering the foster care system or living with elderly grandparents due to the opioid crisis, and many of these children bring trauma with them to the classroom.

330. Defendants' success in extending the market for opioids to new patients and chronic conditions also created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury. According to the Boston Police Department, there has been a general increase in theft-related crimes due to the opioid epidemic. Additionally, the City has experienced thousands of arrests related to opioids. From 2014 until August 2018, the Boston Police Department has had 5,718 calls and/or arrests related to opioids. Additionally, according to the head of the Boston Centers for Youths and Families, violent crimes, such as child homicides, have increased due to resources being reallocated from gang-outreach in order to assist children

and families who deal with opioid addiction. Additionally, more thefts are occurring on City property. For example, many thefts have occurred in Faneuil Hall, as people are stealing laptops, backpacks, and items from retail stores owned by the City in order to pay for drugs.

331. The opioid epidemic in Boston has caused an additional increase in crimes such as prostitution. There are currently 405 vacant properties in Boston, and these properties are often used as centers for prostitution, where individuals offer sexual activity in exchange for money to purchase drugs. Individuals addicted to opioids also use these vacant buildings to use drugs. Additionally, elderly residents in Boston have been victims of crime due to the opioid crisis. Many of these residents are vulnerable, and have family members who are addicted to opioids who have stolen from them in order to pay for drugs. Boston's elderly population also has a high-risk for home burglaries where either their medications or their money is stolen to pay for drugs.

332. Contrary to Defendants' misrepresentations, most of the illicit use originates from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.

333. Those who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. The heroin epidemic has directly impacted Boston. Boston EMS responded to 2,433 cases involving heroin, which increased by 20% in 2017 to 2,927 cases.

334. Fentanyl is a relatively recent, even more deadly problem stemming from the prescription opioid epidemic. Fentanyl—a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into communities across the country. In

February 2018, state and federal law enforcement officials seized 77 pounds of illicit drugs in the Boston-area, which included over 30 pounds of fentanyl. Approximately $300,000 cash was also seized in the raid, along with heroin and opioids. According to a Suffolk County District Attorney, this one was of the most successful and "far-reaching" investigations in Massachusetts history

1. Programs Created by the City of Boston and Cost Expenditures from the City

335. In light of this crippling epidemic, Boston has instituted a number of cutting edge programs aimed at curbing addiction and abuse. For example, the City's Public School system has created programs to help children who suffer from opioid abuse, as well as provide support for children who have family members who are dealing with addiction. Additionally, the school system has a Wellness Policy which requires a comprehensive health education program that teaches skills and knowledge to prevent substance abuse. The Health and Wellness Department has curriculum and training available to all of the City's Public School staff. However, due to staffing and funding limitations, less than half of the City's Public Schools are able to offer this education. Additionally, the Schools' Health Services Department is working to create Screening, Brief Intervention, and Referral to Treatment (SBIRT) and under this program nurses will screen middle school and high school students for addiction and refer students for additional support if they are identified as at risk for substance abuse. Ostiguy High School, which is operated by Action for Boston Community Development in conjunction with the City, is a school designed for Boston's youth who struggle to succeed in conventional schools due to their histories with substance abuse. In fiscal year 2018, the City spent over $300,000 on funding for the school

336. Despite offering these services, the Boston Public School System would like to implement the Mayor's Youth Substance use Prevention Strategic Plan, but lacks the funding and resources to fully implement the program. The program's recommendations include, but are not limited to, implementing Boston Public School's Wellness Policy in all elementary, middle, and

high schools; which the City estimates would cost approximately $3.2 million, expanding data collection from the Youth Risk Behavior Survey to include Census Sampling, which the City estimates would cost $230,00 full implementation of the SBIRT program, stocking naloxone in all schools, and increasing support for substance abuse programs.

337. The City's Police Department has created programs to combat the opioid crisis as well. The Boston Police Department has an overdose squad which goes out into the community and knocks on Boston residents' doors to discuss recovery and to educate Boston residents about treatment and recovery services. The Boston Police Department has spent millions of dollars in fighting the opioid epidemic in the City. The Boston Police Department has spent millions of dollars in fighting the opioid epidemic in the City. From 2014 until August 2018, the Boston Police Department spent over $7.1 million on costs associated with opioids, such as Detective and officer payroll related to opioid arrests, investigations related opioids, Narcan training, opioid seminars, a drug control truck, and protective equipment for City Police officers.

338. The City has expended substantial resources combatting the opioid epidemic, which has placed significant burdens on its social, criminal justice, and emergency response services. For example, since fiscal year 2014, the Department of Property Management spent at least $50,000 in security costs directly related to opioids. Between January 1, 2012 and April 30, 2018, the City health plan spent over $9.5 million on opioid prescriptions. Additionally, during this time period the City's health plan spent over $1.3 million on in-patient treatment for opioid-use disorder. The City's workers' compensation program has also incurred a significant expense due to opioids. From July 2012 until August 1, 2018, the City's workers' compensation program spent over $100,000 on opioid medications for those in the program.

339. The City's Fire Department has spent a large amount of money on Narcan. From 2014 to 2018, the Department spent approximately $2,000,000 on Narcan-related costs. The Fire Department has also experienced an increase in spending due to other opioid-related costs which include, but are not limited to community outreach, overtime for firefighters, and the "knock and talk" program. In the "knock and talk" program, after the Boston Fire Department responds to an incident where Narcan is administered, the Department, through its Employee Assistance Program members and the Office of Recovery Services staff, will follow-up at the address where it responded to the call and inquire (1) whether the person involved is interested in drug treatment, and provide treatment information, (2) whether the person is interested in a needle exchange program, and (3) whether the person or family is interested in learning how to administer Narcan.

340. In 2014, the Fire Department spent approximately $300,000 on opioid-related costs. In 2015, this number nearly doubled to approximately $550,000. In 2018, the number nearly tripled from 2015 yet again, to approximately $1.5 million on opioid-related costs. In total, from 2014 to 2018, the Fire Department spent over $4.2 million on opioid-related costs. The Fire Department has also spent a significant amount of money on additional video cameras and security for its headquarters due to the opioid crisis. The cost incurred upon the Fire Department for its additional cameras and security is approximately $388,000.

341. The City's Parks Department has also incurred a significant expense due to extensive clean-up of needles and drug paraphernalia in parks, hiring park rangers, purchasing drug retrieval supplies, adding fencing for additional security, tearing down bleachers and playing fields due to drug usage, and other expenses. From June 2011 until August 16, 2018, the City's Parks Departments spent approximately $119,000 on such expenses.

342. The City's Property Management Department has expended funds and resources due to the opioid epidemic in Boston as well. Since fiscal year 2014, the Department of Property Management spent at least $50,000 in security costs directly related to opioids. The Opioid epidemic has also forced the City to add two extra security shifts at the Bolling Building, a building owned by the City. In 2017 and 2018, the City spent additional funds on these security shifts.

343. The City's Public Library system has also incurred expenses due to the opioid crisis. The library system has agreed to fund outreach and engagement services at its Public Library and in the surrounding neighborhoods. Additionally, 22 active library branches have boxes in restrooms in which individuals can dispose needles, and the boxes are picked up twice per year or as needed if/when the boxes fill up. Since the installation of the boxes in January 2018, one box in the Johnson Library ladies' restroom has required two services calls due to being filled. The City has spent just under approximately $10,000 for a one year contract for the needle disposal boxes.

2. Programs Created by the Public Health Commission and Cost Expenditures from the Boston Public Health Commission

344. The Boston Public Health Commission has taken numerous significant steps to fight the opioid epidemic in Boston. Annually, Boston EMS dedicates 80 percent of a department paramedic's time to review every potential Boston EMS narcotic-related incident, the dataset of verified cases allows for near-real time reporting and trend analysis supporting situational awareness, outreach and recovery services. Data analysis and case review is supported in-house by a deputy superintendent and a medical director. In 2017, Boston Emergency Medical Services added a non-transport Community Assistance Team, referred to as Squad 80, to support emergency medical calls in two sections of the city with a high volume of overdoses. Squad 80 has four additional EMTs, who work full-time day and evening shifts, with 75% of the call volume for the

day crew and 50% of the evening crew being for incidents that are narcotic-related.[1] In fiscal year 2018, the Boston Public Health Commission spent approximately $303,000 on personnel time to support the city's opioid response efforts. The Boston Public Health Commission's EMS has incurred additional opioid-related costs, as well, including naloxone, oxygen, gloves, needles, saline, staff, physician support, and other expenses. In fiscal year 2014, Emergency Medical Services spent approximately $154,000 on these expenses. In fiscal year 2016, this number increased to approximately $180,000. In fiscal year 2017, Emergency Medical Services spent a total of approximately $221,000 on these expenses. In fiscal year 2018, when Squad 80 was introduced, Emergency Medical Services spent approximately $420,000 on opioid-related expenses, nearly double the amount spent in 2017. From fiscal year 2014 until fiscal year 2019, Emergency Medical Services spent a total of approximately $1,672,000 on opioid-related costs and expenses, with additional approximately $522,000 projected to be spent in fiscal year 2019.

345. Under the Office of Recovery Services, which was established in 2015, the Public Health Commission has created several programs to help those seeking recovery from opioid addiction. In 2017, the Public Health Commission opened an Engagement Center, which is a drop in center for Boston residents that has snacks, a television, books, as well as a nurse, street outreach workers, and clinical workers who can connect Boston residents to recovery programs. The Center is open daily and assists Boston Police Department officers and Street outreach workers as a resource to guide individuals in need of support. Additionally, in 2016, the Public Health Commission greatly expanded the Providing Access to Addiction Treatment, Hope, and Support ("PAATHS Program"). Under the PAATHS program, anyone in Boston is able to dial 311, 24 hours a day, seven days a week, in order to access all levels of substance abuse and addiction treatment recovery-related support services for friends and family members, and answers to

general questions related to substance use and addiction. When the PAATHS Program first opened, it had 5 or 6 full-time staff members. As of 2018, the program has tripled its staff to 15 full-time staff members.

346. The Office of Recovery Services who supports a program called "Entre Familia," or "Between Family," which provides bilingual, gender-specific treatment programs to pregnant women and postpartum mothers who suffer from substance abuse disorder. Entre Familia primarily serves the Hispanic and Latino population of Boston, and helps these women, as well as their children, in their paths to recovery. Through Entre Familia, the women who participate in the program receive clinical treatment services such as screening, assessment, and referrals to medical and mental health services, childcare, residential care, and other specialized referrals for behavioral difficulties and early intervention. The Office of Recovery Services also provides a Narcan administration program which is open to Boston residents, in which staff members teach residents how to administer Narcan in the event of an opioid overdose.

347. The Boston Public Health Commission has also created the Access, Harm Reduction, Overdose Prevention and Education ("AHOPE") program, which offers services to injection drug users. Such services include integrated HIV, Hepatitis, and STI testing, a free, legal and anonymous needle exchange, referrals to medical treatment, overdose prevention education and training, risk reduction supplies to reduce to spread of HIV and Hepatitis C, risk reduction counseling, and referrals to substance abuse treatment. The AHOPE program has a walk-in center which is open Monday through Friday, as well as a mobile van which provides services to Boston residents.

348. The Boston Public Health Commission's Office of Recovery Services also has several outreach workers who visit areas known for drug use to help connect those who suffer

from drug addiction with treatment services. The outreach workers carry duffle bags with boxed syringes, as well as items to help them pick-up used drug paraphernalia. In less than a six month time-span, the outreach workers connected over 600 Boston residents with treatment services and services from other Boston agencies. In addition to the outreach workers, in 2015 the Boston Public Health Commission created the "Mobile Sharps Collection Team," which safely cleans up and disposes discarded needles. Boston residents are able to report the locations of the needles through its "Citizens Connect" app, or the 24-hour 311 line. In June of 2015, the program collected over 2,000 loose needles in Boston.

349. From fiscal year 2014, until fiscal year 2018, the Boston Public Health Commission spent over $32 million on its various programs to help Boston residents who suffer from opioid addiction. In fiscal year 2019 the Boston Public Health is projected to spend over $8.5 million.

350. Additionally, prior to 2014, many of Boston's homeless residents and residents in recovery lived in the Long Island section of the Boston. However, in 2014, the Mayor of Boston, Marty Walsh, was forced to shut down the bridge to the island due to safety concerns, and relocated the island's residents into Boston. In April 2017, in conjunction with the Boston Public Health Commission, Mayor Walsh committed $92 million to rebuild the bridge to provide addiction recovery services on the island. The Boston Public Health Commission has also agreed to fund $1.8 million to make the engagement center a permanent location. (*See supra* paragraph 351.)

3. Programs Created by the Boston Housing Authority and Cost Expenditures from the Boston Housing Authority.

351. The Boston Housing Authority has also spent significant funds for security cameras in order to deal with the opioid crisis. The Boston Housing Authority has spent approximately $5.2 million to install 556 security cameras within its buildings, in order to prevent drug dealing and

violent crimes, many of which have been related to opioids. They have allocated an additional approximate $4 million to install more cameras in its buildings.

M. Defendants Fraudulently Concealed Their Misconduct

352. Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history 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 FDA and other regulators warned Manufacturing Defendants and Defendant Insys of this, and likewise, Purdue and Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of these Defendants' misrepresentations.

353. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful and fraudulent conduct. Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. Purdue, Endo, Teva, and Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Teva, and Janssen masked or never disclosed their role in shaping, editing, and approving the content of this information.

354. Manufacturing Defendants thus successfully concealed from the medical community, patients, and Boston facts sufficient to arouse suspicion of the claims that Boston now asserts. Boston did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

355. The Distributor Defendants also fraudulently concealed their misconduct. They have declined to publicly release the ARCOS data which provides detailed tracking information about their shipments. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion, and publicly portray themselves as committed to fighting the opioid epidemic, while failing to prevent diversion.

356. Defendants thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that the Plaintiffs now asserts. The Plaintiffs did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

357. Further, Defendants 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 prescribers and pharmacy orders.

V. CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

358. The Plaintiffs incorporate the allegations within all other paragraphs of this Complaint as if fully set forth herein.

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

360. Defendants, individually and acting through their employees and agents, through fraudulent and deceptive marketing, the operation of pill mills, excessive distribution of opioids, and/or other fraudulent schemes as described herein, created and maintained the opioid epidemic in the City of Boston, which is harmful and disruptive to and unreasonably annoys, injures, endangers, and interferes with the public health, public safety, public peace, public comfort, and/or public convenience. The public nuisance caused by Defendants has significantly harmed the Plaintiffs and a considerable number of Boston residents.

361. The Marketing Defendants fraudulently and deceptively marketed opioids. Further, Defendant Purdue misleadingly portrayed itself as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, it failed to satisfy even the minimum, legally-required obligations to report suspicious prescribers.

362. In addition, by causing dangerously addictive drugs to flood the community, and to 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 Boston to public health, safety, peace, comfort, and convenience. The public nuisance caused by Defendants' actions has caused substantial annoyance, inconvenience, and injury to the public.

363. By distributing, selling, and prescribing dangerously addictive opioid drugs not connected to a legitimate medical, scientific, or industrial purpose, all Defendants have committed

a course of conduct that injuriously affects the safety, healthy, and morals of the people of Boston.

364. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes and by failing to report suspicious orders of opioids, Manufacturing Defendants, Defendant Insys and Distributor Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the people of Boston.

365. Defendants knowingly, intentionally, unlawfully, recklessly, and fraudulently manufacture, market, distribute, sell, and prescribe prescription opioids, which Defendants know, or reasonably should know, will produce widespread distribution of prescription opioids in and/or to Boston, resulting in addiction and abuse, an elevated level of crime, death, and injuries to the residents of Boston, a higher level of fear, discomfort, and inconvenience to the residents of Boston, and direct costs to Plaintiffs.

366. All Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in the City. Defendants' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted.

367. Defendants knew of the public health hazard their conduct would create.

368. It was foreseeable to Defendants that their conduct would unreasonably interfere with the public health, public safety, public peace, public comfort, and/or public convenience.

369. Defendants' conduct is unreasonable, intentional, unlawful, reckless, or negligent.

370. Defendants' conduct is widespread and persistent, and creates substantial and ongoing harm. The harm inflicted outweighs any offsetting benefit. Defendants' conduct has caused deaths, serious injuries, and a severe disruption of public peace, health, order and safety. Defendants' ongoing and persistent misconduct is producing permanent and long-lasting damage.

371. Defendants had control over their conduct in Boston as is described in this Complaint, and that conduct has had an adverse effect on the public. Defendants had sufficient control over, and responsibility for, the public nuisance they created—Defendants were in control of the "instrumentality" of the nuisance, namely prescription opioids, including the process of marketing, promotion, distribution, prescribing, and creation and maintenance of the demand for prescription opioids at all relevant times.

372. Defendants' conduct and the opioid epidemic it created is likely to continue to cause significant harm to the Plaintiffs and Boston residents.

373. Plaintiffs have suffered and continue to suffer special injuries distinguishable from those suffered by the general public. As discussed herein, they have incurred and continue to incur substantial costs from investigating, monitoring, policing, and remediating the opioid epidemic.

374. 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.

375. The public nuisance – i.e. the opioid epidemic - created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

WHEREFORE, Plaintiffs demand judgment in their favor against the Defendants for injunctive relief, abatement of the public nuisance, and for compensatory damages in an amount to be determined by a jury, together with prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT II
Violations of Massachusetts General Laws Chapter 93A
(Against Manufacturing Defendants, Defendant Insys, and Distributor Defendants)

376. Plaintiffs incorporate the allegations within all other paragraphs of this Complaint as if fully set forth herein.

377. Through the acts alleged herein Defendants engaged in deceptive trade practices in violation of Massachusetts law.

378. Defendants were and still are engaged in "trade" and "commerce" as defined by Massachusetts General Laws, Chapter 93A, Section 1.

379. Plaintiffs were and are engaged in "trade" and "commerce" as defined by Massachusetts General Laws, Chapter 93A, Section 1.

380. The transactions, actions and inaction of Defendants, as described herein, constitutes unfair and deceptive acts and practices as defined by, and in violation of, Massachusetts General Laws, Chapter 93A, Sections 2 and 11.

381. Defendants committed and continue to commit repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in the conduct of commerce.

382. Each Defendant wrongfully represented that the opioid prescriptions they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have. These misrepresentations include but are not limited to the following:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that opioid doses can be increased until pain relief is achieved and there is no ceiling dose;

d. Defendants' overstatement of the risks of NSAIDs, when compared to opioids;

e. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

f. Defendants' claims that screening tools effectively prevent addiction;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Purdue's and Endo's claims that abuse-deterrent opioids prevent tampering and abuse;

i. Purdue's claims OxyContin provides a full 12 hours of pain relief;

j. Purdue's claims that it cooperates with and support efforts to prevent opioid abuse and diversion;

k. Insys' unsubstantiated claims that Subsys was appropriate for treatment of non-cancer pain and its failure to disclose that Subsys was not approved for such use;

l. Teva's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use; and

m. Defendants' use of front groups, to suggest that the deceptive statements from these sources described in this Complaint came from objective, independent sources.

383. The Defendants used exaggeration and/or ambiguity as to material facts and omitted and concealed material facts, which tended to deceive and/or did in fact deceive. The omissions and concealments of material fact include but are not limited to the following:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines, particularly while exaggerating the risks of competing products, such as NSAIDs;

e. claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

h. Defendants' failure to disclose their financial ties to and role in connection with KOLs and front groups.

384. The Defendants' omissions rendered even their seemingly truthful statements about opioids deceptive.

385. In addition, each Manufacturer and Distributor Defendant engaged in unfair and/or deceptive trade practices by failing to report suspicious orders of opioids and/or prevent the diversion of highly addictive prescription drugs to illegal sources.

386. 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, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell or distribute opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

387. Defendants' unfair, deceptive, and unconscionable misrepresentations, concealments, and omissions were reasonably calculated to deceive the public, the healthcare community, and the Plaintiffs.

388. Defendants acted knowingly, intentionally, and unlawfully.

389. Defendants' representations, concealments, and omissions constitute a willful course of conduct that continues to this day.

390. Without Defendants' unfair and/or deceptive trade practices, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted. Defendants' actions were immoral, unethical and unscrupulous and unlawfully caused the opioid epidemic in Massachusetts and in Boston.

391. Defendants' manufacturing, marketing, sales, and distribution practices unlawfully caused an opioid and heroin plague and epidemic in the City. Each Defendant had a nondelegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate channels.

392. The damages that the Plaintiffs seek to recover were sustained as a direct and proximate result of the Defendants' intentional and unlawful acts and omissions.

393. The Plaintiffs seek injunctive relief and economic losses resulting from Defendants' deceptive trade practices. The Plaintiffs do not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

394. 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. The Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFORE, the Plaintiffs demand judgment against the Defendants in an amount to be determined at trial, with said amount doubled or trebled in accordance with the provisions of Chapter 93A; and, that said judgment include an award of attorney's fees and costs; and for such other relief as this Court deems just and equitable.

COUNT III
Negligence and Negligent Misrepresentation
(Against Manufacturing Defendants, Defendant Insys, and Distributor Defendants)

395. The Plaintiffs incorporate the allegations within all other paragraphs of this Complaint as if fully set forth herein.

396. To establish actionable negligence, the Plaintiffs must show, in addition to the existence of a duty, a breach of that duty and injury resulting proximately therefrom. All such elements exist here.

397. Defendants have a duty to exercise reasonable care in manufacturing, marketing, distributing, and selling highly dangerous opioid drugs.

398. Defendants have a duty to exercise reasonable care under the circumstances. This includes a duty not to cause foreseeable harm to others. In addition, Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

399. Manufacturing Defendants repeatedly breached their duties by deceptively marketing opioids as described herein, including minimizing their risks, such as the risks of addiction and overdose, and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain. Manufacturing Defendants omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. These Defendants' omissions rendered even their seemingly truthful statements about opioids deceptive.

400. 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 purpose of these duties was to prevent the resulting harm – misuse and/or diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

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

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

403. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

404. The foreseeable harm from a breach of these duties is the abuse and diversion of prescription opioids, and addiction, overdose, and death in the Plaintiffs' communities.

405. Reasonably prudent manufacturers of pharmaceutical products would know that deceptively and misleadingly marketing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Defendants. Reasonably prudent manufacturers and distributors would know that failing to report suspicious orders and prescribing, particularly while assuring the public of their commitment to

fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

406. Reasonably prudent manufacturers and distributors 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. The closed system of opioid distribution whereby 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.

407. These Defendants' breach of the duties described herein directly and proximately resulted in the injuries and damages alleged by the Plaintiffs.

408. The Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Defendants. They do not seek damages which may have been suffered by individual citizens of the City for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants

409. The misconduct alleged in this case is ongoing and persistent.

410. 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. The Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFORE, the Plaintiffs demand judgment in its favor against the Defendants for compensatory damages in an amount to be determined by a jury and punitive damages, together with prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such

other relief as this Court deems just and equitable.

COUNT IV
Fraud and Fraudulent Misrepresentation
(Against Manufacturing Defendants, Defendant Insys, and Distributor Defendants)

411. The Plaintiffs incorporate the allegations within all other paragraphs of this Complaint as if fully set forth herein.

412. Defendants, individually and acting through their employees and agents, knowingly and intentionally made misrepresentations and omissions of facts material to the Plaintiffs and Boston residents and medical professionals to induce them to purchase, administer, and consume opioids as set forth in detail above.

413. Manufacturing Defendants' fraudulent misrepresentations are detailed in this Complaint and include overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; falsely promoting abuse-deterrent formulations as reducing abuse; falsely claiming that OxyContin provides 12 hours of relief; and falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids.

414. Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead City prescribers and consumers.

415. All Defendants made false statements regarding their compliance with state and federal law regarding their duties to monitor, report, and halt suspicious orders and to prevent diversion, and/or they concealed their noncompliance with these requirements.

416. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

417. Defendants knew or should have known that the Plaintiffs would be adversely impacted economically by their misrepresentations in that citizens of the City would become addicted to the Defendants' opioids which, in turn, would cause the Plaintiffs to expend funds on emergency response; law enforcement, social services, and other municipal services to care for their citizens, thereby proximately causing the Plaintiffs injuries and damages. As such, the Defendants owed a duty of care to the Plaintiffs.

418. Defendants' false representations and concealments were reasonably calculated to deceive the Plaintiffs and Boston residents and the physicians who prescribed and the patients who took opioids in the City, were made with the intent to deceive, and did in fact deceive these persons and the Plaintiffs.

419. Defendants intended for the Plaintiffs, Boston residents, and health care providers to rely on their misrepresentations and omissions, and knew that such reliance would cause the Plaintiffs to suffer loss.

420. The Plaintiffs and healthcare providers and residents in the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, using, and paying for prescriptions for Defendants' opioids. As a result of Defendants' fraudulent misrepresentations, the use of Defendants' opioid medicines became widespread and continuous, and resulted in the scourge of addiction, overdose, and death that is plaguing the country and the City.

421. Plaintiffs suffered actual pecuniary damages proximately caused by Defendants' misrepresentations and omissions of material fact, which include expending additional funds on emergency response; law enforcement, social services, and other municipal services that the Plaintiffs otherwise would not have incurred.

422. The Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from the fraud of Defendants. They do not seek damages which may have been suffered by individual citizens of the City for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

423. The fraud alleged in this case is ongoing and persistent.

424. 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. The Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFORE, the Plaintiffs demand judgment in its favor against the Defendants for compensatory damages in an amount to be determined by a jury and punitive damages, together with prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT V
Unjust Enrichment
(Against All Defendants)

425. The Plaintiffs incorporate the allegations within all other paragraphs of this Complaint as if fully set forth herein.

426. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the City, including from opioids foreseeably and deliberately diverted within and into the City.

427. The Plaintiffs have expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

428. These expenditures include the provision of healthcare services and benefits, emergency services, social services, and other services in excess of what would normally be provided were it not for the opioid epidemic.

429. These expenditures have helped sustain Defendants' businesses.

430. The Plaintiffs have conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper marketing, distribution, and prescribing practices.

431. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

432. The Plaintiffs have paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers and patients with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, improper and excessive distribution of prescription opioids, and operation of pill mills, each Defendant obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the Plaintiffs lack a remedy provided by law.

433. Defendants have unjustly retained benefits to the detriment of Plaintiffs, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

434. Defendants' misconduct alleged in this case is ongoing and persistent.

435. 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.

436. Plaintiffs have incurred expenditures for special programs over and above its ordinary public services.

WHEREFORE, the Plaintiffs seek all legal and equitable relief as allowed by law, including disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law and such other relief as this Court deems just and equitable.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs requests the following relief:

A. A finding that, by the acts alleged herein, Defendants have created a public nuisance;

B. An injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance;

C. An order directing Defendants to abate and pay damages for the public nuisance;

D. A finding that Defendants engaged in unfair and deceptive trade practices in violation of Massachusetts General Laws Chapter 93A, Sections 2 and 11;

E. A finding that by the acts alleged herein, the Defendants were negligent and grossly negligent, and that Defendants engaged in fraudulent misrepresentations;

F. Compensatory damages in an amount sufficient to fairly and completely compensate for all damages alleged herein;

G. Punitive damages;

H. Disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein;

I. For costs, filing fees, pre and post judgment interest, and attorney's fees; and;

J. For all other relief at law or in equity, deemed just by this Court.

PLAINTIFFS DEMAND A TRIAL BY JURY AS TO ALL ISSUES SO TRIABLE.

Respectfully submitted,

CITY OF BOSTON

/s/ Eugene L. O'Flaherty
Eugene L. O'Flaherty BBO#567653
Corporation Counsel
City of Boston Law Department
Room 615, City Hall
Boston, MA 02201
(617) 635-4034
eugene.oflaherty@boston.gov

/s/ Timothy J. Harrington
Timothy J. Harrington, Esq. BBO#652549
General Counsel
Boston Public Health Commission
Boston Emergency Medical Services
617-534-4322
tharrington@bphc.org

/s/ Robert J. McConnell
Robert J. McConnell BBO# 550625
Kate E. Menard BBO# 682087
MOTLEY RICE LLC
55 Cedar Street, Suite 100
Providence, RI 02903
Tel: 401-457-7700
Fax: 401-457-7708
bmcconnell@motleyrice.com
kmenard@motleyrice.com

/s/ Donald A. Migliori
Donald A. Migliori BBO# 567562
MOTLEY RICE LLC
28 Bridgeside Blvd
Mt. Pleasant, SC 29464
Tel: 843-216-9241
Fax: 843-216-9450
dmigliori@motleyrice.com

/s/ Linda Singer
Linda Singer
Elizabeth Smith
Sara Aguiñiga
Pro Hac Vice to be submitted

MOTLEY RICE LLC
401 9th Street, NW
Suite 1001
Washington, DC 20004
Tel. 202-386-9626
Fax 202-386-9622
lsinger@motleyrice.com
Esmith@Motley Rice LLC
saguiniga@motleyrice.com

Robert T. Naumes, Sr., BBO # 367660
Christopher C, Naumes, BBO # 671701
NAUMES LAW GROUP, LLC
2 Center Plaza, Suite 620
Boston, MA 02108
Tel.: 617-227-8444
Fax: 617-227-1270
robert@naumeslaw.com
christopher@naumeslaw.com

Attorneys for Plaintiffs