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IN THE CIRCUIT COURT OF THE 11TH JUDICIAL CIRCUIT IN AND FOR MIAMI-DADE COUNTY, FLORIDA

CIRCUIT CIVIL DIVISION

CASE NO.:

THE CITY OF MIAMI

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC; CARDINAL HEALTH, INC.; INSYS THERAPEUTICS; MALLINCKRODT, LLC; MCKESSON CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; AND WALGREENS BOOTS ALLIANCE.

Defendants.

_____/

COMPLAINT/

DEMAND FOR JURY TRIAL

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I. PRELIMINARY STATEMENT

1. Plaintiff City of Miami, Florida ("Plaintiff" or "City") brings this action to redress Purdue Pharma, L.P.'s, Purdue Pharma, Inc.'s, the Purdue Frederick Company's, Teva Pharmaceuticals USA's, Cephalon, Inc.'s, Janssen Pharmaceuticals, Inc.'s, Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s, Janssen Pharmaceutica Inc.'s, Endo Health Solutions Inc.'s, Endo Pharmaceuticals Inc.'s, Mallinckrodt, LLC (together, "Manufacturing Defendants"), and Insys Therapeutics, Inc.'s ("Defendant Insys") campaign of unfairly, deceptively, and fraudulently marketing and promoting opioids in the City. These Defendants created a public nuisance, violated Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 8501.201, *et seq,* made fraudulent and negligent misrepresentations, were negligent and grossly negligent, created a public nuisance, and were unjustly enriched.

2. Defendants Purdue Pharma, L.P., Purdue Pharma Inc., and the Purdue Frederick Company (collectively "Purdue"), Teva Pharmaceuticals USA, Inc. and Cephalon, Inc. (collectively, "Teva"), and Janssen Pharmaceuticals, Inc. and Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc. (collectively "Janssen"), Endo Health Solutions Inc., and Endo Pharmaceuticals Inc. (collectively "Endo"), Defendant Mallinckrodt, and Defendant Insys 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, Nucynta/Nucynta ER, Duragesic, generic oxycodone, and Subsys.

3. 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 Miami.

4. 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 work to 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 often prolonged withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

5. 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.[1] Consequently, the market for prescription opioids was sharply restricted.

6. 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, together with Teva, Janssen, and Endo ("Manufacturing Defendants"), helped cultivate a narrative that pain was undertreated and pain treatment should be a higher priority for health care providers. This paved the way for increased prescribing of opioids for chronic pain. Manufacturing Defendants' promotional efforts dovetailed with this narrative, as Manufacturing Defendants began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this

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

strategy, Manufacturing Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

7. Between the 1990s and 2011, prescriptions of oxycodone, an active ingredient in opioid drugs manufactured by the Manufacturing Defendants and others, more than doubled in the United States. During the same time period, opioid prescriptions increased some 31% from approximately 1.6 million to approximately 2.2 million. According to a U.S. Department of Health and Human Services Fact Sheet, "[i]n 2014, more than 240 million prescriptions were written for prescription opioids, which is more than enough to give every American adult their own bottle of pills."

8. Manufacturing Defendants spent hundreds of millions of dollars on promotional activities and materials that continued to falsely deny or trivialize the risk of addiction and overstate the benefits of opioids. These Defendants continued to deceptively market opioids to prescribers through advertising, websites, and in-person sales calls. They also relied upon continuing medical education ("CME") seminars, non-credit education programs, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that were flawed and misleading, but seemed independent and therefore credible.

9. Through these efforts, Manufacturing Defendants were able to persuade prescribers that, even though opioids were addictive, that risk could be allayed by doctors carefully supervising their use by appropriate patients. Part of these Defendants' message was that doctors should treat the right patients: legitimate patients who took the drugs as directed (orally) to treat their pain, rather than abusers seeking to snort or inject the drugs for recreation. By defining the class of individuals who should not receive opioids as only these abusers, Manufacturing

Defendants gave doctors a false sense of security that they could safely prescribe opioids to patients they trusted without fear that these patients would become addicted.

10. In 2007, Purdue and three of its executives pled guilty to federal charges for misleading doctors, patients, and regulators about the risk of addiction and OxyContin's potential to be abused. As laid out in its plea agreement, Purdue systematically misrepresented the risk of addiction, including promising that opioid addiction occurred in less than 1% of patients and that opioids were not addictive when legitimately prescribed. This was how Purdue explained away what doctors had previously believed about opioids: it was not that opioids were not addictive, but rather opioids would not addict patients under a doctor's care.

11. Purdue's guilty plea seemed to have little effect on Purdue's operations and marketing, or that of other Manufacturing Defendants. In the decade that followed, these Defendants created and sustained a multi-billion dollar pain franchise through the same pattern of deceptive marketing. Specifically:

a. Manufacturing Defendants informed and instructed doctors that patients receiving opioid prescriptions for pain generally would not become addicted, and that doctors could use screening tools to exclude patients who might.

b. Manufacturing Defendants informed and instructed doctors that patients who did appear addicted were not; they were instead "pseudoaddicted" and needed more opioids.

c. Manufacturing Defendants informed and instructed doctors that opioids relieved pain when used long-term, without any studies to support this claim and without disclosing the lack of evidence that opioids were safe or effective long-term or the other risks from long-term use of opioids.

d. Manufacturing Defendants informed and instructed doctors that opioids could be taken in higher and higher doses without disclosing the increased risk to patients.

e. Manufacturing Defendant Purdue Pharma informed and instructed doctors that OxyContin provided 12 hours of relief when Purdue knew that, for many patients, it did not.

f. Manufacturing Defendants promised that opioids would improve patients' function and quality of life while trivializing or omitting the many adverse effects of opioids that diminish patients' function and quality of life.

12. Manufacturing Defendants knew that their representations regarding the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence.

13. When faced with a rising tide of opioid addiction, overdose, and death—precisely the risks that they denied in their marketing—Purdue and Endo falsely promoted their abuse-deterrent opioids as preventing abuse and diversion and "safe." Both Defendants knew, and evidence showed, that the "abuse-deterrent" features of their opioids could be easily defeated, did not affect oral use, which is the most common means of abuse, and increased harmful outcomes, like injection or conversion to heroin. Purdue's and Endo's marketing was intended to, and did, reassure prescribers who became concerned about addiction that they not only could continue to prescribe opioids, but in fact needed to switch to their brands of opioids, thus preserving and expanding these Defendants' market.

14. In the same vein, Purdue and Endo also misrepresented their efforts to rein in the diversion and abuse of opioids, while privately failing to report suspicious prescribing. Upon information and belief, based on the reporting of an industry-wide practice, all Manufacturing Defendants paid reimbursements known as "chargebacks" to wholesale distributors, and thereby obtained information about where their drugs were going as they progressed from wholesalers to retailers and down the supply chain. Also upon information and belief, Manufacturing Defendants also had access to detailed prescribing data, which they monitored regularly to target and monitor their marketing efforts. Upon information and belief, Manufacturing Defendants failed to report suspicious orders or retailers that information obtained from the chargeback and prescribing data, as well as their own observations, would have revealed.

15. Defendant Insys created fraudulent and misleading marketing schemes to promote its opioid, Subsys, which was approved for cancer-related pain. Insys promoted Subsys as safe and appropriate for neck and back pain and failed to disclose the lack of evidence for such use. Insys paid prescribers in exchange for prescribing Subsys. Between 2013 and 2015, Insys paid nearly $90,000 in speaking fees to one Miami pain doctor.

16. Manufacturing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. Opioids are now among the most prescribed classes of drugs. 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.

17. In 2015, Purdue reaped an estimated $2.4 billion in revenue, virtually all of it from opioids. Since its launch in 1996, OxyContin alone has generated $35 billion in sales. In the last three years, the city has spent over $495,000 on Schedule II and Schedule III opioids in its employee health plan.

18. Once the Manufacturing Defendants created mass market for prescription opioids, Distributor Defendants flooded it. Distributor Defendants are responsible for delivering opioids marketed and made by the Manufacturing Defendants to pharmacies throughout the country. Distributor Defendants have a duty under state law to report and to not ship suspicious orders of controlled substances including orders of opioids that exceed reasonable volume or frequency, into Miami. Yet, Distributor Defendants have supplied opioids in quantities that they knew or should have known exceed any legitimate market for opioids—even the wider market for chronic pain-

and ignored red flags of suspicious orders of these drugs in the City. Upon information and belief, they routinely failed to do so, deepening the crisis of opioid abuse, addiction and death in the City.

19. Indeed, rather than compassionately helping patients, this explosion in opioid use—and Defendants' profits—has come at the expense of chronic pain patients. The CDC concluded in 2016 that "for the vast majority of [chronic pain] patients, the known, serious, and too-often-fatal risks [of opioids] far outweigh the unproven and transient benefits."[2] As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[3]

20. As a direct result of the Manufacturing Defendants' dangerously false marketing, the nation is now swept up in what the CDC called a "public health epidemic" and what the U.S. President deemed a "public health emergency."[4] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription 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.

21. Every day, 91 people die across the country from an opioid-related overdose and over 1,000 patients are given emergency treatment for misusing them. Many others are swept into a cycle of addiction and abuse with which they will struggle their entire lives. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings

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[2] Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).

[3] *Id.*

[4] The New York Times, Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds, October 26, 2017, available at https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html.

struggle with addiction. In 2014, almost 2 million Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 194,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War.

22. The outcomes in Florida, including the City of Miami, are equally catastrophic—and getting worse. In 2016, the City of Miami saw 641 opioid-related overdoses, up nearly 20 percent from the year before. In 2016, the City of Miami Department of Fire-Rescue responded to 1,717 calls that involved Naloxone, an antidote to opioids, which increased by over a thousand calls from 2015, when there were 668 calls that involved Naloxone.

23. While opioids have been diverted through illicit prescribing and sales, it is the regular, legitimate prescribing of opioids that created and fueled this crisis. A study of 254 accidental opioid overdose deaths in Utah found that 92% had been receiving prescriptions from health care providers for chronic pain. Indeed, the majority of patients seeking treatment for opioid and heroin addiction in treatment centers in Miami started with an opioid prescription for pain.

24. Defendants' conduct has violated, and continues to violate the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201 *et sq.* Additionally, Defendants' conduct constitutes a common law public nuisance, negligence, gross negligence, and fraudulent misrepresentation, and resulted in their unjust enrichment.

25. Accordingly, the City brings this action to hold Defendants accountable for their conduct; and seeks disgorgement, restitution, abatement, damages, and any other injunctive and equitable relief within this Court's powers to redress and halt these unfair, deceptive, and unlawful practices.

II. PARTIES

A. Plaintiffs

26. Miami, Florida is a chartered City of the State of Florida established under the Laws of Florida, Chapter 10847.

27. Pursuant to §21 of Miami's Code of Ordinances, the City Attorney, and the Director of the Department of Law, has the authority to prosecute all suits on behalf of the City.

28. The City is the second largest city in Florida by population. The City provides many services for its residents, including public health, public assistance, and law enforcement services, emergency care, and services for families and children. For its employees, the City also funds its own health insurance and workers' compensation claims.

29. The City brings this action on its own behalf and as *parens patriae* in the public interest.

B. Defendants

30. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut. These Defendants are collectively referred to herein as "Purdue."

31. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, Hysingla ER in the United States and in the City of Miami.[5] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of

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

OxyContin have fluctuated between $2 billion and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

32. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon 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 and the City of Miami. Teva USA also sells generic opioids in the United States and the City of Miami, 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. Teva USA and Cephalon are collectively referred to herein as "Teva."

33. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill, in the U.S. and City of Miami. Actiq and Fentora have been approved by the 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.

34. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), 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 Pharmaceutical 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 Defendants are collectively referred to herein as "Janssen."

35. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and the City of Miami, 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.

36. 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 Defendants are collectively referred to herein as "Endo."

37. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and the City of Miami. 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 to 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 Miami, 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. *See infra*, Section F.2.

38. Insys Therapeutics, Inc. ("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. In 2016, Insys made approximately $330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United States and in the City of Miami. Insys's founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. Other Insys executives and managers were previously indicted.

39. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware and licensed to do business in Florida. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

40. 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 United States, with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, in Miami and throughout the country. 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 U.S. patients travels through the Cardinal Health network.

41. 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 in Miami and throughout the country. McKesson is incorporated in Delaware and its principal place of business is in San Francisco, California.

42. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids, and for failing to maintain effective controls against diversion at its distribution centers.

43. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids in Miami and throughout the country. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania and it is incorporated in Delaware.

44. Walgreens Boots Alliance ("Walgreens") includes a captive distributor that supplies pharmaceutical drugs and opioids to Walgreens pharmacies in Miami and throughout the country. Walgreens is headquartered in Deerfield, Illinois, and has a distribution center in Jupiter, Florida, which distributes medications, including opioids, to several states and Puerto Rico, and was the largest distributor of oxycodone to retail pharmacies in Florida. According to the Florida Department of State website, Walgreens is registered to do business in Florida under the name Walgreen Co.

45. In June 2013, Walgreens entered into an $80 million settlement with the DEA for

allowing oxycodone and other prescription drugs to be diverted for illicit sales and use. In addition to the settlement, the Jupiter, Florida distribution center lost its authority to distribute or dispense controlled substances, including opioids, for two years. This revocation ended in 2014.

46. The Distributor Defendants dominate the wholesale distribution market, including in City. Defendants McKesson, Cardinal, AmerisourceBergen, and Walgreens together distribute 85% to 90% of the prescription drugs in the United States. The Distributor Defendants accounted for 73% of opioids distributed to Florida between 2006 and 2016.

III. JURISDICTION AND VENUE

47. The venue for this claim is proper in the 11th Judicial Circuit of Florida in Miami-Dade County.

48. Venue as to each Defendant is proper in this court because each of the Defendants either reside, carry on regular business, or are employed in the City of Miami.

49. This court has personal jurisdiction over Defendants pursuant to Fla. Stat. Ann. § 48.193 (West) because they transact business in the state of Florida, contract to supply goods and manufactured products in the state of Florida, carry on a continuous and systematic part of their general businesses within Miami, have transacted substantial business with Miami entities and residents, and have caused grave harm in Miami as a result.

IV. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

50. 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.

51. 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.

52. 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 targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate both Defendants' marketing and patients' pain conditions.

53. Thus, 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 required opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

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

54. 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. Not surprisingly, all of the Manufacturing Defendants', and Defendant Insys' sales representatives visited prescribers in Miami. Sales representatives from Insys, and Purdue were the most frequent visitors to Miami prescribers with at least 1,398 and 368 visits, respectively between the third quarter of 2013 and 2016. These visits frequently coincided with payments to

the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." Purdue, Teva, Janssen, Endo, and Mallinckrodt and Insys paid City of Miami prescribers over $340,368.24 during this 2013—2016 time period.

55. 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."[6] 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."

56. To ensure that sales representatives delivered the desired messages to prescribers, Purdue, Endo, Teva, and Janssen, 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,[7] their sales forces in Florida and the City of Miami carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

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

[7] 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 the City of Miami in the same manner as elsewhere.

57. 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. 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. 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.

58. 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 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 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."

59. 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 its website.

1. Minimizing or mischaracterizing the risk of addiction

60. To convince prescribers and patients that opioids are safe, 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. According to Miami prescribers, these Defendants' sales representatives regularly omitted from their sales conversations with prescribers in the City of Miami 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. 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 the City. 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, Defendants' sales representatives also failed to disclose to prescribers in the City 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, prescribers in the City.

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 substantial 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*. It is still available to City prescribers online.

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."[8]

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." This website was still available online after May 21, 2011.

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

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

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."[9]

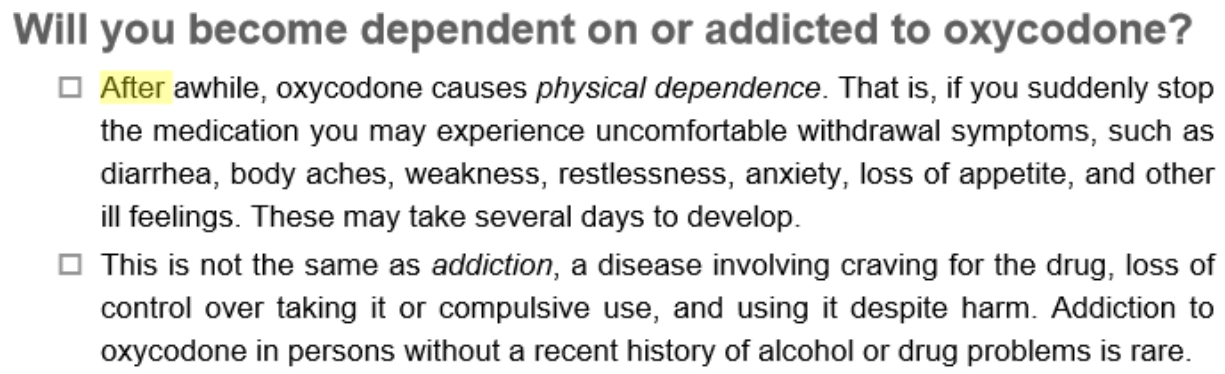
74. The FAQs section of pain-topics.org contained misleading information about pseudoaddiction, discussed further in subsection 2. Specifically, the website described pseudoaddiction as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'" [10]

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."[11] The handout stated the following misleading information regarding the risk of addiction:

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

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

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



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.

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:

- "Only rarely does opioid medication cause a true addiction."
- The issue of tolerance is "overblown."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "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."

This book is still available online in Miami and elsewhere.

77. Neither these third-party unbranded materials, nor the marketing messages or scripts relied on by Manufacturing Defendants' 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 Miami prescribers and patients through sales representative visits, medical education programs, marketing materials, websites, and other sources.

78. 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."[12] That same month, after a "systematic review of the best available evidence" by

[12] *FDA announces safety labeling changes and postmarket study requirements for*

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).[13] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[14] 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

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

80. Purdue, through its unbranded imprint *Partners Against Pain*[15], promoted

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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.

[13] CDC Guideline at 2.

[14] *Id.* at 21.

[15] *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."

pseudoaddiction through at least 2013 on its website.

81. The Federation of State Medical Boards ("FSMB"), a trade organization representing Florida's 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."

82. *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 Florida.

83. 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.

84. 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.

85. 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.

86. The 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,"[16] 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."[17]

3. Overstating the efficacy of screening tools

87. 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 by reassuring doctors that, despite the general warnings about addiction, their patients would not become addicted.

88. 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

[16] CDC Guideline at 13.

[17] *Id.* at 25.

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.

89. These Defendants' conveyed these safe prescribing messages through their in-person sales calls to doctors. Purdue sales representatives, according to one Miami doctor, are "very big" on screening tools, and claim that the tools are helpful for managing the risk of addiction.

90. On information and belief, based on their use elsewhere, Purdue sales representatives in the City 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.

91. 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 City prescribers.

92. 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."

93. 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.

94. 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 the City, attended these conferences.

95. 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.

96. 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.

97. 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 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.

98. Further, the 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."[18]

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

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

99. To convince prescribers and patients that opioids should be used to treat chronic pain, Manufacturing Defendants had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[19] 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

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

[19] *Id.* at 10.

randomized trials ≤ 6 weeks in duration)"[20] 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."[21] 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.

100. Manufacturing Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence. A Miami prescriber, for example, recalled that sales representatives from Janssen and Purdue provided him with brochures on their opioids that promoted the drugs for long-term use.

101. 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

[20] *Id.* at 9.

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

statement was taken down from AAPM's website only after a doctor complained.

102. 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. 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.

103. 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.

104. 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.

105. 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.

106. 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]."[22] 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."[23] 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.

[22] 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).

[23] *Id.*

107. 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.

108. 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.

109. 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 not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing[24] 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.

110. 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

[24] 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.

either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

111. 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.

112. 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.

113. 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.

114. 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

115. Manufacturing Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. Prescribers in Miami stated that representatives who visited prescribers in the City promoted opioids as improving patients' function and quality of life. For example, one physician stated that detailers from Janssen and Purdue provided materials that promised that their opioids would improve patients' ability to function.

116. Manufacturing Defendants' and Defendant-sponsored materials that, upon information and belief, were distributed or made available in the City, 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. 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. 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."[25] Additional illustrative examples are described

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

below:

a. 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.'"

b. 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.

c. *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.

d. 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.

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

f. 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.

117. 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.

118. 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."[26] 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. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $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.

119. The CDC Guideline notes that "there is no good evidence that opioids improve pain or function with long-term use."[27] The FDA and other federal agencies have made this clear for years.[28] The CDC also noted that the risks of addiction and death "can cause distress and inability

[26] 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?

[27] *Id.* at 20.

[28] 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

to fulfill major role obligations."[29] 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."[30] 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]."[31]

120. 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

121. 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,"[32] in

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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.

[29] CDC Guideline at 2.

[30] *Id* at 18.

[31] *See* n. 2, *supra*.

[32] *See* n. 21, *supra*.

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).

122. 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).[33] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

123. 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.

124. 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.

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

125. 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].)

126. 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.[34]

127. 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%. The CDC reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.

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

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

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 the City of Miami also misleadingly suggested that higher opioid doses carried no added risk.

130. Through at least June 2015, Purdue's In the Face of Pain website promoted the nation 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. 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.

132. *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. This publication is still available online.

133. 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."

134. 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."

135. 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.

136. 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."[35] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[36]

D. Purdue Misleadingly Promoted Oxycontin as Supplying 12 Hours Of Pain

[35] 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."

[36] CDC Guideline at 16.

Relief When Purdue Knew That, For Many Patients, It Did Not

137. 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.

138. 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.

139. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Yet it was Purdue's decision to submit OxyContin for approval with 12-hour rather than 8-hour dosing

140. 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. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," Purdue has conducted no such studies.

141. 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.

142. 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%.

143. 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, 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."[37] 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.

144. 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." Purdue also falsely promoted

[37] 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/.

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 Miami.

145. 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.[38]

146. 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 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."[39]

[38] For example, Kadian, an opioid manufactured by Allergan, was designed to be taken once a day, but the label acknowledges and advises dosing of up to every 12 hours for certain patients.

[39] CDC Guideline at 16.

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

147. 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—and thereby prolonged the opioid epidemic in Miami.

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

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

149. 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.

150. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis. A Miami prescriber recalled a Purdue representative who claimed that because of the abuse-deterrent formulations, the company's drugs were "safer" and could not be crushed. Another prescriber stated that Purdue representatives regularly discussed the abuse-deterrent formulations and said that their opioids were "safer" and had a "lower abuse potential" than other opioids.

151. 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.

152. 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.

153. Purdue knew or should have known that "reformulated OxyContin is not better at

tamper resistance than the original OxyContin"[40] 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.

154. 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.

155. 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.

156. 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."[41] Tom Frieden, the Director of the CDC,

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

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

reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."[42]

157. 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."[43] 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.

158. 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 show that Purdue's ADF opioids are being abused in large numbers.

2. Endo's deceptive marketing of reformulated Opana ER

159. 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

[42] 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.

[43] 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.

deterrence a key to its marketing strategy and its ability to maintain and increase profits from Opana ER.

160. 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."

161. 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 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.

162. 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.[44] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[45]

163. 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."[46]

164. 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

[44] 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).

[45] 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).

[46] *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).

percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

165. 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.[47] 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.

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

167. 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

[47] 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.

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."

168. 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."[48] 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."[49] 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."[50]Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the Pain Medicine News website, which was accessible to patients and prescribers nationally. 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

[48] 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).

[49] *Id*.

[50] 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).

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

171. 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").

172. 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."[51] Prescribers must enroll in TIRF REMS before writing a prescription for Subsys.

173. 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.

174. 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

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

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."[52]

175. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center (IRC) to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.

176. 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%.

177. 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

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

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.

178. 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. The compensation structure was heavily weighed on commissions, and rewarded reps more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.[53]

179. 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."[54]

180. 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

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

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

prescribers across the country, as well as in a number of lawsuits against the company itself. Insys paid nearly $90,000 in "speaking fees" from 2013 until 2015 to just one Miami pain doctor.

181. 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.

182. 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; 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.

183. 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. [55]

184. In February of 2016, a former Insys sales manager pled guilty to conspiracy to

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

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.

185. 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.

186. 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.

187. In December of 2016, six Insys executives and managers were indicted. 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."[56]

188. Insys' kickback scheme and misleading marketing of Subsys as appropriate for non-cancer pain contributed to the opioid epidemic in Florida. Publicly available data shows that between the third quarter of 2013 and 2016 Insys provided benefits to Miami prescribers of $241,888. Insys spent as much as $129,780 on one physician in Miami (when speaking fees and other compensation, such as food, travel, and hotels are included).

G. Manufacturing And Distributor Defendants Deliberately Disregarded Their Duties To Report And Terminate Suspicious Orders

1. Manufacturing and Distributor Defendants have a duty to report suspicious orders and not ship those orders unless due diligence disproves their suspicions

232. The conduct of the Manufacturing Defendants, Defendant Insys, and Distributor Defendants created a vastly and dangerously larger market for opioids in Miami. Defendant Distributors, along with Manufacturing Defendants, compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of Manufacturing Defendants and Distributor Defendants to investigate, report, and terminate orders that they knew or should have known were suspicious, such as orders affiliated with the pill mills described above, breached both their statutory and common law duties to the City.

233. First, by flooding the City with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that it should have realized were likely being diverted for illicit uses, Distributor and Manufacturing Defendants breached their duty to exercise reasonable care in delivering narcotic substances and both created and failed to prevent a

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

foreseeable risk of harm to the City. Second, Distributor Defendants assumed a duty, when speaking publically about opioids and their efforts and commitment regarding diversion of prescription opioids, to speak accurately and truthfully.

234. Third, Distributor Defendants, also referred to as wholesalers, violated their statutory obligations under Florida law, which incorporates the federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.* and its implementing regulations. Florida Comprehensive Drug Abuse Prevention and Control Act, Fla. Stat. Ann. § 893.01 *et seq.*

235. Under Florida law and federal law, distributors must register with the Drug Enforcement Administration pursuant to the Controlled Substances Act ("CSA") and comply with a stringent series of federal statutes and regulations designed to prevent the diversion of narcotics. *See* Florida Comprehensive Drug Abuse Prevention and Control Act, Fla. Stat. Ann. § 893.031; *See* 21 U.S.C. § 823(b)(1) (requiring that registrants maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.").

236. Through its incorporation of federal law, Florida places a duty on Distributor Defendants to monitor, detect, investigate, refuse to fill, and report suspicious orders of opioids. 21 C.F.R 1301.74. Distributor Defendants have a non-delegable duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the [DEA] in his area of suspicious orders when discovered by the registrant." 21 C.F.R. § 1301.74(b).

237. Suspicious orders include orders of "unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b). Any of the red flags identified by law—size, deviation, or frequency—trigger a duty to report. However, this list

is not exclusive. Other factors, such as whether the order is skewed toward high dose pills, which are more attractive to abusers and diverters, or orders that are composed largely of drugs valued for abuse (opioids, as well as drugs like benzodiazepines), instead of other high-volume drugs, such as cholesterol medicines, also should alert distributors to potential problems. The distributor's own observations—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 individual history or its comparison to other customers in the area. Thus, the determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the customary activity of other customers of similar size or in the same area.

238. Under the CSA, Manufacturing and Distributor Defendants are required to register annually with the U.S. Attorney General in accordance with federal rules and regulations. *See* 21 U.S.C. § 822(a)(1). Any registration must be consistent with the public interest based on a consideration of, among other factors:

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

21 U.S.C. § 823.

239. Federal regulations further 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 be passive (but profitable) observers, but rather "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."[57]

240. In sum, Manufacturing and Distributor Defendants have several responsibilities with respect to suspicious orders of opioids. First, they must set up a system designed to detect such 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. Second, they must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels. And, third, all flagged orders must be reported to relevant enforcement authorities.

2. Manufacturing and Distributor Defendants understood the importance of their reporting obligations

241. The purpose of the reporting rules is to create a "closed" system intended to reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[58] Both because wholesale distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to

[57] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006)

[58] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.[59]

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

243. Trade organizations to which the Distributor Defendants belong have acknowledged that wholesale distributors such as the Distributor Defendants 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 of pharmaceutical distributors to which Distributor Defendants belong, has 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."[60] Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform

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

[60] *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).

due diligence in order to help support the security of the controlled substances they deliver to their customer."[61]

244. The FTC, too, has recognized the unique role of wholesale distributors. Since their inception, Wholesaler Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, these Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Wholesaler Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Wholesaler Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with generic 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, Wholesaler

[61] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, *filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

245. In a recent settlement with the DEA, Defendant Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)."[62] This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well. The practice of obtaining "chargeback" data would have enabled Mallinckrodt not only to see red flags in the orders it filled itself as a wholesaler, but also additional red flags from the added data it received from its distributor customers.

246. The DEA also repeatedly has made clear that Defendant Distributors' and Manufacturers' obligations under federal law, incorporated by Florida law, obligate them to report and decline to fill suspicious orders. The DEA also repeatedly has made clear that Defendants' obligations under federal law, mirrored in and incorporated by Florida law, *see infra* ¶¶ 234-239, obligate them 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

[62] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 5 (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

about diversion trends and regulatory changes.[63] Each of the Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

247. The DEA, for example, advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances (which included the Distributor Defendants McKesson, AmerisourceBergen, and Cardinal) 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 American people."[64] The DEA's September 27, 2006 letter also expressly reminded the Distributor Defendants McKesson, AmerisourceBergen, and Cardinal that registrants, *in addition* to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be

[63] Drug Enf't Admin., *Distributor Conferences*: https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin., *anufacturer 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.

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

diverted into other than legitimate medical, scientific, and industrial channels."[65]

248. The DEA sent another letter to each of the Distributor Defendants, and to the Manufacturing Defendants as well, 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."[66] 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 report suspicious orders and "some criteria to use when determining whether an order is suspicious."[67]

3. Mallinckrodt failed its duty to maintain effective controls against diversion and report suspicious prescribing

249. Recently, Mallinckrodt admitted in a settlement with the 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

[65] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter]

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

[67] *See* 2007 Rannazzisi Letter.

DEA."[68]

250. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The Department of Justice and DEA determined that Mallinckrodt ignored its responsibility to report suspicious orders of as many as 500 million of its pills that were sent to Florida from 2008 and 2012, which was 66% of all oxycodone sold in the state.

251. In the press release accompanying the settlement, the Department of Justice stated: "Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[69]

252. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious

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

[69] *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.

orders' for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[70]

253. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[71]

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

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. detect and report to the DEA orders of unusual size and frequency;
>
> ii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

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[70] *Id.*

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

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

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

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

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

iv. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[72]

255. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[73]

[72] *Id*. at 2-3.
[73] *Id.*

256. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[74]

4. Manufacturer and Distributor Defendants have repeatedly violated their reporting requirements

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

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

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

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

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

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center

[74] *Id.*

("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

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

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

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone. The *Order* alleged, among other things, that Cardinal Lakeland failed to conduct "meaningful due diligence of its retail pharmacy customers, including its retail chain pharmacy customers, to ensure that controlled substances were not diverted into other than legitimate channels."[75] The *Order* resulted in a two-year suspension of Cardinal's registration to distribute Class II narcotics from the Lakeland Facility.

i. On February 12, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension of Registration* against Defendant Walgreens' Jupiter, Florida distribution center, ("Jupiter Center") for failure to maintain effective controls against the diversion of opioids. The DEA found, among other things, that the Jupiter Center failed to conduct adequate due diligence and should have known that the Walgreens pharmacies were dispensing controlled substances, including opioids, for other than legitimate medical purposes. From 2009 until at least February 2012, Defendant Walgreens' Jupiter, Florida distribution center was the largest distributor of oxycodone products in Florida. The Jupiter, Florida distribution center supplied pharmacies in Florida and, upon information and belief, pharmacies and customers in Miami. After submitting an inaccurate suspicious order report in 2011, the Miami DEA field office did not receive a suspicious order report for any orders placed in 2012, despite the large volume of orders from that center.

[75] *Settlement Agreement* at para. G(1), December 20, 2016

j. In June 2013, the DEA entered into a settlement with Defendant Walgreens, which agreed to pay $80 million in civil penalties under the Controlled Substances Act, the largest DEA settlement at that time. The settlement included the revocation of the Jupiter Center's authority to distribute or dispense controlled substances for two years.

258. These violations reflect a pervasive pattern and practice over the last decade of failing to report and stop suspicious orders that would have affected Defendant Distributors' operations in Florida and the supply of opioids into Miami. In addition, these violations of federal law and regulations also constituted violations of Florida law.

259. Moreover, both Defendant Cardinal Health and Defendant McKesson have been fined for violations involving pharmacies or distribution facilities in Florida. On December 23, 2016, Cardinal Health agreed to pay a $34 million fine to the DEA to settle allegations raised in the February 2, 2012 *Order to Show Cause and Immediate Suspension Order* that it violated the CSA by failing to report suspicious orders sent from its Lakeland, Florida distribution centers to pharmacies in Florida.[76]

260. Defendant McKesson recently admitted to breach of its duties to monitor, report, and prevent suspicious orders and agreed to pay a $150 million civil penalty for the violations. 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

[76] The Settlement also included a related $10M settlement in New York. *Id.*; Margie Manning, Cardinal Health Agrees to $44 M Settlement in Lakeland, New York Cases, Tampa Bay Business Journal, December 23, 2016.

DEA Letters."[77] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[78] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300, *et seq*., at the McKesson Distribution Centers" including the McKesson Distribution Center located in Miami. Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from the Miami facility (among other facilities).[79] Upon information and belief, the McKesson facility located in Miami supplied opioids to the City.

261. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended

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[77] 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.

[78] *Id.*

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

a much larger penalty, as much as $1 billion dollars, and delicensing of certain facilities. 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."[80] In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement],'" as a DEA official working on the case noted.[81] Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'"[82] 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."[83] "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."[84] 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.

[80] 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).

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

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

[83] *Id.*

[84] *Id.*

People die. "[85] 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.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.[86]

262. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[87] 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."[88]

263. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' Jupiter Center, which was responsible for significant opioid diversion in Florida. According to the *Order to Show Cause*, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and

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[85] 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

[86] *Id.*

[87] *Id.*

[88] *Id.*

found that the highest-raking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

264. Defendant Walgreens' Jupiter Center was responsible for numerous instances of diversion in Florida. The Jupiter Center supplied prescription opioids to two Walgreens pharmacies in Oviedo, Florida, one of which increased its oxycodone prescriptions from 6,600 dosage units in June 2010 to 169,780 dosage units in June 2011. Multiple arrests at the Oviedo Walgreens for illicit sales prompted the local chief of police to write letters to the Chairman and CEO of Walgreens and asked for their assistance in fighting the prescription drug epidemic. In the letter, the police chief reported that at both locations drugs were "sold, distributed as payment, crushed, and snorted, liquefied and injected, or multiple pills swallowed while in the parking lot of your pharmacies."[89] Defendant Walgreens' Jupiter Center continued to supply prescription opioids to the Oviedo pharmacies, and increased its quantities of 30 mg oxycodone from 73,300 tablets in February 2011, to 145,300 dosage units in July 2011. The Jupiter Center nearly doubled its distribution of oxycodone to one of these pharmacies within a six month period.

265. In September 2010, a pharmacist who worked at a Walgreens pharmacy in Ft. Pierce, which also received shipments from the Jupiter Center, contacted law enforcement after mistakenly providing an additional 120 doses of 15 milligram oxycodone to a customer. When the pharmacist contacted the customer to ask that he return the opioids, he spoke with his girlfriend who said that the customer was addicted to drugs and also sells his prescription drugs. She also explained that he would not return the drugs. Despite this incident, the pharmacy continued to

[89] In the Matter of Walgreens Co. *Order to Show Cause*, September 13, 2012.

provide several additional prescriptions of oxycodone to the customer, all of which were supplied by the Jupiter Center.

266. The Jupiter Center, along with Defendant Walgreens' headquarters, ignored warnings and concerns from its own employees about large shipments of opioids. In January 2011, the Center's Function Manager, who was responsible for all Schedule II drug operations (including opioids), sent an email to the manager of Walgreens' drug stores at its headquarters about the suspiciously "large quantity," of oxycodone that was being ordered by three stores in Florida.[90] The Jupiter Center continued to supply opioids to these locations, and provided a Walgreens' pharmacy in Port Richey, a town of less than 3,000 people, 285,800 30 milligram doses of oxycodone in January 2011. Despite the warning from an employee, Defendant Walgreens did not report any of these orders as suspicious.

267. Purdue's failure to report suspicious activity was the subject of detailed reporting by the Los Angeles Times, which relied, in part, on internal Purdue documents and interviews with former employees and law enforcement. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Health care providers added to the database were supposedly no longer were detailed, and sales representatives received no compensation tied to these providers' prescriptions.

[90] *Id.*

268. Yet Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. In an interview with the *Los Angeles Times*, which first reported this story, Purdue's former senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

269. The same was true of prescribers. For example, despite Purdue's knowledge of illicit prescribing from one Los Angeles, CA clinic which its district manager called an "organized drug ring," Purdue did not report its suspicions from 2009 until 2013—long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

270. The New York Attorney General found that Purdue placed 103 New York health care providers on its No-Call List between January 1 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period" and spending approximately $3,000 dollars in meal expenses for 38 of these providers.[91]

271. They New York Attorney General similarly found that Endo knew, as early as 2011, that Opana was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed

[91] Attorney General of the State of New York, In the Matter of Purdue Pharma L.P., Assurance No.: 15-151, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

5. Distributor and Manufacturing Defendants worked together to sustain their markets and boost their products

272. Upon information and belief, each of the Manufacturing and Distributor Defendants disregarded their reporting and due diligence obligations under Florida law in and affecting the City.

273. Upon information and belief, each of the Distributor and Manufacturing Defendants also worked with trade or other organizations, such as the HDA and Pain Care Forum ("PCF"), to safeguard the market for Manufacturing Defendants' opioids.

274. HDA's website indicates that Distributor Defendants McKesson, AmerisourceBergen, Cardinal, and the Manufacturing Defendants were members of the HDA. Upon information and belief, the HDA and the Distributor Defendants McKesson, AmerisourceBergen and Cardinal sought the active membership and participation of the Manufacturing Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels. The HDA touted the benefits of membership to the Manufacturing Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA

Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[92]

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

a. Industry Relations Council,

b. Business Technology Committee,

c. Logistics Operation Committee,

d. Manufacturer Government Affairs Advisory Committee, and

e. Contracts and Chargebacks Working Group.

276. HDA also offers a multitude of conferences, including annual business and leadership conferences. HDA advertises these conferences to Manufacturing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[93] These conferences provided HDA members "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry"[94] and an opportunity for

[92] Manufacturer Membership Benefits, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.

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

[94] *Id.*

Manufacturing and Distributor Defendants McKesson, AmerisourceBergen, and Cardinal to work together.

277. Distributor Defendants and Manufacturing Defendants also coordinated 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 the Manufacturing Defendants and the Distributors' trade association, the HDA—has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade."[95] This coordination in their lobbying further supports an inference that Distributor Defendants and Manufacturing Defendants worked together in other ways, including through the enterprises described in this Complaint.

6. Manufacturing Defendants and Distributors ignored red flags of abuse and diversion

278. 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 (Automation of Reports and Consolidated Orders System) database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants, but has not been disclosed to the public.

279. Yet, publicly available information confirms that Manufacturing and Distributor Defendants funneled far more opioids into Miami than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along

[95] 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), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

with the information known only to Manufacturing and Distributor Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting the City of Miami.

280. The City's information and belief rests upon the following facts:

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

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. manufacturers regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described above;

d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that their own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

e. Manufacturing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

281. Upon information and belief, Manufacturing and Distributor Defendants engaged in this practice of paying rebates and/or chargebacks to wholesale drug distributors for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide.

282. Publicly available ARCOS data shows the high volume of oxycodone and other opioids distributed to Miami. According to the ARCOS data, in Miami—with a population of 453,579 resident—in 2016, an average of 135 milligrams of oxycodone were distributed per resident. From 2010 to 2016, an average of 223 milligrams of oxycodone were distributed per every Miami resident. In 2012, Distributor Defendants supplied [redacted] of the market share of

oxycodone to Florida. Notably, oxycodone was one of the opioids prescribed in large volume by doctors who were the subject of administrative complaints filed with the Florida Department of Health for improperly prescribing controlled substances.

283. The volume of opioids prescribed and distributed in the City should have raised a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

284. In addition, the increase in fatal overdoses from prescription opioids has been widely publicized for years. Miami in particular has faced a spike in fatal drug overdoses. According to the 2016 Florida Medical Examiners Commission Drug Report, a total of 541 people in Miami died of prescription drug-related deaths in 2015. The number of fatal perception drug-related overdoses rose by exactly 100 to 641 deaths in 2016. The CDC estimates that for every opioid-related death, there are 733 non-medical users. The Distributor Defendants thus had every reason to believe that illegal diversion was occurring in the City.

285. In 2012, the DEA conducted an investigation into overprescribing and pill diversion throughout Florida, and filed charges against seven doctors, including at least one who practiced in Miami. Between the seven doctors, over two million 30 milligram oxycodone tables were dispensed in just one year. This vast quantity of opioids should have put Defendants on notice that they were supplying an illicit market.

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

H. The Distributor and Manufacturing Defendants Hid Their Lack Of Cooperation With Law Enforcement And Falsely Claimed To Be Actively Working To Prevent Diversion

287. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to correct their actions 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.

288. More generally, the Distributor 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."[96] 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."[97] Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as

[96] (http://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance.html)

[97] (http://cardinalhealth.mediaroom.com/valuestatement)

effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[98]

289. 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." [99] A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."[100]

290. Defendant Mallinckrodt similarly claims to be "committed . . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances, ..."[101]

291. These public statements created the false and misleading impression that the Distributer 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

[98] 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.

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

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

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

prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

I. Purdue and Endo Failed To Report Suspicious Prescribing

292. 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."[102]

293. As described in Section A.1, Purdue's public stance long has been that "bad apple" patients and drug diversion to illicit secondary channels—and not widespread prescribing of OxyContin and other opioids for chronic pain—are to blame for widespread addiction and abuse. To address the problems of illicit use and diversion, Purdue promotes its funding of various drug abuse and diversion prevention programs and introduction of ADF opioids. This allows Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use.

294. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

[102] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, 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, http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

295. 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 . . . ."[103] 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."[104] 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."[105]

296. 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.

J. By Increasing Opioid Prescriptions and Use, Defendants Collectively Fueled the Opioid Epidemic and Significantly Harmed Miami and Its Residents

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

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

[105] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, 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.

297. Manufacturing Defendants' and Defendant Insys' misrepresentations prompted Miami health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through its early marketing, Purdue overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. Through their continued deceptive marketing, including to the present, Manufacturing Defendants have both benefited from and extended their prior misrepresentations, sustaining and expanding a market for their opioids. The opioids that flooded into and were dispensed throughout Miami as a result of Defendants' wrongful conduct have devastated the City and its residents. Distributor Defendants compounded these harms by supplying opioids beyond even what this expanded market could bear, funneling so many opioids into the City that they could only have been delivering opioids for diversion and illicit use.

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

299. Both historically and currently, Purdue accounts for the lion's share of sales of brand name opioids. In 2013, there were 6 million prescriptions of OxyContin, resulting in $2.6 billion in sales—giving Purdue 44% of market value for ER/LA opioids, and 24% of the overall market (which includes widely prescribed generics). No other branded drug accounts for more than 3% of the ER/LA prescriptions annually.[106]

[106] During the same period, Purdue accounted for 47% of branded prescription revenue,

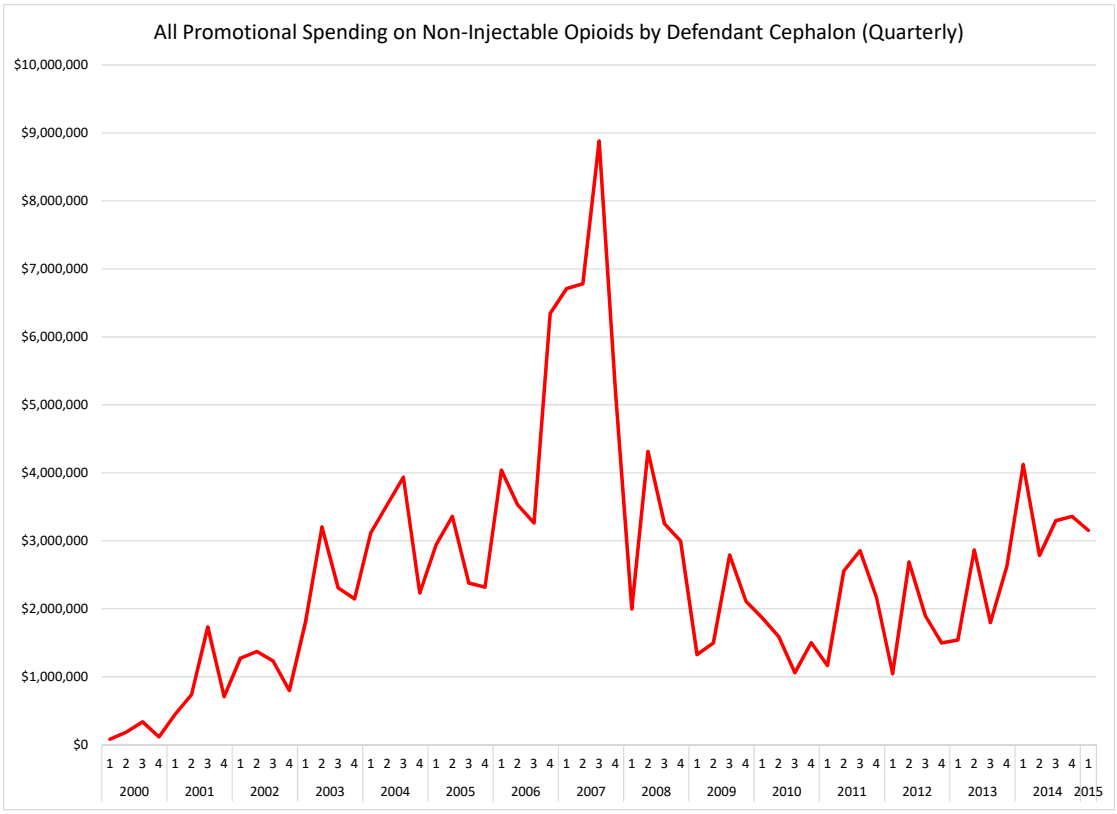
300. Overall sales of opioids in Florida have skyrocketed, and Miami is no exception. *See infra*, paragraph 20. The Manufacturing Defendants' drugs and/or their generic equivalents have been prescribed in Miami. OxyContin, Nucynta, and Opana are among the most prescribed opioids in the City by spending.

301. Manufacturing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturing Defendants spent $165 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.

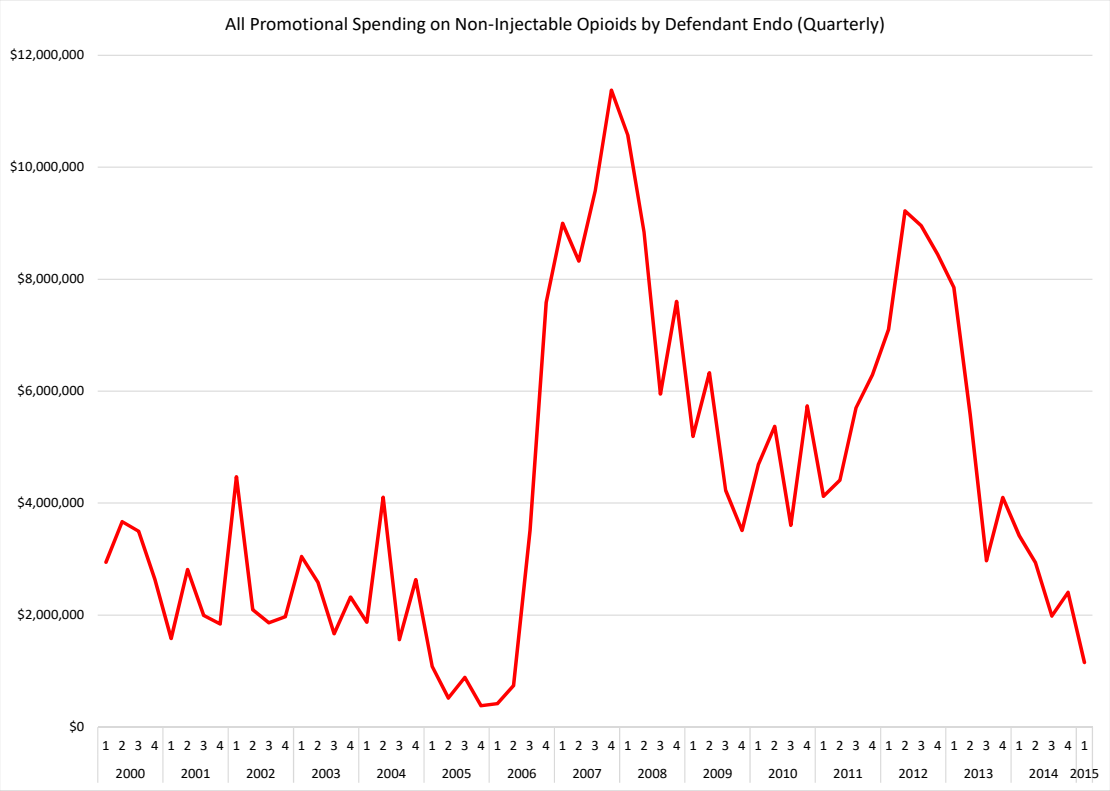
302. Cephalon's quarterly promotional spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak,

39% of long-acting opioid revenue, and 55% of branded-long acting revenue. In the last 4 years, from 2013-2016 coinciding with the removal of generic versions of long-acting oxycodone and the introduction of generic versions of common short-acting drugs, Purdue's market share of branded drugs has increased to 81%.

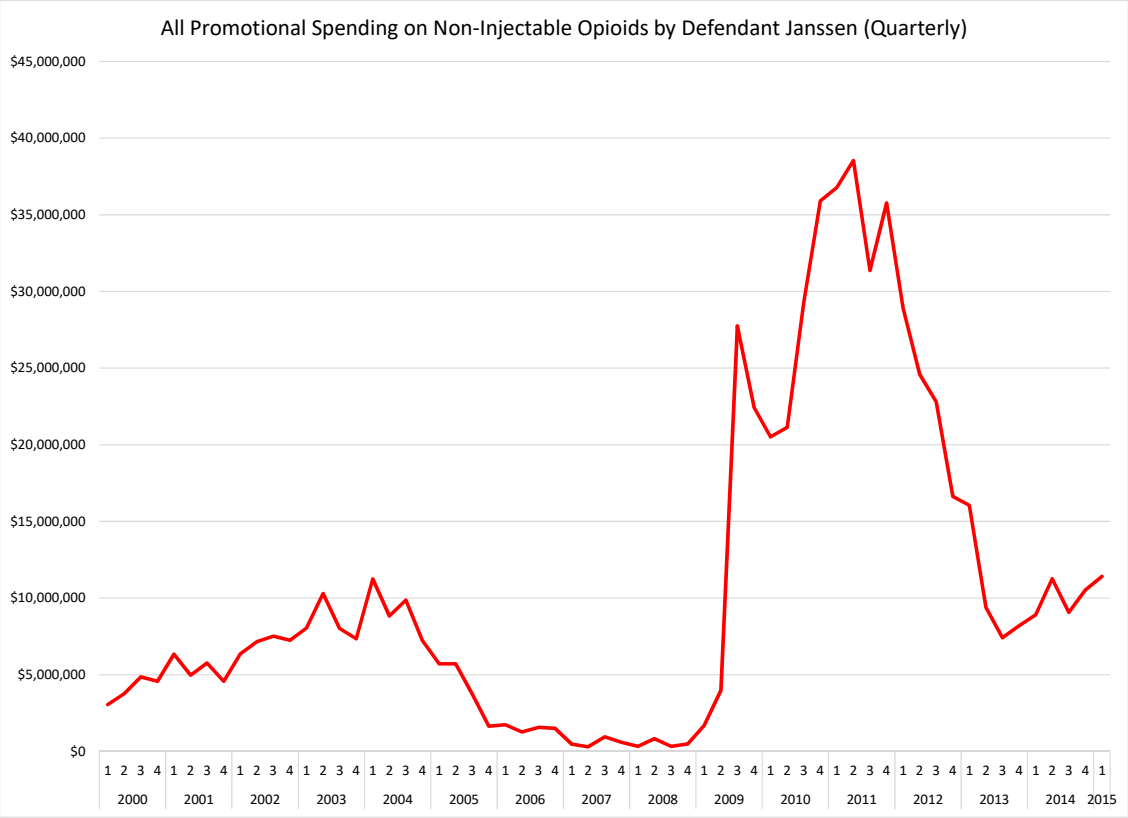
coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:



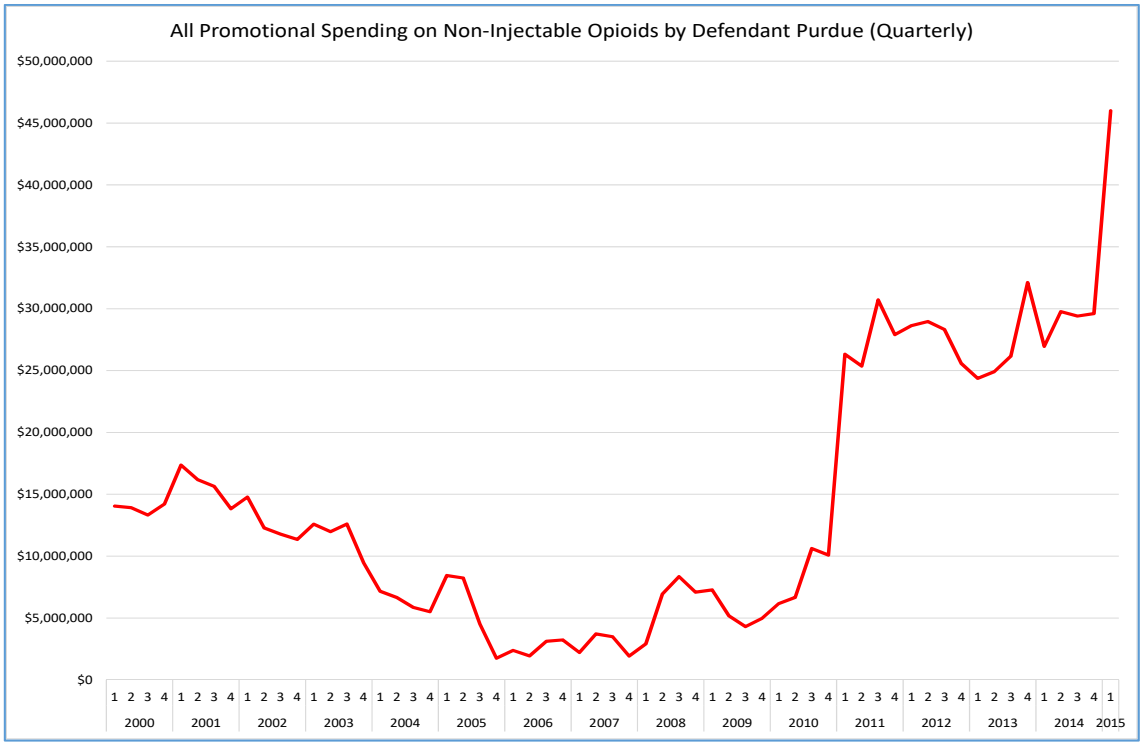
303. Endo's quarterly promotional spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in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



304. Janssen's quarterly promotional 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:



305. Purdue spent roughly $15 million per quarter in 2000 on marketing. Its promotional spending decreased from 2000 to 2007, as the company came under investigation by the U.S. Department of Justice and various state attorneys general. But by 2010, with the introduction of Butrans and reformulated OxyContin, Purdue ramped up its marketing once again. In 2011, Purdue's marketing spiked to more than $25 million per quarter, and by the end of 2015, with the introduction of Hysingla ER, it soared to more than $40 million per quarter.



306. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence.

307. The sharp increase in opioid use resulting from Defendants' marketing has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in the City. 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."[107]

308. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[108]

309. 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,"[109] with particularly compelling data for extended release oxycodone—*i.e.*, OxyContin.

310. 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."[110] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[111]

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[107] "America's Addiction to Opioids: Heroin and Prescription Drug Abuse," *Senate Caucus on Int'l Narcotics Control*, hr'g, Testimony of Dr. Nora Volkow (May 14, 2014) http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

[108] *See* n.4, *supra*.

[109] 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).

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

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

311. 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."[112]

312. By continuing to fill and failing to report suspicious orders of opioids, Defendant Distributors have enabled an oversupply of opioids, which allows non-patients to become exposed to opioids, and facilitates access to opioids for both patients who could no longer access or afford prescription opioids and addicts struggling with relapse. Distributor Defendants had financial incentives to distribute higher volumes and not to report suspicious orders or guard against diversion. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

313. 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 According to the 2016 Florida Medical Examiners Commission Drug Report, in 2015 a total of 541 people in Miami died of prescription

[112] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., et al. "Increases in drug and opioid overdose deaths—United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.

drug-related deaths. In 2016, the number of fatal perception drug-related overdoses rose to 641. Fatal heroin overdoses have increased in the City as well. From 2015 to 2016, the number of fatal heroin overdoses increased from 92 to 139.

314. Manufacturing Defendants' and Defendant Insys' conduct has significantly harmed veterans. Sixty percent (60%) of veterans returning from deployment suffer from chronic pain, double the national average of thirty percent (30%) of U.S. citizens. Veterans are twice as likely to suffer addiction, and to die from opioid abuse, than non-veterans according to a 2011 Veterans Administration study.

315. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose. The City of Miami Department of Fire-Rescue responded to 1,717 opioid related calls involving the use of naloxone in 2016, up from 668 calls in 2015. This amounted to more than 841 hours spent on opioid overdoses, more than double the 419 hours devoted to similar calls in 2015.

316. 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.

317. The abuse of opioids has caused additional medical conditions that have injured City residents and required care often paid for by the City. There are swelling costs from the

growing universe of 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. In addition, there are also the costs of dispensing opioids—in-office visits to obtain refills, count pills, or obtain toxicology screens to monitor potential abuse. All of these costs were born by the City in its employee healthcare plan and in workers' compensation claims. From January 2015 until November 2017, the City of Miami's employee healthcare plan spent over $495,000 on opioid prescriptions. The City of Miami's workers' compensation program spent over $320,000 on opioids between 2012 and 2017.

318. 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. Additionally, the adolescent misuse of opioid medications greatly predicts the later use of heroin. However, according to the CDC Guidelines, there has been a significant increase in prescribing of opioids to adolescents and children for headaches and injuries. A treatment specialist at a local addiction treatment center confirmed that children in Miami are receiving opioid prescriptions for sports injuries or other medical needs, and then developing opioid use disorders.

319. Children in Miami have borne the costs of opioid use and abuse. In June 2017, a ten-year-old Overtown boy died suddenly after leaving a neighborhood pool. An autopsy

confirmed that the boy had heroin and fentanyl in his system due to accidental exposure when he passed away. A Captain in the City of Miami Department of Fire-Rescue reported arriving at the scene of an emergency call at a McDonald's across the street from a school to find three or four people who were unconscious from overdoses in one bathroom while students ate in the restaurant. According to the Captain, it is not uncommon to find adults overdosed in cars with children inside the vehicles.

320. 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.

321. In 2015, 2,487 newborns in Florida showed signs of drug withdrawal or were affected by narcotics, which increased significantly from 1,903 babies the year before. Upon information and belief, a significant share of newborns in Miami suffer from NAS. Many of these children must receive in-home services and some must be placed in foster care.

322. 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.

323. 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. Addiction treatment centers in Miami report that the majority of their patients treated for heroin migrated from prescription opioids to heroin. One addiction treatment specialist in the City noted that many people with use disorders are switching from prescription opioids to heroin because heroin is much cheaper.

324. In fact, people 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. A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into the City's communities. There were 185 fentanyl-related deaths in Miami in 2016.

325. The City has incurred substantial expense to address the opioid epidemic created by Defendants' misconduct. Specifically, the City of Miami Department of Fire-Rescue spent over $175,000 on naloxone in order to help save those who overdose from opioids in 2016.

326. In addition, the City has incurred substantial expense in paying for opioid prescriptions, including through its employee healthcare workers' compensation programs. The expenditures from the healthcare plan alone are over $495,000 in the past three years, not including associated expenses for doctors' visits and drug screening and for treating the adverse effects associated with opioids. The City's workers' compensation program also spent over $321,000 on

opioids between 2012 and 2017.

K. Defendants Fraudulently Concealed Their Misconduct

327. Defendants promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The 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. Manufacturing 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 expose the known falsity of these Defendants' misrepresentations.

328. Notwithstanding this knowledge, at all times relevant to this Complaint, Manufacturing Defendants, and Defendant Insys took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. Manufacturing 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. Defendants also distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support.

329. Manufacturing Defendants, and Defendant Insys thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that the City now asserts. The City 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.

330. The Distributor Defendants also fraudulently concealed their misconduct. They have declined to release the ARCOS data that would provide detailed tracking information about their own shipments and buyers. In addition, as explained above, these Defendants publically portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion, and publically portray themselves as committed to fighting the opioid epidemic, while failing to meet their obligations to report suspicious orders and prevent diversion.

V. CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

331. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

332. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of the public in Miami. In particular, Defendants unreasonably interfered with rights common to the general public within

the City by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances and/or by failing to report and reject suspicious orders of opioids as required by Florida law and the federal CSA. In addition, Manufacturing Defendants unreasonably interfered with rights common to the general public within the City by their deceptive promotion, marketing, and sale of opioids for use by residents of Miami.

333. Since their inception, Florida laws, which are no less stringent than the federal CSA, have been designed to prevent precisely the type of harm that Defendants caused. Defendants' statutory obligations are key to maintaining a "closed" system intended to reduce the diversion of drugs dangerous enough to be regulate as controlled substances outside of legitimate channels and into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[113]

334. In light of Defendants' failures to disclose suspicious orders of opioids and maintain adequate controls to prevent diversion, the City was unaware of, and could not reasonably know or have learned through reasonable diligence, that it had been exposed to the risks alleged herein. Information pertaining to the suspicious orders of opioids Defendants were required to disclose—but did not—was information that the Defendants, given their placement in the supply chain, are uniquely positioned to possess and which was otherwise unavailable to the City. At all times relevant to this Complaint, Defendants were in complete control over the instrumentalities constituting the public nuisance.

[113] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

335. 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.

336. Defendants have created or assisted in the creation of a condition that is injurious to public health, public safety, public peace, and public comfort and offends the moral standards of the community.

337. Defendants' acts and omissions offend, significantly and unreasonably interfere with, and cause damage to the public rights common to all, such as the public health, public safety, public peace, and the public comfort. Defendants had control over their conduct in Miami and that conduct has had an adverse effect on the public right. The public nuisance caused by Defendants has significantly harmed the City and a considerable number of City residents.

338. Defendants' conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peace, health, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

339. Defendants' conduct is unreasonable intentional, and unlawful.

340. Defendants knew and should have known that their unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance.

341. Defendants intentionally, recklessly, or negligently engaged in conduct proscribed by statute, ordinance or administrative regulation, as described in this Complaint, including violations of the Florida Comprehensive Drug Abuse Prevention and Control Act, Fla. Stat. Ann. § 893.01 *et seq.*, and Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §501.201-501.207, which require that manufacturers and distributors honestly market prescription drugs and satisfy registration and licensing requirements mandating that they "maintain effective controls

against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels" and comply with "applicable federal, state, and local law," including the mandates of the federal Controlled Substances Act set forth in 21 U.S.C. § 823 and 21 C.F.R. 1301.74 and the Florida Comprehensive Drug Abuse Prevention and Control Act, Fla. Stat. Ann. § 893.01 *et seq.*

342. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic and state of emergency described in the complaint.

343. Defendants had control over their acts and omissions, the instrumentalities causing the public nuisance, at the time the damage occurred. Manufacturing Defendants controlled the acts and omissions causing the nuisance, namely the process of marketing and the creation and maintenance of the demand for prescription opioids at all relevant times, which included control of the misleading representations they conveyed through branded and unbranded marketing and product promotion. Manufacturing Defendants controlled their deceptive marketing schemes and the instrumentalities they used to disseminate their messages and mislead the public, such as detailing by their sales representatives, online communications, publications, CME programs and other speaking events, and other means described in this complaint. Likewise, Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems it developed to control against diversion, including the criteria and process used to identify red flags of suspicious orders or prescribing. Defendants also controlled whether and to what extent they trained their employees to report and exercise due diligence not to fill such orders or supply such prescribers, whether they intentionally manipulated their systems or ordering process to avoid reporting red flags or

declining shipments, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

344. All Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in Miami. Manufacturing Defendants', and Defendant Insys' 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. Defendants controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. 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 or much less severe. Moreover, by failing to report or cease supplying known pill mills in the City, Defendants exacerbated the opioid crisis in the City, and failed to limit its reach.

345. Defendants' conduct directly and proximately caused injury to Plaintiff and its residents.

346. The City suffered special injuries distinguishable from those suffered by the general public. As discussed herein, it has incurred substantial costs from investigating, monitoring, treating, policing, and remediating the opioid epidemic. The City's damages are not merely derivative of harm to third parties.

347. 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 by (a) educating prescribers (especially primary care physicians and the most prolific prescribers) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; (c) retrieving and disposing of excess opioids,

eliminating a primary pathway of exposure for adolescents; (d) providing screening and treatment to pregnant women and newborns to reduce the incidence and impact of prenatal exposure; (e) making naloxone widely available so that overdoses are less frequently fatal; and (f) restraining the channels for diverting opioids by appropriately setting and enforcing customer limits, reporting suspicious orders, prescribers, and customers, and stopping, rather than simply delaying, the shipment of suspicious orders, among other measures.

348. Defendants have the ability to act to abate the public nuisance, and in certain respects, the law recognizes that they are uniquely well positioned to do so. Manufacturing Defendants successfully mislead healthcare providers and patients alike, and changed the perception and practices regarding opioids. It is the manufacturer of a drug that has primary responsibility to assure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. This responsibility exists independent of any FDA regulation, to assure that its products and promotion meet both federal and state consumer protection laws and regulations. *Compare, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009) (explaining that "[t]hrough many amendments to the [Food Drug and Cosmetic Act] and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times" and "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market"); *id.* at 578-79 & n. 11 (further stating that "state law actions" continue to "play a critical role in "uncover[ing] unknown drug hazards and provid[ing] incentives for drug manufacturers to disclose safety risks promptly"). All Defendants are also uniquely well-positioned to stop fueling, and to cut off at the source, diversion of prescription opioids. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility. Because of their direct

relationship with customers in the supply chain, they are uniquely capable of determining whether a pharmacy is facilitating the diversion of prescription opioids. Because distributors both handle such large volumes of controlled substances, and are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, their obligation to maintain effective controls to prevent diversion of controlled substances is critical. Manufacturers such as Purdue possessing detailed information about prescribing practices and ordering data purchased from opioid distributors are also positioned to act as a first line of defense.

349. The 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.

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

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

COUNT II
Florida Deceptive and Unfair Trade Practices Act
Fla. Stat. Ann. §501.201- 501.207
(Against Manufacturing Defendants, and Defendant Insys)

351. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

352. Florida's Deceptive and Unfair Trade Practices Act ("DUTPA") provides:

> Unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful. Fla. Stat. Ann. § 501.204(1).

353. Manufacturing Defendants, and Defendant Insys have violated Florida's DUTPA because they engaged in unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of commerce.

354. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Defendants have engaged in unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts.

355. Specifically, the deceptive and unfair acts, unfair methods of competition, and unconscionable acts include, but are not limited to:

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 screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

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

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 reduce tampering and abuse;

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

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

k. Insys' claims that Subsys was appropriate for treatment of non-cancer pain.

l. Teva's 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.

356. By engaging in the acts and practices alleged herein, Manufacturing Defendants further committed unfair methods of competition, unconscionable acts, unfair and deceptive acts, including, but 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. exaggerating the risks of competing products, such as NSAIDs, while ignoring 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;

e. Defendants' 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. Manufacturing Defendants, and Defendant Insys failed to report suspicious

prescribers; and

i. Insys' use of kickback and insurance fraud schemes.

357. Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by the CDC and FDA.

358. Defendant Insys' statements that Subsys was appropriate for treatment of non-cancer pain were false and unsupported by scientific evidence.

359. The City of Miami, as a legal entity, is part of the broad class of persons that may avail themselves of a remedy under Fla. Stat. Ann. §501.207.

360. The City has been injured and suffered actual damages as a direct and proximate result of Defendants' violations of the Deceptive and Unfair Trade Practices as alleged in this Complaint.

361. Had the City known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, or of Insys' kickback and insurance fraud schemes, the City would have undertaken efforts to avoid payments of related claims.

362. The City has suffered injury and loss as a result of Defendants' acts and practices alleged in this Complaint.

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

364. The 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 City alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

365. The City has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFOE, the City demands judgment in its favor against the Defendants for damages pursuant to Fla. Stat. Ann § 501.201, *et seq.* together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT III
Fraudulent Misrepresentation
(Against Manufacturing Defendants and Defendant Insys)

366. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

367. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

368. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Manufacturing Defendants, and Defendant Insys have engaged in misrepresentations and knowing omissions of material fact.

369. Specifically, misrepresentations or omissions include, but are not limited to:

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 screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

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

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 reduce tampering and abuse;

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

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

k. Insys' claims that Subsys was appropriate for treatment of non-cancer pain; and

l. Teva's 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.

370. By engaging in the acts and practices alleged herein, Defendants omitted material facts that it had a duty to disclose by virtue of Defendants' other representations, including, but 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. exaggerating the risks of competing products, such as NSAIDs, while ignoring 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;

e. Defendants' 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. Manufacturing Defendants and Defendant Insys failed to report suspicious prescribers; and

i. Insys' use of kickback and insurance fraud schemes.

371. Defendants' statements about the use of opioids to treat chronic pain and/or non-cancer pain conditions were false and not supported by or contrary to the scientific evidence.

372. Further, 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.

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

374. Defendants intended that the City and its residents would rely on their misrepresentations and omissions, knew that the City and its residents would rely on their misrepresentations, and that such reliance would cause the City to suffer loss.

375. Healthcare providers and residents in the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and the City and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

376. Had the City known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, or of Insys' kickback and insurance fraud schemes the City would have undertaken efforts to avoid payments of related claims.

377. By reason of their reliance on Defendants' misrepresentations and omissions of material fact the City suffered actual pecuniary damage.

378. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

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

380. The 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 City alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

381. The City has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, compensatory damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT IV
Negligent Misrepresentation
(Against Manufacturing Defendants and Defendant Insys)

382. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

383. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

384. Defendants had a duty to exercise reasonable care in marketing and selling highly dangerous opioid drugs in the City.

385. Defendants negligently asserted false statements and omitted material facts regarding the benefits of and evidence for the use of opioids for chronic pain, while understating their very serious risks, including the risk of addiction.

386. These false statements included but are not limited to:

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 screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

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

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 reduce tampering and abuse;

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

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

k. Insys' claims that Subsys was appropriate for treatment of non-cancer pain; and

l. Teva's 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.

387. Defendants intended that the City and its residents would rely on their misrepresentations and omissions, knew that the City and its residents would rely on their misrepresentations, and knew that such reliance would cause the City to suffer loss.

388. Healthcare providers and residents in the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and the City and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

389. Had the City known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, or of Insys' kickback and insurance fraud schemes the City would have undertaken efforts to avoid payments of related claims.

390. By reason of their reliance on Defendants' misrepresentations and omissions of material fact the City suffered actual pecuniary damage.

391. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

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

393. The 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 City alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

394. The City has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, compensatory damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT V
Negligence
(Against All Defendants)

395. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

396. Under Florida law, to establish actionable negligence, the City 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, selling, and distributing highly dangerous opioid drugs in Miami.

398. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these 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. In addition, Defendants each had a duty under Florida law, which incorporates the federal Controlled Substances Act, to maintain effective controls against diversion of prescription opioids, to report suspicious orders of opioids, and not to fill suspicious orders unless and until due diligence had eliminated the suspicion.

400. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants

failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

401. Upon information and belief, each of the Defendants repeatedly and intentionally breached its duties. These breaches included:

a. Selling prescription opioids in the supply chain when they knew, or should have known, that there was a substantial likelihood the sale was for non-medical purposes and that opioids are an inherently dangerous product when used for non-medical purposes;

b. Using unsafe distribution practices;

c. Inviting criminal activity into the County by disregarding precautionary measures built into Florida's statutory and regulatory requirements related to controlled substances, to which they agreed to adhere in obtaining licenses or registrations from the Florida Board of Pharmacy and the DEA;

d. Failing to comply with the public safety laws described above;

e. Failing to acquire or utilize special knowledge or skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such significant dangers;

f. Failing to review prescription orders for red flags;

g. Failing to report suspicious orders or refuse to fill them; and

h. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances.

402. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

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

404. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

405. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City's communities.

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. Indeed, it is a violation of Florida law for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

407. Reasonably prudent manufacturers and distributors of pharmaceutical products would know that aggressively 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 would know that failing to report suspicious 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.

408. The City seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Defendants. It does not seek damages which may have been suffered by individual residents of the City for wrongful death, physical personal injury,

serious emotional distress, or any physical damage to property caused by the actions of any of the Defendants.

409. The City is not asserting a cause of action under the CSA or other controlled-substances laws cited above. Rather, it seeks to remedy harms caused to it by the breach of duty created by these statutes and under common law.

410. These Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

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

412. The 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 City alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

413. The City has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, compensatory damages, and

all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT VI
Gross Negligence
(Against All Defendants)

414. The City the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

415. To establish gross negligence, the City must show that Defendants acted with the absence of even slight diligence or scant care, or that they acted with indifference, or were negligent in a very high degree. The City has met its burden here.

416. Defendants have a duty to exercise reasonable care in manufacturing, marketing, and selling highly dangerous drug opioids in the City of Miami.

417. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these 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.

418. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

419. Upon information and belief, each of the Defendants repeatedly and intentionally breached its duties. These breaches included:

a. Selling prescription opioids in the supply chain when they knew, or should have known, that there was a substantial likelihood the sale was for non-medical

purposes and that opioids are an inherently dangerous product when used for non-medical purposes;

b. Using unsafe distribution practices;

c. Inviting criminal activity into the County by disregarding precautionary measures built into Florida's statutory and regulatory requirements related to controlled substances, to which they agreed to adhere in obtaining licenses or registrations from the Florida Board of Pharmacy and the DEA;

d. Failing to comply with the public safety laws described above;

e. Failing to acquire or utilize special knowledge or skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such significant dangers;

f. Failing to review prescription orders for red flags;

g. Failing to report suspicious orders or refuse to fill them; and

h. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances.

420. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

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

422. In breaching these duties, each Defendant showed the absence of even slight diligence or scant care, or that they acted with indifference, or were negligent in a very high degree.

423. As is described throughout this Complaint, Defendants acted without even slight diligence or scant care, and with indifference, and were negligent in a very high degree, disregarding the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

424. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

425. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City's communities, and among its employees and their dependents.

426. Reasonably prudent manufacturers 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.

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

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

429. Defendants' conduct, as described in this Complaint, constitutes an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another, including the City, and also implies an indifferent and thoughtless disregard of the consequences without the exertion of any effort to avoid them. Defendants have acted

wantonly and willfully by inflicting injury intentionally or, alternatively, they have been utterly indifferent to the rights of others, including the City, in that they acted as if such rights did not exist.

430. The City is not asserting a cause of action under the CSA or other controlled-substances laws cited above. Rather, it seeks to remedy harms caused to it by the breach of duty created by these statutes and under common law.

431. Defendants conduct as described in this Count demonstrates wanton and willful disregard and indifference for others, including the City.

432. These Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

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

434. The 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 City alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

435. The City has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, compensatory damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT VII
Unjust Enrichment
(Against All Defendants)

436. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

437. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Manufacturing Defendants and Defendant Insys have profited and benefited from opioid purchases made by the City, and all Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the City.

438. In exchange for the opioid purchases, and at the time the City made these payments, the City expected that Manufacturing Defendants and Defendant Insys had not engaged in deceptive practices or practices contrary to the City's public policy and had not misrepresented any material facts regarding those risks.

439. In addition, the City has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

440. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

441. These expenditures have helped sustain Defendants' businesses.

442. The City has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

443. The City has also conferred a benefit upon Defendants by paying for purchases by unauthorized users of prescription opioids from the Defendants' supply chain for non-medical purposes.

444. By distributing a large volume of opioids within the City and by acting in concert with third parties, Distributor Defendants have unjustly enriched themselves at the City's expense. By deceptively marketing opioids and engaging in the unlawful and unfair practices described in this Complaint, Manufacturing Defendants, and Defendant Insys have unjustly enriched themselves at the City's expense.

445. The City has paid for the cost of each Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiffs lack a remedy provided by law.

446. In addition, by deceptively marketing opioids and engaging in the unlawful and unfair practices described in this Complaint, Manufacturing Defendants and Defendant Insys have unjustly enriched themselves at the City's expense. These Defendants have unjustly retained a benefit to the Plaintiffs' detriment, and these Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience. The enrichment was without justification and Plaintiffs lack a remedy provided by law.

447. Defendants have been unjustly enriched at the expense of the City. It would be inequitable for Defendants to retain the profits and benefits they have reaped from the deceptive practices, misrepresentations, and unlawful conduct alleged herein.

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

449. The 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 City alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

450. The City has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, the City seeks 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, Miami, Florida requests the following relief:

a. A finding that by the acts alleged herein, Defendants violated the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.204, *et seq.*;

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

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

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

e. A finding that Defendants were negligent;

f. A finding that Defendants were grossly negligent;

g. A finding that Defendants were unjustly enriched;

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

i. Restitution or 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;

j. Costs, filing fees, pre and post judgment interest, and attorney's fees; and

For all other and further relief to which this Court finds it is entitled.

CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that the foregoing document was electronically filed via the Florida Courts E-Filing Portal, this 16th day of April, 2018.

By: **/s/Julie Braman Kane**.

Julie Braman Kane
Florida Bar No. 980277
Lewis S. Eidson
Florida Bar No.: 151088
julie@colson.com
mike@colson.com
Primary E-mail: julie@colson.com
Secondary E-mail: b.cancela@colson.com
eservice@colson.com;
COLSON HICKS EIDSON
Attorneys for the Plaintiff
255 Alhambra Circle, Penthouse
Coral Gables, Florida 33134
Telephone: (305) 476-7400
Facsimile: (305) 476-7444

Victoria Méndez
City Attorney
CITY OF MIAMI
Office of the City Attorney
Miami Riverside Center, Suite 945
444 Southwest 2nd Avenue
Miami, Florida 33130-1910
Tel.: (305) 416-1800
Fax: (305) 416-1801
vmendez@miamigov.com

Linda Singer (*pro hac vice* to be submitted)
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
saguiniga@motleyrice.com

Dan Gelber
GELBER SCHACHTER & GREENBERG, P.A.
1221 Brickell Avenue, Suite 2010
Miami, FL 33131
Tel.: (305) 728-0950
Fax: (305) 728-0951
dan@gsgpa.com

Thomas L. Young (*pro hac vice* to be submitted)
LAW OFFICE OF THOMAS L. YOUNG, P.A.
3302 West Mullen Avenue
Tampa, FL 33609
Tel.: (813) 251-9706
tyoung@tlylaw.com

J.R. Whaley
WHALEY LAW FIRM
6700 Jefferson Highway
Building 12, Suite A
Baton Rouge, LA 70806
Tel.: (225) 302-8810

James W. Cusack (FL Bar No. 963879)
JAMES W. CUSACK, P.A.
201 Alhambra Circle, Suite 702
Coral Gables, FL 33134
Tel.: (305) 476-0550
Fax: (305) 461-0261
jwc@jwcusack.com

Julio J. Ayala, Esq. (FL Bar No. 0977070)
LAW OFFICE OF JULIO J. AYALA, P.A.
113 Almeria Avenue
Coral Gables, FL 33134
Tel.: (305) 374-9099
crewesq@crewadvocacy.com
Attorneys for Plaintiff