IN THE CIRCUIT COURT OF THE THIRTEENTH JUDICIAL CIRCUIT
HILLSBOROUGH COUNTY, FLORIDA

HILLSBOROUGH COUNTY, A POLITICAL SUBDIVISION OF THE STATE FLORIDA

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; ALLERGAN FINANCE LLC (f/k/a ACTAVIS, INC.); WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; INSYS THERAPUETICS, INC.; MALLINCKRODT, LLC; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISCOURCEBERGEN CORPORATION; H.D. SMITH, LLC; ANDA PHARMACEUTICALS, INC.; CVS HEALTH CORPORATION, , and WALGREENS CORPORATION

Defendants,

Plaintiff, Hillsborough County, a political subdivision of the State of Florida ("Plaintiff"), by and through its counsel, brings this lawsuit against opioid manufacturers and distributors alleging as follows:

PRELIMINARY STATEMENT

1. Plaintiff brings this action pursuant to its Constitutional authority to redress Purdue Pharma, L.P.'s, Purdue Pharma, Inc.'s, the Purdue Frederick Company's, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc.'s, Cephalon, Inc.'s, Johnson & Johnson, Janssen Pharmaceuticals, Inc.'s, Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s, Janssen Pharmaceutica Inc.'s, Endo Health Solutions Inc.'s, Endo Pharmaceuticals Inc.'s, Allergan plc's, Actavis plc's, Allergan Finance LLC's, Actavis, Inc.'s, Watson Pharmaceuticals, Inc.'s, Watson Laboratories, Inc.'s, Actavis LLC's, Actavis Pharma, Inc.'s, Watson Pharma, Inc.'s, Insys Therapeutics, Inc.'s, and Mallinckrodt, LLC's campaign of unfairly, deceptively, and fraudulently marketing and promoting opioids in Hillsborough County ("County").

2. These Defendants manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Nucynta/Nucynta ER, Duragesic, Norco, Kadian, and Subsys, and related generics.

3. 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.

4. McKesson Corporation d/b/a McKesson Drug Company, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and H.D. Smith, LLC, Anda Pharmaceuticals, Inc, CVS

Health Corporation, and Walgreens Corporation distribute opioid medications, including the medications listed above, to pharmacies, pain clinics and other dispensaries across the country and in the County.

5. As shown below, all Defendants contributed to the opioid crisis plaguing America and the County and must address the damages their actions caused.

OVERVIEW OF CLAIMS

6. No company should ever place its desire for profits above the health and wellbeing of its customers or the communities where those customers live. This is particularly so when the product that the company manufactures, distributes, and sells is a narcotic. Specifically, because they know prescribing doctors and other health-care providers rely on drug companies' statements in making treatment decisions, drug companies must tell the truth when marketing narcotic drugs and ensure that their marketing claims are supported by science and medical evidence. Likewise, a distributor of those narcotics must follow applicable laws and act prudently as it distributes narcotics in communities.

7. Defendants broke these simple rules. As a result, Defendants helped unleash a healthcare crisis that has had far-reaching financial, social, and deadly consequences in Florida and across the nation.

8. 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.

9. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (like back pain, migraines and arthritis),[1] opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

10. However, by the late 1990s, and continuing today, the Manufacturing Defendants began a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturing Defendant spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain. As to the risks, the Manufacturing Defendants falsely and misleadingly, and sometimes contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Conversely, Manufacturing Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support these claims.

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

11. Manufacturing Defendants disseminated these common messages to reverse the medical understanding of opioids in order to exploit the lucrative market for chronic pain treatments. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians recruited by the Manufacturing Defendants. Borrowing a page from Big Tobacco's playbook, the Manufacturing Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Manufacturing Defendants persuaded doctors and patients that what they had long known—that opioids are addictive drugs, unsafe in most circumstances for long-term use—was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

12. Each Manufacturing Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by, or were directly contrary to, the scientific evidence. Indeed, the falsity of each Manufacturing Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA ("2016 CDC Guideline"). The FDA and CDC have found that continuing use of opioids for over three months creates a risk of "opioid disorder" and that opioid use creates a substantial risk of misuse, abuse, withdrawal, addiction, overdose,

and death. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into settlement agreements with public entities that (in the case of Purdue) prohibit them from making many of the misrepresentations identified in this Complaint. Yet even now, each Manufacturing Defendant continues to misrepresent the risks and benefits of long-term opioid use while failing to correct past misrepresentations.

13. Manufacturing Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[2] The result has been a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

14. Once the Manufacturing Defendants created the 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 to report and to not ship suspicious orders of controlled substances, including orders of opioids that exceed reasonable volume or frequency, into the County. 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

[2] Vivek H. Murthy, *Letter from the Surgeon General,* August 2016, available at http://turnthetiderx.org/.

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

15. 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." As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

16. The County has been acutely affected by Defendants' practices and is confronting a public health crisis of historic proportions. In 2015, the County had a prescribing rate of 65.6 opioid prescriptions per 100 people according to the CDC.[3]

17. As these opioid prescriptions have increased in the County, so have the opioid deaths. In 2016 alone, the County had 197 overdose deaths. In 2016, more infants were born in the County suffering from opioid-related neonatal abstinence syndrome than any other county in the State of Florida.[4]

JURISDICTION AND VENUE

18. This is an action for damages in excess of $15,000 exclusive of interest, costs, and attorney fees. This Court has jurisdiction over this action pursuant to the provisions of Florida Statute §48.193 in that Defendants, by and through their authorized agents, servants, and

[3] CDC, U.S. State Prescribing Rates, 2016, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html.

[4] http://www.tampabay.com/news/health/Johns-Hopkins-All-Children-s-will-treat-babies-exposed-to-opioids-with-anonymous-2-5M-donation_166779146.

employees, regularly transacted business in Florida; manufactured, supplied, and distributed opioids in Florida; and further through their acts and omissions, tortuously caused injuries in Florida by engaging in a persistent course of conduct in Florida that violated Florida law. Defendants derived substantial revenue as the result of the opioids that were distributed to Florida physicians, patients, and others and later by persons then residing in Florida.

19. Venue is proper in Hillsborough County pursuant to §§ 47.011, 47.041, and 47.051 in that the Defendants committed tortious acts, omissions, and/or injuries in the County. Further, Defendants transacted substantial business in the County.

PARTIES

A. Plaintiff

20. Plaintiff is a political subdivision of the State of Florida with approximately 1,352,797 residents. It is the fourth most populous county in Florida and the 28th most populous county in the United States.

21. Plaintiff provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care. For its employees, Plaintiff also funds its own health insurance and workers' compensation plans.

22. Plaintiff brings this action on its own behalf and as parens patriae in the public interest.

B. Manufacturing Defendants

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

corporation with its principal place of business in Stamford, Connecticut. (These Defendants are hereafter referred to as "Purdue.")

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

25. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

26. Cephalon, Inc. manufactures opioids, including Actiq and Fentora, for distribution and sale in the United States, including in Florida. 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."[5] In 2008, Cephalon pled guilty to a criminal violation of the federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million in fines.

[5] Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain.

27. Teva Ltd., Teva USA, and Cephalon, Inc. work in concert to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Florida, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Florida, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012—the year immediately following the Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in Florida and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon are hereinafter referred to as "Cephalon.")

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

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

30. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are hereinafter referred to as "Endo.")

31. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States and Florida. 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 through 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States and Florida, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

32. ALLERGAN PLC (f/k/a Actavis plc) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and an administrative headquarters in Parsippany, New Jersey. ALLERGAN FINANCE LLC, a wholly-owned subsidiary of Allergan plc, is a Nevada limited liability company headquartered in Parsippany, New Jersey. Allergan Finance, LLC is the product of a series of acquisitions beginning in 2012, when WATSON PHARMACEUTICALS, INC. acquired ACTAVIS GROUP and the combined company changed its name to Actavis, Inc. While Actavis, Inc., Allergan Finance, LLC acquired Warner Chilcott plc in a stock-for-stock transaction in 2013 through the establishment of Allergan plc, which operated essentially as a continuation of Actavis, Inc. with substantially the same management team operating the business under a different entity. There is no indication Allergan Finance, LLC received any consideration for this transaction. Similarly, on information and belief, since its establishment, Allergan plc has exercised extensive control over Allergan Finance, LLC, including transferring a variety of pharmaceutical products from Allergan Finance, LLC to its other subsidiaries without consideration. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California. ACTAVIS PHARMA, INC. (f/k/a WATSON PHARMA, INC) is a Delaware corporation with its principal place of business in New

Jersey. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is or was owned by Allergan plc, which uses or has used them to manufacture, distribute, market, and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Allergan Finance, LLC, Actavis Group, Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are hereinafter referred to as "Actavis.").

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

34. 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.

35. 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 U.S. Department of Justice ("DOJ") that it failed to detect and notify the DEA of suspicious orders of controlled substances.

36. 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 County. Insys' 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.

37. Purdue, Cephalon, Johnson & Johnson, Janssen, Actavis, and Mallinckrodt, collectively referred to in this Complaint as "Manufacturing Defendants," and Defendant Insys are companies whose primary business is the manufacture, marketing, and distribution of prescription drugs, including opioids.

C. Distributor Defendants

38. MCKESSON CORPORATION is a Delaware Corporation with its principal place of business in San Francisco, California. McKesson has a distribution center in Lakeland, Florida that distributes medications, including opioids. 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 distributes pharmaceuticals to retail pharmacies and institutions in all 50 states, including the State of Florida and the County. Upon information and belief, McKesson is a pharmaceutical distributor licensed to do business in Florida. McKesson does substantial business in the State of Florida and the County.

39. Due to reporting irregularities, in September 2015 the DOJ barred McKesson from distributing for one year one type of opioid, hydromorphone, from its Lakeland, Florida warehouse. In January 2017, McKesson paid a record $150 million to resolve an investigation by the 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.

40. CARDINAL HEALTH, INC. is an Ohio Corporation with its principal place of business in Dublin, Ohio. 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 pharmaceuticals to retail pharmacies and institutions in all 50 states, including the State of Florida and the County. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to U.S. patients travels through the Cardinal Health network. Upon information and belief, Cardinal is a pharmaceutical distributor licensed to do business in Florida and does substantial business in the State of Florida and the County.

41. AMERISOURCEBERGEN DRUG CORPORATION is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania. Upon information and belief, Amerisource is a pharmaceutical distributor licensed to do business in the State of Florida and does substantial business in the State of Florida and the County.

42. H.D. SMITH, LLC ("H.D. SMITH") is a Delaware Corporation with its principal place of business in Sprinfield, Illisnois. H.D. Smith is a pharmaceutical distributor licensed to do business in the State of Florida and does substantial business in the State of Florida and the County.

43. ANDA PHARMACEUTICALS, INC. ("Anda") is a Florida Corporation with its principal place of business located in Weston, Florida. Anda is a licensed to do business in the State of Florida and does substantial business in the State of Florida and the County.

44. CVS HEALTH CORPORATION ("CVS") is a Delaware Corporation with is principal place of business located in Woonsocket, Rhode Island. CVS is a pharmaceutical distributor licensed to do business in the State of Florida and does substantial business in the State of Florida and the County.

45. WALGREENS CORPORATION ("Walgreens") includes a captive distributor that supplies pharmaceutical drugs and opioids to Walgreens pharmacies throughout the country. Walgreens is headquartered in Deerfield, Illinois, and has a distribution center in Jupiter, Florida that distributes medications, including opioids, to several states and Puerto Rico, and was the largest distributor of oxycodone to retail pharmacies in Florida.

46. 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.

47. McKesson, Cardinal, AmerisourceBergen, H.D. Smith, Anda, CVS and Walgreens, collectively referred to in this Complaint as "Distributor Defendants," are in the chain of distribution of prescription opioids. Upon information and belief, the Distributor Defendants have distributed opioids to physicians in Florida and the County.

48. The Distributor Defendants dominate the wholesale distribution market, including in the County. Defendants McKesson, Cardinal, and AmerisourceBergen 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.

FACTUAL ALLEGATIONS – MANUFACTURING DEFENDANTS

49. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other

side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

50. Tens of millions of Americans suffer from and seek treatment for chronic pain. To take advantage of the lucrative market for chronic pain patients, each Defendant developed a well-funded marketing scheme based on deception. Each Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use—statements that benefited not only themselves and the third-parties who gained legitimacy, but all opioid manufacturers. Yet these statements were not only unsupported by and contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

A. Defendants Used Every Available Avenue to Disseminate Their False and Deceptive Statements About Opioids

51. Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Florida. Defendants also bankrolled and controlled professional societies and other ostensibly neutral third parties in order to lend these deceptive statements a veneer of independence and scientific legitimacy.

B. Defendants Spread and Continue to Spread Their False and Deceptive Statements Through Direct Marketing of Their Branded Opioids

52. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted, and many continue to conduct, advertising campaigns touting the purported benefits of their branded drugs. For example, Defendants spent more than $14 million

on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

53. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed, and made available on its website opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs such as construction worker and chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement. Purdue also ran a series of ads called "Pain vignettes" for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Janssen used branded advertising and published reprints of journal articles promoting the use of opioids to treat osteoarthritis, even though the FDA found, in reviewing the New Drug Application for Janssen's drug Nucynta ER, that Nucynta ER was no more effective than placebo in reducing osteoarthritis pain. Actavis distributed a product advertisement that falsely claimed that use of Kadian to treat chronic non-cancer pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives. The FDA later warned Actavis such claims were misleading.[6]

54. Second, each Defendant promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual doctors and medical staff in their offices—and small-group speaker programs. Defendants have not corrected this misinformation. In 2014 alone, Defendants spent $168 million on detailing branded opioids to doctors. This

[6] Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Florida.

amount is twice as much as Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis.

55. Defendants' detailers have been reprimanded for their deceptive and misleading promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

56. Defendants also identified doctors to serve, for payment, on their speakers bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. They were also one of the key ways Defendants' messages were disseminated as medical knowledge: these speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

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

This, of course, is why pharmaceutical companies engage in the practice. Defendants, moreover, know that detailing is effective because they purchase, manipulate, and analyze some of the most sophisticated data available in *any* industry to track, precisely, the rates of initial prescribing and renewal by individual doctors. This data allows Defendants to target, tailor, and monitor the impact of their core messages.

58. Defendants employed the same marketing strategies and deployed the same messages in Florida as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

59. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

60. In February 2018, with legal challenges mounting, Purdue announced that it would cease detailing physicians in respect to Purdue's branded opioids. Purdue did not, however, make any commitment to correct the misrepresentations its multi-decade detailing campaign has engendered in the medical community. Nor did Purdue commit to cease other deceptive marketing

tactics, including the practice addressed below of laundering promotional messages through Front Groups and other ostensibly unbiased third parties. Far from reversing course, Purdue has indicated that it will aggressively promote its drugs that treat opioid-induced constipation—drugs that can only be profitable if opioids are widely prescribed.

C. Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Deceptive Statements About the Risks and Benefits of Opioids

61. Defendants also deceptively marketed opioids in Florida through unbranded advertising—*i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much in the same way Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

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

63. Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted the fine print in its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (Branded)
"People who take opioids **as prescribed usually do not become addicted."**	"All Patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addition even under appropriate medical use."**

D. Key Opinion Leaders ("KOLs")

64. Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

65. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

66. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not

support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

67. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

68. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that through March 2015 the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

69. Thus, even though some of Defendants' KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, those admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and in Florida in Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

70. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

(1) Russell Portenoy

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

72. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

73. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Florida and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[7]

74. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer

[7] Good Morning America television broadcast, ABC News (Aug. 30, 2010).

than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[8] Dr. Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[9]

(2) Lynn Webster

75. Another KOL, Dr. Lynn Webster, was the founder of Lifetree Pain Clinic and Lifetree Clinical Research in Salt Lake City. In 2013, Dr. Webster became the president of the American Academy of Pain Management (AAPM), a Front Group for the opioid industry (discussed further below), and he remained on AAPM's board of directors for a period thereafter. In these capacities, Dr. Webster authored numerous studies and CMEs supporting chronic opioid treatment, and the industry handsomely rewarded his efforts. Between 2009 and 2013, Dr. Webster received millions of dollars from drug companies, including at least eight payments from Defendant Cephalon—*the largest exceeding $1.6 million.*[10]

76. Among the misconceptions Dr. Webster peddled was the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indicators of undertreated pain. The only way to differentiate the two, Dr. Webster claimed, was to *increase* a patient's dose of opioids. As he wrote in his book *Avoiding Opioid Abuse While*

[8] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012.

[9] *Id.*

[10] ProPublica Data, available at https://projects.propublica.org/d4d-archive/search?company%5Bid%5D=&period%5B%5D=&services%5B%5D=&state%5Bid%5D=45&term=Lynn+Webster&utf8=%E2%9C%93.

Managing Pain (2007), which is still available, when facing signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors and all Defendants latched onto the pseudoaddiction concept it articulated.

77. Another devastating contribution of Dr. Webster's is the so-called Opioid Risk Tool, a widely used five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to opioids. In reality, and as the CDC has advised, the Opioid Risk Tool is "extremely inconsistent."[11] But by giving doctors the false impression that opioids can be safely prescribed to a "screened" population, the Opioid Risk Tool became a catalyst for risky prescribing and one that, conveniently, could be billed as a risk-mitigation tool for conscientious practitioners. It is thus little surprise that the tool has been aggressively promoted by Defendants, with versions of it appearing on websites run by Endo, Janssen, and Purdue.

78. Dr. Webster also maintained an active practice at his Lifetree Pain Clinic in Salt Lake City and, tragically, he practiced what he preached. As rumors of overdosed LifeTree patients spread, the DEA raided Dr. Webster's offices and discovered an entire file cabinet labeled "deceased patients."[12] Although Dr. Webster ultimately was not prosecuted, the investigation revealed that 20 patients overdosed and died under his care.

79. Today, Dr. Webster no longer treats patients. He does, however, still function as a mouthpiece for opioid manufacturers' agenda, who continue to pay him significant sums in

[11] CDC Guideline for Prescribing Opioids for Chronic Pain (March 18, 2016), available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[12] https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html.

consulting and other fees. Between 2013 and 2015, Dr. Webster received more than $150,000 from drug companies, most of it from manufacturers of opioids, including Defendant Cephalon.[13]

E. Front Groups

80. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

81. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. For example, Purdue's consulting agreement with American Pain Foundation ("APF") gave it direct, contractual control over APF's work. These efforts assured that Front Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups concealed the extent to which they were bankrolled by Defendants, holding themselves out as independent professional societies faithfully serving the needs of their constituencies—whether patients suffering from pain or doctors treating those patients.

82. The U.S. Senate Homeland Security & Government Affairs Committee recently completed an investigation into the financial connections between opioid manufacturers and fourteen different Front Groups advocating opioid-related policies and practices. The

[13] *See* ProPublica Data, available at https://projects.propublica.org/docdollars/doctors/pid/1136720.

investigation revealed that Defendants Purdue and Janssen, along with opioid manufacturers Mylan, Depomed, and Insys, contributed more than $10 million to opioid Front Groups and their affiliates between 2012 and 2017.[14] Of these manufacturers, Purdue contributed the most, with payments exceeding $4 million between 2012 and 2017. Janssen was the second largest contributor until 2015, when it sold the licensing rights to its opioid Nucynta.[15]

83. These disturbing contributions are only the tip of the iceberg. The Senate did not investigate contributions of other opioid manufacturers, including Defendants Endo and Cephalon, and thus, admittedly, did not "capture the full extent of the financial ties between opioid manufacturers and patient advocacy groups and professional societies."[16]

84. The results of the Senate's investigation are set forth in a February 2018 report authored by Missouri Senator McCaskill's office. The report identifies a "direct link between corporate donations" made by opioid manufactures and the Front Groups' "advancement of opioids-friendly messaging."[17] Elaborating, the report observes:

> Initiatives from the groups in this report often echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of opioid manufacturers. These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over prescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain—the first national standards for prescription opioids and a key federal response to the ongoing epidemic.[18]

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[14] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member McCaskill's Office, *Fueling the Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 2018), at 1.

[15] *Id*. at 5-6.

[16] *Id.* at 15.

[17] *Id*. at 1.

[18] *Id*.

85. Senator McCaskill's report concluded that "[t]hrough criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies."[19]

86. To reach a wide audience, and give the impression of professional consensus, opioid manufacturers have bankrolled a diverse array of Front Groups. All told, Purdue, Janssen, Endo and Cephalon contributed to more than a dozen Front Groups, including many of the same ones. Two of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), the Federation of State Medical Boards ("FSMB), the U.S. Pain Foundation ("USPF"), the American Geriatrics Society ("AGS"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

(1) American Pain Foundation ("APF")

87. The most prominent of Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.[20] Endo alone provided more than half that funding; Purdue was next, at $1.7 million.

88. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers.

[19] *Id*. at 3.

[20] Senator McCaskill's February 2018 report studied contributions between 2012 and 2017 and thus did not look into industry contributions to APF.

APF also engaged in a significant multimedia campaign – through radio, television and the Internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Florida.

89. In addition to Dr. Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue), Dr. Portenoy, and Dr. Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all of whom served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

90. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Dr. Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

91. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was

Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

92. In practice, APF operated in close collaboration with opioid manufacturers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

93. APF assisted in other marketing projects for drug companies. One project funded by another drug company – *APF Reporter's Guide: Covering Pain and Its Management* (2009) – recycled text that was originally created as part of the company's training document.

94. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year – this would be a very good issue on which to use some of that. How does that work?"

95. The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Defendants. APF's clear lack of independence – in its finances, management, and mission – and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

96. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an

objective and neutral third party, and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

(2) American Academy of Pain Medicine

97. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

98. AAPM has received millions of dollars from opioid manufacturers since 2009, including nearly $1.2 million from Purdue and Janssen in 2012 through 2017 alone. AAPM also maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

99. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top

industry-supported KOLs Dr. Fine, Dr. Portenoy, and Dr. Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[21]

100. AAPM's staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

101. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed 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. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and was taken down from AAPM's website only after a doctor complained, though it lingers on the Internet elsewhere.

102. Recognizing the importance of opioid treatment guidelines in securing the acceptance of chronic opioid therapy, AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Fine, received support from Janssen, Cephalon, Endo, and Purdue.

103. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is

[21] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829.

manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. The AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Florida during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

104. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

105. When the CDC issued guidelines in 2016 recommending the use of non-opioid therapies in the treatment of chronic pain, AAPM's immediate past president, Daniel Carr, was highly critical, stating "that the CDC guideline makes disproportionally strong recommendations based upon a narrowly selected portion of the available clinical evidence.[22]

106. In an effort to retain credibility, AAPM has obscured its financial ties to opioid manufacturers. Nowhere on AAPM's website is it disclosed that AAPM has received millions of dollars in funding from the industry it has supported. Far from it, AAPM has a page on its website purporting to list the "patrons" who have donated to the organization between January 1, 2017 and

[22] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member McCaskill's Office, *Fueling the Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 2017), at 1.

October 31, 2017—not a single opioid manufacturer (or other pharmaceutical company) is identified.[23]

107. AAPM recently became known as the Academy of Integrative Pain Management ("AIPM"). Despite the change in name, the academy has remained a vehicle funded by and operated on behalf of pharmaceutical companies generally and opioid manufacturers specifically. AIPM's executive director, Bob Twillman, recently reported that AIPM receives fifteen (15) percent of its funding from pharmaceutical companies, not including revenue from advertisements in its publications. Its state advocacy project, the Academy's lobbying arm, is 100 percent funded by drug manufacturers and their allies.

(3) Mallinckrodt's Efforts

108. Defendant Mallinckrodt also provided funding to organizations in order to disseminate false messages about opioids.

109. 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."

110. The FAQs section of the website 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.'"

[23] *See* http://aapmfoundation.org/donors.

111. 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."[24] The handout stated the following misleading information regarding the risk of addiction:

> ☐ 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.

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

a. "Only rarely does opioid medication cause a true addiction."

b. The issue of tolerance is "overblown."

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

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

d. "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."

113. This book is still available online in the County and elsewhere.

F. Efforts to Spread False and Deceptive Marketing Messages

114. Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Defendants determined would reduce prescribing. PCF also worked to address a perceived "lack of coordination" among its members and developed "key" messages that were disseminated in programs and industry-run websites.

G. This Marketing Scheme Misrepresented the Risks and Benefits of Opioids

115. To convince doctors and patients in Florida and across the nation that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and

guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and they continue to spread them today.

H. Manufacturing Defendants Falsely Trivialized or Failed to Disclose the Known Risks of Long-term Opioid Use

116. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

117. ***First***, Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly, and they failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in all states in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction." This publication is still available online.

h. Detailers for Purdue, Endo, Janssen, and Cephalon minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

118. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication

use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

119. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA (Extended Release/Long Acting) opioids in 2013 and for IR (immediate release) opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

120. Defendants' claims are further proven false by the warnings on their FDA-approved drug labels that caution that opioids "expose users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

121. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo

had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in Florida, and it has not engaged in a campaign to reverse the impact of previous statements that were to the contrary.

122. ***Second***, Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction" – a term coined by the now infamous Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real.

b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

f. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." This publication is still available online.

123. The 2016 CDC Guideline rejects the concept of pseudoaddiction. Nowhere in the Guideline does it recommend that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," 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."

124. Even one of the Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the State of New York, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Consistent with this, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York. Endo, however, remains free to do so in Florida.

125. ***Third,*** Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Endo, Janssen, and Purdue all linked websites they ran or administered to Dr. Webster's Opioid Risk Tool, a brief questionnaire that gave doctors false confidence in prescribing opioids for chronic pain.

c. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

d. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

126. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." As a

result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

127. ***Fourth***, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and they failed to disclose the increased difficulty of stopping opioids after long-term use.

128. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.

129. Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The

Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause and restart" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

130. ***Fifth***, Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,"[25] challenging the correlation between opioid dosage and overdose.

131. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established," while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

132. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged in response to a citizen petition by a physician group "that the

[25] www.cpdd.org.

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." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain.

133. ***Finally***, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids, described below, has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.[26]

134. These abuse deterrent formulations (AD opioids) are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids are not "impossible to abuse."[27] They can be defeated – often quickly and easily – by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.

135. Because of these significant limitations, and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has

[26] Catherine S. Hwang, *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175(2) JAMA INTERN. MED. 302-4 (Dec. 8, 2014).

[27] FDA Facts: Abuse-Deterrent Opioid, available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm [as of September 24, 2017].

cautioned that "[a]ny communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling) and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health."[28]

136. Despite this admonition, Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations. For example, until July 2017 when Endo withdrew Opana ER from the market in response to pressure from the FDA to do so, Endo marketed Opana ER as tamper, or crush, resistant and less prone to misuse and abuse even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse.

137. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. The State 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.

[28] *Id.*

138. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017, and requested that Endo withdraw Opana ER from the market.[29] Approximately one month later, Endo did so.[30]

139. Likewise, Purdue has engaged in deceptive marketing of its AD opioids – *i.e.*, reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, beginning in 2013 and continuing until at least February 2018, detailers from Purdue regularly used the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, these detailers: (1) claimed that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claimed that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) claimed that Purdue's AD opioids are "safer" than other opioids; and (4) failed to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

140. These statements and omissions by Purdue are false and misleading and conflict with or are inconsistent with the FDA-approved label for Purdue's AD opioids – which indicates that abusers do seek them because of their high likability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent

[29] Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

[30] Press Release, "Endo Provides Update On Opana ER," July 6, 2017, available at http://www.endo.com/news-events/press-releases.

properties, and which does not indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

141. To the contrary, testimony in litigation against Purdue and other evidence indicates that Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and Reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a study it conducted that found continued abuse of OxyContin with so-called abuse deterrent properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other opioid products.

142. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.[31] Despite this, David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

143. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common

[31] Cicero, Theodore J., and Matthew S. Ellis, "Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin," 72.5 JAMA Psychiatry 424-430 (2015).

route of opioid abuse, and can still be abused by nonoral routes." Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."[32]

144. Defendants' false and misleading claims about the abuse deterrent properties of their opioids are especially troubling. First, these claims are falsely assuaging doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraging doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. These claims are therefore causing doctors to prescribe more AD opioids – which are far more expensive than other opioid products – even though they provide little or no additional benefit.

145. Second, Defendants are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. In response to the flood of litigation filed against the company, Purdue has been taking out full-page advertisements in the *Wall Street Journal* touting its efforts to stem the opioid epidemic. Chief among Purdue's claims is its development of opioids with "abuse-deterrent properties." Notably, the advertisement contains a footnote that Purdue's marketing materials never included, which states: "Opioids with abuse-deterrent properties are not abuse-proof and don't prevent addiction, but they are part of a multifaceted approach to addressing the prescription opioid abuse crisis."

146. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

[32] Perrone, *Drugmakers push profitable, but unproven, opioid solution*, dated Dec. 15, 2016, available at https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution.

I. Gross Overstatement of the Benefits of Chronic Opioid Therapy

147. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guidelines now make clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" 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." Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

148. For example, Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are described below:

a. Actavis distributed an advertisement that claimed the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stair and

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

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

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

f. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life [they] deserve." The guide was available online until APF shut its doors in 2012.

g. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.

j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.

k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients'

quality of life, and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.

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

149. These claims find no support in the scientific literature. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

a. "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."

b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."

c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

150. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

151. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described in paragraph 40, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical

and mental functioning, daily activities, or enjoyment of life."[33] And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

152. Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, Defendants have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

153. Defendants also have promoted opioids as providing far more effective pain relief than NSAIDs and other non-opioid alternatives. Studies indicate that this claim, too, is false. Researchers recently analyzed the comparative effectiveness of four pain relief regimens in treating 411 adult patients admitted to emergency rooms for acute extremity pain. Three of the regimens included an opioid combined with acetaminophen (*e.g.*, Tylenol). The fourth was

[33] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

composed of ibuprofen and acetaminophen. The researchers asked patients receiving these regimens to rank their pain on a scale of 0-10 both before receiving medication and two hours later. Researchers found that all four regimens reduced pain, but that there was no statistically significant difference in the reported reduction—in other words, ibuprofen can be just as effective as opioids in treating pain.[34]

154. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing twelve continuous hours of pain relief with one dose. In fact, OxyContin does not last for twelve hours – a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under ten hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of twelve hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

155. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full twelve hours. Indeed, Purdue's sales

[34] *See* Andrew K. Chang, MD, MS, Polly E. Bijur, PhD, David Esses, MD, Douglas P. Barnaby, MD, MS, Jesse Baer, MD, *Effect of Single Dose Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department*, JAMA (Nov. 2017).

representatives continue to tell doctors that OxyContin lasts a full twelve hours. And if a doctor suggests that OxyContin does not last twelve hours, these sales representatives, at Purdue's instruction, recommend increasing the dose, rather than the frequency of use. Purdue gave its sales representatives these instructions to prevent doctors from switching to a different drug and to address the unwillingness of insurers to pay for more frequent use of OxyContin.

J. Other Unlawful, Deceptive, and Unfair Misconduct

156. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for nor has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harms, 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.

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

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine*

News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

b. Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

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

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

159. For over a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as is required) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—

in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that

Purdue's district manager described internally as "an organized drug ring" until years after law enforcement it shut down. In doing so, Purdue protected its own profits at the expense of public health and safety.

160. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

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

K. Targeting of Susceptible Prescribers and Vulnerable Patient Populations

162. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States, including in Florida. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids, because they would therefore be more likely to accept Defendants' misrepresentations. Those primary care doctors then became sources of information for other doctors, including doctors in Florida.

163. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even

though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

L. Although Defendants Knew That Their Marketing of Opioids Was False and Deceptive, They Fraudulently Concealed Their Misconduct

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

165. Nor have Defendants revealed the extent to which they have funded KOLs and Front Groups. Many Front Groups selectively disclose donors or provide no information whatsoever concerning industry backers. After studying payments to opioid-advocacy Front Groups in the 2012-2017 period, the Senate concluded that neither pharmaceutical companies nor Front Groups "fully or routinely disclose the extent of their financial relationships" and both the companies and the groups "fail to adequately disclose manufacturer contributions" resulting in a "lack of transparency."[35]

166. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Plaintiff.

167. Thus, Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of Defendants' industry-wide deception and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

M. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes To Promote Subsys

168. 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

[35] Senate Homeland Security & Governmental Affairs Committee, Ranking Member McCaskill's Office, *Fueling the Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 2018), at 1, 2, 11.

around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys contains 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").

169. 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." Prescribers must enroll in TIRF-REMS before writing a prescription for Subsys.

170. 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.

171. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied . . . meaning no reimbursement would be due."

172. These prior authorization requirements proved daunting. Initially, 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.

173. 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%.

174. 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 supporting such uses, and misrepresented the appropriateness of Subsys for treatment those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speaker 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.

175. 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 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.

176. 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."

177. Insys' sham speakers program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself. Insys paid nearly $90,000 in "speaking fees" from 2013 through 2015 to just one Florida pain doctor.

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

179. In June 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, pled guilty to receiving $83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at 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.

180. In August 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 ailments for which Subsys is neither safe nor effective, and employing an unconscionable scheme, including paying "speaking fees" that were actually kickbacks to doctors to incentivize the doctor to prescribe Subsys.

181. In February 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of the Alabama prescribers discussed above to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients.

182. In August 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 were encouraged to obtain the majority of their sales from one or two high volume prescribers.

183. The Illinois complaint also details how Insys used its speakers 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 to $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.

184. In December 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."

185. 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 Florida 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).

N. Defendants Have Created a Public Nuisance

1. Defendants' Marketing Conduct Foreseeably Led to Opioid Abuse that has Wrought Havoc in the County

186. Most opioid use begins with prescribed opioids, and that is why the Defendants' deceptive marketing campaign was a primary cause of the opioid epidemic that has unfolded in the County and across the country.[36] For opioids to be widely prescribed, Defendants had to

[36] *See* U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012), available at https://www.samhsa.gov/data/sites/default/files/2011MHFDT/2k11MHFR/Web/NSDUHmhfr2011.htm.

convince doctors that they were a safe and effective means of treating chronic conditions such as back pain, headaches, arthritis, and fibromyalgia. And they were successful in doing so. Had doctors in the County and elsewhere been provided accurate and complete information, they would not have prescribed as many opioids.

187. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Without Defendants' deception, fewer patients in the County would be using opioids long-term to treat chronic pain, those patients using opioids would be using less of them, and there would not have been as many opioids available for misuse and abuse.

188. The efficacy of Defendants' marketing efforts can be seen by comparing opioid use in the United States against other countries, where restrictions on pharmaceutical advertising typically are more stringent. Although the United States contains only 4.6% of the world's population, Americans consume 80% of the global supply of prescription opioids.[37] Moreover, escalating opioid prescribing rates in the United States neatly track the elevated sums Defendants have expended on marketing their drugs, sums that rose from $91million in 2000 to $288 million in 2011.

189. The role of Defendants' marketing scheme in contributing to the opioid epidemic has now been acknowledged by members of the medical community. 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."[38]

[37] American Society of Interventional Pain Physicians, Fact Sheet, available at https://www.asipp.org/documents/ASIPPFactSheet101111.pdf.

[38] United States Cong., Senate Caucus on Int'l Drug Control, May 14, 2014, 113th Cong. 2nd sess. (Statement of Dr. Nora Volkow).

190. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent 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."[39]

191. Scientific evidence also demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids 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."

192. The individual and combined effects of Defendants' conduct has caused an explosion in opioid prescribing, abuse, and overdose in the County, in the State of Florida, and across the country. The data are staggering. In 2016, the opioid prescribing rate in the County was 65.6 prescriptions per 100 people.[40]

2. Defendants Knew and Should Have Known That Their Conduct Would Lead to Overprescribing and Catastrophic Human and Economic Costs.

193. Defendants knew and should have known about the harms that their deceptive marketing would cause. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors

[39] Vivek H. Murthy, *Letter from the Surgeon General,* August 2016, available at http://turnthetiderx.org/.

[40] CDC, U.S. State Prescribing Rates, 2016, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html.

were receiving their messages and how they were responding. Defendants also had access to and carefully watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. In short, Defendants knew—and, indeed, intended—that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain, and they knew the lethal consequences of that endeavor.

194. Defendants also knew that patients were not the only ones harmed by their conduct. They knew that opioid dependency would place enormous burdens on government resources, including those of Plaintiff.

3. Defendants' Conduct Is Not Excused by the Actions of Any Third Parties.

195. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

196. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

O. Defendants' Conduct Has Led To Record Profits

197. While the use of opioids has taken an enormous toll on Plaintiff and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each

Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

FACTUAL ALLEGATIONS – DISTRIBUTOR DEFENDANTS

A. Distributor Defendants Flooded the County and Surrounding Communities with Suspiciously Large Amounts of Opioids.

198. Distributor Defendants are opioid distributors in the County and the State of Florida.

199. Distributor Defendants purchased opioids from manufacturers, such as the named defendants herein, and sold them to pharmacies throughout the County and the State of Florida.

200. Distributor Defendants played an integral role in the chain of opioids being distributed throughout the County and the state of Florida.

201. Defendants were each on notice that the controlled substances they manufactured and distributed were the kinds that were susceptible to diversion for illegal purposes, abused, overused, and otherwise sought for illegal and unhealthy purposes.

202. Defendants were each on notice that there was an alarming and suspicious rise in manufacturing and distributing opioids to retailers within the County during this time period.

203. As entities involved in the manufacture and distribution of opioid medications, Defendants were engaged in abnormally and/or inherently dangerous activity and had a duty of care under Florida Law.

204. Distributor Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies including the DEA and the Florida Department of Health.

205. Distributor Defendants knew or should have known that they were supplying vast amounts of dangerous drugs in the County, which was already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

206. Distributor Defendants failed in their duty to take any action to prevent or reduce the distribution of these drugs.

207. Distributor Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the manufacture and flow of these drugs to the County.

208. Distributor Defendants, in the interest of their own massive profits, intentionally failed in this duty.

209. Distributor Defendants have displayed a continuing pattern of failing to submit suspicious order reports.

210. In so doing, Distributor Defendants violated their duties.

211. 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*.

212. 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; 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").

213. 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).

214. 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.

215. 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.

216. Federal regulations further mandate that all registrants, manufacturers, and distributors "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."

217. In 2008, McKesson paid a $13.25 million fine to settle similar claims regarding suspicious orders from internet pharmacies.[41]

218. Despite these prior penalties, McKesson's pattern of failing to report suspicious orders continued for many years.

[41] https://www.wvgazettemail.com/news/health/suspicious-drug-order-rules-never-enforced-by-state/article_3c9f1983-9044-5e97-87ff-df5ed5e55418.html (accessed April 16, 2018).

219. According to the DEA, McKesson "supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills" during the time in question, and "frequently misused products that are part of the current opioid epidemic."[42]

220. On January 17, 2017, the DEA announced that McKesson had agreed to pay a record $150 million fine and suspend the sale of controlled substances from distribution centers in several states, including McKesson's distribution center in Lakeland, Florida.[43]

221. In 2008, defendant Cardinal paid a $34 million penalty to resolve allegations that it failed to report suspicious opioid orders.[44]

222. Despite this past penalty, in 2017, it was announced that defendant Cardinal agreed to a $44 million fine to "resolve allegations that it failed to alert the Drug Enforcement Agency to suspicious orders of powerful narcotics by pharmacies in Florida, Maryland, and New York.

223. Defendant Amerisource faced a criminal inquiry "into its oversight of painkiller sales" in 2012. They have paid out fines for similar claims to the state of West Virginia.

224. Despite the charges, fines, and penalties brought against the Distributor Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids, including into the County.

225. Distributor Defendants are also members of the Healthcare Distribution Management Association ("HDMA"). The HDMA created "Industry Compliance Guidelines"

[42] https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (accessed April 12, 2018).

[43] *Id.*

[44] https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under (access April 12, 2018).

which stressed the critical role of each member of the supply chain in distributing controlled substances. The HDMA guidelines provided that "[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

226. Between the years in question, including 2007 through 2018, the Distributor Defendants have shipped millions of doses of highly addictive controlled opioid pain killers into the County.

227. Many of these orders should have been stopped, or at the very least, investigated as potential suspicious orders.

228. The sheer volume of the increase in opioid pain medications, including Oxycodone, being distributed to retailers, should have put Distributor Defendants on notice to investigate and report such orders.

229. Defendants manufactured and delivered an excessive and unreasonable amount of opioid pain medications to retailers in the County.

230. Upon information and belief, Defendants did not refuse to manufacture, ship, or supply any opioid medications to any pharmacy in the County from 2007 to the present.

231. The Defendants knew or should have known that they were manufacturing and distributing levels of opioid medications that far exceeded the legitimate needs of the County.

232. Defendants also paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications within the County.

233. Defendants made substantial profits from the opioids sold in the County.

234. Defendants violated Florida law and regulations for manufacturers and distributors, by failing to properly report suspicious orders.

235. By the actions and inactions described above, Defendants showed a reckless disregard for the safety of the residents of the County.

236. On December 27, 2007, the DEA sent a letter to Cardinal stating, "This letter is being sent to every entity in the United States registered with the Drug Enforcement Agency (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b)."

237. The DEA has provided briefings to each of the Defendant Distributors and conducted a variety of conferences regarding their duties under federal law.

238. The DEA sent a letter to each of the Distributor Defendants on September 26, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

239. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007. This letter reminded Distributor Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explains:

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

an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the pattern throughout the segment of the regulated industry. Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

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

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

240. As a result of the decade-long refusal by Distributor Defendants to abide by federal law, the DEA has repeatedly taken administrative action to force compliance. The DOJ Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final

decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 177 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. Drug Enforcement Administration Adjudication of Registrant Actions, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014). The public record reveals many of these actions:

> 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 which resulted in the suspension of its DEA registration;
>
> 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;
>
> 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;
>
> 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;
>
> On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center (Stafford Facility) for failure to maintain effective controls against diversion of hydrocodone;
>
> 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 the DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

> 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, Florida (McDonough Facility), Valencia, California (Valencia Facility) and Denver, Colorado (Denver Facility);
>
> 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;
>
> On June 11, 2013, Walgreens paid $80 million in civil penalties for dispensing violations under the CSA regarding the Walgreens Jupiter Distribution Center and six Walgreens retail pharmacies in Florida;
>
> On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
>
> On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Sante Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA

241. Rather than abide by these public safety statutes, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the DOJ to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm"

and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[45]

DEFENDANTS' CONDUCT HAS CAUSED PLAINTIFF SUBSTANTIAL ECONOMIC INJURY.

242. Plaintiff has been especially hard hit by the opioid crisis caused by Defendants' conduct.

243. One of the nation's most notorious "pill mills" operated on Dale Mabry Highway in Hillsborough County.

244. First Medical Group became known by drug traffickers as a clinic to get prescriptions. In a six-month period, the clinic saw over 3800 patients. Prescriptions were written at the clinic for 2.3 million oxycodone pills. The medical director of First Medical prescribed about 1.9 million of the pills. 80% of the medical director's patients were prescribed high doses – 30 mg strength – of oxycodone. A high percentage of those patients were given prescriptions for 240 pills.

245. Patients streamed into First Medical from throughout the country. More patients came from out-of-state than Florida.

246. Some clinic patients died of overdoses, but the exact amount is unknown. Some analyses show that 30 patients died of various causes and their average age was 34 years old.

[45] *See* Lenny Bernstein and Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.f643792a8e61; Lenny Bernstein and Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.238e21724b50.

247. The clinic owner and office manager were convicted in March 2014 of multiple charges of drug trafficking, conspiracy, racketeering, and operating a drug trafficking conspiracy after a four-month trial in Hillsborough Circuit Court.[46]

248. The DOJ has recognized central Florida as an opioid "hot spot", identifying Florida's Middle District, headquartered in the County, for the assignment of one of twelve DOJ prosecutors to focus solely on investigating and prosecuting opioid-related health care fraud.[47]

249. Opioid overdoses in the County began to spike in late 2014. In 2016, the majority of the County's 197 fatal drug overdoses involved opioid use.[48]

250. In 2016, the County led the state with 579 babies born with neonatal abstinence syndrome.[49]

251. Through a tax supported health plan, Plaintiff provides residents living at or below 110% of the poverty level who do not qualify for other coverage, including Medicare and Medicaid, access to health care through the Hillsborough County Health Care Plan. This health plan has incurred inordinate costs treating County residents suffering from opioid addiction and other related costs.

252. Defendant's deceptive marketing scheme, and the flood of opioids it has unleashed, also has created a larger public health crises that imposes an enormous tax burden on Plaintiff's resources. The cost of mitigating the crisis is borne across an array of Plaintiff's Governmental

[46] http://www.tbo.com/news/crime/owners-of-tampa-pain-clinic-convicted-of-drug-trafficking-20140327/.

[47] https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-department-justice-s-efforts-combat-drug.

[48] https://www.hillsboroughcounty.org/en/media-center/assets/press-releases/local-national-experts-gather-in-hillsborough-to-tackle-opioid-epidemic.

[49] http://www.tampabay.com/news/health/Johns-Hopkins-All-Children-s-will-treat-babies-exposed-to-opioids-with-anonymous-2-5M-donation_166779146.

Departments that include, but are not limited to healthcare, law enforcement, and children and family services.

253. These economic costs are direct, quantifiable, and would not have been incurred but for Defendants' conduct. They also do not express the full extent of the Plaintiff's injuries. Abating the opioid crisis in the County will require a sustained and expanded outlay of County resources, including police to address opioid-related crime and the means to process and rehabilitate opioid offenders through the criminal justice system.

CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

254. Plaintiff hereby incorporates and re-alleges paragaphs 1 through 253 above, as if fully set forth herein.

255. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

256. 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 the County. In particular, Defendants unreasonably interfered with rights common to the general public within the County 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 County by their deceptive promotion, marketing, and sale of opioids for use by residents of the County.

257. 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.

258. In light of Defendants' failure to disclose suspicious orders of opioids and maintain adequate controls to prevent diversion, Plaintiff 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 Plaintiff. At all times relevant to this Complaint, Defendants were in complete control over the instrumentalities constituting the public nuisance.

259. 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.

260. 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.

261. 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 the County

and that conduct has had an adverse effect on the public right. The public nuisance caused by Defendants has significantly harmed Plaintiff and a considerable number of Plaintiff's residents.

262. 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.

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

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

265. 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.

266. All Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in the County. 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 County, Defendants exacerbated the opioid crisis in the County, and failed to limit its reach.

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

268. Plaintiff 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. Plaintiff's damages are not merely derivative of harm to third parties.

269. 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 also be abated.

270. 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.

271. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFORE, Plaintiff 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)

272. Plaintiff hereby incorporates and re-alleges paragaphs 1 through 253 above, as if fully set forth herein.

273. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

274. 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).

275. 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.

276. 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 twelve 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.

277. 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 twelve 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.

278. By engaging in the acts and practices alleged herein, Defendants further committed unfair methods of competition, unconscionable acts, and unfair and deceptive acts, including, but not limited to, the following:

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

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

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

p. 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;

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

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

s. 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;

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

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

279. 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.

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

281. Plaintiff, a legal entity as a subdivision of the State of Florida, is part of the broad class of persons that may avail themselves of a remedy under Fla. Stat. Ann. §501.207.

282. Plaintiff 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.

283. Had Plaintiff 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, Plaintiff would have undertaken efforts to avoid payments of related claims.

284. Plaintiff has suffered injury and loss as a result of Defendants' acts and practices alleged in this Complaint.

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

286. 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. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

287. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, Plaintiff 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)

288. Plaintiff hereby incorporates and re-alleges paragaphs 1 through 253 above, as if fully set forth herein.

289. 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.

290. 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 twelve 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.

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

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

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

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

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

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

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

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

cc. Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

dd. Purdue's claims OxyContin provides a full twelve hours of pain relief;

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

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

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

292. 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:

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

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

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

kk. 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;

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

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

nn. 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;

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

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

293. 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.

294. 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 County prescribers and consumers.

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

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

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

298. Had Plaintiff 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, Plaintiff would have undertaken efforts to avoid payment of related claims.

299. By reason of their reliance on Defendants' misrepresentations and omissions of material fact Plaintiff suffered actual pecuniary damage.

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

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

302. 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. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

303. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, Plaintiff 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)

304. Plaintiff hereby incorporates and re-alleges paragaphs 1 through 253 above, as if fully set forth herein.

305. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

306. 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.

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

308. 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.

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

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

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

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

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

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

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

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

xx. Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

yy. Purdue's claims OxyContin provides a full twelve hours of pain relief;

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

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

bbb. 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.

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

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

312. Had Plaintiff 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 Plaintiff would have undertaken efforts to avoid payments of related claims.

313. By reason of their reliance on Defendants' misrepresentations and omissions of material fact Plaintiff suffered actual pecuniary damage.

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

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

316. 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. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

317. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, Plaintiff 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)

318. Plaintiff hereby incorporates and re-alleges paragaphs 1 through 253 above, as if fully set forth herein.

319. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

320. Under Florida law, to establish actionable negligence, Plaintiff 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.

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

322. 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.

323. 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.

324. 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.

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

ccc. 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;

ddd. Using unsafe distribution practices;

eee. 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;

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

ggg. 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;

hhh. Failing to review prescription orders for red flags;

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

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

326. 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.

327. 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.

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

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

330. 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.

331. 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.

332. Plaintiff 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 citizens of the County for wrongful death, physical personal injury,

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

333. Plaintiff 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.

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

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

336. 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. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

337. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, Plaintiff 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)

338. Plaintiff hereby incorporates and re-alleges paragaphs 1 through 253 above, as if fully set forth herein.

339. Plaintiff the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

340. To establish gross negligence, Plaintiff 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. Plaintiff has met its burden here.

341. Defendants have a duty to exercise reasonable care in manufacturing, marketing, and selling highly dangerous drug opioids in the County.

342. 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.

343. 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.

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

kkk. 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;

lll. Using unsafe distribution practices;

mmm. 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;

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

ooo. 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;

ppp. Failing to review prescription orders for red flags;

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

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

345. 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.

346. 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.

347. 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.

348. 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.

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

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

351. 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.

352. 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.

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

354. 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 Plaintiff, 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 Plaintiff, in that they acted as if such rights did not exist.

355. Plaintiff 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.

356. Defendants conduct as described in this Count demonstrates wanton and willful disregard and indifference for others, including Plaintiff.

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

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

359. 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. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

360. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, Plaintiff 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)

361. Plaintiff hereby incorporates and re-alleges paragaphs 1 through 253 above, as if fully set forth herein.

362. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

363. 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 Plaintiff, and all Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the County.

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

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

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

367. These expenditures have helped sustain Defendants' businesses.

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

369. Plaintiff 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.

370. By distributing a large volume of opioids within the County and by acting in concert with third parties, Distributor Defendants have unjustly enriched themselves at Plaintiff'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 Plaintiff's expense.

371. Plaintiff 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 Plaintiff lacks a remedy provided by law.

372. 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 Plaintiff's expense. These Defendants have unjustly retained a benefit to Plaintiff's detriment, and these Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

373. Defendants have been unjustly enriched at the expense of Plaintiff. 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.

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

375. 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. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

376. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

WHEREFORE, Plaintiff 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff 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. For an injunction permanently enjoining Defendants from engaging the acts and practices that caused the public nuisance;

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

e. For a finding that Defendants were negligent.

f. For a finding that Defendants were grossly negligent.

g. For a finding that Defendants were unjustly enriched.

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

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

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

DEMAND FOR JURY TRIAL

The plaintiff demands a trial by jury of any and all issues in this action so triable of right.

DATED: August __, 2018

/s/ /Christine M. Beck, Esq. CHRISTINE M. BECK, ESQ. County Attorney Florida Bar No. 767328 Post Office Box 1110 Tampa, Florida 33601-1110 Phone: (813) 272-5670 ***Co-Counsel for Plaintiff*** Service Email: BeckC@hillsboroughcounty.org	*/s/ Thomas L. Young, Esq.* THOMAS L. YOUNG, ESQ. Florida Bar No: 231680 Law Office of Thomas L. Young, P.A. 320 W. Kennedy Blvd., Suite 650 Tampa, FL 33606 (813) 251-9706 Phone/(813) 364-1908 Fax Primary E-Mail: tyoung@tlylaw.com ***Co-Counsel for Plaintiff***
/s/ J. Stephen Gardner, Esq. J. STEPHEN GARDNER, ESQ. Florida Bar No: 114881 T. TRUETT GARDNER, ESQ. Florida Bar No: 152803 Gardner Brewer Martinez-Monfort, P.A. 400 N. Ashley Drive, Suite 1100 Tampa, FL 33602 (813) 221-9600 Phone/(813) 221-9611 Fax Primary E-Mail: sgardner@gbmmlaw.com ***Co-Counsel for Plaintiff***	*/s/ Mike Moore, Esq.* MIKE MOORE, ESQ. Mississippi Bar No: 3452 Mike Moore Law Firm, LLC 10 Canebrake, Suite 150 Flowood, MS 39323 (601) 933-0070 Phone/(601) 933-0071 Fax Primary E-Mail: mm@mikemoorelawfirm.com ***Co-Counsel for Plaintiff*** ****To be admitted pro hac vice***