IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

THE COUNTY OF ALBANY, NEW YORK, Plaintiff, vs. PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY; 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.; AND JANE DOES 1 – 50. Defendants.	Civil Action No.: **Complaint** **Jury Trial Requested**

I. PRELIMINARY STATEMENT

1. The County brings this action to redress harm from a long-running and far reaching fraudulent scheme perpetuated by Purdue Pharma, L.P.; Purdue Pharma, Inc.; and the Purdue Frederick Company, (collectively, "Purdue"); Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, "Endo"); Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"); Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc. (collectively, "Janssen").

2. Purdue, Endo, Teva, and Janssen (collectively, "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 and Duragesic.

3. 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.

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

the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care.[1] Consequently, the market for prescription opioids was sharply restricted.

5. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions, like back pain, migraines, and arthritis. Purdue, together with Endo, Janssen, and Teva, helped cultivate a narrative that pain was undertreated and pain treatment should be a higher priority for health care providers. This paved the way for increased prescribing of opioids for chronic pain. Defendants' promotional efforts dovetailed with this narrative, as Defendants began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

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

7. Defendants used multiple avenues to perpetuate their deceptive advertising scheme. Collectively, Defendants spent hundreds of millions of dollars on promotional activities and materials that continued to falsely deny or trivialize the risk of addiction and overstated the benefits of opioids. Each Defendant devoted massive resources to direct sales contacts with doctors.

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

8. To avoid regulatory scrutiny, Defendants also marketed through third-party, unbranded advertising – i.e., advertising that promotes opioid use generally but does not name a specific opioid – 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 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.

9. 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.[2]

10. 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." Defendants paid these KOLs to serve as consultants or on their advisory boards and to give talks or present continuing medical education programs (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.

[2] The phrase "acted in concert" includes conspiring to achieve some end and aiding and abetting in the commission of acts necessary to achieve some end.

11. 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.

12. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

13. 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.

14. 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" – which include, but are not limited to, the American Pain Foundation (APF) and the American Academy of Pain Medicine ("AAPM") – 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.

15. 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, Janssen worked with a third-party firm to develop pamphlets which the APF released only after Janssen reviewed, edited, and approved the final language. As another example, Purdue's consulting agreement gave it direct, contractual control over APF's work. In doing so, Defendants made sure that the Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

16. Through the Front Groups, Defendants worked together 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 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. The PCF also worked in 2007 to address a perceived "lack of coordination," and its members to develop "key" messages that were then reflected in materials such as programs and industry-run websites like Purdue's *In the Face of Pain*.

17. Defendants funded the same Front Groups and same KOLs, and were able to meet and communicate about common approaches to messages and marketing opioids at conferences. Often communications from Defendants or Front Groups used the same language and format to disseminate the same deceptive messages.

18. Through these coordinated and systematic efforts, Defendants were able to persuade doctors that opioids were not addictive, despite the previous medical consensus and scientific evidence to the contrary. Defendants convinced prescribers that, even if opioids had some limited potential to be addictive, any risk of addiction could be managed by doctors carefully supervising their use by appropriate patients. Part of Defendants' message was that doctors should treat the right patients: legitimate patients who took the drugs as directed (orally) to treat their pain, rather than abusers seeking to snort or inject the drugs for recreation. By defining the class of individuals who should not receive opioids as only these abusers, Defendants gave doctors a false sense of security that they could safely prescribe opioids to patients they trusted.

19. In persuading doctors that nearly all patients could safely receive opioids, Defendants expressly appealed to their desire to alleviate their patients' suffering. Doctors were receptive to Defendants' message because, after hearing about the scourge of untreated and undertreated pain, they needed a way to safely and effectively relieve that pain. Once doctors grabbed onto Defendants' narrative, the consequence that doctors stopped worrying about signs of addiction or prescribing too high doses followed.

20. As detailed below, Defendants created and sustained a multi-billion dollar pain franchise through their pattern of deceptive marketing. Specifically:

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

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

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

d. Defendants told doctors that opioids could be taken in higher and higher

doses without disclosing the ensuing risk to the patient.

e. Defendant Purdue told doctors that OxyContin provided 12 hours of relief when Purdue knew that, for many patients, it did not.

21. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing opioids and reached civil settlements with 26 States (not including New York) and the District of Columbia. However, rather than reforming its opioid marketing to comply with the law, Purdue continued to mislead and obfuscate, as did the other Defendants.

22. In late 2015 and in 2016, Purdue and Endo, respectively, entered into settlement agreements with the Attorney General of the State of New York ("NY AG"). As part of these agreements, they agreed to stop certain deceptive and misleading practices on websites they maintained and to augment or establish abuse detection and diversion programs. This action does not seek to enforce any provision of the New York Attorney General's settlements with Purdue or Endo, nor did those settlements release any of the County's claims or provide any compensation to the County for damages caused by these Defendants.

23. To this day, Defendants have failed to correct earlier misrepresentations, and, in many respects, persist in the same types of misconduct.

24. Defendants also developed new deceptive marketing practices in response to increasing awareness of the problems with opioids. Rather than admit responsibility, Defendants simply blamed abuse and addiction on people snorting or injecting opioids.

25. Purdue obtained approval for an "abuse-deterrent" formulation ("ADF") of OxyContin and of Hysingla ER but deceptively marketed it to doctors, claiming, upon information and belief based on the uniformity of its nationwide scheme and practices elsewhere that:

a. Purdue's ADF opioids could not be crushed or snorted, which is false.

b. Purdue's ADF opioids reduced opioid abuse and diversion, which is false. Purdue failed to tell doctors that its ADF opioids had no impact on oral abuse.

c. Purdue's ADF opioids were safer than other opioids, which is false.

26. Along with the launch of reformulated OxyContin, Purdue also launched a new campaign—capitalizing upon growing concern about the rising tide of opioid addiction, overdose, and death—falsely promoting the effectiveness of its abuse-deterrent opioids in preventing abuse. Like pseudoaddiction, this marketing was intended to, and did, reassure prescribers who became concerned about addiction that they not only could continue to prescribe opioids, but in fact needed to switch to Purdue's opioids because they were safer.

27. Purdue knew, and evidence showed, that Purdue's reformulated OxyContin, and its later-released Hysingla, which it also promoted as abuse-deterrent could be easily defeated, did not affect oral use, which is the most common means of abuse, and increased harmful outcomes.

28. Similarly, Endo has marketed a reformulated version of Opana ER as tamper- or crush-resistant and less prone to misuse and abuse even though: (1) the FDA rejected Endo's 2012 petition to approve Opana ER as abuse-deterrent; (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

29. In the same vein, Purdue misrepresented its efforts to rein in the diversion and abuse of opioids, while privately failing to report suspicious prescribing.

30. Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has been a commonplace, and often first-

line, treatment since at least the mid-2000s. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Opioids are now among the most prescribed class of drugs. Defendants generated record profits through the success of this scheme. Notably, as a class, opioids generated in $11 billion in revenue for drug companies in 2014 alone. In 2015, Purdue alone reaped an estimated $2.4 billion in revenue, virtually all of it from opioids. Each Defendant continues to profit from the success of their deceptive marketing scheme.

31. Defendants' deceptive marketing caused prescribing not only of their own opioids, but of opioids as a class, to skyrocket. In 2015, health care providers wrote enough opioid prescriptions to medicate every American around the clock for three weeks, and on an average day, more than 650,000 opioid prescriptions are dispensed in the U.S. From 2014-2016, more than 140,000 opioid prescriptions were reported in Albany County, with an estimated population of 309,053.

32. Defendants knew that their representations regarding the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of their representations has been confirmed by the U.S. Food and Drug Administration ("FDA") in recent public statements and the Centers for Disease Control and Prevention ("CDC") in its 2016 *Guideline for Prescribing Opioids for Chronic Pain* ("CDC Guideline"), which exhaustively reviewed the evidence on opioids.

33. Rather than compassionately helping patients, this explosion in opioid use—and Defendants' profits—has come at the expense of chronic pain patients. The director of 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."[3]

34. As a direct result of Defendants' dangerously false marketing, the nation is now swept up in what the CDC called a "public health epidemic" and what the U.S. Surgeon General deemed an "urgent health crisis."[4] A 2016 Report from the New York State Majority Coalition's Joint Senate Task Force on Heroin and Opioid Addiction similarly stated that "[a]ddiction to heroin and opioids is a public health crisis that impacts every city, town and village within the state."[5] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

35. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War. Many others have been swept into a cycle of addiction and abuse with which they will struggle their entire lives. According to the U.S. Centers for Disease Control and Prevention ("CDC"), as many as one in four patients who receive prescription opioids long-term for chronic pain in primary care settings will become addicted. Further, as many as 80% of heroin users start with prescription drugs before turning to heroin.[6] In 2014, almost 2 million Americans were

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

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

[5] New York State Senate Majority Coalition, Joint Senate Task Force on Heroin and Opioid Addiction, 2016 Report at 8.

[6] http://news10.com/2017/05/03/new-task-force-formed-to-battle-opioid-epidemic-in-the-capital-region/

addicted to prescription opioids and another 600,000 to heroin.

36. The outcomes in New York, including Albany County, are equally catastrophic—and getting worse. Total drug deaths in Albany County increased by 29% from 2010 to 2015. In 2016, the County saw 11 heroin deaths and 8 deaths involving opioid pain relievers, 113 outpatient visits and 23 hospitalizations for opioid overdoses, and 1,194 unique clients admitted to treatment programs for heroin and other opioids. Albany County had 31 opioid overdose deaths in 2015, ranking higher than 46 of New York's 62 counties.

37. While opioids have been diverted through illicit prescribing and sales, it is the regular, legitimate prescribing of opioids that created and fueled this crisis. A study of 254 accidental opioid overdose deaths in Utah found that 92% had been receiving prescriptions from health care providers for chronic pain. By contrast, sales to patients who doctor-shop (or visit multiple doctors to hide illicit or over-use) constitute approximately only 1% of opioid volume.

38. Defendants' scheme has violated, and continues to violate, New York General Business Law §§ 349's & 350's prohibitions on unfair or deceptive acts and practices and false advertising, and further violates the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.* Additionally, Defendants are liable for creating and maintaining a public nuisance. The County brings this action to hold Defendants accountable for their conduct; and seeks abatement of the public nuisance, actual and treble damages, and any other injunctive and equitable relief within this Court's powers to redress and halt these deceptive practices.

II. PARTIES

A. Plaintiff

39. Albany County includes a total of 19 villages, towns, and cities within New York.

The County provides many services for its residents, including public health, public assistance, and law enforcement services, emergency care, and services for families and children, including through 82 separate behavioral health programs across 26 community agencies.

40. The County brings this action on its own behalf, as *parens patriae* in the public interest.

B. Defendants

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

42. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, Hysingla ER in the United States and in Albany County.[7] OxyContin is Purdue's best-selling opioid: since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

43. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon in October 2011. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States and Albany County, including generic opioids

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

previously sold by Allergan plc, whose generics business Teva Ltd. acquired in August 2016. These parties are collectively referred to as "Teva."

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

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

46. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Albany County, 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.

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

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

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

III. JURISDICTION AND VENUE

50. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §

1331 because the County's claim under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.* raises a federal question. This Court has supplemental jurisdiction over the County's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

51. This court has personal jurisdiction over Purdue Pharma, Inc. because it is a New York corporation, and over all Defendants under New York Civil Practice Law and Rules 302 because they, in person or through agents, transact business in this state and contract to supply goods in this state, have committed and are committing tortious acts in this state causing injury to people and property in this state, regularly do or solicit business, or engage in a persistent course of conduct, or derive substantial revenue from goods used or consumed or services rendered in this state, or expect or should reasonably expect their conduct to have consequences in New York and derive substantial revenue from interstate commerce.

52. Venue as to each Defendant is proper in this court under 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the Northern District of New York. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants reside, are found, have agents, or transact their affairs in this district.

IV. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

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

54. Through marketing that was as pervasive as it was deceptive, Purdue, Endo, Teva, and Janssen convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven.

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

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

A. DEFENDANTS FALSELY TRIVIALIZED, MISCHARACTERIZED, AND FAILED TO DISCLOSE THE KNOWN, SERIOUS RISK OF ADDICTION.

57. Defendants relied heavily on their sales representatives to convey its marketing messages and materials to prescribers in targeted, in-person settings. Meal reimbursement records show that Purdue, Janssen, and Teva were engaged in detailing in Albany County, and upon information and belief, Endo also detailed doctors in the County. In New York, the NY AG found that over a six year period, Purdue made more than 1,800 sales visits to doctors it had flagged on a "no call" list alone. The NY AG also found that Endo made 326 detailing visits to certain New York prescribers who were subsequently arrested and/or convicted for illegal prescribing of opioids.

58. To ensure that sales representatives delivered the desired messages to prescribers, Defendants directed and monitored their respective sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit. Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies and forbade them to use promotional materials not approved by their company's marketing and compliance departments. They further ensured marketing consistency nationwide through national and regional sales representative training. Thus, their sales forces in New York used the same deceptive messages about the risks and benefits of its opioids that the companies employed nationwide.

1. Minimizing or mischaracterizing the risk of addiction

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

60. Defendants' sales representatives regularly omitted from their sales conversations with prescribers, including, upon information and belief, healthcare providers in Albany County, any discussion of the risk of addiction from long-term use of opioids.[8] These omissions rendered other arguably truthful statements about opioids false and misleading, and they both reinforced and failed to correct their prior misrepresentations regarding the risk of addiction.

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

61. Defendants also deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients. According to Defendants, doctors can screen patients to identify those who are likely to become addicted, and therefore could safely prescribe to everyone else. Defendants discounted general concerns or warnings regarding addiction by reassuring doctors that their patients would not become addicted. One former Purdue sales representative in another region confirmed Purdue's message that opioids were appropriate and safely prescribed to legitimate patients with actual pain; upon information and belief, based on the uniformity of Purdue's practices, the same message was delivered to prescribers in the County. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction. *See* Section IV.A.2, *infra*.

62. In addition, Defendants' sales representatives also failed to disclose to prescribers, including, upon information and belief, prescribers in the County, the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This difficulty in terminating use is a material risk, which can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

63. Promotional materials and other publications disseminated or made available by Defendants in the County have included similar messages minimizing the risk of addiction.

64. In addition to deceptively ascribing signs of addiction to pseudoaddiction, as laid out in Section IV.B below, Defendants falsely portrayed "true" addiction in its narrowest form. For example, *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible

Drug Abuse." Purdue knew that opioid addicts who resort to these extremes are uncommon; they far more typically become dependent and addicted through oral use. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time.

65. These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. Purdue made *Providing Relief, Preventing Abuse* available to sales representatives to show to or leave with prescribers, including, on information and belief, prescribers in the County.

66. Defendants also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"), which prepared "education guides" and other program and materials intended to reach a national audience. Purdue was APF's second-biggest donor. Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby for its interests on Capitol Hill. The close relationship between APF and Purdue was not unique, but mirrors relationships between APF and Defendants. The largest donor, from 2007 until APF closed its doors in 2012, was Endo, which provided more than half of APF's $10 million in total funding during that time period. By 2011, APF was dependent on Purdue, Teva, Endo, and others for funding. Despite its ties to and dependence on Defendants, APF held itself out as an independent organization. In 2012, the U.S. Senate Finance Committee began looking into APF's to ascertain any links between the organization and the manufacturers of prescription opioids. Within days of becoming a target of this investigation, the APF voted to dissolve. APF then closed its doors and declared that the organization had ceased to exist.

67. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction. Purdue provided substantial funding in the form of a $26,000 grant to APF and closely collaborated with APF in creating *A Policymaker's Guide.* On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*. It is still available to County prescribers online.[9]

68. Through APF, 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."

69. Other illustrative examples of the means by which Defendants spread their deceptive messages include a website Purdue maintained from 2008 to 2015, *In the Face of Pain,* that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the NY AG. Although it included the Purdue copyright at the bottom of each page, the site did not refer to any specific Purdue products and cultivated the "impression that it [was] neutral and unbiased."[10]

70. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds

[9] *See* American Pain Foundation., *A Policymaker's Guide to Understanding Pain & Its Management* (2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

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

with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.[11]

71. As another example, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com. In addition, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

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

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

74. Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-

[11] *Id.*

term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk[] of . . . addiction"—"even at recommended doses" —of all opioids.[12] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[13] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[14] As the Director of the CDC has noted: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[15]

75. The 2016 Report of the New York State Majority Coalition's Joint Senate Task Force on Heroin and Opioid Addiction found that many health care professionals were unaware of alternatives to the use of opioids for chronic pain and of the consequences of prescribing certain drugs. The same report noted that "[e]xperts from around the state testified that prevention begins with education, not just in the schools but the community as a whole," and "[c]ountless individuals" impacted by addiction to prescription opioids testified as to lack of knowledge of these drugs' addictive nature.[16]

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

[13] CDC Guideline at 2.

[14] *Id.* at 21.

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

[16] New York State Senate Majority Coalition, Joint Senate Task Force on Heroin and Opioid Addiction, 2016 Report at 9.

2. Overstating the efficacy of screening tools

76. Defendants falsely instructed prescribers and patients, including, upon information and belief, prescribers and patients in the County, that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies will mitigate addiction risk.

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

78. Defendants' conveyed these safe prescribing messages through in-person sales calls to doctors. Former Purdue sales representatives claimed, including, upon information and belief, to prescribers in the County, that doctors could screen out patients at high risk of addiction through urine tests and patient contracts, and that doctors could mitigate risk by prescribing only to trusted patients.

79. On information and belief, Purdue sales representatives in the County also shared the *Partners Against Pain* "Pain Management Kit," which contained several "drug abuse screening tools." These included the "Opioid Risk Tool," which is a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease," ignoring the sensitivity of the topic and the nature of addiction, which make it unlikely that many patients can be counted on to share this information.

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

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

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

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

84. Purdue was not alone in engaging in such conduct. For example, 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.

85. The CDC Guideline confirms the falsity of Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[17]

B. DEFENDANTS FALSELY DESCRIBED ADDICTION AS PSEUDOADDICTION, AND DANGEROUSLY ENCOURAGED DOCTORS TO RESPOND BY PRESCRIBING MORE OPIOIDS.

86. Defendants deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction was a concept invented to convey the idea that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

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

87. Purdue, through its unbranded imprint *Partners Against Pain*,[18] promoted pseudoaddiction through at least 2013 on its website.

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

89. *Responsible Opioid Prescribing* was sponsored by Purdue and other opioid manufacturers. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally, including in New York State.

90. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

91. 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

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

pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

92. Dr. Russell Portenoy, an ostensibly independent "key opinion leader" ("KOL") for Endo, Janssen, Teva, and Purdue popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

93. The CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[19] 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."[20]

C. DEFENDANTS OVERSTATED THE BENEFITS OF CHRONIC OPIOID THERAPY WHILE FAILING TO DISCLOSE THE LACK OF EVIDENCE SUPPORTING LONG-TERM USE

1. Mischaracterizing the benefits of long-term use

94. To convince prescribers and patients that opioids should be used to treat chronic pain, Defendants had to persuade them of a significant upside to long-term opioid use. But as the CDC Guideline makes clear, there is "*insufficient evidence* to determine [the] long-term benefits

[19] CDC Guideline at 13.

[20] *Id.* at 25.

of opioid therapy for chronic pain."[21] 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)"[22] 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."[23] As a result, the CDC recommends that opioids be used not in the first instance for the treatment of chronic pain and instead be used only after prescribers have exhausted alternative treatments.

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

96. Two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Defendants. Upon information and belief, Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. Dr. Portenoy was the sole consultant. The

[21] *Id.* at 19.

[22] *Id.* at 15.

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

consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

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

98. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva made to the sponsoring organizations and committee members.

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

100. A past president of the AAPM, Dr. Scott Fishman, who also served as a KOL for Manufacturing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[24]

101. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, have been a particularly effective channel of deception, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

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

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

role of opioids in a chronic condition such as OA [osteoarthritis]."[25] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[26] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

103. Tevadeceptively 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.

104. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, 11 such as migraines, post-operative pain, or pain due to injury.

105. Despite this, Teva conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker

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

[26] *Id.*

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, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain..

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

107. 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.

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

109. Teva's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses. In New York state, of publicly disclosed visits from July 2013 – December 2016, 10% of visits were to prescribers identified as having an oncology specialty, and they received 1.22% of meal reimbursements. By contrast, anesthesiologists and Physical Medicine and Rehabilitation specialists received the most visits by Teva's sales

representatives and over 70% of spending. None of the 6 unique prescribers visited in Albany County were oncologists – four were pain specialists, one was a neurologist, and one was an internist.

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

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

111. Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. On information and belief, sales representatives promoted the ability of opioids to improve patients' function and quality of life.

112. Defendants' and Defendant-sponsored materials that, upon information and belief, were distributed or made available in the County reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "[m]ultiple clinical studies have shown that long-acting opioids, in particular, are effective in improving daily function" and "overall-health-related quality of life for people with chronic pain." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin

would help him work more effectively. Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Additional illustrative examples are described below:

a. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it *easier* for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

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

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

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

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

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

113. Likewise, Defendants' claims that long-term use of opioids improves patient

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

114. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[27] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

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

115. Assessing existing science, the CDC Guideline found that there was "[n]o evidence show[ing] a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later"[28] and advised that "there is no good evidence that opioids improve pain or function with long-term use."[29] The FDA and other federal agencies have made this clear for years.[30] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[31] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[32] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[33]

3. Omitting or mischaracterizing adverse effects of opioids

[28] CDC Guideline at 15.

[29] *Id.* at 20.

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

[31] CDC Guideline at 2.

[32] *Id* at 18.

[33] *See* n. 3, *supra*.

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

117. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[34] in which the patient becomes more sensitive to pain over time, hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

118. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids).[35] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

[34] *See* n. 23, *supra*.

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

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

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

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

122. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[36]

123. Again, Defendants' misrepresentations were effective. A study of 7.8 million

[36] Meredith Noble M, *et al.*, *Long-term opioid managementTerm Opioid Management for chronic noncancer painChronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.

D. DEFENDANTS CONTINUED TO TELL DOCTORS THAT OPIOIDS COULD BE TAKEN IN EVER-HIGHER DOSES WITHOUT DISCLOSING THEIR GREATER RISKS

124. Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Defendants needed to generate this comfort level among doctors to ensure the doctors maintained patients on the drugs. Further, as described in more detail in Section IV.E, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief.

125. Purdue-sponsored publications and CMEs available in New York also misleadingly suggested that higher opioid doses carried no added risk.

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

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

128. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks

to patients' kidneys), but did not disclose risks from opioids at high doses.

129. 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."

130. Endo distributed a pamphlet edited by Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which is available online. 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."

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

132. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses.[37] As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken

[37] Kate M. Dunn, *et al.*, *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152(2) Annals of Internal Med. 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.

as recommended.

133. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[38] That is why the CDC advises doctors to "avoid increasing dosage" above 90 mg MED.[39]

E. PURDUE MISLEADINGLY PROMOTED OXYCONTIN AS SUPPLYING 12 HOURS OF PAIN RELIEF WHEN PURDUE KNEW THAT, FOR MANY PATIENTS, IT DID NOT.

134. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch. While OxyContin's FDA-approved label directs 12 hour dosing, Purdue sought that dosing frequency in order to maintain a competitive advantage over more frequently dosed opioids. Yet Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours by affirmatively claiming, in its general marketing and upon information and belief, to prescribers in the County, that OxyContin lasts for 12 hours, promoting 12-hour dosing as a key advantage of OxyContin, and by failing to disclose that OxyContin fails to provide 12 hours of pain relief to many patients.

135. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below. Purdue conveyed

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

[39] CDC Guideline at 16.

to prescribers that the solution to end-of-dose failure is not more frequent dosing but higher doses—which pose greater risks, as discussed in Section IV.D.

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

137. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," Purdue has conducted no such studies.

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

139. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it

at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

140. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[40] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

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

142. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover,

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

Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to prescribers what it knew about OxyContin's actual duration, and not to promote more dangerous higher dosing, rather than increased frequency of use, regardless of any marketing advantage.[41]

143. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[42]

F. PURDUE AND ENDO OVERSTATED THE EFFICACY OF ABUSE-DETERRENT OPIOID FORMULATIONS

1. Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER.

144. By the mid-2000s, widespread addiction to and abuse of OxyContin had emerged in the public eye. Rather than acknowledge that these problems were the inevitable result of widespread prescribing of OxyContin for chronic pain, Purdue claimed that abuse and addiction resulted from diversion by abusers snorting or injecting the drugs. Purdue also brought to market an "abuse-deterrent" formulation of OxyContin but deceptively marketed it to doctors as a solution to the opioid epidemic.

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

[42] CDC Guideline at 16.

145. Reformulated, ADF OxyContin was approved by the FDA in April 2010. However, the FDA noted that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties.

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

147. Purdue sales representatives regularly used the so-called abuse-deterrent properties of Purdue's opioids as a primary selling point to differentiate those products from their competitors, including, upon information and belief, in the County. Specifically, Purdue sales representatives:

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

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

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

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

148. These statements and omissions by Purdue are false and misleading and are

inconsistent with the FDA-approved labels for Purdue's ADF opioids—which indicate that abusers seek them because of their high likeability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and which do *not* indicate that ADF opioids prevent or reduce abuse, misuse, or diversion.

149. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[43] 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 ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare OxyContin to be snorted or injected.

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

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

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

pattern of tilting scientific research and literature to support the promotion of opioids discussed in Section IV.A.2.

152. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."[44] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death." [45]

153. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[46] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

154. Yet despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. Haddox, who

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

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

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

had become by that time the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

155. Generic versions of OxyContin, which became available in February 2011, threatened to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

156. Purdue's false and misleading marketing of the benefits of its ADF opioids preserved and expanded its sales by persuading doctors to write prescriptions for ADF opioids in the mistaken belief that they were safer. It also allowed prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—*i.e.*, it allowed them to believe that while patients might abuse, become addicted to, or die from other, non-ADF opioids, Purdue's opioids did not carry that risk.

2. Endo's Deceptive Marketing of Reformulated Opana ER.

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

158. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it could not market new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security

since the product may be chewed and ground for subsequent abuse."[47] In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

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

160. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the

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

reformulated drug to "promote the public welfare" would be lost.[48] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[49]

161. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[50]

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

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

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

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

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

163. Over time, evidence continued to mount that injection was becoming the preferred means of abusing Opana ER, making Opana ER *less safe* than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.[51] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%.

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

165. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example,

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

a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[52] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[53] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[54]

166. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." In a 2016 settlement with Endo, the NY AG found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

G. PURDUE ALSO ENGAGED IN OTHER UNLAWFUL, DECEPTIVE, AND UNFAIR CONDUCT BY FAILING TO REPORT SUSPICIOUS PRESCRIBING

167. Purdue deceptively and unfairly failed to report to New York authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive

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

[53] *Id*.

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

role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[55]

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

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

170. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[56] Purdue's statement on "Opioids Corporate Responsibility" likewise

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

[56] Purdue website, *Opioids With Abuse-Deterrent Properties*, http://www.purduepharma.

states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[57] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[58]

171. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids, which gave rise to its 2007 criminal plea, and make its current marketing seem more trustworthy and truthful. In fact, Purdue has consistently failed to report suspicious prescribing it observed to authorities.

172. Purdue can track distribution and prescriptions of its opioids down to the retail and prescriber level. It has detailed data on opioid prescribing and sales and, through its extensive network of sales representatives, can observe signs of diversion.

173. Purdue identified those doctors – *internally*. Since at least 2002, Purdue maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit

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com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/.

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

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

prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Health care providers added to the database no longer were detailed, and sales representatives received no compensation tied to these providers' prescriptions.

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

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

176. The NY AG found that Purdue placed 103 New York health care providers on its No-Call List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period" and spending approximately $3,000 dollars in meal expenses for 38 of these providers.[59]

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

177. They NY Attorney General has found that Endo knew, as early as 2011, that Opana was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The NY AG further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 scripts for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

H. BY INCREASING OPIOID PRESCRIPTIONS AND USE, DEFENDANTS' DECEPTIVE MARKETING SCHEME FUELED THE OPIOID EPIDEMIC AND SIGNIFICANTLY HARMED ALBANY COUNTY AND ITS CITIZENS

178. Defendants' misrepresentations prompted Albany County health care providers to prescribe, patients to take, and opioids for the treatment of chronic pain. Through their deceptive marketing, Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use and have both benefited from and extended their prior misrepresentations, sustaining and expanding a market for their opioids.

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

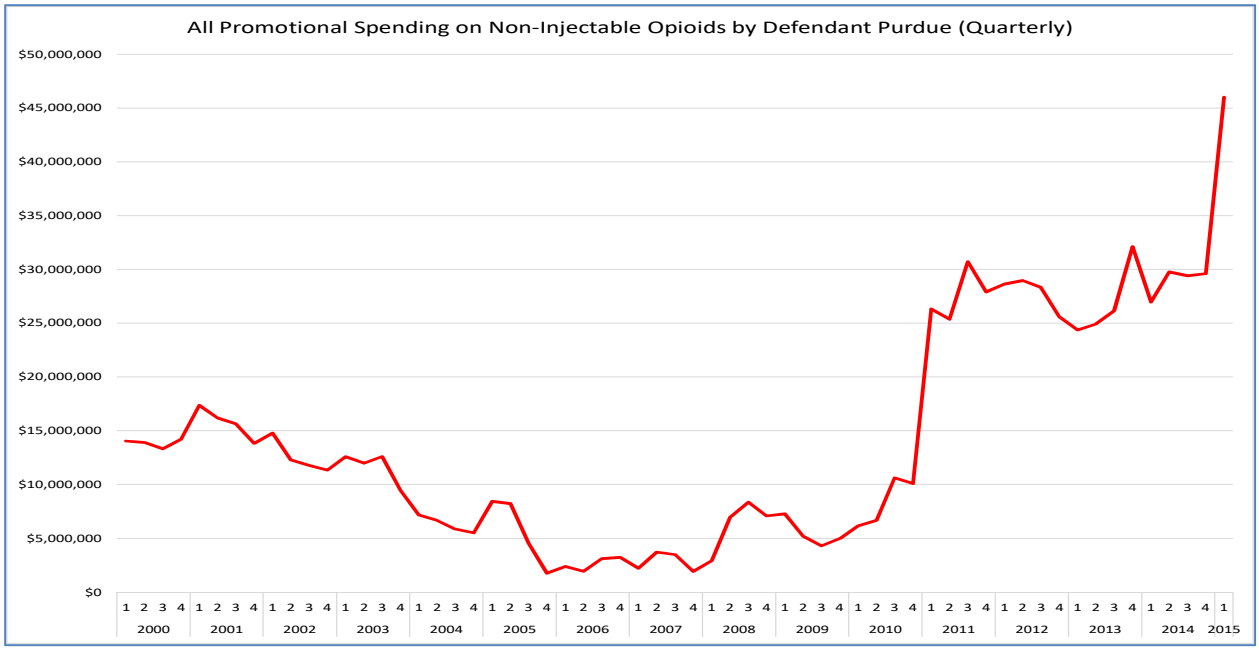
180. Overall sales of opioids in New York have skyrocketed, and Albany County is no exception. In 2015, health care providers wrote enough opioid prescriptions to medicate every American around the clock for three weeks, and on an average day, more than 650,000 opioid prescriptions are dispensed in the U.S. From 2014-2016, more than 140,000 opioid prescriptions

were reported in Albany County, with an estimated population of 309,053.

181. The increase in opioid prescribing corresponds with Defendants' marketing push. As shown in the chart below, according to data obtained from a marketing research company, Purdue spent roughly $15 million per quarter in 2000. Its spending decreased from 2000 to 2007, as the company came under investigation by the U.S. Department of Justice and various state attorneys general. But by 2010, with the introduction of Butrans and reformulated OxyContin, Purdue ramped up its marketing once again. In 2011, Purdue's marketing spiked to more than $25 million per quarter, and by the end of 2015, with the introduction of Hysingla ER, it soared to more than $40 million per quarter.

182. The largest component of this spending was attributable to sales representative visits to individual prescribers, with total detailing expenditures rising from roughly $45 million annually in 2000 to more than $108 million in 2014.

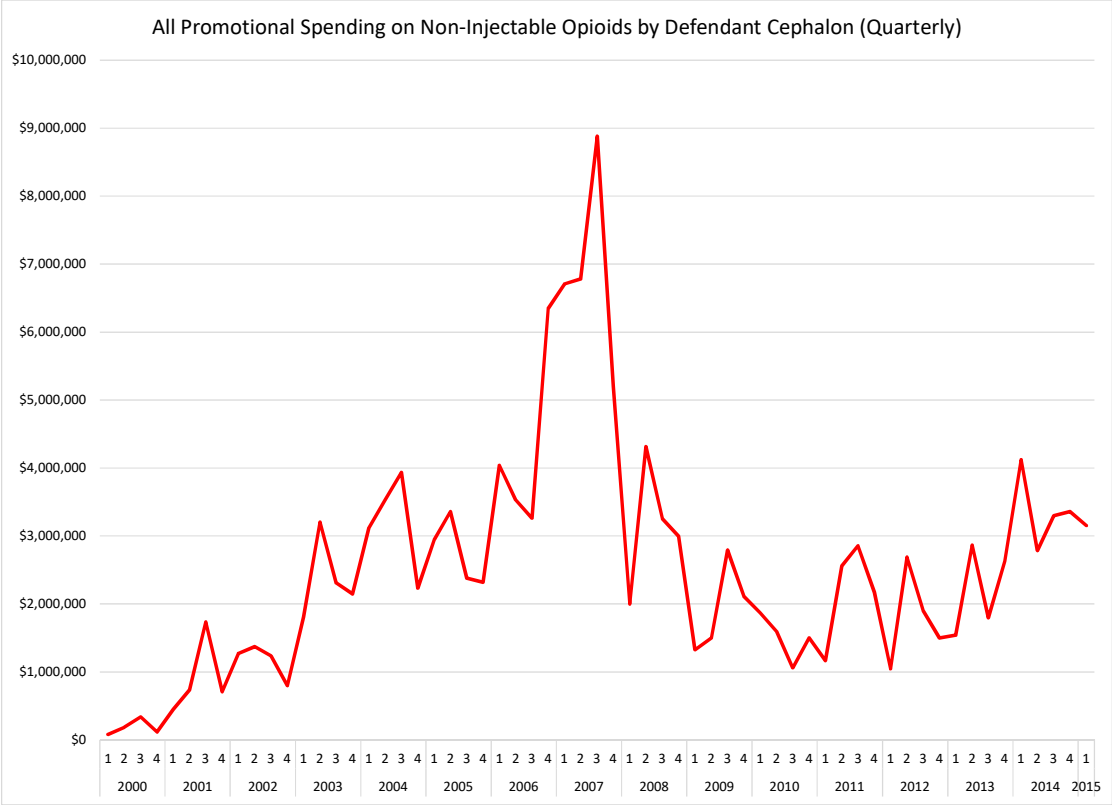
183. Purdue devotes these resources to detailing—notwithstanding increasing efforts of hospitals and physician practice groups to restrict access—because it knows the effectiveness of in-person marketing. The effects of sales calls on prescribing behavior are well-documented in



the literature, including in a 2009 study correlating the nearly 10-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling of sales calls.

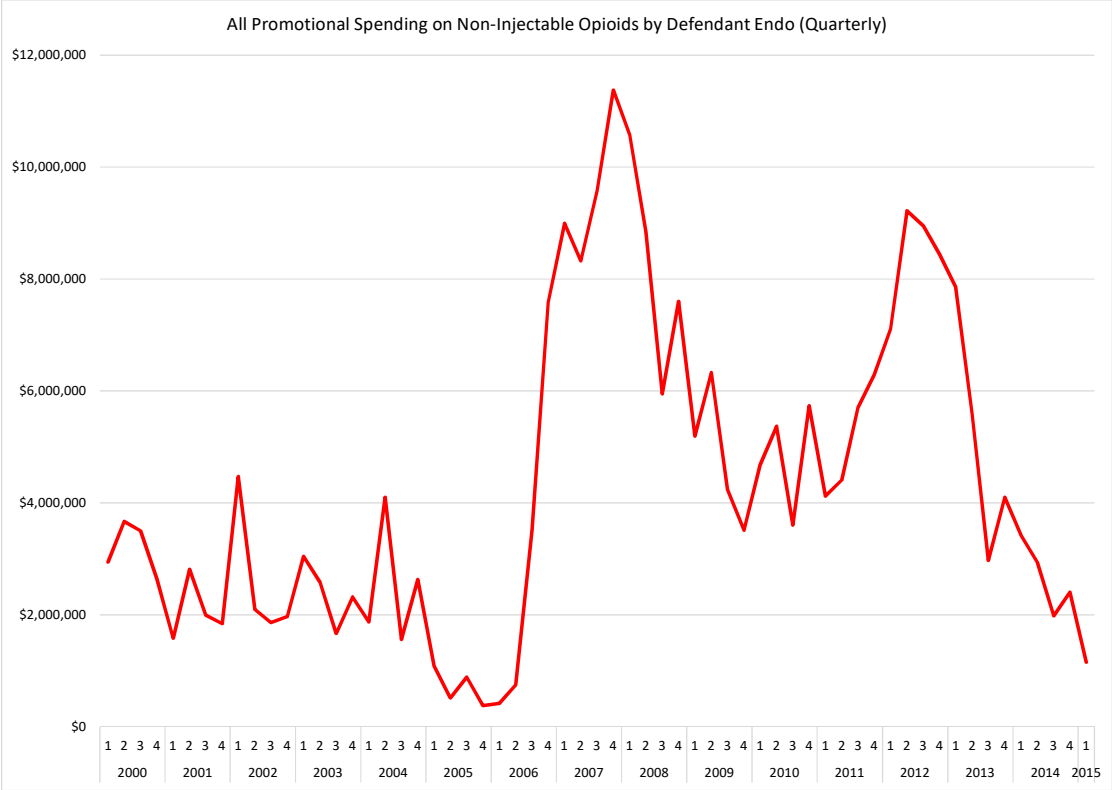
184. Not only Purdue, but also Endo, Teva, and Janssen, devoted and continue to devote massive resources to direct sales contacts with doctors.

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

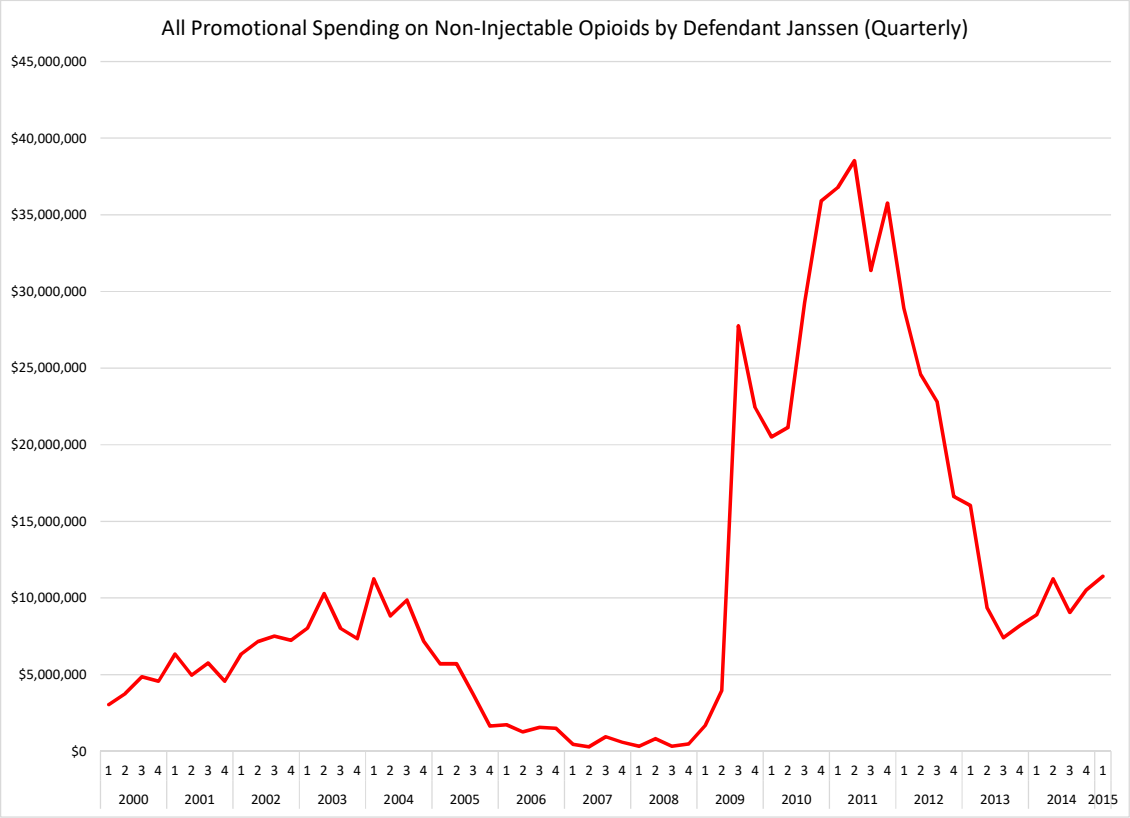


186. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38

million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



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



188. In 2014 alone, Defendants collectively spent $166 million on detailing branded opioids to doctors. This 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 Teva, and $10 million by Endo.

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

190. Through third parties, Defendants also continue to obfuscate the manifest link between detailing and access to opioids. For example, the Purdue-funded Center for Lawful

Access and Abuse Deterrence maintains a fact sheet on its website labeling as "myth" the notion that "[i]ncreased access to controlled substances is directly related to . . . aggressive marketing tactics to prescribers by pharmaceutical sales representatives."

191. The sharp increase in opioid use resulting from Defendants' marketing has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in the County. 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."[60]

192. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[61]

193. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse,"[62] with

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

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

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

particularly compelling data for extended release oxycodone—*i.e.*, OxyContin.

194. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[63]

195. Opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 183,000 people died in the United States from prescription-related overdoses According to the New York State - County Opioid Quarterly Report Published July, 2017, in Albany County, 31 people died from heroin or other opioids in 2015, and 18 heroin and opioid-related deaths have been reported for 2016. In addition, 113 Albany County emergency departments treated 94 heroin overdoses and 19 overdoses from other opioids through outpatient visits, while 13 people were hospitalized for heroin overdoses and 10 people were hospitalized for overdoses of other opioids in 2016. Also in 2016, there were 971 unique clients admitted for heroin to OASAS-certified chemical dependence treatment programs and 1,194 unique clients admitted for any opioid including heroin. Further, Naloxone was administered 216 times by EMS, 8 times by law enforcement, and 29 times by a registered Community Opioid Overdose Prevention program in Albany County.

196. Defendants' conduct has significantly harmed veterans. Sixty percent (60%) of veterans returning from deployment suffer from chronic pain, double the national average of thirty percent (30%) of U.S. citizens. Veterans are twice as likely to suffer addiction and to die from

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

opioid abuse than non-veterans according to a 2011 Veterans Administration study.

197. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of Naloxone—the antidote to opioid overdose.

198. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014 to 2016, and 25% of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

199. There are also swelling costs from the growing universe of medications aimed at treating secondary effects of opioids—including not only addiction and overdose, but also side effects like constipation and sedation. According to a recent analysis by *The Washington Post*, working age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effects medications—essentially, drugs to treat the effects of opioids—generated at least $4.6 billion in spending nationally in 2015, on top of $9.57 billion in spending on opioids themselves. In addition, there are also the costs of dispensing opioids—in office visits to obtain refills, count pills, or obtain toxicology screens to monitor potential abuse. All of these costs were born by the County, as well.

200. The abuse of opioids have caused additional medical conditions that have injured County residents and required care often paid for by the County.

201. The deceptive marketing and overprescribing of opioids also had a significant detrimental impact on children in Albany County. The overprescribing of opioids for chronic pain has given young children access to opioids, nearly all of which were prescribed for adults in their household. Teenagers too, obtain access to prescription drugs, and suffer addiction and overdose. Young people in the County become addicted to prescription opioids after experimenting with the drugs believing, incorrectly, that prescription drugs are less dangerous than illicit drugs sold on the street. When they do, they too may turn to heroin and synthetic opioids. Powerful synthetic opioids, such as fentanyl and carfentanil, are so strong that multiple doses of Narcan or naloxone may be required to reverse an overdose. One mother reported that it took six doses to revive her son. Another mother's son survived 13 overdoses.

202. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour. From 2007 to 2009, for every 1,000 hospital discharges in the County, as many as 102 newborns suffered drug related problems.

203. Children are also injured by the dislocation caused by opioid abuse and addiction. Children in the County have been removed from homes with opioid addiction or abuse and placed in foster care.

204. To combat the opioid epidemic in the County, the County Executive created the Albany County Opioid Task Force. The Task Force brings together leaders in public health, law enforcement, behavioral health, and the community to work collaboratively toward solutions and help individuals and families affected by opioid addiction and abuse. Among the Task Force's priorities are education, prevention, and public outreach, streamlining access to care, and improving data coordination. "Project Orange," a partnership between the Albany County Department of Health and participating local pharmacies, named after the orange label affixed to controlled substances, provides prepaid envelopes that customers may use to return unused prescription opioids to participating pharmacies. The program aims to provide an opportunity for education about the dangers of extended opioid use and the existence of a black market for prescription opioids — of which many County residents are unaware.

205. Defendants' success in extending the market for opioids to new patients and chronic conditions also created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury.

206. Contrary to Defendants' misrepresentations, most of the illicit use originates from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet. Often, patients on prescription opioids fail pill checks or other strategies recommended to monitor addiction, are discharged by their doctors, and then turn to heroin as an alternative.

207. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Roughly 80% of heroin users previously used prescription opioids. A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into New York communities.

208. The County has incurred substantial expense to address the opioid epidemic created by Defendants' misconduct. Specifically, the County spent more than $1 million to implement measures aimed at curbing addiction and abuse, including for responding to overdoses and addressing pill mills, and for prescribing medicine. The Sheriff's Heroin Addiction Program, which also addresses consequences of the deceptively-fueled overprescribing of opioids, has spent nearly $1 million, at latest estimates. The County's Department of Mental Health has spent significant expenses for gross opioid-related costs. The County has spent millions more for probation services through its Department of Social Services and Probation; and for services for children removed from homes with opioid abuse through the County's Department for Children Youth and Families.

I. ALTHOUGH DEFENDANTS KNEW THAT THEIR MARKETING OF OPIOIDS WAS FALSE AND MISLEADING, THEY FRAUDULENTLY CONCEALED THEIR MISCONDUCT

209. Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and likewise, Purdue and Cephalon paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and

reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively expose the known falsity of Defendants' misrepresentations.

210. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. They purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Defendants masked or never disclosed their role in shaping, editing, and approving the content of this information. Defendants also distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support.

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

CAUSES OF ACTION

COUNT I
Deceptive Acts And Practices – New York General Business Law § 349
(Against All Defendants)

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

213. Defendants violated New York General Business Law § 349, because they engaged in deceptive acts or practices in the conduct of business, trade or commerce in this state.

214. Defendants acts were likely to mislead a reasonable consumer acting reasonably under the circumstances.

215. 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, Defendants have engaged in misrepresentations and knowing omissions of material fact. In addition, Purdue and Endo, in falsely promoting abuse-deterrent formulations as reducing abuse, and Purdue, in falsely claiming that OxyContin provides 12 hours of relief, and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, including in Albany County, have engaged in misrepresentations and knowing omissions of material fact.

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

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

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

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

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

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

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

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

h. Purdue's claims that twice-daily dosing of OxyContin provides a full 12 hours of pain relief with each dose;

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

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

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

217. By engaging in the acts and practices alleged herein, Defendants omitted to state material facts that they had a duty to disclose by virtue of Defendants' other representations, including, but not limited to, the following:

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

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

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

d. Opioids carry 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 while exaggerating the risks of competing products, such as NSAIDs;

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

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

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

h. Purdue and Endo failed to report suspicious prescribers.

218. 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.

219. 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 when taken in the context of the surrounding circumstances.

220. Defendants' acts and practices as alleged in this Complaint had a capacity or tendency to deceive. When considered from the perspective of a reasonable prescriber or consumer, these acts or practices were likely to mislead.

221. Defendants' acts and practices regarding prescribers and consumers as alleged in this Complaint are immoral, unethical, and offensive to established public policy, including:

- The policy, reflected in the Albany County 2016-2018 Community Health Improvement Plan and Albany County Opioid Task Force, to promote mental health and prevent substance abuse, and specifically, to curb the opioid epidemic in Albany County;
- The policy, reflected in N.Y. Comp. Codes R. & Regs. tit. 10, § 80.22, requiring manufacturers to report suspicious orders to authorities;

222. The County is part of the broad class of persons that may avail themselves of a remedy under § 349.

223. The County has been injured by reason of Defendants' violations of § 349.

224. The County suffered actual damages by reason of Defendants' violations of § 349.

COUNT II
False Advertising – New York General Business Law § 350
(Against All Defendants)

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

226. Defendants violated New York General Business Law § 350, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.

227. Defendants, by minimizing and misstating the risks of opioids and overstating their benefits, have represented, and continue to represent, that their opioids have characteristics and benefits they do not have in the course of their marketing activities within Albany County.

228. At the time they made or disseminated these statements, Defendants knew or recklessly disregarded that there was no scientific evidence to support the statements or that available science contradicted the statements.

229. At all times relevant to this Complaint, Purdue promoted OxyContin as providing 12 hours of pain relief, and Purdue and Endo promoted abuse-deterrent formulations of their opioids as more difficult to abuse and less addictive, as means of maintaining a competitive advantage against other opioid pharmaceuticals. At all times relevant to this Complaint, Defendants promoted opioids as superior to competing products, such as NSAIDs, and exaggerated the risks of NSAIDs while ignoring risks of adverse effects from opioids.

230. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to the County and its residents.

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

232. The County has been injured by reason of Defendants' violation of § 350.

COUNT III
Public Nuisance
(Against All Defendants)

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

234. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable number of persons in Albany County by their production, promotion, and marketing of opioids for use by residents of Albany County.

235. Defendants' acts and omissions offend, substantially interfere with, or cause damage to the public in the exercise of rights common to all, in a manner such as to offend public morals or endanger or injure the property, health, safety or comfort of a considerable number of persons.

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

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

238. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic described in this Complaint.

239. Defendants' conduct has persisted over a long period of time and caused wide-spread harm. It has caused deaths, serious injuries, and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

240. Defendants knew and should have known that their promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and

fraudulent actions would create or assist in the creation of the public nuisance – i.e., the opioid epidemic.

241. Defendants' conduct constitutes a public nuisance.

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

243. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Defendants therefore 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.

244. Plaintiff suffered special injuries distinguishable from those suffered by the general public.

245. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

COUNT IV

Violations of Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.* (Against all Defendants)

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

247. Defendant corporations are "persons" within the meaning of 18 U.S.C. § 1961(3) which conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962.

248. The County was injured in its business or property as a result of each Defendant's wrongful conduct and is a "person" who can bring an action for violation of section 1962, as that term is defined in 18 U.S.C. § 1961(3).

249. Under Section 1962(a), it is

> unlawful for any person who has received any income derived, directly or indirectly, from a pattern of racketeering activity or through collection of an unlawful debt in which such person has participated as a principal within the meaning of section 2, title 18, United States Code, to use or invest, directly or indirectly, any part of such income, or the proceeds of such income, in acquisition of any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce.

250. Further, Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions.

251. Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, hereinafter the "Opioid Marketing Enterprise," in violation of 18 U.S.C. § 1962(c) and § 1962(d).

A. Description of the Defendants' Enterprise.

252. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

253. A RICO "enterprise" need not have any formal legal structure, so long as it has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose. *See Boyle v. United States*, 556 U.S. 938, 946 (2009).

254. Defendants formed such an enterprise (hereinafter the "Opioid Marketing Enterprise"). The Opioid Marketing Enterprise consisted of Defendants Purdue, Janseen, Teva, and Endo (collectively, “Defendants”), the Front Groups detailed above, KOLs detailed above, and others, including but not limited to employees of entities associated with Defendants.

255. Alternatively, each of the above-named Defendants constitutes a single legal entity or associated-in-fact “enterprise” within the meaning of 18 U.S.C. § 1961(4), through which the members of the enterprise conducted a pattern of racketeering activity.

256. While the Defendants participated in the Opioid Marketing Enterprise, the Defendants also existed separate and distinct from the Opioid Marketing Enterprise.

257. The Defendants maintained an interest and control of the Opioid Marketing Enterprise and also conducted and participated in the conduct of the Opioid Marketing Enterprise's affairs through a pattern of racketeering activity.

258. The Opioid Marketing Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, including but not limited to: (1) the marketing, promotion, and advertisement of Defendants’ opioid medicines, and (2) the issuance of fees, bills, and statements demanding payment for prescriptions of Defendants’ opioid medications.

B. The Defendants used the Opioid Enterprise to fraudulently increase the profits and revenues through a pattern of racketeering activity.

259. The persons engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by the Defendants. They coordinated by, for example, funding the same front groups

and unbranded publications. Their coordination can also be inferred through the consistent misrepresentations described in this Complaint.

260. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which the Defendants, the Front Groups, and the KOL share information regarding the operation of the Opioid Marketing Enterprise.

261. Specifically, the members of the Opioid Marketing Enterprise have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

262. In devising and executing the illegal Scheme, the members of the Opioid Marketing Enterprise devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiff and the public to obtain money by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

263. For the purpose of executing the illegal Scheme, the members of the Opioid Marketing Enterprise committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal Scheme.

264. The Opioid Marketing Enterprise's predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud. The members of the Opioid Marketing Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

b. Wire Fraud: The members of the Opioid Marketing Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling drugs, specifically opioids, that have little or no demonstrated

efficacy for the pain they are purported to treat in the majority of persons prescribed them.

c. Violation of Controlled Substances Act ("CSA"). The members of the Opioid Marketing Enterprise violated 21 U.S.C. § 483(a)(4), which makes it unlawful "for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter," and a violation of which is punishable by up to four years in jail, *see* 21 U.S.C. § 483(d)(1), making it a felony.

265. The mail and wire transmissions were made, and the omissions of information required to be reported under the CSA were undertaken, in furtherance of Defendants' fraudulent scheme and common course of conduct to expand the market for their drugs and increase their profits through misleading and deceptive marketing.

266. The multiple acts of racketeering activity which the members of the Opioid Marketing Enterprise committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

267. The Defendants' control and participation in the Opioid Marketing Enterprise were necessary for the successful activity in which the Defendants engaged that included but was not limited to the acts detailed above and the following acts:

a. Defendants created a body of deceptive and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;

b. Defendants selected, cultivated, promoted, and paid the KOLs based solely on their willingness to communicate and distribute Defendants' messages about the use of opioids for chronic pain;

c. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;

e. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

f. Defendants sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

g. Defendants developed and disseminated pro-opioid treatment guidelines;

h. Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by Defendants, such as veterans and the elderly, and then funded that distribution;

i. Defendants concealed their relationship to and control of Front Groups and KOLs from the County and the public at large; and

j. Defendants intended that Front Groups and KOLs would distribute promotional and other materials that claimed opioids could be safely used for chronic pain.

268. The Front Groups also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;

b. The Front Groups distributed promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

c. The Front Groups concealed their connections to Defendants.

269. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;

b. The KOLs distributed promotional and other materials which claimed that opioids could' be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

c. The KOLs concealed their connections to and sponsorship by Defendants.

270. As detailed above, the Defendants committed various fraudulent acts which constitute fraud and a scheme to defraud. These intentional omissions of material fact and affirmative representations made by the Defendants were false when made, and included, but were not limited to, the acts detailed above and the following acts:

a. Marketing materials about the Defendants' opioids, and their risks and benefits, which the Defendants sent to health care providers located across the country and, upon information and belief, the County;

b. Unbranded marketing materials about the use of opioids in treating chronic pain, and their risks and benefits, which the Defendants sent to health care providers located across the country and, upon information and belief, the County;

c. Upon information and belief, written representations and telephone calls between the Defendants and Front Groups regarding representations about the Defendants' opioids, or the use of opioids for chronic pain generally;

d. Written representations and telephone calls between the Defendants and KOLs regarding Defendants' opioids, or the use of opioids for chronic pain generally;

e. E-mails between the Defendants and the Front Groups agreeing to or effectuating the implementation of the opioid marketing scheme;

f. E-mails between the Defendants and KOLs agreeing to or effectuating the implementation of the opioid marketing scheme;

g. Communications between the Front Groups and publications, groups drafting treatment guidelines and the media effectuating the implementation of the opioid marketing scheme;

h. Communications between the KOLs and publications, groups drafting treatment guidelines and the media effectuating the implementation of the opioid marketing scheme;

i. Failure to report suspicious prescribers to the DEA; and

j. Receipts of increased profits which represented the wrongful proceeds of the scheme.

271. Defendants' mail and wire fraud and CSA violations, and conspiracy to commit mail and wire fraud were each the proximate cause of the County's damages as detailed herein. These violations occurred through the execution of the Defendants' scheme using omissions of material fact and affirmative misrepresentation to perpetrate the fraud upon the County.

272. As a result of Defendants' racketeering activity, the County has been injured in its business and property, including but not limited to injury in the form of costs of providing emergency, child-protective, law-enforcement, and other services to combat opioid addiction and overdose.

273. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and proximately caused injuries and damages to the County, which is entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. § 1964(c).

PRAYER FOR RELIEF

WHEREFORE, the County requests the following relief:

274. A finding that by the acts alleged herein, Defendants engaged in unfair and deceptive acts and practices in violation of New York General Business Law § 349 and false advertising in violation of New York General Business Law § 350;

275. Actual damages and attorneys' fees and costs pursuant to New York General Business Law §§ 349(h) and 350(3);

276. A finding that by the acts alleged herein, Defendants violated 18 U.S.C. § 1961, *et seq*.

277. Actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1961, *et seq*.

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

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

280. An injunction permanently enjoining Defendants from further statutory violations and from engaging the acts and practices that caused the public nuisance;

281. Pre-and post-judgment interest; and

282. Such other and further relief as this Court deems just and equitable.

DATED: January 5, 2018

MOTLEY RICE, LLC

/S/ Donald A. Migliori

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