IN THE CIRCUIT COURT OF THE TWENTIETH JUDICIAL CIRCUIT
ST. CLAIR COUNTY, ILLINOIS

PEOPLE OF THE STATE OF ILLINOIS and ST. CLAIR COUNTY, ILLINOIS, Plaintiffs, vs. PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; ABBOTT LABORATORIES; and ABBOTT LABORATORIES, INC., Defendants.	)	Case No.

COMPLAINT

Plaintiff St. Clair County, Illinois by Brendan Kelly, State's Attorney, and undersigned Special Assistant State's Attorneys, files this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma Inc.; the Purdue Frederick Company, Inc.; Abbott Laboratories; and Abbott Laboratories, Inc. (collectively, "Defendants"). Plaintiff St. Clair County, on behalf of itself and the State of Illinois, alleges as follows:

I. INTRODUCTION

1. A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers. Drug manufacturers have a legal duty to ensure their products are accompanied by full and accurate instructions and warnings to guide prescribing doctors and other healthcare providers in making treatment decisions. They must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence. Defendants broke these simple rules.

2. By the 1990s, Defendants were confronting the limited market for opium-like painkillers ("opioids").

3. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. Yet they also knew—and had known for years—that opioids were addictive and subject to abuse, particularly when used long-term for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as "chronic pain"), and should not be used except as a last-resort. Defendants further knew—and had known for years—that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly increasing the risk of significant side effects and addiction.[1,2]

4. Defendants also knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (*e.g.*, hospitals), where the risk of addiction and other adverse outcomes was much less significant. Indeed, the U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.[3]

5. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled substances.[4] Like heroin, prescription opioids work by binding to receptors on the

[1] *See, e.g.*, Russell K. Portnoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status,* 1 Progress in Pain Res. & Mgmt. 247 (1994).

[2] The authoritative *Diagnostic and Statistical Manual of Mental Disorders*, (5th ed. 2013) ("DSM-V") classifies addiction as a spectrum of "substance use disorders" that ranges from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on the substance use disorder continuum. Throughout this Complaint, "addiction" refers to this range of substance use disorders.

[3] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[4] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S. C. § 812. Schedule II drugs

spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and, ultimately, death.

6. In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a sea change in medical and public perception that would permit the use of opioids not just for acute and palliative care, but also for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches.

7. Defendants, through a sophisticated and highly deceptive and unfair marketing campaign that began in the late 1990s, deepened around 2006, and continues to the present, set out to, and did, reverse the popular and medical understanding of opioids. Chronic opioid therapy—the prescribing of opioids to treat chronic pain long-term—is now commonplace.

8. To accomplish this reversal, Defendants spent hundreds of millions of dollars: (a) developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids used long-term to treat chronic pain, as described in greater detail herein; (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids, as described in greater detail herein; (c) recruiting prescribing physicians as paid speakers, as a means of both securing those physicians' future "brand loyalty" and extending their reach to the

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may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin), fentanyl (Duragesic, Actiq, Fentora), methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dilaudid, Palladone).

Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. Schedule III drugs may not be dispensed without a written or oral prescription, which may not be filled or refilled more than six months after the date of the prescription or be refilled more than five times. 21 U.S.C. § 829. Some opioids had been categorized as Schedule III drugs, including forms of hydrocodone and codeine combined with other drugs, like acetaminophen. However, in October 2013, the FDA, following the recommendation of its advisory panel, reclassified all medications that contain hydrocodone from Schedule III to Schedule II. *See* 21 C.F.R. § 1308.

physicians' peers, as described in greater detail herein; (d) funding, assisting, encouraging, and directing certain doctors, known as "key opinion leaders" ("KOLs"), not only to deliver scripted talks, but also to draft misleading studies, present continuing medical education programs ("CMEs") that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy, as described in greater detail herein; and (e) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups") that developed educational materials and treatment guidelines that were then distributed by Defendants, which urged doctors to prescribe and patients to use opioids long-term to treat chronic pain, as described in greater detail herein.

9. These efforts, executed, developed, supported and directed by Defendants, were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors and patients that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be used safely by most patients. Defendants, and the ostensibly neutral third parties whom they recruited and supported, both profited handsomely through their dissemination of these deceptions. KOLs and Front Groups saw their stature in the medical community elevated dramatically due to Defendants' funding, and Defendants saw an equally dramatic rise in their revenues.

10. Working individually and with and through these Front Groups and KOLs, Defendants, with the assistance and in concert with physicians they recruited, pioneered a new and far broader market for their potent and highly addictive drugs—the chronic pain market. Defendants persuaded doctors and patients that what they had long understood—that opioids are

addictive drugs, unsafe in most circumstances for long-term use—was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids. Ignoring the limitations and cautions in their own drugs' labels, Defendants: (a) overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized or obscured their serious risks and adverse outcomes, including the risk of addiction, overdose, and death; (c) overstated their superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. In lockstep with Defendants were the doctors recruited by Defendants who similarly ignored the cautions and warnings in the drug labels as they created "pill mills", known for dispensing large amounts of opioids. There was, and is, no reliable scientific evidence to support Defendants' marketing claims, and there was, and is, a wealth of scientific evidence that these claims are false. Defendants also deceptively and unfairly marketed the drugs for indications and benefits that were outside of the drugs' labels and not supported by substantial evidence while the doctors they recruited blindly followed this deceptive marketing scheme while creating their own profit centers, the "pill mills".

11. Even Defendants' KOLs initially were very cautious about whether opioids were appropriate to treat chronic pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers, and physicians who have sounded the alarm on the overprescribing of opioids to treat chronic pain, the Defendants continue to disseminate their misleading and unfair marketing claims to this day.

12. Defendants' efforts were wildly successful. The United States is now awash in opioids. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers—enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits in 2010 resulted in the prescription of an opioid, nearly double the rate in 2000. Opioids—once a niche drug—are now the most prescribed class of drugs—more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply. Together, opioids generated $8 billion in revenue for drug companies in 2012, a number that was projected to reach $15.3 billion in 2016.

13. It was Defendants' marketing—and not any medical breakthrough—that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse.

14. The result has been catastrophic. As has been attributed to a doctor in another complaint: "This was an experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected, until they started gathering death statistics."

15. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in an opioid-induced "public health epidemic."[5] According to the CDC, prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012. Upon information and belief one manufacturer's own 2010 internal data shows it knew that the use of prescription opioids gave rise to 40% of drug-related emergency department visits in 2010 and 40% of drug poisoning deaths in 2008, and that the

[5] CDC, *Examining the Growing Problems of Prescription Drugs and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm.

trend of opioid poisonings was increasing from 1999-2008. For every death, more than 30 individuals are treated in emergency rooms. The U.S. Department of Health and Human Services estimated that in 2009 in Chicago for example, there were 40.4 emergency department visits involving adverse reactions to opioids per 100,000 people, which, for Chicago's population, translates into 1,080 trips to the emergency room. But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families throughout this State and in St. Clair County.

16. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors. When turned down by one physician, many of these addicts deploy increasingly desperate tactics—including doctor-shopping, use of aliases, and criminal means—to satisfy their cravings, cravings which Defendants first fostered then fueled.

17. Efforts by doctors to reverse course for a chronic pain patient already on opioids long-term involve managing the physical suffering and psychological distress a patient endures while withdrawing from the drugs. This process is often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that is diverted to supply them. Even though they never would have prescribed opioids in the first place, many doctors feel compelled to continue prescribing opioids to patients who have become dependent on them.

18. According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in 2010, and adolescents are abusing opioids in alarming numbers. The former president of the New Hope Recovery Center on Chicago's

North Side stated: "Five years ago, 70 percent of the people we saw here were heroin addicts. Today, 70 percent of the people we see are prescription drug users."[6]

19. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on St. Clair County and local agencies that address heroin use and addiction, as well as similar agencies throughout the State. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002-2004 to 45.2% in 2011-2013. In Southern Illinois, the DEA has noted that in dosage units of opioids in St. Clair County distributed by pharmacies (1,989,820 dosage units in 2014), those dosage units were more than twenty-seven (27) times the national average of dosage units (71,128 dosage units in 2014), which continues a long trend of St. Clair County having more than twenty (20) times the average dosage units per year as the national average. *See Exhibit 1*, attached. Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost $10-$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person who started on prescription opioids for a back injury to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addition.

20. Dr. Robert DuPont, former director of the National Institute on Drug Abuse and the former White House drug czar, opines that opioids are more destructive than crack cocaine:

> [Opioid abuse] is building more slowly, but it's much larger. And the potential [] for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of

[6] Monifa Thomas, *Prescription Drug Abuse Is Fastest-Growing Drug Problem in Country*, Chi. Sun-Times, Dec 25, 2010.

> people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.[7]

21. Countless St. Clair County residents suffer from chronic pain, which takes an enormous toll on their health, their lives, and their families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Defendants' deceptive and unfair marketing campaign deprived these patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. The Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

22. The Defendants' actions are not permitted or excused by the fact that their labels may have allowed or did not exclude the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids. Indeed, what makes Defendants' efforts particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances. Defendants deceptively and unfairly engaged a patient base that—physically and psychologically—could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

23. Nor is the Defendants' causal role broken by the involvement of doctors. The Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. The Defendants targeted not only pain specialists, but also primary care physicians (PCPs), nurse practitioners, physician assistants, and other non-

[7] Transcript, *Use and Abuse of Prescription Painkillers*, The Diane Rehm Show (Apr. 21, 2011), http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript.

pain specialists who were even less likely to be able to assess the companies' misleading statements. The Defendants also were able to callously manipulate what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

24. The Defendants' course of conduct, individually and/or in concert with the KOLs and Front Groups with which they allied, has violated and continues to violate state, and common law, as laid out herein.

- 815 ILCS 505/1, *et seq*., in that the Defendants have engaged in a scheme to defraud the citizens of St. Clair County and engage in other acts prohibited by the Illinois Consumer Fraud Act, which conduct causes harm to the People of the State of Illinois and the citizens of St. Clair County;

- 720 ILCS 5/170-10.5, in that all Defendants knowingly obtained, attempted to obtain, or caused to be obtained, by deception, control over property of a self-insured entity, St. Clair County, by making a false claim or by causing a false claim to be made to St. Clair County and the People of the State of Illinois, intending to deprive the County and State permanently of the use and benefit of that property.

- The common law prohibition against civil conspiracy, in that all Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner.

- The common law prohibition on unjust enrichment, in that all Defendants have unjustly retained a benefit to the County's detriment, and all Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

25. To redress and punish these violations, the County and the People of the State seek a judgment requiring all Defendants to pay (a) restitution, (b) damages, including multipliers of damages, (c) disgorgement, (d) civil penalties, (e) punitive damages, (f) attorneys'

fees, costs, and expenses, (g) injunctive relief, and (h) any other relief to which the County and the People of the State may be entitled.

II. PARTIES

A. Plaintiffs.

26. Plaintiff, the County of St. Clair, is organized and existing under the laws of the State of Illinois. The State's Attorney of St. Clair County, Brendan Kelly, is the chief legal officer of the County and is authorized to bring suit on its behalf by and through the assistance of other counsel.

27. State's Attorney Brendan Kelly, with the assistance of special counsel, has conducted a rigorous investigation of the conduct of the Defendants, in conjunction with reviewing other matters pending locally, nationally and across this State. State's Attorney Brendan Kelly is authorized to bring claims on behalf of the People of the State of Illinois pursuant to 815 ILCS 505/7 and other provisions of the Illinois Consumer Fraud Act.

B. Defendants.

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

29. Purdue is primarily engaged in the manufacture, promotion, and distribution of opioids nationally, in the State of Illinois, and in St. Clair County, including the following:

(a) OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist[8] tablet first approved in 1995 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are

[8] An opioid agonist is a drug that activates certain opioid receptors in the brain. An antagonist, by contrast, blocks the receptor and can also be used in pain relief or to counter the effect of an opioid overdose.

inadequate." Prior to April 2014,[9] OxyContin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

(b) MS Contin (morphine sulfate extended release) is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, MS Contin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

(c) Dilaudid (hydromorphone hydrochloride is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the "management of pain in patients where an opioid analgesic is appropriate."

(d) Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the "relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."

(e) Butrans (buprenorphine) is a Schedule II opioid partial agonist transdermal patch first approved in 2010 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Butrans was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

(f) Hysingla ER (hydrocodone bitrate) is a Schedule II opioid agonist tablet first approved in 2014 and indicated for a the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

(g) Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) is a Schedule II combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock,

[9] The labels for OxyContin and other long-acting opioids were amended in response to a 2012 citizens' petition by doctors. The changes were intended to clarify the existing obligation to "make an individualized assessment of patient needs." The petitioners also successfully urged that the revised labels heighten the requirements for boxed label warnings related to addiction, abuse, and misuse by changing "Monitor for signs of misuse, abuse, and addiction to" to "[Drug name] exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." Letter from Bob Rappaport, Dir. Ctr. for Drug Evaluations & Res., *Labeling Supplement and PMR [Post-Marketing Research] Required* (Sept. 10, 2013), http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf.

long-term opioid treatment and for which alternative treatment options are inadequate.

30. OxyContin is Purdue's largest-selling opioid, in the nation. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

31. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million—at the time, one of the largest settlements with a drug company for marketing misconduct. Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required the company, *inter alia*, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement.

32. ABBOTT LABORATORIES is a domestic BCA organized under the laws of Illinois. ABBOTT LABORATORIES is a Illinois corporation with its principal place of business in Abbott Park, Illinois, and ABBOTT LABORATORIES, INC.. is a Illinois corporation with its principal place of business in Abbott Park, Illinois (collectively, "Abbott").

33. Abbott was primarily engaged in the promotion, and distribution of opioids nationally, in the State of Illinois, and in St. Clair County, due to a co-promotional agreement with Defendant Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed and distributed Purdue's opioid products set forth in paragraph 29 above.

34. Abbott, as part of the co-promotional agreement, helped make OxyContin into the largest-selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received 25 to 30 percent

of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996 to 2002, following which Abbott continued to receive a residual payment of 6 percent of net sales up through at least 2006.

35. In 2007, when Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million—at the time, one of the largest settlements with a drug company for marketing misconduct.

II. JURISDICTION AND VENUE

36. This court has personal jurisdiction over Defendants because they carry on a continuous and systematic part of their general businesses within Illinois, have transacted substantial business with Illinois entities and residents, and have caused grave harm in Illinois as a result of the specific business activities complained of herein.

37. Venue as to each Defendant is proper in this court under 735 ILCS 5/2-101 as the transactions and occurrences that form the basis for this Complaint occurred in St. Clair County, Illinois.

38. There is no federal court jurisdiction in that there is not complete diversity of citizenship because Abbott is a resident of the State of Illinois. Further, no federal question jurisdiction exists because Plaintiffs herein are not seeking to impose any additional requirements beyond those imposed on Defendants by the federal law and regulations thereunder controlling pharmaceutical development, manufacture, promotion, sale and distribution but, rather, seek only to enforce parallel state causes of action.

IV. JURY DEMAND

39. The Plaintiffs demand a jury trial pursuant to the Illinois Constitution and common law.

V. FACTUAL ALLEGATIONS

A. The Science behind Pain Medicine.

1. Safe and Effective Treatment of Chronic Pain Hinges on Informed Risk Management.

40. The practice of medicine hinges on informed risk management. Prescribers must weigh the potential risks and benefits of each treatment option, as well as the risk of non-treatment. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risks of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.

41. This bedrock principle of full disclosure is particularly important in the context of chronic opioid therapy because of the risk that patients will become physically and psychologically dependent on the drugs and find it difficult to manage or terminate their use.

42. The FDA-approved drug labels on each of Defendants' opioids do not attempt to advise physicians how to maximize the benefit and minimize risk for patients on long-term chronic opioid therapy. The labels contain no dosing cap above which it would be unsafe for any doctor to prescribe to any patient. Nor do any of the labels provide a duration limit, after which the risks to a patient might increase. Thus, doctors and patients rely more heavily on educational materials, such as treatment guidelines, CMEs, scientific and patient education articles and websites, to inform their treatment decisions.

2. The Use of Opioids Is Associated with Known and Substantial Risks.

43. The pain-relieving properties of opium have been recognized for millennia. So has the magnitude of its potential for abuse and addiction. Opioids, after all, are closely related to illegal drugs like opium and heroin. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain—particularly on the battlefield—and were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

44. Minimizing addiction has long been a policy objective of both the Illinois and federal governments. More than 25 years ago, the Illinois legislature announced that "drug addiction [is] among the most serious health problems facing the people of the State of Illinois" and, as a result, "[i]t is hereby declared to be the public policy of the State of Illinois to promote and encourage . . . [the] successful treatment of . . . drug addiction."[10] St. Clair County's workers' compensation program and health benefit plans have expended significant sums of money on addiction treatment services, on top of the County's funding and provision of grants to drug treatment centers for services including the treatment of opioid addiction.

45. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential

[10] 745 ILCS 35/2.

addiction and "[s]erious, life-threatening, or fatal respiratory depression," the result of an excessive dose.

46. Most patients with more than a few weeks of opioid therapy will experience withdrawal symptoms if opioids are discontinued (commonly referred to as "dependence"). Once dependent, a patient experiences deeply unpleasant symptoms when his or her current dose of opioids loses effect and is not promptly replaced with a new dose. Among the symptoms reported in connection with opioid withdrawal are: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long opioids were used.

47. Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, has explained the effect of opioids as akin to "hijack[ing] the brain's reward system," which in turn convinces a user that "the drug is needed to stay alive."[11] A patient's fear of the unpleasant effects of discontinuing opioids combined with the negative reinforcement during a period of actual withdrawal can drive a patient to seek further opioid treatment—even where ineffective or detrimental to quality of life—simply to avoid the deeply unpleasant effects of withdrawal.

48. When under the continuous influence of opioids over a period of time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction he or she has become accustomed to—up to and including doses that are considered to be "frighteningly

[11] David Montero, *Actor's Death Sows Doubt Among O.C.'s Recovering Opioid Addicts*, The Orange Cnty. Reg. (Feb. 3, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html.

high."[12] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. The FDA has acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects.

49. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

50. Further, "a potential side effect from chronic use [of opioids] can be abuse and addiction . . . . [i]n fact, correct use and abuse of these agents are not polar opposites—they are complex, inter-related phenomena."[13] It is very difficult to tell whether a patient is physically dependent, psychologically dependent, or addicted. Drug-seeking behaviors, which are signs of addiction, will exist and emerge when opioids are suddenly not available, the dose is no longer effective, or tapering of a dose is undertaken too quickly.

51. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[14]

52. Each of these risks and adverse effects—dependence, tolerance, and addiction—is fully disclosed in the labels for each of Defendants' opioids (though, as described herein, not in

[12] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med. 1422 (2010).

[13] Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81(2) Drug & Alcohol Dependence 103, 106 (2006).

[14] Joseph A. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US healthcare system*, 105(10) Addiction 1776 (2010); Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3) Journal of Addictive Diseases 185 (2011).

the Defendants' marketing).[15] Prior to Defendants' deceptive marketing scheme, each of these risks was well-recognized by doctors and seen as a reason to use opioids to treat chronic pain sparingly and only after other treatments had failed.

53. Opioids vary by duration. Long-acting opioids are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Purdue's OxyContin and MS Contin are examples of long-acting opioids. In addition, opioids may be taken in short-acting formulations, which last for approximately 4-6 hours. Short-acting opioids may be taken in addition to long-acting opioids to address "episodic pain." The Defendants promoted the idea that pain should be treated first by taking long-acting opioids continuously and then by taking short-acting, rapid-onset opioids on top of that.

54. While it was once thought that long-acting opioids would not be as susceptible to abuse and addiction as short-acting ones, this view has been discredited. OxyContin's label now states, as do all labels of Schedule II long-acting opioids, that the drug "exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." The FDA has required extended release and long-acting opioids to adopt "Risk Evaluation Mitigation Strateg[ies]" on the basis that they present "a serious public health crisis of addiction, overdose, and death."[16]

55. In 2013, in response to a petition to restrict the labels of long-acting opioid products, the FDA noted the "grave risks" of opioids, "the most well-known of which include addiction, overdose, and even death."[17] The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma,

[15] For example, Purdue's OxyContin label (October 5, 2011) states: "Physical dependence and tolerance are not unusual during chronic opioid therapy."

[16] FDA, *Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids* (last updated Oct. 9, 2014), http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm.

[17] Letter from Janet Woodcock, M.D., *supra*, at 2.

and death."[18] The FDA required that—going forward—opioid makers of long-acting formulations clearly communicate these risks in their labels (defined, as noted in greater detail herein, to include promotional materials disseminated by or on behalf of the manufacturer of the drug). Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain—that the adverse outcomes from opioid use include "addiction, unintentional overdose, and death" and that long-acting or extended release opioids "should be used ***only when alternative treatments are inadequate***."[19]

56. Notably, in reaching its conclusion, the FDA did not rely on new or otherwise previously unavailable scientific studies regarding the properties or effects of opioids.

3. The Benefits Offered by Long-Term Opioid Use Are Unproven and Contradicted.

57. Despite the fact that opioids now are routinely prescribed, there never has been evidence of their safety and efficacy for long-term use. The Defendants always have been aware of these gaps in knowledge. While promoting opioids to treat chronic pain, the Defendants have failed to disclose the lack of evidence to support their use long-term and have failed to disclose the contradictory evidence that chronic opioid therapy actually makes patients sicker.

58. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. The first random, placebo-controlled studies appeared in the 1990s, and revealed evidence only for short-term efficacy and only in a minority of patients.[20] A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and found that, while opioids had short-term efficacy, the data was insufficient to establish long-term effectiveness. Subsequent reviews of the use of opioids for

[18] *Id.*

[19] *Id.* agt 7 (emphasis in original).

[20] Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23(4) Clin J. Pain 303 (2007); Roger Chou et al., *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147 (2009).

cancer and non-cancer pain consistently note the lack of data to assess long-term outcomes. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain).

59. On the contrary, evidence exists to show that opioid drugs are not effective to treat chronic pain, and may worsen patients' health. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."[21] Another review of evidence relating to the use of opioids for chronic pain found that up to 22.9% of patients in opioid trials dropped out before the study began because of the intolerable effects of opioids and that the evidence of pain relief over time was weak.

60. One manufacturer's (Endo, not a defendant herein) own research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

[21] Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

61. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

62. As a pain specialist noted in an article titled *Are We Making Pain Patients Worse?*, "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.[22]

63. This is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.

64. As many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

65. The lack of evidence for the efficacy of opioid use long-term has been well-documented nationally in the context of workers' compensation claims, where some of the most detailed data exists. Claims involving workers who take opioids are almost four times as likely

[22] Andrea Rubenstein, *Are we making pain patients worse?*, Sonoma Medicine (Fall 2009).

to reach costs of over $100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription increased the risk that the patient would be on work disability one year later. A prescription for opioids as the first treatment for a workplace injury doubled the average length of the claim.

4. Defendants' Impact on the Perception and Prescribing of Opioids.

66. Before the Defendants began their marketing campaign, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance.

67. In 1986, the World Health Organization ("WHO") published an "analgesic ladder" for the treatment of cancer pain. The WHO recommended treatment with over-the-counter or prescription acetaminophen or non-steroidal anti-inflammatory drugs ("NSAIDs") first, and then use of unscheduled or combination opioids, and then stronger (Schedule II or III) opioids if pain persisted. The WHO ladder pertained only to the treatment of cancer pain, and did not contemplate the use of narcotic opioids for chronic pain—because the use of opioids for chronic pain was not considered appropriate medical practice at the time.

68. Studies and articles from the 1970s and 1980s made clear the reasons to avoid opioids. Scientists observed negative outcomes from long-term opioid therapy in pain management programs: opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of

complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

69. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.[23]

70. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

> The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[24]

[23] Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).

[24] Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status, supra* (emphasis added).

According to Portenoy, these problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[25]

71. For the reasons outlined by Dr. Portenoy, and in the words of one researcher from the Harvard Medical School, "it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids."[26] Defendants changed that perception.

B. Defendants Promoted Their Branded Products Through Direct Marketing to Prescribers and Consumers.

72. The Defendants' direct marketing proceeded on two tracks, serving two related purposes. First, the Defendants worked through branded and unbranded marketing to build confidence in long-term opioid use by overstating its benefits and downplaying its risks, and thereby expand the chronic pain market. In addition, the Defendants worked through their own staffs of sales representatives, physician speakers whom those representatives recruited, and advertising in medical journals to claim their share of that broader market. The Defendants directed all of this activity through carefully designed marketing plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

1. Defendants Relied Upon Branded Advertisements.

73. The Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain and*

[25] *Id.*

[26] Igor Kissin, *Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?*, 6 J. Pain Research 513, 514 (2013) (quoting Loeser JD, *Five crises in pain management*, 20(1) Pain Clinical Updates 1-4 (2012).

Clinical Journal of Pain, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. The advertising budgets peaked in 2011, when the industry collectively spent more than $14 million on medical journal advertising of opioids, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue.[27]

74. As described in greater detail herein, a number of these branded advertisements deceptively portrayed the benefits of opioid therapy for chronic pain. As just one example, a 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "There Can Be Life With Relief." This depiction falsely implied that OxyContin provides both effective long-term pain relief and functional improvement, claims that, as described in greater detail herein, are unsubstantiated and contradicted in the medical literature.

2. Defendants Relied Upon Their Sales Forces and Recruited Physician Speakers.

75. The Defendants promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual physicians and their staff in their offices—and small group speaker programs. By establishing close relationships with doctors, the Defendants' sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain.

76. The Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. In accordance with common industry practice,

[27] In 2011, Actavis spent less than $100,000 on such advertising, and Cephalon spent nothing. These companies' medical journal advertising peaked earlier, with Actavis spending $11.7 million in 2005, and Cephalon spending about $2 million in each of 2007 and 2008.

Defendants purchase and closely analyze prescription sales data from IMS Health that allows them to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their appeals.

77. The Defendants also closely monitored doctors' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

78. The Defendants' sales representatives have visited hundreds of thousands of doctors, including thousands of visits to St. Clair County prescribers, and as described herein, spread misinformation regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. This misinformation includes deceptive and unfair claims regarding the risks of opioids for chronic pain, particularly the risks of addiction, withdrawal, and high doses, as well as the benefits.

79. As described in greater detail herein, the Defendants carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of that company's drugs in particular and opioids in general. Pharmaceutical companies exactingly direct and monitor their sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and other means—to ensure that individual detailers actually deliver the desired messages and do not veer off-script. Pharmaceutical companies likewise require their detailers to deploy sales aids reviewed, approved, and supplied by the company and forbid them to use, in industry parlance, "homemade bread"—*i.e.*, promotional materials not approved by the company's marketing and compliance departments. Sales representatives' adherence to their corporate training typically is included in their work

agreements. Departing from their company's approved messaging can and does lead to severe consequences, including termination of employment.

80. Besides carefully training their sales representatives, the Defendants also used surveys of physicians—conducted by third-party research firms—to assess how well their core messages came across to prescribers. These "verbatim" recollections of detailers' messages are an integral tool in ensuring consistent message delivery. They also help the Defendants gauge physicians' perceptions of, and willingness to prescribe, Defendants' drugs. As described herein in greater detail, data obtained by the City of Chicago and set forth in its lawsuit, reflecting Midwest prescribers' verbatim recollections of sales calls (as well as electronic, meeting, and event promotional activity), corroborate the types of deceptive and unfair detailing messages that Defendants purveyed nationally, across this State and in St. Clair County.

81. In addition to making sales calls, the Defendants' detailers also identified doctors to serve, for payment, on the Defendants' speakers' bureaus and to attend programs with speakers and meals paid for by the Defendants. The Defendants almost always select physicians who are "product loyalists," since one question they will be asked is whether they prescribe the drug themselves. Such invitations are lucrative to the physicians selected for these bureaus; honorarium rates range from $800 to $2,000 per program, depending on the type of event, and even speaker training typically is compensated at $500 per hour.

82. These speaker programs and associated speaker training serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; a forum in which to further market to the speaker him or herself; and an opportunity to market to the speaker's peers. The Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. The Defendants also

track the prescribing of event attendees. It would make little sense for the Defendants to devote significant resources to programs that did not increase their sales.

83. Like the sales representatives who select them, speakers are expected to stay "on message"—indeed, they agree in writing to follow the slide decks provided to them. This is important because the FDA regards promotional talks as part of product labeling, and requires their submission for review. Speakers thus give the appearance of providing independent, unbiased presentations on opioids, when in fact they are presenting a script prepared by the Defendants' marketing departments. Although these meal-based speaker events are more expensive to host and typically have lower attendance than CMEs, they are subject to less professional scrutiny and thus afford the Defendants greater freedom in the messages they present.

84. The Defendants devoted massive resources to these direct sales contacts with prescribers. For example, in 2014, the industry collectively spent $168 million on detailing branded opioids to physicians nationwide. This figure includes $108 million spent by Purdue. The total figure is more than double the Defendants' collective spending on detailing in 2000.

85. The Defendants have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that detailers' sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits,[28] and face-to-face detailing has the highest influence on intent to prescribe.

[28] *See, e.g.*, Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in 34% decline in on-label use of promoted drugs); *see also* Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

The Defendants could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers, whom they targeted for detailing and who responded by prescribing more of the Defendants' drugs. And it worked. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.6 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

3. The Pharma Defendants Directed These Promotional Efforts Through Detailed Marketing Plans.

86. The Defendants guided their efforts to expand opioid prescribing through comprehensive marketing and business plans for each drug. These documents, based on the companies' extensive market research, laid out ambitious plans to bring in new prescribers and increase overall prescribing of the Defendants' opioids.

a. Targeting categories of prescribers

87. The Defendants targeted, by zip codes and other local boundaries, individual health care providers for detailing. The Defendants chose their targets based on the potential for persuading a provider to prescribe, ease of in-person access, and the likelihood of higher numbers of prescriptions at higher doses, with no correlation to demonstrated need or demand for opioid therapy, or to risk of abuse.

88. Collectively, the Defendants' marketing plans, along with the plans of other opioid makers, evince dual strategies, which often operated parallel to one another. Defendants' sales representatives continued to focus their detailing efforts on pain specialists and anesthesiologists, who are the highest-volume prescribers of opioids but are also, as a group, more educated than other practitioners about opioids' risks and benefits. Seeking to develop

market share and expand sales, however, the Defendants also targeted increasing numbers and types of prescribers for marketing.

89. This expanded market of prescribers was, as a group, less informed about opioids and, market research concluded, more susceptible to the Defendants' marketing messages. These prescribers included nurse practitioners and physician assistants.

90. The expanded market also included internists and general practitioners who were low- to mid-volume prescribers. The fruits of the Defendants labors are borne out by DEA statistics that show St. Clair County, and its immediate neighbor, Madison County, have prescription counts for oxycodone and hydrocodone that soar fifty times above the national average for the last year data was available. [29]

b. Increasing "direct to consumer" marketing

91. The Defendants knew that physicians were more likely to prescribe their branded medications when patients asked for those medications. The Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials. These took the form of pamphlets, videos, or other publications that patients could view in their physician's office, as well as employer and workers' compensation plan initiatives.

92. The Defendants also knew that one of the largest obstacles to patients starting and remaining on their branded opioids—including by switching from a competitor's drug—was out-of-pocket cost. They recognized they could overcome this obstacle by providing patients financial assistance with their insurance co-payments, and each of the Defendants did so through vouchers and coupons distributed during detailing visits with prescribers.

[29] http://www.bnd.com/news/local/article74098582.html

c. Differentiating each brand

93. Purdue's OxyContin was the clear market leader in prescription opioid therapy, with 30% of the market for analgesic drugs in 2012. Meanwhile, by 2010, the Defendants faced increasing pushback from the medical community and regulators based on the growing problems of opioid addiction and abuse. Both market conditions prompted the industry including Defendants to pursue product differentiation strategies—and particularly an emphasis on their products being less subject to diversion, abuse, and addiction—as a means of grabbing market share from competitors.

94. Pressure to stand out among other drugs resulted in the Defendants identifying marketing themes that thereafter were reflected in the Defendants' deceptive and harmful messages to physicians and consumers, as described in greater detail herein.

d. Moving beyond office visits

95. The Defendants sought to reach additional prescribers by expanding beyond traditional sales calls and speaker events to new channels for their messages. For their sales forces, these included marketing to prescribers through voice mail, postcards, and email—so-called "e-detailing." The Defendants also created new platforms for their speakers by implementing "peer to peer" programs such as teleconferences and webinars that were available to prescribers nationally. These programs allowed the Defendants to use this more seemingly credible vehicle to market to, among other hard-to-reach audiences, prescribers at hospitals, academic centers, and other locations that limit or prohibit in-person detailing. Employing these new approaches, each Defendant relied heavily on speakers to promote its drugs.

4. Defendants Marketed Opioids in St. Clair County, Illinois Using the Same Strategies and Messages They Employed Nationwide.

96. As part of the St. Louis metropolitan area, St. Clair County is a focus of the Defendants' marketing efforts. St. Clair County and the Midwest generally are attractive targets to pharmaceutical companies based on population density, consequent sales efficiency, and demographics—with opportunities for growth among large elderly and labor populations. The Defendants also perceived St. Clair County and Illinois generally as receptive to their marketing messages**.** As the numbers clearly show, they were effective in St. Clair County.[30]

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

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

[30] *Id.*

99. As they did nationwide, the Defendants extensively tracked the prescribing behavior of St. Clair County health care providers and used that data to target their detailing and speaker-recruiting efforts. Top prescribers were profiled at the city, region, zip code, and sometimes facility levels, with information about their specialty, prescribing patterns (including product and dose), product loyalty and refill history. Upon information and belief, Providers' prescribing volume was ranked and sorted into deciles.

100. This information allowed the Defendants to target, within each sales territory, prescribers who could have the biggest sales impact. Tracking prescribing behavior also enabled the Defendants to zero in on trends.

101. As described herein, misrepresentations and deceptions regarding the risks, benefits, and superiority of opioid use to treat chronic pain were part and parcel of Defendants' joint marketing campaigns in St. Clair County.

102. These misrepresentations are reflected in the accounts of Chicago prescribers whom the City of Chicago interviewed as part of litigation it filed. Upon information and belief, the information relayed by the prescribers interviewed was uniform throughout this State and was part and parcel of the business practice used by the Defendants to recruit more physicians to prescribe their drugs at increasing rates. As set forth herein in greater detail, these prescribers were on the receiving end of Defendants' misleading messaging via detailing visits; CMEs; small-group speaker programs; dinners, and other meals; branded advertisement; and unbranded promotional materials funneled through third parties. These deceptive and unfair messages include the unfounded and untrue claims described in greater detail herein about functional improvement; the risks of abuse, addiction, withdrawal, and higher dosing; the duration of pain relief, and the superiority of opioids to other treatments. The information contained in these

subsections is, upon information and belief, the same information that was shared with St. Clair County physicians in similar presentations.

103. Such misrepresentations also are captured in the verbatim sales message recall data obtained by the City of Chicago and used in its lawsuit. To gain insight into detailing messaging, the City of Chicago obtained data from a market research and analytics company that performs promotional message tracking in the pharmaceutical industry. The data consist of verbatim messages from detailing activity (as well as electronic, meeting, and event promotional activity) to a sample of panelists—office-based physicians, hospital-based physicians, nurse practitioners, and physician assistants—in the Midwest. Each month, panelists report via online surveys on the promotional activity in which they participated that month. The panelists' responses are based on the panelists' perception of the main message of the promotion. The responses received by the research company are reported word-for-word as "verbatims."

104. Surveyed Midwestern health care providers often reported that the Defendants' representatives marketed their drugs as safe, with low risk of addiction or lower risk than competing opioids, and touted that their company's product was the drug of choice for chronic pain conditions such as low back pain and osteoarthritis. As reported by these health care professionals, the Defendants' representatives also repeatedly claimed or implied that their drugs had minimal or low abuse potential; were safer than other pain medications. Individual misrepresentations contained in that data are described in greater detail herein.[31]

[31] As also set forth in that section, many of the misrepresentations reported in the Midwestern verbatim data and in the interviews with Chicago-area prescribers can be traced back to sales training materials produced by Defendants, though this should not be interpreted as all-encompassing. Upon information and belief—based on the careful instruction and monitoring sales representatives receive to ensure that they deliver only company-approved messages— the Defendants' sales representatives received corporate training on each of the deceptive statements reported by prescribers herein.

C. Defendants Used "Unbranded" Marketing to Evade Regulations and Consumer Protection Laws.

105. In addition to their direct marketing efforts, the Defendants used unbranded, third-party marketing, which they deployed as part of their national marketing strategies for their branded drugs. Defendants executed these strategies through a network of third-party KOLs and Front Groups, with which it acted in concert by funding, assisting, encouraging, and directing their efforts, while at the same time exercising substantial control over the content of the messages these third parties generated and disseminated, and distributing certain of those materials themselves. As with their other marketing strategies, the Defendants' unbranded marketing created and relied upon an appearance of independence and credibility that was undeserved but central to its effectiveness. Unlike their direct promotional activities, the Defendants' unbranded marketing allowed them to evade the oversight of federal regulators and gave them greater freedom to expand their deceptive messages.

1. Regulations Governing Branded Promotion Require that it Be Truthful, Balanced, and Supported by Substantial Evidence.

106. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[32] The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

[32] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

107. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[33] "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended."[34] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[35] The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.[36] Thus, the Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.

108. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to ***any*** presentation of efficacy." The FDA notes that" [b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included."[37] Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

109. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly

[33] 21 U.S.C. §§ 352.
[34] 21 C.F.R. § 201.5.
[35] 21 U.S.C. § 321A(m).
[36] *See id.*
[37] FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion,* May 2009, at 14.

cannot be supported by the results of the study."[38] Drug companies further must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[39]

110. While the FDA must approve a drug's label, it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information.[40] Promotional materials also must be submitted to the FDA when they are first used or disseminated. The FDA does not have to approve these materials in advance; if, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

111. The Illinois Consumer Fraud Act reflects a parallel judgment that drug companies, just like other businesses, have a duty to deal honestly with consumers, government, and other payors who purchase and use their products.

2. The Defendants Deployed Front Groups and Doctors to Disseminate Unbranded Information on Their Behalf.

112. Drug companies market both directly and indirectly, using third party validators (such as scientists, physicians, or patient or professional organizations) that appear to be

[38] 21 C.F.R. § 99.101(a)(4).

[39] 21 C.F.R. § 202.1(e)(6)(ii).

[40] *See* 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6)(iii)(A-C) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction" or "strengthen a statement about drug abuse, dependence, psychological effect, or overdosage").

independent and therefore more credible. The FDA has made clear that its promotional requirements apply to both forms of marketing:

> FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf.
>
> . . . .
>
> Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third-party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.[41]

113. In addition to being carried out directly or through third parties, drug companies' promotional activity can be branded or unbranded; unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can sidestep the extensive regulatory framework, described in greater detail herein, governing branded communications.

114. The Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of the Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside of FDA oversight. Through unbranded materials, the Defendants presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on the Defendants' branded marketing materials and drug

[41] FDA, *Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologic,* January 2014, at 1, 4, http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm381352.pdf.

labels and with the Defendants' own knowledge of the risks, benefits and advantages of opioids. The Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

115. Even though such unbranded messages were channeled through third-party vehicles, the Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Unbranded brochures and other materials that are "disseminated by or on behalf of [the] manufacturer" constitute drug "labeling" that may not be false or misleading in any particular. *See* 21 C.F.R. 202.1(e)(7)(1)(2).[42] As described in greater detail herein, the Defendants' sales representatives distributed third-party marketing material that was deceptive to the Defendants' target audiences. The Defendants are responsible for these materials.

116. Moreover, the Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that the Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials, Defendants exercised control over their deceptive messages and acted in concert[43] with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

[42] This regulation provides: "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and the references published . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling, as defined in section 201(m) of the act." As labeling, such third party-created content distributed by a drug company may not be misleading and must meet the accuracy, substantiation, and fair balance requirements in the FDCA.

[43] As used in this Complaint, the allegation that Defendants "acted in concert" with third parties is intended to mean *both* that they conspired with these third parties to achieve some end and that they aided and abetted these third parties in the commission of acts necessary to achieve it.

117. For example, drug companies have been admonished for making functional claims in FDA-reviewed branded materials because there is no evidence for such claims. Thus, drug companies were put on notice that the FDA would not allow such claims in branded materials. The Defendants instead created and disseminated these same unsupported claims—that opioids allow patients to sleep, return to work, or walk more easily—through *unbranded* marketing materials.

118. The third-party publications the Defendants assisted in creating and distributing did not include the warnings and instructions mandated by their FDA-required drug labels and consistent with the risks and benefits known to the Defendants. For example, these publications either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction.

119. By acting through third parties, the Defendants were able to both avoid FDA scrutiny and give the false appearance that the messages reflected the views of independent third parties. Later, the Defendants would cite to these sources as "independent" corroboration of their own statements. As one physician adviser to the Defendants noted, third-party documents not only had greater credibility, but broader distribution, as doctors did not "push back" at having materials from, for example, the non-profit American Pain Foundation (APF") on display in their offices, as they might with first party, drug company pieces. Nevertheless, the independence of these materials was a ruse — the Defendants were in close contact with these third parties, paid for and were aware of the misleading information they were disseminating about the use of opioids to treat chronic pain, and regularly helped them to tailor and distribute their misleading, pro-opioid messaging.

120. As part of a strategic marketing scheme, the Defendants spread and validated their deceptive messages through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

a. Defendants' Use of KOLs

121. The Defendants cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by the Defendants solely because they favored the aggressive treatment of chronic pain with opioids. The Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid the Defendants by touting the benefits of opioids to treat chronic pain.

122. Pro-opioid doctors have been at the hub of the Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. The Defendants were able to exert control of each of these modalities through their KOLs.

123. In return, the KOLs' association with the Defendants provided not only money, but prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community.

124. Although some KOLs initially may have advocated for more permissive opioid prescribing with honest intentions, the Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. The Defendants selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.[44] These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

125. The Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, the Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy. Indeed, one prominent KOL sponsored by the Defendants, Russell Portenoy, M.D., stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding. Some KOLs have even gone on to become direct employees and executives of Defendants, like Dr. David Haddox, Purdue's Vice President of Risk Management.

126. The Defendants provided substantial opportunities for KOLs to participate in research studies on topics the Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr.

[44] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

127. The Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences. On information and belief, these payments total millions of dollars.

128. These KOLs were carefully vetted to ensure that they were likely to remain on-message and supportive of a pharmaceutical industrial agenda. One measure was a doctor's prior work for trusted Front Groups.

129. The Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said—as they did with all their recruited speakers, as discussed in greater detail herein. The KOLs knew or deliberately ignored the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and the Defendants, all the while causing harm to St. Clair County, Illinois residents and Illinois prescribers and patients.

i. *Russell Portenoy*

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

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

132. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[45]

133. To his credit, Dr. Portenoy has recently admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[46] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[47]

[45] Good Morning America television broadcast, ABC News (Aug. 30, 2010).
[46] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012.
[47] *Id.*

ii. *Lynn Webster*

134. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy.[48] He is a Senior Editor of *Pain Medicine*, the same journal that published special advertising supplements touting opioids. Dr. Webster was the author of numerous CMEs sponsored by Purdue and other opioid makers. At the same time, Dr. Webster was receiving significant funding from Defendants.

135. Dr. Webster has been under investigation for overprescribing by the DEA, which raided his clinic in 2010. More than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Purdue and other opioid manufacturers. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk.* Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach St. Clair County doctors.

[48] Journal supplements are paid for by drug manufacturers and, although they may be designed to blend into the rest of the journal, are not peer-reviewed and constitute drug company advertising.

136. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Years later, Dr. Webster reversed himself, as described in greater detail herein, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[49]

b. "Research" That Lacked Supporting Evidence

137. Rather than find a way to actually test the safety and efficacy of opioids for long-term use, the Defendants led everyone to believe that they already had. The Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to shape the perceptions of prescribers, patients and payors. This literature was, in fact, marketing material focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

138. To accomplish this, the Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

139. The Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other

[49] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wise. J. Sentinel (Feb. 19, 2012).

publications to support the launch and sales of their drugs. The plans for materials did not originate in the departments within the Defendant organizations that were responsible for research, development or any other area that would have specialized knowledge about the drugs and their effects on patients, but in the Defendants' marketing departments and with the Defendants' marketing and public relations consultants. The Defendants often relied on "data on file" or presented posters, neither of which are subject to peer review. They also published their articles not through a competitive process, but in paid journal supplements, which allowed the Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

140. The Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study. Most notably, Purdue promoted a 1980 reference in the well-respected *New England Journal of Medicine:* J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (1980) ("Porter-Jick Letter"). It is cited 856 times in Google Scholar, and 86 times since 2010. It appears as a reference in two CME programs in 2012 sponsored by Purdue and another opioid manufacturer.[50] The Defendants and those acting on their behalf fail to reveal that this "article" is actually a letter-to-the-editor, not a peer-reviewed study (or any kind of study at all). The Porter-Jick Letter[51], as it has become known, describes a review of the charts of hospitalized patients who had received opioids. (Because it was a 1980 study, standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.)

[50] AAPM, Safe Opioid Prescribing Course, February 25-26, 2012, sponsored by Purdue and Endo; "Chronic Pain Management and Opioid Use," October 11, 2012, sponsored by Purdue. Each CME is available for online credit, including to prescribers in Chicago.

[51] http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5

141. The Porter-Jick Letter notes that, when these patients' records were reviewed, it found almost no references to signs of addiction, though there is no indication that caregivers were instructed to assess or document signs of addiction. None of these serious limitations is disclosed when the Defendants or those acting on their behalf cite the Porter-Jick Letter, typically as the sole scientific support for the proposition that opioids are rarely addictive, even when taken long-term. In fact, Dr. Jick later complained that his letter had been distorted and misused.

142. The Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. The Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, the Defendants—often with the help of third-party consultants—targeted a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

143. The Defendants' strategies—first, to plant and promote supportive literature and then, to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicts those claims—are flatly inconsistent with their legal obligations, as laid out in greater detail herein. The strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief and distorted prescribing patterns as a result.

c. Treatment Guidelines

144. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by the Defendants, who are otherwise not experts, nor trained, in the

treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Furthermore, one opioid manufacturer, Endo, has internal documents indicating that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

i. *FSMB*

145. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

146. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB admitted was produced "in collaboration with pharmaceutical companies." The FSMB Guidelines taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and they discussed addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

147. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also make these same claims. These

guidelines were posted online and were available to and intended to reach St. Clair County physicians.

148. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Defendants. the FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies for bulk sales and distribution to sales representatives (for distribution to prescribing doctors).

149. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), and the FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale.[52] The FSMB website describes the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

150. Drug companies relied on FSMB guidelines to convey the message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head—doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

151. FSMB, more recently, has moderated its stance. Although the 2012 revision of *Responsible Opioid Prescribing* continues to teach that pseudoaddiction is real and that opioid addiction risk can be managed through risk screening, it no longer recommends chronic opioid therapy as a first choice after the failure of over-the-counter medication and has heightened its addiction and risk warnings.

[52] According to the Federation of State Medical Boards, the Illinois Department of Financial and Professional Regulators distributed 500 copies of *Responsible Opioid Prescribing* within Illinois.

ii. *AAPM/APS Guidelines*

152. AAPM and the APS are professional medical societies, each of which received substantial funding from the Defendants and the industry from 2009 to 2013 (with AAPM receiving over $2 million). They issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[53] The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.[54]

153. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Purdue.

154. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including the Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only

[53] Consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), *available at* http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCHRONICO.pdf.

[54] *Id.*

treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Illinois during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

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

iii. *American Geriatrics Society*

156. The American Geriatrics Society ("AGS"), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.[55] These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

157. AGS contracted with Purdue and others in the industry to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. Purdue was aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were released at the May 2009 AGS Annual Scientific Meeting in Chicago and first published online on July 2, 2009. AGS submitted grant requests to the Purdue beginning July 15, 2009. Internal

[55] Pharmacological Management of Persistent Pain in Older Persons, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), *available at* http://www.americangeriatrics.org/files/documents/2009_Guideline.pdf.

AGS discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they have approved the message, AGS ceded significant control to these companies. Purdue agreed to provide support to distribute the guidelines.

158. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[56] Five of 10 of the experts on the guidelines panel disclosed financial ties to the Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by the Defendants, receiving grants from the Defendants, and investing in the Defendants' stock. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

iv. *Guidelines That Did Not Receive Defendants' Support*

159. The extent of the Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines—the authors of which did not accept drug company funding—reached very different conclusions. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further

[56] John FAuber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel, May 30, 2012.

advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain stating with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."[57]

160. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.[58]

161. The *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their view:

> revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps . . . include: lack of effectiveness studies on long-term benefits and harms of opioids . . .; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification . . .; lack of evidence on the utility of informed consent and opioid management plans . . .; and treatment of

[57] Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

[58] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids*, (2011), *available at*: http://beta.acoem.org/uploadedFiles/Knowledge-_Centers/Practice_Guidelines/Chronic%20Pain%20Opioid%202011.pdf.

> patients with chronic non-cancer pain at higher risk for drug abuse or misuse.[59]

162. CMEs are ongoing professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are delivered by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

163. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, the Defendants aimed to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Defendants' deceptions.

164. In all, the Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

165. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in

[59] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010), *available at* http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf.

which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[60]

166. Dozens of CMEs that were available to and attended or reviewed by St. Clair County and Illinois doctors during the relevant time period did not live up to the AMA's standards.

167. The influence of the Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non-industry-funded CME mentioned the risks of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.[61]

168. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Defendants could expect messages to be favorable to them, as these organizations were otherwise dependent on the Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid

[60] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011), *available at* http://www.ama-assn.olrg/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion90115.page.

[61] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010), *available at* pharmedout.galacticrealms.com/Fush-BermanPrescriptionforConflict6-25-10.pdf.

therapy, as described in greater detail herein. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Defendants measured the effects of CMEs on prescribers' view on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

e. Unbranded Patient Education

169. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[62] Evidence also demonstrates that physicians are willing to acquiesce to patient demands for a particular drug—even for opioids and for conditions for which they are not generally recommended.[63] Recognizing this fact, the Defendants put their relationships with Front Group to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

170. The drug companies expect that they will recoup their investment in direct-to-consumer advertisements because they will capture at least some of any additional prescriptions that result from patients "asking their doctor" about drugs that can treat their pain. Doctors also may review direct-to-consumer materials sales representatives give them to distribute to patients.

f. Defendants' Use of Front Groups

171. As noted above, Purdue entered into arrangements with numerous organizations to promote opioids. These organizations depend upon Purdue and others in the industry for significant funding and, in some cases, for their survival. They were involved not only in

[62] Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

[63] Prescribers often accede to patient requests. According to one study, nearly 20% of sciatica patients requesting oxycodone would receive a prescription for it, compared with 1% making no request. More than half of patients requesting a strong opioid received one. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting the Defendants' marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by the Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. The Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

172. Several representative examples of such Front Groups are highlighted below, but there are others, too, such as APS, AGS, FSMB, American Chronic Pain Association ("ACPA"), AAPM, American Society of Pain Educators ("ASPE"), NPF, and PPSG. Some of these Front Groups were subject to and did cooperate with investigatory subpoenas issued by the City of Chicago in its investigation and subsequent litigation regarding opioids. Some of the available evidence demonstrating how Defendants controlled their allied Front Groups is laid out below.

i. *American Pain Foundation*

173. The most prominent of the Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Purdue provided $1.7 million in funding during a time when sales of its OxyContin, being co-promoted by Abbott, was skyrocketing.

174. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, as described

in greater detail herein, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach St. Clair County and the State of Illinois.

175. In addition to Perry Fine, Russell Portenoy, and Scott Fishman, who served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

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

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

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

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

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

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

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

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

objective and neutral third party and the Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[64]

ii. *The American Academy of Pain Medicine*

183. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of the Defendants, issued the treatment guidelines discussed in greater detail herein, and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

184. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Purdue was a member of the council and presented deceptive programs to doctors who attended this annual event.

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

[64] http://www.painfoundation.org (last visited Aug. 24, 2015).

Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront of teaching that "the risks of addiction are . . . small and can be managed."[65]'

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

3. Defendants Acted In Concert with KOLs and Front Groups in the Creation, Promotion, and Control of Unbranded Marketing.

187. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, the Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market the risks, benefits, and superiority of opioids to treat chronic pain.

188. The Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages. These KOLs have worked reciprocally with the Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated to St. Clair County and Illinois prescribers and patients.

189. One vehicle for their collective collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the Forum as "a

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

deliberate effort to positively merge the capabilities of industry, professional associations, and patient organizations."

190. PCF is comprised of representatives from opioid manufacturers and distributors (including Purdue and others); doctors and nurses in the field of pain care; professional organizations (*e.g.*, American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other like-minded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from the Defendants.

191. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Society ("REMS") for long-acting opioids that the FDS mandated in 2009 to communicate the risks of opioids to prescribers and patients.[66] This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would deflate the Defendants' marketing efforts. The recommendations—drafted by Will Rowe of APF—claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers."[67] As laid out in greater detail herein, the Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

4. The Defendants Targeted Vulnerable and Lucrative Populations.

a. The Elderly

[66] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

[67] Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

192. Elderly patients taking opioids have been found to suffer elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which, as the Defendants acknowledge in their labels (but not in their marketing), occurs more frequently in elderly patients. A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs. The Defendants' targeted marketing to the elderly and the absence of cautionary language in their promotional materials flies in the face of scientific evidence and their own labels, and creates a heightened risk of serious injury to elderly patients.

193. The Defendants also promoted the notion—also without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. AGS's 2009 Guidelines, for example, which Purdue publicized, described the risk of addiction as "exceedingly low in older patients with no current or past history of substance abuse." Yet, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

194. The Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. In Chicago, for example, use of chronic opioid therapy by elderly patients who are seen in one of the City's 17 senior wellness program sites, for example, is significant. According to a pharmacist associated with the program, many seniors *start* on opioids to treat chronic back pain or arthritis.

b. Veterans

195. Veterans, too, are suffering greatly from the effects of the Defendants' targeted marketing. A 2008 survey showed prescription drug abuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001. Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days. Although many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment. Among former service members receiving VA services nationally in a single year (2005), 1,013 had died of accidental drug overdose—double the rate of the civilian population.

196. The Plaintiffs have a substantial population of veterans who must cope with the consequences of overprescribing opioids and the damaging effects the Defendants' conduct has had on them.

197. Opioids are particularly dangerous to returning combat veterans. According to a study published last year in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, like overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death. Yet, according to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines. Again, as with elderly patients, the Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids posed to them.

198. *Exit Wounds*, a 2009 publication sponsored by Purdue, distributed by APF with grants from other Opioid makers, and written as a personal narrative of one veteran, describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications." The book also asserts that "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards." As laid out above, the FSMB itself received support from Defendants during the time it created and published its guidelines.

199. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose the risk that opioids may cause fatal interactions with benzodiazepines, which were taken by a significant number of veterans.[68] It is not the unbiased narrative of a returning war veteran. It is pure marketing, sponsored by Purdue and the industry. Yet, Janssen (one of the sponsors and a competitor opioid manufacturer of Defendants), for example, supported the marketing effort, and its insufficient disclosures, despite acknowledging on the label for its opioid Duragesic that its use with benzodiazepines "may cause respiratory depression, hypotension, and profound sedation or potentially result in coma." A similar warning is found on the labels of other opioids including Defendants'.

200. The deceptive nature of *Exit Wounds* is obvious in comparing it to guidance on opioids published by the VA and DOD in 2010 and 2011. The VA's *Taking Opioids*

[68] FDA guidance states that materials designed to target a particular audience should disclose risks particular to that audience. *See* FDA Notice, Guidance for Industry, "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs," August 6, 2015.

Responsibly describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death—none of which is disclosed in *Exit Wounds*.

D. Why The Defendants' Marketing Messages Are Misleading and Unfair.

201. The Defendants' marketing of opioids for long-term use to treat chronic pain, both directly and with and through third parties, included information that was false, misleading, contrary to credible scientific evidence and their own labels, and lacked balance and substantiation. Their marketing materials omitted material information about the risks of opioids, and overstated their benefits. Moreover, the Defendants inaccurately suggested that chronic opioid therapy was supported by evidence, and failed to disclose the lack of evidence in support of treating chronic pain with opioids.

202. As described in greater detail herein, there are seven primary misleading and unfounded representations. The Defendants and the third parties with which they teamed:

- misrepresented that opioids improve function;
- concealed the link between long-term use of opioids and addiction;
- misrepresented that addiction risk can be managed;
- masked the signs of addiction by calling them "pseudoaddiction";
- falsely claimed withdrawal is easily managed;
- misrepresented or omitted the greater dangers from higher doses of opioids; and
- deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

203. In addition to these misstatements, Purdue and Abbott purveyed an eighth deception—laid out in greater detail herein—that OxyContin provides a full 12 hours of pain relief.

204. Exacerbating each of these misrepresentations and deceptions was the collective effort of the Defendants and third parties to hide from the medical community the fact that the FDA "is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[69]

1. The Defendants and Their Third-Party Allies Misrepresented that Opioids Improve Function.

205. Each of the following materials was created with the expectation that, by instructing patients and prescribers that opioids would improve patients' function and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy in the belief that failure to improve pain, function, or qualify of life could be overcome by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

206. However, not only is there no evidence of improvement in long-term functioning, a 2006 study-of-studies found that "[f]or functional outcomes . . . other analgesics were significantly more effective than were opioids."[70] Studies of the use of opioids in chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back

[69] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[70] Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(1) Can. Med. Ass'n J. 1589-1594 (2006). This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

injuries does not cause patients to return to work or physical activity.[71] Indeed, one Defendant's own internal marketing plans characterized functional improvement claims as "aspirational." Another acknowledged in 2012 that "[s]ignificant investment in clinical data [as] needed" to establish opioids' effect on mitigating quality of life issues, like social isolation.

207. As laid out in greater detail herein, the long-term use of opioids carries a host of serious side effects, including addiction, mental clouding and confusion, sleepiness, hyperalgesia, immune-system and hormonal dysfunction, that degrade, rather than improve, patients' ability to function. The Defendants often omitted these adverse effects from their publications, as well as omitting certain risks of drug interactions.

208. Yet each of the following statements by the Defendants suggests that the long-term use of opioids improve patients' function and quality of life, and that scientific evidence supports this claim.

Purdue	s. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain vignettes," which were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, "Paul," is described to be a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively. t. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The *Policymaker's Guide* is still available online.

[71] Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. They also were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

	u. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the guide currently is available online. v. Purdue sponsored APF's *Exit Wounds*, which taught veterans that opioid medications "increase your level of functioning." *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. w. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over $100,000 to support distribution of the book. x. Purdue sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.

2. Defendants and Their Third-Party Allies Concealed the Truth About the Risk of Addiction from Long-Term Opioid Use.

209. The fraudulent representation that opioids are rarely addictive is central to the Defendants' scheme. To reach chronic pain patients, the Defendants, and the Front Groups and KOLs that they directed, assisted, and collaborated with, had to overcome doctors' legitimate fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk—condemning patients to, among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. But for the Defendants' campaign to convince doctors otherwise, finding benefits from opioid use for common chronic pain conditions sufficient to justify that risk would have, and previously had, posed a nearly insurmountable challenge.

210. Through their well-funded, comprehensive marketing efforts, the Defendants and their KOLs and Front Groups were able to change prescriber perceptions, despite the well-settled

historical understanding and clear evidence that opioids taken long-term are often addictive. The Defendants and their third-party partners: (a) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (b) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk—and the Defendants' own labels—compelled disclosure.

211. Further, in addition to falsely claiming opioids had low addiction risk or omitting disclosure of the risk of addition altogether, the Defendants employed language that conveyed to prescribers that the drugs had lower potential for abuse and addiction. Further, in addition to making outright misrepresentations about the risk of addiction, or failing to disclose that serious risk at all, the Defendants used code words that conveyed to prescribers that their opioid was less prone to abuse and addiction. For instance, sales representatives for Purdue promoted their drugs as having "steady-state" properties with the intent and expectation that prescribers would understand this to mean that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction. Further, Purdue claimed that its opioids were not favored by addicts and did not produce a buzz, all of which falsely suggested that its opioids were less likely to be abused or addictive.

212. Each of the following was created with the expectation that, by instructing patients and prescribers that addiction rates are low and that addiction is unlikely when opioids are prescribed for pain, doctors would prescribe opioids to more patients. For example, one publication sponsored exclusively by Purdue—APF's 2011 *A Policymaker's Guide to Understanding Pain & Its Management*—claimed that opioids are not prescribed often enough because of "misconceptions about opioid addiction."

213. Acting directly or with and through third parties, each of the Defendants claimed that the potential for addiction from its drugs was relatively small, or non-existent, even though there was no scientific evidence to support those claims, and the available research contradicted them. A recent literature survey found that while ranges of "problematic use" of opioids ranged from <1% to 81%,[72] abuse averages between 21% and 29% and addiction between 8% and 12%.[73] These estimates are well in line with Purdue's own studies, showing that between 8% and 13% of OxyContin patients became addicted, but on which Purdue chose not to rely, citing instead the Porter-Jick letter.

214. The FDA has found as well that 20% of opioid patients use two or types, 26% obtain opioids from two or more prescribers, and 16.5% seek early refills—all potential "red flags" for abuse or addiction.[74] The FDA in fact has ordered manufacturers of long-acting opioids to "[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain," in recognition of the fact that it found "high rates of addiction" in the medical literature.[75]

215. Of course, the significant (and growing) incidence of abuse, misuse, and addiction to opioids also is powerful evidence that the Defendants' statements regarding the low risk of addiction were and are untrue. This was well-known to the Defendants, who had access to sales

[72] Cited for the low end of that range was the 1980 Porter-Jick letter in the *New England Journal of Medicine*.

[73] Kevin Vowels et al., *Rates of opioid misuse, abuse, and addition in chronic pain: a systematic review and data synthesis*, 156 PAIN 569-76 (April 2015).

[74] Len Paulozzi, M.D., "Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse," *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM233244.pdf.

[75] September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics, *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf; Letter from Janet Woodcock, M.D., *supra*.

data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

216. Acting directly or through and with third parties, each of the Defendants claimed that the potential for addiction even from long-term use of its drugs was relatively small, or non-existent, even though that was false and there was no scientific evidence to support it.

217. In addition to denying or minimizing the risk of addiction and abuse generally, and as laid out in greater detail herein, the Defendants also falsely claimed that their particular drugs were safer, less addictive, and less likely to be abused or diverted than their competitors' or predecessor drugs. In making these claims, the Defendants said or implied that because their drug had a "steady-state" and did not produce peaks and valleys, which cause drug-seeking behavior—either to obtain the high or avoid the low—it was less likely to be abused or addicting. Defendants had no evidence to support any of these claims which, by FDA regulation, must be based on head-to-head trials;[76] the claims also were false and misleading in that they misrepresented the risks of both the particular drug and opioids as a class.

218. Further, rather than honestly disclose the risk of addiction, the Defendants, and the third parties they directed and assisted and whose materials they distributed, attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. To increase pressure on doctors to prescribe chronic opioid therapy, the Defendants turned the tables; it was doctors who fail to treat their patients' chronic pains with opioids—not doctors who cause their patients to become addicted to opioids—who are failing their patients (and subject to discipline). The Defendants and their third-party allies claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-

[76] *See Guidance for Industry*, "Abuse-Deterrent Opioids—Evaluation and Labeling," April 2015 (describing requirements for premarket and postmarket studies).

regulated and under-prescribed. This mantra of under-treated pain and under-used drugs reinforced the Defendants' messages that the risks of addiction and abuse were not significant and were overblown.

219. For example, one industry website, *Let's Talk Pain*, sponsored by opioid maker Janssen, warns in a video posted online that "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program goes on to say: "Because of the potential for abuse and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients . . . . This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."

220. In the same vein, a Purdue website called *In the Face of Pain* complains, under the heading of "Protecting Access," that, through at least mid-2013, policy governing the prescribing of opioids was "at odds with" best medical practices by "unduly restricting the amounts that can be prescribed and dispensed"; "restricting access to patients with pain who also have a history of substance abuse"; and "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe." This unsupported and untrue rhetoric aims to portray doctors who do not prescribe opioids as uncaring, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

3. The Defendants and Their Third-Party Allies Misrepresented that Addiction Risk Can Be Avoided or Managed.

221. The Defendants each continue to maintain to this day that most patients safely can take opioids long-term for chronic pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, the Defendants and their third-party allies have come to admit that some patients could become addicted, but that doctors can avoid

or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

222. Three are three fundamental flaws in these assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction. Second, there is no reliable scientific evidence that high-risk or addicted patients can take opioids long-term without triggering addiction, even with enhanced monitoring and precautions. Third, there is no reliable scientific evidence that patients without these red flags are necessarily free of addiction risk.

223. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. A recent Evidence Report by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified '[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[77] Furthermore, attempts to treat high-risk patients, such as those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening are not proven to work in the real world, if busy doctors even in fact attempt them.

[77] *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, Agency for Healthcare Res. & Quality (September 19, 2014).

224. Most disturbingly, despite the widespread use of screening tools, patients with past substance use disorders—which every tool rates as a risk factor—receive, on average, higher doses of opioids.

225. As described in greater detail herein, the industry players claimed that the risk of addiction could be avoided or managed, claims that are deceptive and without scientific support:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction.
Cephalon	b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."
Endo	c. Endo paid for a 2007 supplement[78] available for continuing education credit in the *Journal of Family Practice* and written by a Chicago-based doctor who later became a member of Endo's speakers bureau. This publication, titled *Pain Management Dilemmas in Primary Care: Use of Opioids*, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely (*e.g.*, without becoming addicted) receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
Purdue	d. Purdue's unbranded website, *In the Face of Pain* (inthefaceofpain.com) states that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is "severe" are "at odds with" best medical practices.[79] e. Purdue sponsored a 2012 CME program taught by a Chicago-based KOL titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. This presentation recommended that use of screening tools, more frequent refills, and switching opioids

[78] The Medical Journal, *The Lancet* found that all of the supplement papers it received failed peer-review. Editorial, "The Perils of Journal and Supplement Publishing," 375 *The Lancet* 9712 (347) 2010.

[79] *See In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment*, Purdue Pharma L.P. (Resources verified Mar.2012), www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf.

	could treat a high-risk patient showing signs of potentially addictive behavior. f. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." g. Purdue sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction.

4. The Defendants and their Third-Party Allies Created Confusion By Promoting the Misleading Term "Pseudoaddiction."

226. The Defendants and their third-party allies developed and disseminated each of the following misrepresentations with the intent and expectation that, by instructing patients and prescribers that signs of addiction are actually the product of untreated pain, doctors would prescribe opioids to more patients and would continue to prescribe, and patients to use, opioids despite signs that the patient was addicted. The concept of "pseudoaddiction" was coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, who consulted for opioid makers Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other the Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction," as if patients could not experience both. As KOL Dr. Lynn Webster wrote: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. . . . It led us down a path that caused harm. It is already something we are debunking as a concept."[80]

227. Each of the publications and statements of Purdue below, which are further discussed, in greater detail herein, falsely states or suggests that the concept of

[80] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb. 19, 2012).

"pseudoaddiction" is substantiated by scientific evidence and accurately describes the condition of patients who only need, and should be treated with, more opioids:

a. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which under the heading, "Indications of Possible Drug Abuse," shows pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. Thus, these misrepresentations wrongly reassure doctors that as long as they do not observe those signs, they need not worry that their patients are abusing or addicted to opioids.

b. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. This publication is still available online. This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction."

c. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

d. A Purdue-funded study with a Purdue co-author claimed that "evidence that the risk of psychological dependence or addiction is low in the absence of a

history of substance abuse." The study relied only on the 1980 Porter-Jick letter to the editor concerning a chart review of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. Although the term "low" is not defined, the overall presentation suggests the risk is so low as not to be a worry.

e. Purdue contracted with AGS to produce a CME promoting the 2009 guidelines for the Pharmacological Management of Persistent Pain in Older Persons. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after this completion.

f. Purdue sponsored APF's Exit Wounds (2009), which counseled veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests it is so low as not to be a worry.

g. Purdue sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush

or euphoric effect, and therefore were less addictive and less likely to be abused.

h. Purdue sales representatives told prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamper-proof and, after a certain point, patients no longer experience a "buzz" from increased dosage.

i. Advertisements that Purdue sent to prescribers stated that OxyContin ER was less likely to be favored by addicts and, therefore, less likely to be abused or diverted, or result in addiction.

j. In discussions with prescribers, Purdue sales representatives omitted discussion of addiction risks related to Purdue's drugs.

5. The Defendants and their Third-Party Allies Claimed Withdrawal is Simply Managed.

228. The Defendants and their third-party allies promoted the false and misleading messages below with the intent and expectation that, by misdescribing the difficulty of withdrawing from opioids, prescribers and patients would be more likely to start chronic opioid therapy and would fail to recognize the actual risk of addiction.

229. In an effort to underplay the risk and impact of addiction, the Defendants and their third-party allies frequently claim that while patients become "physically" dependent on

opioids, physical dependence can be addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal. They fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs.

230. In reality, withdrawal is prevalent in patients after more than a few weeks of therapy, and common symptoms of withdrawal include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long opioids were used. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

231. Each of the publications and statements below, which are further discussed in greater detail herein, falsely states or suggests that withdrawal from opioids was not a problem and they should not be hesitant about prescribing or using opioids:

Purdue	a. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use. b. Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be successfully manage. c. Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butran's low potency and its extended release mechanism.

6. The Defendants and Their Third-Party Allies Misrepresented that Increased Doses Pose No Significant Additional Risks.

232. Each of the following misrepresentations was created with the intent and expectation that, by misrepresenting and failing to disclose the known risks from high dose opioids, prescribers and patients would be more likely to continue to prescribe and use opioids, even when they were not effective in reducing patients' pain, and not to discontinue opioids even when tolerance required them to reach even higher doses.

233. The Defendants and their third-party allies claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. The Defendants' claims also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

234. These claims are false. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The FDA has itself acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—the signs of addiction.

235. Each of the following claims, which are further discussed in greater detail herein, suggests that high-dose opioid therapy is safe:

Purdue	a. Purdue's *In the Face of Pain* website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what—in their view—is a sufficient dose of opioids, they should find another doctor who will. In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands. b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that does escalations are "sometimes necessary," even indefinitely high ones, which suggested that high does opioids are safe and appropriate and did not disclose the risks from high does opioids. This publication is still available online. c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language fails to disclose heightened risks at elevated doses. d. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit. e. Purdue sales representatives told prescribers that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses.

7. The Defendants and Their Third-Party Allies Deceptively Omitted or Minimized Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment.

236. Each of the following misrepresentations was created with the intent and expectation that, by omitting the known, serious risks of chronic opioid therapy, including the

risks of addiction, abuse, overdose, and death, and emphasizing or exaggerating risks of competing products, prescribers and patients would be more likely to choose opioids. The Defendants and their third-party allies routinely ignored the risks of chronic opioid therapy. These include (beyond the risks associated with misuse, abuse, and addiction): hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time."[81] 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 benzodiazapines, which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions).[82]

237. Despite these serious risks, the Defendants asserted or implied that opioids were appropriate first-line treatments and safer than alternative treatments, including NSAIDs such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal, renal, and cardiac risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks were deceptive in themselves, and also made their omissions regarding the risks of opioids all the more striking and misleading. The Defendants and their third-party allies described over-the-counter NSAIDs as like-threatening and falsely asserted that they were responsible for 10,000-20,000 deaths annually (more than opioids), when the real number is closer to 3,200. This description of NSAIDs starkly contrasted with their representation of opioids, for which the listed risks were nausea, constipation, and sleepiness (but

[81] *See* Letter from Janet Woodcock, M.D., *supra*, at 10 n.41.

[82] Several of these risks do appear in the FDA-mandated warnings. *See, e.g.*, the August 13, 2015 OxyContin Label, Section 6.2, identifying adverse reactions including: "abuse, addiction ... death, ... hyperalgesia, hypogonadism ... mood altered ... overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria [hives]."

not addiction, overdose, or death). Compared with NSAIDs, opioids are responsible for roughly four times as many fatalities annually.

238. As with the preceding misrepresentations described above, the Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.

239. Each of the following, which are further discussed in greater detail herein, reflects the Defendants' deceptive claims and omissions about the risks of opioids, including in comparison to NSAIDs:

Purdue	m. Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. n. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which advised 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 attributes 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. o. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013, and the 2013 version is still available for CME credit. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses. p. Purdue sales representatives told prescribers that NSAIDs were more toxic than opioids.

8. Purdue Misleadingly Promoted OxyContin as Providing 12 Hours of Pain Relief.

240. In addition to making the deceptive statements above, Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action.

241. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the charts linked in the footnote, incorporated herein by reference, which was, upon information and belief, adapted from Purdue's own sales materials.[83] The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the 12 hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

242. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid—OxyContin is roughly twice as powerful as morphine—triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full 12 hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure (The FDA found in 2008 that a "substantial number" of chronic pain patients will experience "end-of-dose failure" with OxyContin.) The combination of fast onset and end-of-dose failure makes OxyContin particularly addictive, even compared with other opioids.

[83] Jim Edwards, *"How Purdue Used Misleading Charts to Hid OxyContin's Addictive Power*," *CBSNews.com*, Sept. 28, 2011, http://www.cbsnews.com/news/how-purdue-used-misleading-charts-to-hide-oxycontins-addictive-power/. The 160 mg doze is no longer marketed. Purdue's promotional materials in the past displayed a logarithmic scale, which gave the misleading impression the concentration remained constant.

243. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full 12 hours.

244. More recently, other Purdue advertisements also emphasized "Q12h" (meaning twice-daily) dosing, as discussed in greater detail herein. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. Other advertisements that ran in the 2005 and 2006 issues of the *Journal of Pain* depict a sample prescription for OxyContin, with "Q12h" handwritten for emphasis. All of these advertisements, on information and belief, were utilized by co-promoter Abbott in marketing OxyContin.

245. The information that OxyContin did not provide pain relief for a full 12 hours was known to Purdue, and Purdue's competitors, but was not disclosed to general practitioners. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two (which would have compensated for end-of-dose failure) was set out in Purdue's internal documents as early as 1999 and is apparent from MEDWATCH Adverse Event reports for OxyContin.[84] Even Purdue's competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering "durable" pain relief, which Endo understood to suggest a contract to OxyContin. Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

246. Purdue and Abbott's failure to disclose the prevalence of end-of-dose failure meant that prescribers in St. Clair County and Illinois were not informed of risks relating to addiction, and that they received the misleading message that OxyContin would be effective for treating chronic pain for the advertised duration. Furthermore, doctors would compensate by

[84] MEDWATCH refers to the FDA's voluntary adverse event reporting system.

increasing the dose or prescribing "rescue" opioids, which has the same effect as increasing the amount of opioids prescribed to a patient, as described in greater detail herein.[85] [86]

E. Each Defendant Engaged in Deceptive Marketing, Both Branded and Unbranded, that Targeted and Reached St. Clair County and Illinois Prescribers.

247. The Defendants—and the Front Groups and KOLs who depended on and worked alongside them—were able to effect a sea change in medical opinion in favor of accepting opioids as a medically necessary long-term treatment for chronic pain. As set forth below, each Defendant contributed to that result through a combination of both direct marketing efforts and third-party marketing efforts over which that Defendant exercised editorial control. These deceptive and misleading statements were directed to and reached St. Clair County and Illinois prescribers and patients, with the intent of distorting their views on the risks, benefits, and superiority of opioids for treatment of chronic pain.

248. The Defendants engaged in their deceptive marketing campaign, both nationwide and in Illinois, using a number of strategies. The Defendants trained their sales forces and recruited physician speakers to deliver these deceptive messages and omissions, and they in turn conveyed them to prescribers. The Defendants also broadly disseminated promotional messages and materials, both by delivering them personally to doctors during detailing visits and by mailing deceptive advertisements directly to prescribers. Because they are disseminated by Defendant drug manufacturers and relate to the Defendants' drugs, these materials are considered "labeling" within the meaning of 21 C.F.R. § 1.3(a), which means the Defendants are liable for their content.

[85] Purdue's *Clinical Issues in Opioid Prescribing*, put out in 2005 under Purdue's unbranded *Partners Against Pain* banner, states that "it is recommended that a supplementary immediate-release medication be provided to treat exacerbations of pain that may occur with stable dosing." References to "rescue" medication appear in publications Purdue sponsored such as APF's *A Policymaker's Guide* (2011) and the 2013 CME *Overview of Pain Management Options*.

[86] Actavis also sold various generic opioids, including Norco, which were widely prescribed in Chicago and benefited from Actavis's overall promotion of opioids, but were not directly marketed by sales representatives.

249. As described below, the State and St. Clair County has a number of prescribers who received Defendants' misrepresentations. Each of the misrepresentations received by these doctors—as well as other misrepresentations outlined in greater detail herein—constitutes an integral piece of a centrally directed marketing strategy to change medical perceptions regarding the use of opioids to treat chronic pain. The Defendants were aware of each of these misrepresentations, and the Defendants approved of them and oversaw their dissemination at the national, corporate level.

1. Purdue

250. Purdue promoted its branded opioids—principally, Oxycontin, Butrans, and Hysingla—and opioids generally in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement. Purdue did so through its sales force, branded advertisements, promotional materials, and speakers, as well as a host of materials produced by its third-party partners, most prominently APF. Purdue's sales representatives and advertising also misleadingly implied that OxyContin provides a full 12 hours of pain relief, and its allied Front Groups and KOLs conveyed the additional deceptive messages about opioids' safety at higher doses, the safety of alternative therapies, and the effectiveness of addiction screening tools.

251. Based on the highly coordinated and uniform nature of Purdue's marketing, and as confirmed by verbatim message data and interviews with prescribers, Purdue conveyed these deceptive messages to Illinois prescribers. The materials that Purdue generated in collaboration with third parties also were distributed or made available in Illinois. Purdue distributed these messages, or facilitated their distribution, in Illinois with the intent that Illinois prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Purdue's Deceptive Direct Marketing

252. Purdue directly disseminated deceptive branded and unbranded marketing focused on minimizing the risks associated with the long-term use of opioids to treat chronic pain. Purdue directed these messages to prescribers and consumers through its sales force and branded advertisements.

253. According to the complaint filed by the City of Chicago, Purdue engaged in in-person marketing to doctors in Chicago and operated speakers bureau programs that included and targeted Chicago prescribers. Like the other Defendants' detailers, Purdue sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed, identically, across the State and country. These sales representatives were critical in delivering Purdue's marketing strategies and talking points to individual prescribers.[87] Indeed, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines, which deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories, with doctors during individual sales visits.

254. Purdue's spending on detailing reached its nadir in 2006 and 2007, as the company faced civil and criminal charges for misbranding OxyContin. Since settling those charges in 2007, however, Purdue has sharply increased its quarterly spending on promotion through its sales force, from under $5 million in 2007 to more than $30 million by the end of 2014.

[87] But Purdue did not stop there. It also tracked around 1,800 doctors whose prescribing patterns demonstrated a probability that they were writing opioid prescriptions for addicts and drug dealers. Purdue kept the program secret for nine years and, when it finally did report information about these suspicious doctors to law enforcement authorities, it only did so with respect to 8% of them.

255. Purdue also marketed its drugs through branded advertisements, which relied on, among other deceptive tactics, misleading statements about the efficacy and onset of OxyContin. As described in greater detail herein, Purdue has marketed its drug as effective for12 hours. Purdue knew, however, that these claims were misleading because, for many patients, the pain relief lasted for as little as eight hours, which led to end-of-dose failure and withdrawal symptoms and prompted doctors to prescribe or patients to take higher or more frequent doses of opioids, all of which increased the risk of abuse and addiction.

256. Purdue advertisements that ran in 2005 and 2006 issues of the *Journal of Pain* depict a sample prescription for OxyContin with "W12h" handwritten. Another advertisement Purdue ran in 2005 in the *Journal of Pain* touted OxyContin's "Q12h" dosing convenience: and displayed two paper dosing cups, one labeled "8 am" and one labeled "8 pm," implying that OxyContin is effective for the 12 hour period between 8 a.m. and 8 p.m. Similar ads appeared in the March 2005 *Clinical Journal of Pain*.

257. Further, to this day, Purdue includes prominent 12-hour dosing instructions in its branded advertising, such as in a 2012 Conversion and Titration Guide, which states: "Because each patient's treatment is personal / Individualize the dose / Q12h OxyContin Tablets."

258. As outlined in greater detail herein, however, these statements are misleading because they fail to make clear that a 12 hour dose does not equate to 12 hours of pain relief.

259. As described below, these deceptive statements regarding the efficacy of OxyContin were also carried into Illinois by Purdue's detailers.

260. Purdue's direct marketing materials also misrepresented that opioids would help patients regain functionality and make it easier for them to conduct everyday tasks like walking, working, and exercising.

261. For example, in 2012, Purdue disseminated a mailer to doctors titled "Pain vignettes." These "vignettes" consisted of case studies describing patients with pain conditions that persisted over a span of several months and the vignettes imply that an OxyContin prescription will help them work. None of these ads, however, disclosed the truth—that there is no evidence that opioids improve patients' lives and ability to function (and there was substantial evidence to the contrary).

262. Some of the greatest weapons in Purdue's arsenal, however, were unbranded materials it directly funded and authored. These were in addition to the unbranded materials, described below, that Purdue channeled through third parties.

263. In 2011, Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse*, which deceptively portrayed the signs—and therefore the prevalence—of addiction. However, Purdue knew, as described in greater detail herein, that OxyContin was used non-medically by injection less than 17% of the time. Yet, *Providing Relief, Preventing Abuse* prominently listed side effects of injection like skin popping and track marks as "Indications of Possible Drug Abuse"—downplaying much more prevalent signs of addiction associated with OxyContin use, such as asking for early refills, and making it seem that addiction only occurs when opioids are taken illicitly.

264. *Providing Relief, Preventing Abuse* also deceptively camouflaged the risk of addiction by falsely supporting the idea that drug-seeking behavior could, in fact, be a sign of "pseudoaddiction" rather than addiction itself. Specifically, it noted that the concept of pseudoaddiction had "emerged in the literature" to describe "[drug-seeking behaviors] in patients who have pain that has not been effectively treated." Nowhere in *Providing Relief, Preventing*

Abuse did Purdue disclose the lack of scientific evidence justifying the concept of pseudoaddiction, nor that it was coined by a Purdue vice president.

265. *Providing Relief, Preventing Abuse* was available nationally and was intended to reach Chicago prescribers. As described below, the deceptive statements in *Providing Relief, Preventing Abuse* regarding addiction were the very same messages Purdue directed at Illinois prescribers through its sales force.

266. Purdue also disseminated misrepresentations through two of its unbranded websites, *In the Face of Pain* and *Partners Against Pain*.

267. Consistent with Purdue's efforts to portray opioid treatment as "essential" for the proper treatment of chronic pain and label skepticism related to chronic opioid therapy as an "inadequate understanding" that leads to "inadequate pain control," *In the Face of Pain* criticized policies that limited access to opioids as being "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. This was meant to imply that patients should keep looking until they find a doctor willing to prescribe opioids.

268. *In the Face of Pain* was available nationally and was intended to reach Illinois and St. Clair County prescribers.

269. Purdue also used its unbranded website *Partners Against Pain* to promote the same deceptive messages regarding risk of addiction that are described in greater detail herein and delivered by its sales representatives. On this website, Purdue posted *Clinical Issues in Opioid Prescribing*, a pamphlet that was copyrighted in 2005. Purdue distributed a hard-copy version of this pamphlet at least as of November 2006. *Clinical Issues in Opioid Prescribing* claimed that "illicit drug use and deception" were not indicia of addiction, but rather indications

that a patient's pain was undertreated. The publication indicated that "[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated." In other words, Purdue suggested that when faced with drug-seeking behavior from their patients, doctors should prescribe more opioids—turning evidence of addiction into an excuse to sell and prescribe even more drugs.

270. Purdue's misleading messages and materials were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included Illinois. As described in greater detail herein, Purdue's nationwide messages would have reached Illinois prescribers in a number of ways. For example, they were carried into Illinois by Purdue's sales representatives during detailing visits as well as made available to Illinois patients and prescribers through websites and ads, including ads in prominent medical journals. They would have also been delivered to Illinois prescribers by Purdue's paid speakers, who were required by Purdue policy and by FDA regulations to stay true to Purdue's nationwide messaging.

b. Purdue's Deceptive Third-Party Statements

271. Purdue's efforts were not limited to making misrepresentations through its own sales force (including that of co-promoter Abbott) and its own branded and unbranded marketing materials. As described above, Purdue knew that regulatory constraints restricted what it was able to say about its drugs through direct marketing. For this reason, Purdue enlisted the help of third parties to release misleading information about opioids. The most prominent of these was APF.

i. *APF*

(a) Purdue's Control of APF

272. Purdue exercised considerable control over APF, which published and disseminated in many of the most blatant falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, is described in greater detail herein.

273. Purdue exercised its dominance over APF over many projects and years. Purdue was APF's second-biggest donor, with donations totaling $1.7 million. Purdue informed APF that the grant money reflected Purdue's effort to "strategically align its investments in nonprofit organizations that share [its] business interests," making clear that Purdue's funding depended upon APF continuing to support Purdue's business interests. Indeed, Purdue personnel participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors to talk about pain within companies and hospitals." Thus, Purdue suggested what role APF could play that would complement its own marketing efforts. On that call, Purdue personnel also committed to provide APF with a list of "industry state advocates" who could help promote chronic opioid therapy, individuals and groups that, upon information and belief, APF reached out to. Purdue personnel remained in constant contact with their counterparts at APF.

274. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the

project (and, thus, APF's funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of independence and willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

275. Purdue used this agreement to conduct work with APF on the *Partners Against Pain* website. *Partners Against Pain* is a Purdue-branded site, and Purdue holds the copyright. However, its ability to deploy APF on this project illustrates the degree of control Purdue exercised over APF. In 2011, it hired an APF employee to consult on the *Partners Against Pain* rollout, to orchestrate the media campaign associated with the launch of certain content on the website, and to make public appearances promoting the website along with a celebrity spokesperson. Purdue contemplated paying this consultant $7,500 in fees and expenses for 26 hours of work. Purdue would require this consultant "to discuss and rehearse the delivery of [Purdue's] campaign messages" and Purdue committed that "[m]essage points will be provided to [the] Consultant in advance and discussed on [a planned] call." At all times, decisions regarding the final content on the *Partners Against Pain* website were "at the sole discretion of Purdue."

276. APF also volunteered to supply one of its staff (a medical doctor or a nurse practitioner) to assist Purdue as a consultant and spokesperson in connection with the launch of one of Purdue's opioid-related projects, *Understanding & Coping with Lower Back Pain*, which appeared on *Partners Against Pain*. One of the consultants was APF's paid employee, Mickie Brown. The consultant's services would be provided in return for a $10,000 in consulting fees for APF and $1,500 in honoraria for the spokesperson. All documents used by the consultant in her media appearances would be reviewed and approved by individuals working for Purdue.

Purdue initiated this project, and it was not until later that APF worried about "how Purdue sees this program fitting in with our [existing] grant request."

277. Given the financial and reputational incentives associated with assisting Purdue in this project and the direct contractual relationship and editorial oversight, APF personnel were acting under Purdue's control at all relevant times with respect to *Partners Against Pain*.

278. Purdue often asked APF to provide "patient representatives" for *Partners Against Pain*, and APF fulfilled these requests. Moreover, APF staff and board members and Front Groups ACPA and AAPM, among others (such as Dr. Webster), appear on *Inthefaceofpain.com* as "Voices of Hope"—"champions passionate about making a difference in the lives of people who live with pain" and providing "inspiration and encouragement" to pain patients. APF also contracted with Purdue for a project on back pain where, among other things, it provided a patient representative who agreed to attend a Purdue-run "media training session."

279. According to an Assurance of Voluntary Compliance ("AVC") entered into between the New York Attorney General and Purdue on August 19, 2015, *Inthefaceofpain.com* received 251,648 page views between March 2014 and March 2015. Except in one document linked to the website, *Inthefaceofpain.com* makes no mention of opioid abuse or addiction. Purdue's copyright appears at the bottom of each page of the website, indicating its ownership and control of its content. There is no other indication that 11 of the individuals who provided testimonials on *Inthefaceofpain.com* received payments, according to the AVC, of $231,000 for their participation in speakers programs, advisory meetings and travel costs between 2008 and 2013. Therefore, the New York Attorney General found Purdue's failure to disclose its financial connections with these individuals had the potential to mislead consumers by failing to disclose the potential bias of these individuals.

280. Nowhere was Purdue's influence over APF so pronounced as it was with the APF's "Pain Care Forum" ("PCF"). Based on interviews conducted and documents reviewed by the City of Chicago in connection with its lawsuit, PCF was and continues to be run not by APF, but by Defendant Purdue's in-house lobbyist, Burt Rosen. As described by a former drug company employee, Burt Rosen was able to tell PCF "what to do and how to do it," and also asserted that this allowed him to run APF. According to this employee, to Rosen's thinking, "PCF was APFR, which was Purdue." The group meets regularly in-person and via teleconference and shares information through an email listserv.

281. In 2011, APF and another third-party advocacy group, the Center for Practical Bioethics, were contemplating working together on a project. Having reviewed a draft document provided by the Center for Practical Bioethics, the APF employee cautioned that "this effort will be in cooperation with the efforts of the PCF" and acknowledged that "I know you have reservations about the PCF and involvement, but I do believe working with them and keeping the lines of communications open is important." The Center for Practical Bioethics CEO responded by indicating some confusion about whom to speak with, asking "[i]s Burt Rosen the official leader" and reflecting what other sources have confirmed.

282. In 2007, the PCF Education Subgroup, consisting of drug companies Purdue and Al, and Front Groups APF and ACPA (self-described as "industry-funded" groups), developed a plan to address a perceived "lack of coordination" among the industry and pro-opioid professional and patient organizations. PCF members agreed to develop simplified "key messages" to use for public education purposes. Their messages were reflected in programs like NIPC's *Let's Talk Pain* (put together by Endo and APF), and Purdue's *In the Face of Pain*.

283. When the FDA required drug companies to fund CMEs related to opioid risks in connection with its 2009 REMS, Purdue, along with these Front Groups, worked through the PCF to ensure that, although it was mandatory for drug companies to fund these CMEs, it would not be mandatory for prescribers to attend them. A survey was circulated among Endo, Janssen, and Purdue, which predicted that the rates of doctors who would prescribe opioids for chronic pain would fall by 13% if more than four hours of mandatory patient education were required in connection with the REMS. With a push from PCF, acting under Purdue's direction, they were not.

284. APF showed its indebtedness to Purdue and its willingness to serve its corporate agenda by testifying on the company's behalf at a July 2007 hearing before the Senate Judiciary Committee "evaluating the propriety and adequacy of the OxyContin criminal settlement."[88] Despite its ostensible role as a patient advocacy organization, APF was willing to overlook substantial evidence—resulting in the jailing of Purdue executives—that Purdue blatantly, and despite its clear knowledge to the contrary, told physicians and patients that OxyContin was "rarely" addictive and less addictive than other opioids. Like Purdue and despite the leadership of numerous medical doctors and researchers on its board, APF ignored the truth about opioids and parroted Purdue's deceptive messaging. APF testified on Purdue's behalf that addiction was a "rare problem" for chronic pain patients and asserted: "[T]he scientific evidence suggests that addiction to opioids prescribed by legitimate chronic non-cancer pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal

[88] *Evaluating the Propriety and Adequacy of the Oxycontin Criminal Settlement Before the S. Comm. On the Judiciary*, 110th Cong. 46-50, 110-116 (2007) (statements of Dr. James Campbell, Chairman, APF). Purdue also was able to exert control over APF through its relationships with SPF's leadership. Purdue-sponsored KOLs Russell Portenoy and Scott Fishman chaired APF's board. Another APF board member, Perry Fine, also received consulting fees from Purdue. APF board member Lisa Weiss was an employee of a public relations firm that worked for both Purdue and APF. Weiss, in her dual capacity, helped vet the content of the Purdue-sponsored *Policymaker's Guide*, which is described below.

effect has been demonstrated between the marketing of OxyContin and the abuse and diversion of the drug." There was, and is, no scientific support for those statements.

285. APF President Will Rowe reached out to opioid makers—including Purdue—rather than his own staff to identify potential authors to draft an answer to an article critical of opioids that appeared in the *Archives of Internal Medicine* in 2011.

286. Purdue's control over APF shaped and was demonstrated by specific APF, pro-opioid publications. These publications had no basis in science and were driven (and can only be explained) by the commercial interest of pharmaceutical companies—Purdue chief among them.

(b) *A Policymaker's Guide*

287. Purdue provided significant funding to and was involved with APF in creating and disseminating *A Policymaker's Guide to Understanding Pain & Its Management*, which was originally published in 2011 and is available online to this day. *A Policymaker's Guide to Understanding Pain & Its Management* misrepresented that there were studies showing that the use of opioids for the long-term treatment of chronic pain could improve patients' ability to function.

288. Specifically, *A Policymaker's Guide to Understanding Pain & Its Management* claimed that "multiple clinical studies" demonstrated that "opioids . . . are effective in improving [d]aily function, [p]sychological health [and] [o]verall health-related quality of life for people with chronic pain" and implied that these studies established that the use of opioids long-term led to functional improvement. The study cited in support of this claim specifically noted that there were no studies demonstrating the safety of opioids long-term and noted that "[f]or functional outcomes, the other [studied] analgesics were significantly more effective than were opioids."[89]

[89] Andrea D. Furlan *et al., Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006).

289. The *Policymaker's Guide* also misrepresented the risk of addiction. It claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and that "less than 1% of children treated with opioids become addicted."

290. Moreover, the *Policymaker's Guide* attempted to distract doctors from their patients' drug-seeking behavior by labeling it as pseudoaddiction, which, according to the guide, "describes patient behaviors that may occur when pain is undertreated." Like *Partners Against Pain, A Policymaker's Guide* noted that "[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." The similarity between these messages regarding pseudoaddiction highlights the common, concerted effort behind Purdue's deceptive statements.

291. The *Policymaker's Guide* further misrepresented the safety of increasing doses of opioids and deceptively minimized the risk of withdrawal. For example, the *Policymaker's Guide* claimed that "[s]ymptoms of physical dependence" on opioids in long-term patients "can often be ameliorated by gradually decreasing the dose of medication during discontinuation" while omitting the significant hardship that often accompanies cessation of use. Similarly, the *Policymaker's Guide* taught that even indefinite dose escalations are "sometimes necessary" to reach adequate levels of pain relief, but it completely omitted the safety risks associated with increased doses.

292. Purdue provided substantial assistance toward the creation and dissemination of the *Policymaker's Guide*, which APF ultimately disseminated on behalf of Defendants, including Purdue. Purdue provided $26,000 in grant money to fund the development and dissemination of its content. Purdue kept abreast of the content of the guide as it was being developed, and, based

on the periodic reports APF provided to Purdue regarding its progress on the *Policymaker's Guide*, had editorial input into its contents.

293. The *Policymaker's Guide* was posted online, and was available to and intended to reach St. Clair County and Illinois prescribers and consumers. As described below, the deceptive statements in *Policymaker's Guide* regarding addiction and functionality were the very same messages Purdue directed at Illinois and St. Clair County through its own sales force.

(c) *Treatment Options: A Guide for People Living with Pain*

294. Purdue's partnership with APF did not end with the *Policymaker's Guide*. Purdue also substantially assisted APF by sponsoring *Treatment Options: A Guide for People Living with Pain*, starting in 2007. Based on Purdue's control of other APF projects, Purdue also would have exercised control over *Treatment Options*.

295. *Treatment Options* is rife with misrepresentations regarding the safety and efficacy of opioids. For example, *Treatment Options* misrepresented that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids "give [pain patients] a quality of life [they] deserve."

296. Further, as outlined in greater detail herein, *Treatment Options* claimed that addiction is rare and, when it does occur, involves unauthorized dose escalations, patients who receive opioids from multiple doctors, or theft, which paints a narrow and misleading portrait of opioid addiction.

297. *Treatment Options* also promoted the use of opioids to treat long-term chronic pain by denigrating alternate treatments, most particularly NSAIDs. *Treatment Options* noted that NSAIDs can be dangerous at high does and inflated the number of deaths associated with NSAID use, and distinguished opioids as having less risk. According to *Treatment Options*,

NSAIDs were different from opioids because opioids had "no ceiling dose," which was beneficial since some patients "need" larger doses of painkillers than they are currently prescribed. *Treatment Options* warned that the risks associated with NSAID use increased if NSAIDs were "taken for more than a period of months," but deceptively omitted any similar warning about the risks associated with the long-term use of opioids.

298. *Treatment Options* was posted online and remains online today. It was available to and intended to reach Illinois prescribers and patients. As described below, the deceptive statements in *Treatment Options* regarding addiction and functionality echo the messages Purdue directed at Illinois through its own sales force.

(d) *Exit Wounds*

299. Purdue also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described in greater detail herein, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

300. Purdue provided APF with substantial assistance in distributing *Exit Wounds* in Illinois and throughout the nation by providing grant money and other resources.

301. By way of one example of intent to reach Illinois, APF mailed copies of *Exit Wounds* to the "Wounded Heroes Foundation" in Chicago.

ii. *Purdue's Work with Other Third Party Front Groups and KOLs*

302. Purdue also provided other third-party Front Groups with substantial assistance in issuing misleading statements regarding the risks, benefits, and superiority of opioids for the long-term treatment of chronic pain.

(a) *FSMB – Responsible Opioid Prescribing*

303. In 2007, Purdue sponsored FSMB's *Responsible Opioid Prescribing*, which, as described in greater detail herein, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* also was drafted by "Medical Writer X."

304. Purdue spent $150,000 to help FSMB distribute *Responsible Opioid Prescribing*. The book was distributed nationally, and was available to and intended to reach prescribers in Chicago, Illinois and St. Clair County.

(b) *AGS – Pharmacological Management of Persistent Pain in Older Persons*

305. Along with Janssen, Purdue worked with the AGS on a CME to promote the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. As discussed in greater detail herein, these guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse" when the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that "[a]ll patients with moderate to severe pain should be considered for opioid therapy (low quality of evidence, strong recommendations)."

306. Controversy surrounding earlier versions of AGS guidelines had taught AGS that accepting money directly from drug companies to fund the guidelines' development could lead to allegations of bias and "the appearance of conflict." Accordingly, AGS endeavored to eliminate "the root cause of that flack" by turning down commercial support to produce the 209 Guidelines. Having determined that its veneer of independence would be tarnished if it accepted drug company money to create the content, AGS decided to develop the guidelines itself and turn to the drug companies instead for funding to *distribute* the pro-drug company content once it had been created. As explained by AGS personnel, it was AGS's "strategy that we will take

commercial support to disseminate [the 2009 Guidelines] if such support is forthcoming." AGS knew that it would be difficult to find such support unless the report was viewed favorably by opioid makers.

307. AGS sought and obtained grants from Endo and Purdue to distribute *Pharmacological Management of Persistent Pain in Older Persons*. As a result, the publication was distributed nationally, and was available to and was intended to reach St. Clair County and Illinois prescribers. Indeed, internal documents of another opioid maker, Endo, indicate that pharmaceutical sales representatives employed by Purdue discussed treatment guidelines that minimized the risk of addiction to opioids with doctors during individual sales visits.[90]

(c) *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*

308. Purdue sponsored a 2012 CME program taught by Steven Stanos, a Chicago-based KOL, 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.

(d) *Managing Patient's Opioid Use: Balancing the Need and Risk*

309. Purdue also sponsored a 2011 CME taught by KOL Lynn Webster via webinar titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation likewise deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." At the time, Dr. Webster was

[90] As described in greater detail herein, Purdue also provided substantial support for the AAPM/APS guidelines. The 1997 AAPM and APS consensus statement *The Use of Opioids for the Treatment of Chronic Pain* was authored by one of its paid speakers, and 14 out of 21 panel members who drafted the AAPM/APS Guidelines received support from Defendants Janssen, Cephalon, Endo, and Purdue.

receiving significant funding from Purdue. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Purdue (and other opioid makers). The webinar was available to and was intended to reach Illinois prescribers.

(e) *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*

310. Purdue also sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. *Path of the Patient* is devoted entirely to treating chronic pain with opioids. Although the program purports to instruct a treating physician how to manage chronic pain in younger adults at risk for abuse, it does no such thing. This "educational" program, addressing treatment of a population known to be particularly susceptible to opioid addiction, presents none of the alternative treatment options available, but only discusses treatment of chronic pain with opioids.

311. In a role-play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of drug and alcohol abuse. Despite these facts, the narrator notes that, because of a condition known as "pseudoaddiction," the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role play treats this patient by prescribing a high-dose, long-acting opioid. This CME was available online and was intended to reach Illinois prescribers.

(f) *Overview of Management Options*

312. Purdue also sponsored a CME titled *Overview of Management Options* and issued by the American Medical Association in 2003, 2007, and 2013 (the latter of which is still available for CME credit). The CME was edited by KOL Russell Portenoy, among others. It

deceptively instructed physicians that NSAIDS and other drugs, but not opioids, are unsafe at high doses. In fact, the data indicates that patients on high doses of opioids are more likely to experience adverse outcomes than patients on lower doses of the drugs. Dr. Portenoy received research support, consulting fees, and honoraria from Purdue (among others), and was a paid Purdue consultant. This CME was presented online in the United States and was available to Illinois prescribers.

iii. *Purdue's Misleading Science*

313. Purdue also misrepresented the risks associated with long-term opioid use by promoting scientific studies in a deceptive way. In 1998, Purdue funded two articles by Dr. Lawrence Robbins in Chicago, which showed that between 8% and 13% of the patients he studied became addicted to opioids—a troubling statistic for Purdue, whose market, and marketing, depended upon the claim that opioids were rarely addictive.[91] Purdue had these articles placed in headache-specific journals, where they would be less likely to be encountered by pain specialists or general practitioners. The first of these articles has been cited a mere 16 times; the second does not even appear on Google scholar. Five years later, Purdue also funded a study of OxyContin in diabetic neuropathy patients, which was published in 2003. Notwithstanding that Purdue-funded studies, testing Purdue's own drugs, had previously indicated that addiction rates were between 8% and 13%, Purdue's 2003 article reached back to the 1980 Porter-Jick Letter to support its claim that OxyContin was not commonly addictive. This article was placed in a prominent pain journal and has been cited 487 times.[92] While this

[91] Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Q. 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Q. 305 (1999).

[92] C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy*, 105 Pain 71 (2003).

article was drafted over a decade ago, it continues to be relied upon to further the misrepresentations that opioids are not addictive.

c. Purdue's Deceptive Statements to Illinois Prescribers and Patients

314. Purdue directed the dissemination of the misstatements described above to Illinois patients and prescribers through the Front Groups, KOLs, and publications described above, as well as through its substantial sales force in Illinois and through advertisements in prominent medical journals. The deceptive statements distributed through each of these channels reflect a common theme of misrepresenting the benefits of Purdue's opioids, unfairly portraying the risks of addiction associated with their use, and deceptively implying that they would improve patients' ability to function.

315. The deceptive message that OxyContin provided 12 hours of pain relief not only was available to and intended to reach Illinois prescribers through nationally circulated advertising, but also was carried directly into the offices of Illinois doctors by Purdue's sales representatives. For example, according to the complaint filed by the City of Chicago, Chicago Prescriber DD reported being told by a Purdue sales representative that OxyContin would provide his patients with 12 hours of pain relief.

316. Likewise, the deceptive messages minimizing addiction were not only directed at Illinois patients and prescribers through the publications circulated above, but also were disseminated directly by Purdue's sales force. For example, again according to the City of Chicago's complaint, Chicago Prescribers B, EE, F, D, E, and Q all received messages and/or omissions regarding addiction and potential for abuse from Purdue sales representatives that were deceptive.

317. Purdue also used its sales force to disseminate misleading statements about the ability of opioids to improve functionality. According to the complaint filed by the City of Chicago, Chicago Prescribers B, C, and S all reported being told by Purdue sales representatives that opioids improve function.

318. The experiences of specific prescribers confirm both that Purdue's national marketing campaign included the misrepresentations described in greater detail herein, and that the company disseminated these same misrepresentations to Illinois prescribers and consumers. In particular, these prescriber accounts reflect that Purdue detailers omitted or minimized the risk of opioid addiction; claimed that Purdue's drugs would be less problematic for patients because they had extended release mechanisms, were tamper proof, and were "steady state"; claimed that OxyContin would provide 12 hours of pain relief; represented that screening tools could help manage the risk of addiction; minimized the symptoms of withdrawal; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

319. A survey of a sample of Midwestern physicians, who reported the messages that they retained from detailing visits and other promotional activity, documented that Purdue sales representatives promoted OxyContin as being effective for a full 12 hours at least between 2008 and 2012. Purdue sales representatives also promoted OxyContin as improving patients' sleep (an unsubstantiated functional improvement) to a Midwestern orthopedic surgeon in 2006 and to a physicians' assistant in 2013. Purdue sales representatives also told Midwestern internists that the reformulation of OxyContin prevented illegal drug use and that the formulation was "less addicting," rather than being harder to adulterate. Purdue sales representatives also claimed in

2011 that the sustained-release property of OxyContin reduced patient "buzz," which is neither based on scientific evidence nor true.

320. The same survey indicated that Purdue sales representatives promoted its Schedule III opioid Butrans as having low or little abuse potential. Other misrepresentations regarding Butrans include telling a Midwestern ear-nose-throat doctor in 2012 that Butrans had a "ceiling effect," reducing its abuse potential and telling a general practitioner that Butrans was "essentially tamperproof," even though there is nothing in the label to support such claims.

321. In addition, according to the complaint filed by the City of Chicago, the City of Chicago interviewed a number of Chicago-area prescribers who reported that they were detailed by Purdue sales representatives and heard similar claims, as well as other messages described in greater detail herein. In each instance, Purdue intended that the prescriber rely on these messages. Most of these physicians did, in fact, prescribe Purdue's opioids. For example:

a. Chicago Prescriber B, an anesthesiologist, sees opioid drug company representatives on a regular basis. Purdue representatives have detailed him on OxyContin, Hysingla, and Butrans. About a year ago, these representatives pushed the message that "steady-state" extended release drugs have less potential for abuse. Opioid manufacturers, including Purdue, told him that opioids improve patient function and quality of life. Prescriber B relies on the information he receives from drug company representatives because he does not have time to conduct the research himself.

b. Chicago Prescriber P recalled attending *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes* and *Managing Patient's Opioid Use: Balancing the Need and Risk*, Purdue-sponsored CMEs that are described in greater detail herein.

c. Chicago Prescriber C, a pain specialist, is based in Wisconsin but treats Chicago residents. In their meetings with him, sales representatives from each Defendant, including Purdue, routinely omitted any discussion about addiction and overdose death and frequently overstated the benefits of opioids. These

representatives taught that opioids would increase his patients' ability to function and increase their quality of life. He has prescribed OxyContin.

d. Chicago Prescriber S, a nurse practitioner who is based in Indiana but prescribed opioids to a number of City of Chicago employees, recalls being visited by drug representatives detailing OxyContin and Butrans. These representatives emphasized that opioids could help her patients regain function by becoming more physically active and returning to work.

e. Chicago Prescriber F, a headache specialist, reported being detailed by Purdue representatives on OxyContin—primarily between 1997 and 2002, but also since then. He recalls being told that OxyContin was less addicting than other opioids. Prescriber F explained that Purdue representatives now mislead doctors by active omission rather than through aggressive misrepresentations made previously.

f. Chicago Prescriber D was visited by opioid sales representatives from Purdue, Endo, Janssen, and Actavis. He relied on the representations made by these sales representatives and, in the past, had not comprehended the true addictive potential of opioids. Representatives from each of these companies told Prescriber X that their drugs were "steady state," which he interpreted to mean that they were less addictive.

g. Chicago Prescriber G indicated that he was visited by sales representatives from all Defendants, including Purdue. He recalls that he was never told about the risk of addiction. According to Prescriber G, opioid sales representatives—including those employed by Purdue—told him that opioids would increase patients' ability to complete activities of daily living and that patients could be managed to avoid addiction. Purdue's sales representatives told him that patients can be screened to address addiction risks, and provided him with a "pain questionnaire" from *Partners Against Pain* for use in screening potential opioid patients. Purdue sales representatives also told Prescriber G that OxyContin provided patients with 12 hours of pain relief.

h. Chicago Prescriber E, an anesthesiologist and pain specialist, explained that he received visits from sales representatives from all Defendants, including Defendant Purdue, until a few years ago. Other than to promote long-acting, "steady-state" opioids as

having less potential for abuse, representatives from Purdue did not discuss addiction with him.

i. Chicago Prescriber DD was visited by sales representatives from Purdue, who informed him that OxyContin would provide his patients with 12 hours of pain relief.

j. Chicago Prescriber O recalled a CME "similar" to *Chronic Pain Management and Opioid Use*, which was held on or around October 11, 2012 and attended *Managing Patient's Opioid Use: Balancing the Need and Risk*, which was held on or around September 22, 2011, both of which are described in greater detail herein.

k. Chicago Prescriber GG indicated that he was visited by sales representatives from Purdue. These sales representatives told Prescriber GG that Butrans would improve his patients' ability to function. They also explained that screening tools can be used to select patients appropriate for opioid therapy and manage addiction.

l. Chicago Prescriber J, a nurse practitioner, indicated that she was visited (or sat in on visits) by sales representatives from Purdue, Cephalon, Janssen, and Actavis. These drug representatives, including from Defendant Purdue, never mentioned the risks of addiction associated with opioid use. Prescriber J also recalls sales representatives from Defendant Purdue explaining that Butrans has less abuse potential than other drugs because, after a certain point, the patient no longer experiences a better "buzz" from increased doses and that OxyContin as less likely to be abused because it could not be liquefied or injected when crushed. Purdue sales representatives also told Prescriber J that their drugs were "steady state."

m. Chicago Prescriber Z, a pain specialist, indicated that he was visited by sales representatives from Defendants Purdue and Janssen. These sales representatives never discussed the risks of addiction associated with their opioids, and they frequently referenced studies their company had sponsored.

n. Chicago Prescriber HH indicated that he was visited by sales representatives from Purdue. Prescriber HH explained that the sales representatives never discussed the side effects or adverse effects of their opioids. He has also been told by drug representatives, including Purdue's, that the effects of withdrawal from opioid use can be successfully managed.

Purdue's sales representatives also told Prescriber HH that Purdue's reformulated oxycodone—Hysingla—is long acting, has fewer "peaks and troughs," and is less likely to lead to euphoria than other opioids. Prescriber HH also was familiar with Purdue's claims that OxyContin has "true 12 hour dosing," and noted that short acting opioids are often prescribed to handle patients' pain once the 12 hour dose prematurely wears off.

o. Chicago Prescriber T indicated that he was visited by sales representatives from Purdue, Endo, and Janssen. Purdue's sales representatives told Prescriber T that Butrans was a weak opioid with lower risks of withdrawal and pseudoaddiction. These sales representatives also told him that the potential for withdrawal on Butrans was very low due to its low potency and extended release mechanism. Purdue took Prescriber T's entire class out to dinner when they finished their fellowships, and, during this dinner, a speaker recommended Butrans as a "reasonable drug."

p. Chicago Prescriber QQ, a Chicago-area anesthesiologist, has met with representatives from Defendant Purdue within the last five years. He recalls having numerous discussions with Purdue representatives in which he was told that OxyContin provides 12 hours of pain relief.

q. Chicago Prescriber Q recalls being visited by representatives from Purdue, Endo, and Cephalon. Prescriber Q indicated that none of the representatives discussed abuse, addiction, or overdose, which are not part of the sales conversation.

322. These accounts reported by physicians to City of Chicago investigators reflect specific examples of instances in which Purdue's (and Abbott's) sales representatives made the misrepresentations outlined in greater detail herein directly to Chicago prescribers. Based on the nationwide and uniform character of Purdue's marketing campaign, these examples support the inference that Purdue sales representatives made similar misstatements to the other Illinois and St. Clair County prescribers they detailed.

323. Like the other Defendants, Purdue also promoted its opioids through a network of recruited, paid speakers. Prescriber G above was not only a prescriber of Purdue's opioids, he was also a paid speaker for Purdue. He attended Purdue's speaker training in Florida, and he

received visits from a Purdue regional supervisor, who came to his office and asked him to do a practice run through the Purdue-approved slide deck. According to the City of Chicago's complaint, Chicago Prescriber G was required to stick to the company-approved messaging during his speaking engagements. Chicago Prescriber G characterized this district manager as a mercenary who would do whatever it took to sell Purdue's drug and told Chicago Prescriber G that Purdue would spare no expense in furtherance of that goal.

2. Abbott

324. Abbott was a much larger company than Purdue when the two joined forces in 1996 and entered a co-promotion agreement for OxyContin. Abbott had a sales force entrenched in hospitals and surgical centers with existing relationships with all the people: anesthesiologists, emergency room doctors, surgeons, and pain management teams.

325. Abbott devoted at least 300 sales reps to OxyContin sales which was approximately the same number of people Purdue initially dedicated to the drug.

326. Abbott actively marketed OxyContin from 1996 through 2002 then continued to participate with Purdue through 2006. With Abbott's help, sales of OxyContin went from $49 million in its first full year on the market to $1.6 billion in 2002. Over the life of the agreement, Abbott was paid hundreds of millions of dollars.

327. Abbott heavily incentivized its sales staff to push OxyContin, offering $20,000 cash prizes and luxury vacations to top performers. The company used Middle Age Crusade terminology: Sales reps were called "royal crusaders" and "knights" in internal documents and they were supervised by the "Royal Court of OxyContin", executives referred to in memos as the "Wizard of OxyContin", "Supreme Sovereign of Pain Management" and the "Empress of Analgesia". The head of pain care sales, Jerry Eichhorn, was the "King of Pain" and signed

memos simply "King". According to one Abbott memo, sales staff were urged forward: "As you continue to carry the OxyContin banner onto the field of battle, it's important to keep highlighting OxyContin benefits to your doctors."

328. In another Abbott memo, sales staff were instructed that if a doctor was concerned about the euphoria a patient was experiencing on the shorter-acting painkiller Vicodin, they should tell the physician, "OxyContin has fewer such effects." Yet another Abbott memo told reps to highlight the "less abuse/addiction potential" of OxyContin which could be taken just twice a day because of its time-release formulation. Reps were also trained to discussed potential abuse with doctors only if they brought it up and to tell physicians that "street users" were misusing the drug not "true pain patients."

329. Abbott utilized many of the same techniques as Purdue with direct-to-physician marketing including food, gifts, and influence peddling, techniques which netted Abbott a huge portion of profits from opioid sales in St. Clair County and Illinois. The sales forces of Abbott and Purdue worked in tandem, holding regular strategy sessions, alternating meeting locations between Purdue's Connecticut headquarters and Abbott's corporate offices in Illinois.

F. The Result of Defendants' Fraudulent Scheme

330. Through their direct promotional efforts, along with those of the third-part Front Groups and KOLs they assisted and controlled, and whose seemingly objective materials they distributed, the Defendants accomplished exactly what they set out to do: change the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain. As a result, Illinois and St. Clair County doctors began

prescribing opioids long-term to treat chronic pain—something most would never have considered prior to the Defendants' campaign.

331. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain. As outlined below, the impact of the Defendants' deceptive marketing on doctors' prescribing and patients' use of opioids is evidenced by: (a) the increase in opioid prescribing nationally and locally in concert with the Defendants' marketing; (b) St. Clair County's own increased spending on opioids resulting from the Defendants promotional spending; (c) the City of Chicago's interviews with Chicago prescribers, who confirmed that they prescribed opioids based on deceptive marketing, patients' demand, and/or to continue opioids therapy begun by other doctors; and (d) the consequences of opioid prescription—including addiction, overdose, and death—that have been visited on St. Clair County, Illinois and its residents, as confirmed by interviews with victims and addiction treatment programs.

1. The Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to St. Clair County and Illinois.

332. In the first instance, St. Clair County was damaged directly, through its payments of false claims for chronic opioid therapy by (a) its self-insured health care plans and (b) its workers' compensation program. For example, St. Clair County's self-insured health plan made payments for opioids totaling $51,751.53 in 2016 alone. This represents only direct payments by the plan for opioids, not any of the payments for opioid-related injury, treatment or death.

333. The Defendants' marketing of opioids caused health care providers to prescribe and St. Clair County, through its health plans and workers' compensation program, to pay for prescriptions of opioids to treat chronic pain. Because of the Defendants' unbranded marketing, health care providers wrote and St. Clair County paid for prescriptions of opioids for chronic

pain that were filled not only with their drugs, but with opioids sold by other manufacturers. All of these prescriptions were caused by Defendants' fraudulent marketing and therefore all of them constitute false claims. Because, as laid out below, St. Clair County is obligated to cover medically necessary and reasonably required care, it had no choice but to pay these false and fraudulent claims.

334. The fact that St. Clair County would pay for these ineligible prescriptions is both the foreseeable and intended consequence of the Defendants' fraudulent marketing scheme. The Defendants set out to change the medical and general consensus supporting chronic opioid therapy *so that* doctors would prescribe and government payors, such as St. Clair County, would pay for long-term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

a. Increase in Opioid Prescribing Nationally

335. Defendants' scheme to change the medical consensus regarding opioid therapy for chronic pain worked. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide. During 2009, they provided 83 million more.

336. Opioid prescriptions increased even as the percentage of patients visiting the doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[93]

[93] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care 870 (2013).

337. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids. Indeed, "[o]pioids are the most common means of treatment for chronic pain."[94] From 1980 to 2000, opioid prescriptions for chronic pain visits doubled. This is the result not of an epidemic of pain, but an epidemic of prescribing. A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010—even though the number of office visits in which patients complained of pain did not change and prescribing of non-opioid pain medications ***decreased***. For back pain alone—one of the most common chronic pain conditions—the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs, or acetaminophen declined and referrals to physical therapy remained steady—and climbing.

338. This increase corresponds with, and was caused by, the Defendants' massive marketing push. The industry's spending nationwide on marketing of opioids stood at more than $20 million per quarter and $91 million annually in 2000. By 2011, that figure hit its peak of more than $70 million per quarter and $288 million annually, a more than three-fold increase. By 2014, the figures dropped to roughly $45 million per quarter and $182 million annually, as the Defendants confronted increased concern regarding opioid addiction, abuse, and diversion. Even so, the Defendants still spend double what they spent in 2000 on opioid marketing.

339. By far the largest component of this spending was opioid drug makers' detailing visits to individual doctors, with total detailing expenditures more than doubling between 2000 and 2014 and now standing at $168 million annually.

b. <u>St. Clair County's Increased Spending on Opioids</u>

[94] Deborah Grady et al., *Opioids for Chronic Pain*, 171(16) Arch. Intern. Med. 1426 (2011).

340. Commensurate with the Defendants' heavy promotion of opioids and the resultant, massive upswing in prescribing of opioids nationally, St. Clair County has seen its own spending on opioids—through claims paid by its health care plans and workers' compensation program—increase dramatically.

i. *Health Care Plans*

341. St. Clair County provides comprehensive health care benefits, including prescription drugs coverage, to its employees and retirees. These benefits are provided under one health plan that St. Clair County self-insures, including a preferred provider organization ("PPO") for employees, among other benefits for retirees.

342. The prescription drug plan under the PPO is self-insured: the costs of prescription drugs are paid directly by St. Clair County.

343. Throughout the relevant time period for this action, the PPO's prescription drug costs have been paid by St. Clair County.

344. Doctors submit claims directly to St. Clair County's applicable health plan, in this instance, UMR, for their costs associated with prescribing opioids, including office visits and toxicology screens for patients' prescribed opioids. In addition, prescriptions for opioids written by these doctors for patients covered by St. Clair County's self-insured health plans are filled by pharmacies, which submit claims for reimbursement to St. Clair County's pharmacy benefit manager, OptumRx.

345. St. Clair County's applicable health plans provide benefits for all "medically necessary" services associated with opioids, including treatment related to any adverse outcomes from chronic opioid therapy, such as overdose or addiction treatment.

346. The Defendants caused doctors and pharmacies to submit, and St. Clair County to pay, claims to its health plans that were false by: (a) causing doctors to write prescriptions for chronic opioid therapy based on deceptive representations regarding the risks, benefits, and superiority of those drugs; (b) causing doctors to certify that these prescriptions and associated services were medically necessary; (c) causing claims to be submitted for drugs that were promoted for off-label uses and misbranded, and therefore not FDA-approved; and (d) distorting the standard of care for treatment of chronic pain so that doctors would feel not only that it was appropriate, but required, that they prescribe and continue prescriptions for opioids long-term to treat chronic pain. Each—or any—of these factors made claims to St. Clair County for chronic opioid therapy false.

347. St. Clair County's self-insured health plans only cover the cost of prescription drugs that are medically necessary and dispensed for a FDA-approved purpose. Prescription drugs that are not medically necessary or that are dispensed for a non-FDA approved purpose are expressly excluded from coverage under St. Clair County's plans. Generally under any PPO plan, a medically necessary prescription is one which is "customary for the treatment or diagnosis of an Illness or Injury, and is consistent with generally accepted medical standards."

348. Doctors who care for St. Clair County employees and retirees and their dependents are bound by the provider agreements that entitle them to participate in St. Clair County's health plans. These agreements generally permit doctors to charge only for treatments that are medically necessary: treatments prescribed "in accordance with generally accepted standards of medical practice," and "clinically appropriate . . . and considered effective for the patient's illness, injury or disease." "Generally accepted standards of medical practice" are defined in the agreement as standards "based on credible scientific evidence."

349. St. Clair County is obligated to pay for the medically necessary treatment of covered employees.

350. In prescribing opioids for chronic pain, doctors certify that the treatment is medically necessary and the drugs dispensed for an FDA approved purpose, and—at least with respect to the self-insured plans (the PPO)—the health plans authorize payment from St. Clair County funds.

351. As described above, the use of opioids to treat chronic pain is not "in accordance with generally accepted standards of medical practice" nor "clinically appropriate . . . and considered effective for the patient's illness, injury or disease."

352. Further, the Defendants' deceptive marketing rendered opioids misbranded as prescribed for chronic pain because they were false and misleading and because, by minimizing the risks associated with the drugs, they did not contain adequate directions for use. The written, printed, or graphic matter accompanying the Defendants' drugs did not accurately describe the risks associated with long-term use of their products, rendering them misbranded. Due to this misbranding, the Defendants' opioids were not FDA-approved, within the meaning of the St. Clair County's health plans, for the long-term treatment of chronic pain.

353. For each and all of the reasons above, chronic opioid therapy and its attendant and consequential costs are not eligible for reimbursement through St. Clair County's health plan. St. Clair County would not have knowingly reimbursed claims for prescription drugs that were not eligible for coverage.

354. As a result of the Defendants' deceptive marketing, St. Clair County patients who used opioids long-term to treat chronic pain also incurred additional costs and suffered additional injuries requiring care, including doctors' visits, toxicology screens, hospitalization for

overdoses, treatment and other adverse effects of opioids, and long-term disability, among others, which caused St. Clair County's to incur additional costs.

355. In 2016 alone, based on a preliminary review, St. Clair County spent approximately $40,905.11 for 1,492 prescriptions for opioids. This does not include any other costs, such as doctor visits, which would also be included with these prescriptions. This includes approximately $16,053,62 for Purdue Schedule II and III opioids. The balance includes prescriptions that also were caused by Defendants' deceptive marketing, including prescriptions for Defendants' generic opioid products and prescriptions for opioids from other manufacturers. These figures do not reflect the cost to the County of prescribing opioids, such as doctors' visits or toxicology screens, or the costs of treating the adverse effects of prescribing opioids long-term, such as overdose and addiction. They also do not reflect the total damages for all years to St. Clair County, which will be determined at trial, and which will include costs to the health plan for the treatment of opioid abuse and dependency.

356. The claims—and the attendant and consequential costs—for opioids prescribed for chronic pain, as opposed to acute and cancer or end-of-life pain, were ineligible for payment and the result of the Defendants' deceptive and unfair conduct.

ii. *Workers' Compensation Program*

357. St. Clair County, through a partially self-insured program, provides workers' compensation, including prescription drug benefits, to eligible employees injured in the course of their employment. When an employee is injured on the job, he or she may file a claim for workers' compensation, if the injury is deemed work-related, St. Clair County is responsible for paying its share of the employee's medical costs and lost wages.

358. St. Clair County uses IPMG, a medical management vendor, to help manage medical benefits under the workers' compensation program. Doctors submit claims to St. Clair County's workers' compensation program for the costs associated with prescribing opioids, including office visits and toxicology screens for patients prescribed opioids. Upon information and belief, IPMG uses ClaimsOne as the pharmacy and drug utilization management program to manage prescriptions for St. Clair County 's workers' compensation program.

359. St. Clair County's workers' compensation program covers all costs associated with opioids, including treatment related to any adverse outcomes from chronic opioid therapy, such as addiction treatment.

360. The Defendants caused doctors and pharmacies to submit, and St. Clair County to pay claims to its workers' compensation program that were false by: (a) causing doctors to write prescriptions for chronic opioid therapy based on deceptive representations regarding the risks, benefits, and superiority of those drugs; (b) causing doctors to certify that these prescriptions and associated services were "[m]edically appropriate, so that expected health benefits (such as, but not limited to, increased life expectancy, improved functional capacity, prevention of complications, relief of pain) materially exceed the expected health risks" or "reasonably required to cure . . . the effects of [an] accidental injury"; and (c) distorting the standard of care for treatment of chronic pain so that doctors would feel not only that it was appropriate, but required, that they prescribe opioids long-term to treat chronic pain. Each—or any—of these factors made claim to St. Clair County for chronic opioid therapy false.

361. The Illinois Workers' Compensation Act requires employers to pay for "all the necessary first aid, medical and surgical services, and all necessary medical, surgical and hospital

services thereafter incurred, limited, however, to that which is reasonably required to cure or relieve from the effects of the accidental injury." 820 ILCS 305/8(a).

362. In prescribing opioids for chronic pain, doctors certify that the treatment is medically necessary and reasonably required, and the workers' compensation program authorizes payment from St. Clair County funds.

363. St. Clair County's workers' compensation program is obligated to cover all "medically necessary" and "reasonably required" treatment arising from a compensable work-related injury.

364. As described above, however, the use of opioids to treat chronic pain is not medically necessary or reasonably required in that their risks do not materially exceed their benefits; they do not improve physiological function; and their use is not consistent with guidelines that are *scientifically based* (as opposed to marketing-driven).

365. Nevertheless, the amount of such prescriptions paid by worker's compensation programs is monumental. A study by the National Council on Compensation Insurance ("NCCI") concluded that, in 2011, approximately 38% of pharmacy costs in workers' compensation are for opioids and opioid combinations, amounting to approximately $1.4 billion.

366. Upon information and belief, those trends are reflected in St. Clair County's experience with paying for opioids through its worker's compensation plan.

367. Upon information and belief, data for 2016 shows that the St. Clair County worker's compensation plan spent over thirteen-thousand ($13,000) dollars on opiates in 2016 alone. These figures do not reflect the cost to the County of prescribing opioids, such as doctors' visits or toxicology screens, or the costs of treating the adverse effects of prescribing opioids long-term, such as overdose and addiction.

368. However, the costs of long-term opioid use are not limited to costs of opioid prescriptions. Long-term opioid use is accompanied by a host of consequential costs, including costs related to abuse, addiction, and death.

369. These claims—and their attendant and consequential costs—for opioids prescribed for chronic pain, as opposed to acute and cancer or end-of-life pain, were ineligible for payment and the result of the Defendants' fraudulent scheme.

iii. *St. Clair County's Increased Costs Correlate With the Defendants' Promotion.*

370. Upon information and belief, a review of St. Clair County's costs related to opioid prescriptions, and the costs associated with those prescriptions, will show that as the Defendants spent more to promote their drugs, doctors began prescribing them more often and as a result, the costs to St. Clair County went up.

371. This trend is reflected by an expert analysis performed for the City of Chicago for their complaint using data on Defendants' promotional spending. That analysis showed that spending had a direct impact on opioid use (and its consequences in abuse, addiction, and overdose) in Chicago. Upon information and belief, that same trend occurred throughout Illinois and St. Clair County.

372. It is also distressing (and a sign of further problems ahead) that the drop in opioid prescribing beginning in 2014 has been accompanied by a corresponding increase in the Defendants' promotional spending, which is headed towards a new high, despite evidence of the grave toll that opioids are taking on law enforcement, public health, and individual lives.

c. <u>City of Chicago Interviews with Chicago Prescribers</u>

373. According to the City of Chicago complaint, the connection between the Defendants' marketing and opioid prescribing is confirmed both by documents provided by

Defendants, which begin to describe their efforts to train, target, market to, and track Chicago prescribers, and by the City's interviews with many of these doctors.

374. As described above, the Defendants' marketing in Chicago, and throughout Illinois and St. Clair County, took varied forms. The Defendants heavily relief on speakers bureau programs, in which physicians received very prescriptive training—including slide decks and scripts to which they were expected to adhere—and then were paid to speak to other physicians at Defendant-funded events.

375. Those speakers identified by the City of Chicago responded to the Defendants' marketing by prescribing opioids, comprising 7,480 prescriptions, representing $1.36 million, written by these physicians and paid for by the City of Chicago's health plans in the period June 1, 2005 – June 28, 2015, which was roughly 10% of the City of Chicago health plans' total opioid spending.[95]

376. But the true value of these speakers was as a force multiplier, generating prescriptions by passing on the Defendants' biased messages supporting opioid treatment for chronic pain, with the misrepresentations contained in their scripts, to the speakers' peers.

377. The Defendants also targeted Illinois prescribers and potential prescribers for visits by the companies' sales representatives. As described in greater detail herein, the Defendants carefully tracked the prescribing behavior of prescribers, targeting them by specialty, prescribing volume, and other criteria. Upon information and belief, these physicians, many of whom were visited numerous times, responded to the marketing pitches by prescribing the Defendants' opioids.

[95] These speakers bureau members were three times more likely to prescribe branded drugs, which were the subject of the Pharma Defendants' speaking programs, than the other prescribers in the City of Chicago health plans' data.

378. Also as noted, the City of Chicago interviewed numerous Chicago doctors who prescribed opioids for chronic pain to Chicago consumers and employees, and these interviews confirmed the influence of the Defendants' deceptive marketing in this State. These doctors relied on treatment guidelines or scientific articles, attended CMEs, were visited by drug representatives, and were trained by doctors who provided the Defendants' deceptive messages. These doctors explained that: (a) many of their chronic pain patients became addicted to opioids; (b) they frequently had to prescribe opioids for months—or longer—solely to taper addicted chronic pain patients from the drugs; (c) few of their patients were advised or aware of the risks of addiction from long-term use of opioids; and (d) based on their own experience, they now regard opioids as inappropriate for chronic pain, largely because of the incidence of addiction, the lack of efficacy of opioids over time and without escalating doses, and other adverse effects, like hyperalgesia. The City of Chicago, as part of interviews conducted with prescribers, found that the Defendants' deceptive marketing had a profound effect on prescribers, which, upon information and belief also affected St. Clair County prescribers.

379. According to the City of Chicago, Chicago Prescriber B, an anesthesiologist, has used many of the major brands and types of opioids, including those marketed by Actavis, Endo, Janssen and Purdue. As noted herein in greater detail, Prescriber B reported that he talked with opioids manufacturers' sales representatives on a regular basis and that he has met with detailers from Actavis, Endo, Janssen, and Purdue.

380. Prescriber B also has attended, and continues to attend, drug company-sponsored CMEs on the use of opioids. He knows that the programs may be biased, but he relies on the information because he has no time to research the issue on his own. Prescriber B indicated he

was most likely to trust information presented in CMEs by other physicians, even where he knew those CMEs were sponsored by drug companies.

381. Prescriber B has reigned in his opioid prescribing in recent years because of the problems he has seen related to abuse and addiction. Knowing what he knows now, he would have prescribed fewer opioids in the past. He feels he did not previously have complete information about the risks and benefits of opioids.

382. According to the City of Chicago investigation, Chicago Prescriber D is a family care physician in Melrose Park, Illinois. He has met with sales representatives from Actavis, Endo, and Purdue. Representatives from all of these companies said that their products were "steady state" drugs without peaks and troughs, which he interpreted to mean that the drugs were less likely to be addictive. The sales representatives did not typically bring up addiction other than to represent that there is a lower addiction risk with long-acting opioids.

383. Prescriber D indicated he has relied on sales representatives and the information they provide. In the past, his understanding was that long-acting opioids were less addictive. He did not comprehend how addictive opioids could be, but he came to that knowledge over time as he experienced it in his practice. He believes sales representatives should be more up front about opioid addiction.

384. According to the City of Chicago complaint, Chicago Prescriber RR specializes in internal medicine at the University of Illinois Hospital and Health Sciences System (located in Chicago) and regularly treats pain patients. He explained that most of the patients for whom he prescribed opioids complained of chronic pain in their lower back or, less frequently, osteoarthritis. He noted that many patients seeking treatment for pain were already prescribed

opioids prescribed by another doctor, typically their primary care physician. He noted, further, that many of the patients he followed had taken opioids for more than a year.

385. Though Prescriber RR observed that most patients eventually begin to self-escalate their dose, and then seek early refills—a sign of addiction—he explained that he learned through medical school and in his early residency that opioids were safer than NSAIDs and more effective. Prescriber RR described this view as engrained in the curriculum.

386. Based on his own clinical experience and research, Prescriber RR does not now believe that opioids are medically appropriate for chronic pain as a first-line treatment, but reluctantly prescribes opioids to patients to try to taper them off the drugs. Prescriber RR described opioids as almost always requiring escalating doses. He further noted that it is very hard to end opioid therapy. Even successful weaning takes six months to a year, depending on how long the patient was on the drugs.

387. Prescriber RR noted further that one of the dangers of opioids, beyond the risk of addiction, is that they distract from other, more successful treatments, such as physical therapy, weight loss, or treatment for mental health issues.

388. According to the City of Chicago complaint, Chicago Prescriber SS, a physician who has worked with veterans seeking treatment for pain, indicated that he unfortunately prescribes opioids for chronic pain. He explained, based on his clinical experience and observations, that opioids are taken for much longer than is safe or necessary. Prescriber SS based his opinion on the fact that patients—even if they had no intention to abuse the drug—often become so tolerant and dependent that it is difficult to stop using the drugs. Prescriber SS has prescribed opioids that he would not have prescribed but for the fact that patients become addicted through chronic opioid therapy and thus need to be tapered off the drug.

389. As a result of the Defendants' conduct, Prescriber SS previously learned that opioids are the most appropriate treatment for chronic pain. He also observed other providers using opioids for chronic pain and found support for their opioid use in medical literature he had read. He also specifically pointed to the AAPM/APS Guidelines as one source of his support for his opinions about opioids. These guidelines, Prescriber SS explained, made him more willing to prescribe opioids for chronic pain; as he explained, doctors want to know what others are doing and that there is science behind the practice. He also noted, generally, that professional organizations promoted opioids to treat chronic pain.

390. More recently, the prevalence of opioid abuse and addiction changed Prescriber SS's views on the use of opioids. He explained that the institution at which he works has similarly experienced a change in practice as to the proper way to treat chronic pain. He also observed that doctors often feel their hands are tied because their patients come to them already on opioids for chronic pain.

391. The influence of the Defendants' deceptive marketing in Chicago and throughout Illinois extends far beyond the physicians who were detailed by Defendants' sales representatives or attended their talks or CMEs, however. The Defendants' campaign to change the medical and public perception of opioids resulted in health care providers writing opioid prescriptions to treat chronic pain even though they never were direct targets of the Defendants' deceptive marketing. They prescribed these drugs because it was the new normal—their patients demanded them, and their colleagues prescribed them, and the medical profession more generally had adopted the Defendants' message that the appropriate treatment of pain required such drugs. Even some who were more circumspect about prescribing opioids for chronic pain

ended up doing so because they had patients who were addicted or they wished to avoid conflict with patients who requested them.

392. As evidence of how this process worked, the City of Chicago interviewed physicians who had not been detailed by the Defendants' representatives. Upon information and belief, similar patterns are present throughout Illinois and St. Clair County.

393. According to the City of Chicago complaint, Chicago Prescriber JJ, a family practice physician, does not recall being exposed to opioid marketing but does prescribe the drugs. In the past, she prescribed opioids primarily to treat acute pain. More and more, however, she uses opioids—generally hydrocodone with Tylenol, and also OxyContin—for the treatment of chronic pain associated with non-terminal illnesses. Recently, she has been uncomfortable with the amount of opioid prescriptions she writes. Prescriber JJ has become aware of heightened concerns about opioid addiction and the risk of overdose. She believes there is an epidemic of pain medication, and is worried she may be contributing to this epidemic.

394. According to the City of Chicago complaint, Chicago Prescriber KK, who practices internal and geriatric medicine, "unfortunately" prescribes opioids. He has not attended a pain CME, unless it was part of a larger internal medicine or primary care presentation, and sales representatives are not permitted in his building. However, he has patients who became addicted to opioids, and he does prescribe opioids to this population. He has patients who have been on OxyContin for more than a year and are "going nowhere but up"; some of his patients take opioids "like candy." He believes doctors in general, responding to a message that patients should experience no pain, have gone overboard in using opioids.

395. According to the City of Chicago complaint, Chicago Prescriber LL, an internist, does not attend drug company CMEs and does not receive any sales representatives at his office.

Nevertheless, his practice has been "inundated" with patients who started elsewhere on prescription opioids to treat chronic pain and are now addicted. Patients "just come in asking for opioids." He has seen in his health center that it is very difficult to break these patients' habits, an effort that is the source of arguments between patients and physicians. Two years ago he instituted a "chronic pain contract," requiring patients to do more than take opioids if they wanted refills, including, for example, doing physical therapy, losing weight, or tapering off the drugs over time.

d. Examples of Opioid-Related Claims Paid by St. Clair County's Health Plans and Workers' Compensation Program

2. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to St. Clair County and Illinois Consumers.

396. Nationally, the sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and opioid abuse. "Deaths from opioid overdose have risen steadily since 1990 in parallel with increasing prescription of these drugs."[96] Prescription opioid use contributed to 16,917 overdose deaths nationally in 2011—more than twice as many deaths as heroin and cocaine combined; drug poisonings now exceed motor vehicle accidents as a cause of death. More Americans have died from opioid overdoses than from participation in the Vietnam War.

397. Contrary to Defendants' misrepresentations, most of the illicit use stems from *prescribed* opioids; in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet. According to the CDC, the 80% of

[96] Grady, *supra*, at 1426.

opioid patients who take low-dose opioids from a single prescriber (in other words, who are not illicit users or "doctor-shoppers") account for 20% of all prescription drug overdoses.

398. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).

399. Widespread opioid use and abuse in St. Clair County are problems even where they do not result in injury or death.

b. Increased Opioid Use Has Increased Costs Related to Addiction Treatment.

400. By May 2014, Illinois had seventy-one Certified Opioid Treatment Programs. By way of contrast, Tennessee, whose opioid epidemic is among the worst in the nation, has only twelve. These treatment programs, by all reports, do not even begin to meet the need for services.

401. In addition to intense counseling, many treatment programs prescribe additional drugs to treat opioid addiction. Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction—buprenorphine/naloxone and naltrexone—were written and paid for. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payors at $72.5 billion.

402. As noted above, in 2014, 9,031,240 pills were sold in St. Clair County of **just** oxycodone and hydrocodone, a ratio of 34 pills per St. Clair County resident compared with an average of 1.22 pills per Illinois resident and 1.73 pills per U.S. resident[97].

[97] http://www.bnd.com/news/local/article74098582

403. The Defendants, who track prescriptions in real time, can obviously determine that abuse of prescription pills is occurring in St. Clair County, yet have done nothing to abate this issue, change their marketing to doctors or notify anyone of the dramatic over-prescription of opiates.

c. Increased Opioid Use Has Fueled An Illegal Secondary Market for Narcotics and the Criminals Who Support It

404. The Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. The Defendants' scheme supplies both ends of a secondary market for opioids—producing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that a "substantial increase[] in the nonmedical use of opioids is a predictable adverse effect of substantial increases in the extent of prescriptive use."[98] It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

405. A significant black market in prescription opioids also has arisen, which has not only created and supplied additional addicts, but fueled other criminal activities. According to the Chicago field division of the DEA, "[s]treet gangs, too, have become increasingly involved in prescription drug diversion."[99]

406. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373, 000 to 669,000 individuals and, in 2010, more than 3,000 people in

[98] G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308(18) JAMA 1865 (2012).

[99] Monifa Thomas, *supra*.

the U.S. died from heroin overdoses, also nearly double the rate in 2006; nearly 80% of those who used heroin in the past year previously abused prescription opioids. Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street. In the words of one federal DEA official, "Who would have ever thought in this country it would be cheaper to buy heroin than pills . . . [t]hat is the reality we're facing.[100]

407. That reality holds in St. Clair County and throughout Illinois. According to the Illinois prescription monitoring program, while fewer than 10% of the Illinois population lives south of Interstate 70 (the vast majority of St. Clair County sits just south of Interstate 70 in St. Clair County and is the largest County by population south of Interstate 70), 25% of Illinois schedule II narcotic prescriptions came from this geographic area.

3. Defendants' Fraudulent Marketing Has Led to Record Profits.

408. While the use of opioids has taken an enormous toll on Illinois and St. Clair County and its residents, the Defendants have realized blockbuster profits. In 2012, health care providers wrote 259 million prescriptions for painkillers—roughly one prescription per American adult. Opioids generated $8 billion in revenue for drug companies just in 2010.

409. Financial information—where available—indicates that the Defendants experienced a material increase in sales, revenue, and profits from the fraudulent, misleading, and unfair market activities laid out above. Purdue's OxyContin sales alone increased from $45 million in 1996 to $3.1 billion in 2010. In 2010, Research firm Frost & Sullivan projected an increase to $15.3 billion in overall revenue from opioid sales by 2016.

4. The Defendants Fraudulently Concealed their Misrepresentations.

[100] Matt Pearce & Tina Susman, *Philip Seymour Hoffman's death calls attention to rise in heroin use*, L.A. Times, Feb. 3, 2014, http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204.

410. At all times relevant to this Complaint, the Defendants took steps to avoid detection of and fraudulently conceal their deceptive marketing and conspiratorial behavior.

411. First, and most prominently, the Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. The Defendants purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

412. While the Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and exerting final approval over their content. The Defendants exerted their considerable influence on these promotional and "educational" materials.

413. In addition to hiding their own role in generating the deceptive content, the Defendants manipulated their promotional materials and the scientific literature to make it appear that they were accurate, truthful, and supported by substantial scientific evidence. The Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The true lack of support for the Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by St. Clair County.

414. Thus, while the opioid epidemic was evident, the Defendants, in furtherance of their respective marketing strategies, intentionally concealed their own role in causing it. The Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that St. Clair County now asserts.

St. Clair County was not alerted to the existence and scope of the Defendants fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

415. Through their public statements, marketing, and advertising, the Defendants' deceptions deprived St. Clair County of actual or presumptive knowledge of facts sufficient to put them on noticed of potential claims.

G. Operation Dr. Feelgood

416. In 2007, the United States Department of Health and Human Services ("HHS"), the Office of the Inspector General ("OIG") and the United States Drug Enforcement Agency ("DEA") launched an operation called "Dr. Feelgood," the purpose of which was to "identify and eradicate the medically unnecessary dispensing of prescription medications" to government health care beneficiaries in the Southern District of Illinois (which includes St. Clair County).[101] The task force also identified medical practitioners who diverted opiates for their own use.[102]

417. As a result of this operation, numerous doctors were convicted and/or suspended for misprescribing opiates.[103]

418. One such doctor was Defendant Naeem Kohli, M.D., of Effingham, Illinois, who was convicted on January 27, 2015 of illegally dispensing Schedule II controlled substances to patients who suffered from addiction.

419. Viwathna Bhuthimethee, M.D. pled guilty to providing prescriptions for 1,585 pain pills for hydrocodone to two patients in 2008 and 2009. He surrendered his license to prescribe opiates in 2010.

420. Walter Dawkins, D.M.D. was sentenced on December 21, 2012 for the illegal prescription of hydrocodone prescriptions he wrote to numerous Illinois patients.

[101] https://www.dea.gov/divisions/stl/2010/stlouis052410dp.html
[102] *Id.*
[103] *Id.*

421. Yolanda Rice was indicted on October 23, 2013 for illegally obtaining Oxycodone through her employer's office in Belleville. As a result of a plea she received 5 years of probation in 2014. Upon information and belief, these pills were distributed throughout St. Clair County and Illinois.

422. David Sherman Lustig and Jeffrey Todd Chenoweth, both pharmacists, were indicted for illegally distributing schedule II narcotics such as oxycodone and hydromorphone. Lustig received 5 years of probation in 2011 and Chenoweth received 3 months in prison and 3 years of probation.

423. Reginald Vernier, M.D., was sentenced on December 13, 2010 to 14 months imprisonment for illegal distribution of schedule II controlled substances in Illinois, such as hydrocodone.

424. Sukhdarshan Bedi, M.D. pled guilty to illegal dispensation of methadone and was sentenced to 16 months imprisonment.

425. Hung Nguyen, M.D. of Carmi pled guilty to illegally distributing controlled substances in 2009.

426. Joseph Smith, M.D., of Mt. Vernon pled guilty to illegally distributing hydrocodone and was sentenced to, among other things, 5 months imprisonment.

427. Hung Nguyen, M.D. of Carmi pled guilty to illegally dispensing narcotics, which upon information and belief included opiates.

428. As noted above, far from being an outlier and unforeseeable, physicians overprescribing, fraudulently prescribing, off-label prescribing and filling prescriptions for drug-addicted individuals was the guaranteed result of the Defendant's practices.

429. The above individuals in many cases, upon information and belief, received information from the Defendants which caused them to believe that the opiates they were prescribing were not as dangerous as they otherwise might have been.

430. As a result, these individuals did not give proper information about the safety of opiate medication due to the misrepresentations made by the Defendants.

431. Additionally, as noted above, the Defendants knew or should have known about the prescriptions that individuals, and others, were writing because the Defendants tracked this prescription information closely.

432. Indeed, the Defendants' passing of information to medical professionals including these individuals, who then prescribed the Defendants' products at alarming numbers, was the goal of the Defendants.

433. As highlighted by the DEA statistics cited above, the explosion of opiate prescriptions in southern Illinois, and St. Clair County, was not an accident and was not invisible to the Defendants as they were closely monitoring prescriptions for these drugs.

434. Nevertheless, the Defendants took no action because this explosion of prescriptions was actually the goal.

VII. COUNT ONE

CONSUMER FRAUD—DECEPTIVE PRACTICES

VIOLATIONS OF 815 ILCS 505/1, *et seq.* AGAINST ALL DEFENDANTS

435. St. Clair County realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

436. 815 ILCS 505/1, *et seq*. ("Illinois Consumer Fraud Act" or "ICFA") makes it unlawful for a person or business to use "unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with the intent that others rely upon the concealment, suppression or omission of such material fact" in the conduct of any trade or commerce." *815 ILCS 505/2*. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2, also makes unlawful "the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act."

437. The Defendants have engaged in unlawful and deceptive business practices in violation of ICFA as set forth above.

438. The Defendants' practices as described in the Complaint are deceptive business practices that violate ICFA because the practices were and are intended to deceive consumers and occurred and continue to occur in the course of conduct involving trade and commerce in St. Clair County and throughout Illinois.

439. At all times relevant to this Complaint, the Defendants, directly, through their control of third parties, and/or by aiding and abetting third parties, violated ICFA by making and disseminating untrue, false, and misleading statements to Illinois prescribers and consumers to promote the sale and use of opioids to treat chronic pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated to Illinois prescribers and consumers in order to promote the sale and use of opioids to treat chronic pain. These untrue, false, and misleading statements included, but were not limited to:

a. Claiming or implying that opioids would improve patients' function and quality of life;

b. Mischaracterizing the risk of opioid addiction and abuse, including by stating or implying that opioids were rarely addictive, that "steady state" and abuse-resistant properties meant the drugs were less likely to be addictive or abused, and that specific opioid drugs were less addictive or less likely to be abused than other opioids;

c. Claiming or implying that addiction can be avoided or successfully managed through the use of screening and other tools;

d. Promoting the misleading concept of pseudoaddiction, thus concealing the true risk of addiction;

e. Mischaracterizing the difficulty of discontinuing opioid therapy, including by mischaracterizing the prevalence and severity of withdrawal symptoms;

f. Claiming or implying that increased doses of opioids pose no significant additional risk;

g. Misleadingly depicting the safety profile of opioids prescribed by minimizing their risks and adverse effects while emphasizing or exaggerating the risks of competing products, including NSAIDs; and

h. In the case of Purdue, mischaracterizing OxyContin's onset of action and duration of efficacy to imply that the drug provided a full 12 hours of pain relief.

440. At all times relevant to this Complaint, the Defendants, directly, through their control of third parties, and by aiding and abetting third parties, also violated ICFA by making statements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic pain. The Defendants and their third-party allies repeatedly failed to disclose or minimized material facts about the risks of opioids, including the risk of addiction, significant risks of side effects, and their risks compared to alternative treatments, including NSAIDs. Such material omissions were deceptive and misleading in their own right, and further rendered even

otherwise truthful statements about opioids untrue, false, and misleading, creating a misleading impression of the risks, benefits, and superiority of opioids for treatment of chronic pain.

441. At all times relevant to this Complaint, the Defendants, directly, through their control of third parties, and by aiding and abetting third parties, made and disseminated the foregoing untrue, false and misleading statements, and material omissions, through an array of marketing channels, including but not limited to: in-person and other forms of detailing; speaker events, including meals, conferences, and teleconferences; CMEs; studies, and journal articles and supplements; advertisements; and brochures and other patient education materials.

442. The Defendants knew at the time of making or disseminating these misstatements and material omissions, or causing these misstatements and material omissions statements to be made or disseminated, that they were untrue, false, or misleading and therefore likely to deceive the public. In addition, the Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks, benefits, and superiority of opioids.

443. The third-party KOLs and Front Groups which the Defendants aided and abetted likewise knew at the time of making or disseminating these misstatements and material omissions that such statements were untrue, false, or misleading and therefore likely to deceive the public. The Defendants were aware of the misleading nature of the misstatements and material omissions made by KOLs and Front Groups, and yet the Defendants provided them substantial assistance and encouragement by helping them develop, refine and promote these misstatements and material omissions and distributing them to a broader audience. The Defendants also substantially encouraged the dissemination of these misstatements and material

omissions by providing the Front Groups and KOLs with funding and technical assistance for the shared purpose of issuing misleading, pro-opioid messaging.

444. In sum, the Defendants: (a) directly engaged in untrue, false, and misleading marketing; (b) exercised editorial control over and disseminated the untrue, false, and misleading marketing of KOLs and Front Groups; and (c) aided and abetted the untrue, false, and misleading marketing of KOLs and Front Groups. Thus, while the Defendants made, controlled, and disseminated deceptive marketing themselves, the Defendants also are independently liable for the deceptive activity of third parties.

445. All of this conduct, separately and collectively, was intended to deceive Illinois consumers who used or paid for opioids for chronic pain; Illinois physicians who prescribed opioids to consumers to treat chronic pain; and Illinois payors, including St. Clair County, who purchased, or covered the purchase of, opioids for chronic pain.

446. As a direct result of the foregoing acts and practices, the Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of ICFA as described in this Complaint.

447. Because Defendants' unbranded marketing caused the doctors to prescribe and St. Clair County to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makes, Defendants caused and are responsible for those costs and claims, as well.

448. In addition, 815 ILCS 505/7 specifically allows the State's Attorney of St. Clair County to bring this claim for a penalty for each violation by the Defendants.

WHEREFORE, Plaintiffs, the State of Illinois and the People of St. Clair County, respectfully requests that this Court enter an order (a) awarding judgment in their favor and against Defendants on Count One of the Complaint; (b)compelling Defendants to pay restitution

of any money acquired as a result of Defendants' consumer fraud and deceptive practices; (c) compelling Defendants to pay civil penalties up to $50,000 per violation pursuant to 815 ILCS 505/7(b) for each violations; (d) compelling Defendants to disgorge their ill-gotten profits; (e) compelling Defendants to pay the costs of the suit, including attorneys' fees; and (f) awarding the Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

VII. COUNT TWO

UNIFORM DECEPTIVE ACTS AND PRACTICES VIOLATION

VIOLATIONS OF 815 ILCS 510/1, *et seq.* AGAINST ALL DEFENDANTS

449. Plaintiffs reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Court.

450. 815 ILCS 510/1 *et seq.* ("Uniform Deceptive Trade Practices Act" or "UDAP") makes it unlawful for a person or business to represent that goods have a quality, use, benefit or characteristic they do not possess or engages in any conduct which may cause a likelihood of confusion or misunderstanding.

451. At all times relevant to this Complaint, the Defendants, directly, through their control of third parties, and/or by aiding and abetting third parties, violated the Uniform Deceptive Trade Practices Act by engaging in unfair acts or practices to promote the sale and use of opioids to treat chronic pain. These acts or practices are unfair in that they offend public policy; are immoral, unethical, oppressive, or unscrupulous; and have resulted in substantial injury to Illinois consumers.

452. The Defendants' unfair acts or practices include, but are not limited to:

a. Targeting a vulnerable population—the elderly—for promotion of opioids to treat chronic pain in the face of the known,

heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death;

b. Targeting a vulnerable population—veterans—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, overdose, and self-inflicted or accidental injury;

c. Engaging in untrue, false, unsubstantiated, and misleading marketing, directly and with and through third parties in violation of 21 C.F.R. § 202.1(e), thereby causing their drugs to be misbranded;

d. Promoting other purported advantages of their opioid products, including but not limited to deceased risk of abuse, addiction, or withdrawal symptoms or their superiority to NSAIDs, without substantial scientific evidence to support their claims, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

e. Failing, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information in their promotion of opioids, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

f. Deliberately using unbranded marketing to evade FDA oversight and rules prohibiting deceptive marketing; and

453. The Defendants engaged in these practices both directly and through the KOLs and Front Groups that they controlled and/or which they aided and abetted. The Defendants were aware of the unfair conduct of the KOLs and Front Groups, and yet the Defendants provided them substantial assistance and encouragement by helping them engage in the unfair practices. The Defendants also substantially encouraged the unfair practices by providing the Front Groups and KOLs with funding and technical support for the shared purpose of issuing unfair, pro-opioid messaging.

454. The Defendants' promotional practices as described above offend deep-seated public policies. As the Illinois legislature has decreed, "drug addiction [is] among the most serious health problem[] facing the people of the State of Illinois."[104] Nevertheless, by engaging in the conduct alleged above, the Defendants actively worked to conceal the risk of addiction related to opioids from Illinois patients and prescribers in the hopes of selling greater quantities of their dangerous drugs. The Defendants also worked to undermine public policy, enshrined by regulations contained in state and federal law, that is aimed at ensuring honest marketing and safe and appropriate use of pharmaceutical drugs.

455. The Defendants' conduct also was oppressive to both patients and prescribers. Patients are laypersons who put their trust in physicians to appropriately convey and balance the risks and benefits of various treatment options. Physicians, in turn, are inclined to trust the advice of KOLs, Front Groups, and other seemingly independent sources of objective medical information. By engaging in the conduct described above, the Defendants co-opted the sources reasonable physicians relied upon to convince those physicians that the risks related to opioids were minimal, that the benefits were substantial, and—as a result—that opioids were medically necessary to treat their patients' chronic pain. The Defendants deliberately targeted non-specialist physicians and non-physician prescribers, who lacked the time and expertise to evaluate their deceptive claims. This is even more true of the patients who were both the subject and object of the Defendants' marketing; patients have little ability to independently evaluate the medical necessity of the treatments they are prescribed and rely on the judgment of their physicians instead—the same judgment that was compromised by the Defendants' unlawful conduct.

[104] 745 ILCS 35/2.

456. Finally, the Defendants' conduct has caused substantial, indeed grievous, injury to Illinois consumers. The staggering rates of opioid use, abuse, and addiction, in St. Clair County alone, resulting from the Defendants' marketing efforts have caused substantial injury to Illinois residents, including, but not limited to:

a. A substantial number of adults have used opioids, with the vast majority of the use stemming from prescribing for chronic pain conditions.

b. A substantial number of Illinois residents prescribed opioids long-term for chronic pain have experienced the life-upending effects of addiction, abuse, misuse, overdose and death. For those who can stop taking narcotic opioids, there are years of struggling with the pull of the drugs and the fear of relapse (and often relapse itself), counseling sessions, or lining up each morning for daily maintenance drugs. And those who cannot overcome the need for opioids must deal with the compulsive use of and need for opioids, the haziness when they are on the drugs, and the nearly constant struggle to maintain their supplies of the drugs, whatever the cost. Both groups face a dramatically heightened risk of serious injury to death and sometimes an unrecoverable roll on their health, work, and family.

c. Elderly Illinoisans and Illinois veterans are particularly vulnerable to serious adverse outcomes, including overdose, injury, and death;

d. Illinoisans who have never taken opioids also have also been injured. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids. Infants born to mothers who abuse opioids have suffered neonatal abstinence syndrome.

e. Illinois consumers have incurred health care costs due to the prescription of opioids for chronic pain and the treatment of opioids' adverse effects, including addiction and overdose.

f. The Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an

abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. The Defendants' scheme created both ends of a new secondary market for opioids—providing both the supply of narcotics to sell and the demand of addicts to buy them.

g. This demand also has created additional illicit markets in other opiates, particularly heroin. Patients addicted to opioids frequently migrate to lower-cost heroin, with the serious personal costs that accompany their use of unlawful drugs.

h. All of this has caused substantial injuries to consumers—in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken lives, families, and homes.

457. The profound injuries to Illinois and St. Clair County consumers are substantial. No public policy justifies the Defendants' conduct in overstating the benefits, denying or downplaying the risks, and misrepresenting the superiority of opioids for chronic pain, which deprived Illinois patients and doctors of the honest and complete information they need to make informed choices about their treatment. In light of this campaign of misinformation (and especially given the addictive nature of these drugs), consumers could not reasonably have avoided their injuries.

458. By reason of the Defendants' unlawful acts, Illinois consumers and St. Clair County have been damaged and seek to enjoin the Defendants from continuing their deceptive acts and practices.

WHEREFORE, Plaintiffs, the State of Illinois and the People of St. Clair County, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Two of the Complaint; (b) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (c) awarding the St. Clair County such other, further, and different relief as this Honorable Court may deem just.

VIII. COUNT THREE

CIVIL CONSPIRACY

459. Plaintiff St. Clair County realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

460. Defendants Purdue and Abbott conspired with various KOLs and Front Groups to commit unlawful acts or lawful acts in an unlawful manner. Defendants Purdue and Abbott, and the various KOLs and Front Groups with which each of them allied, knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote the use of opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers. Defendants Purdue and Abbott enlisted various KOLs and Front Groups to make and disseminate these statements in furtherance of their common strategy to increase opioid sales, and Defendants Purdue and Abbott—along with the KOLs and Front Groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

461. By engaging in the conduct described in this Complaint, Defendants agreed with Front Groups APF, FSMB and AGS that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, FSMB, and AGS, Purdue and Abbott provided support for APF, FSMB, and AGS's deceptive statements promoting opioids and APF, FSMB, and AGS used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Purdue's drugs. The *Partners Against Pain* website (Purdue and APF), *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue and APF), *Treatment Options: A Guide for People Living with Pain* (Purdue and APF), *Exit*

Wounds (Purdue and APF), [105] *Responsible Opioid Prescribing* (Purdue and FSMB), and a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Purdue and AGS) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined in greater detail herein. They are products of these conspiracies, and the collaboration between Defendants and each of these entities in creating and disseminating these publications, CMEs, and websites is further evidence of each conspiracy's existence.

462. Each of the participants to the conspiracies outlined above was aware of the misleading nature of the statements they planned to issue and of the role they played in each scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. Defendants and third parties nevertheless agreed to misrepresent the risks, benefits, and superiority of using opioids to Illinois patients and prescribers in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

463. As outlined in greater detail herein, opioid makers Cephalon, Endo, Janssen, along with Defendants Purdue in concert with Abbott played an active role in determining the substance of the misleading messages issued by KOLs and Front Groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was an unrelenting stream of misleading information about the risks, benefits, and superiority of using opioids to treat chronic pain from sources Defendants knew were trusted by prescribers. Defendants exercised direct editorial control over most of these statements. However, even if

[105] Purdue's collaboration with APF through APF's "Corporate Roundtable" and Purdue and APF's active collaboration in running PCF constitute additional evidence of the conspiracy between Purdue and APF to deceptively promote opioids.

Defendants did not directly disseminate or control the content of these misleading statements, they are liable for conspiring with the third parties who did.

464. Defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

a. violating, aiding and abetting in the violation, or causing the violation of the Illinois Consumer Fraud Act;

b. violating, aiding and abetting in the violation, or causing the violation of the Uniform Deceptive Practices Act;

c. violating, aiding and abetting in the violation, or causing the violation of 720 ILCS § 5/17-10.5; and

d. committing common law unjust enrichment.

465. By reason of Defendant's unlawful acts, St. Clair County has been damaged and continues to be damaged by paying for the costs of opioid prescriptions for chronic pain and has suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

466. Because Defendant's marketing caused doctors and other health care providers to prescribe and St. Clair County to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Defendant caused and are responsible for those costs and claims, as well.

WHEREFORE, Plaintiff, St. Clair County, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants Purdue and Abbott on Count Three of the Complaint; (b) compelling these Defendants to pay St. Clair County's direct and consequential damages; and (c) awarding St. Clair County such other, further, and different relief as this Honorable Court may deem just.

XII. COUNT FOUR

INSURANCE FRAUD

VIOLATIONS OF 720 ILCS 5/17-10.5
AGAINST ALL DEFENDANTS

467. Plaintiff, St. Clair County, realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

468. 720 ILCS § 5/17-10.5(a)(1) provides in pertinent part:

> (1) A person commits insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property.

469. 720 ILCS § 5/17-10.5(e)(1) provides in pertinent part:

> Civil damages for insurance fraud. A person who knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of any insurance company by the making of a false claim or by causing a false claim to be made on a policy of insurance issued by an insurance company, or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property, shall be civilly liable to the insurance company or self-insured entity that paid the claim or against whom the claim was made or to the subrogee of that insurance company or self-insured entity in an amount equal to either 3 times the value of the property wrongfully obtained or, if no property was wrongfully obtained twice the value of the property attempted to be obtained, whichever amount is greater, plus reasonable attorney's fees.

470. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and by acting in concert with third parties: (a) knowingly caused false claims to be made to St. Clair County's health plan and workers' compensation program, which are self-

insured; and (b) knowingly obtained or caused to be obtained through deception the property of St. Clair County in payments for those false claims. Defendants' scheme caused prescribers to write prescriptions for opioids to treat chronic pain that were presented to St. Clair County's health plans and workers' compensation program for payment. Therefore, each claim for reimbursement to St. Clair County for chronic opioid therapy is the direct result of Defendants' marketing, which presented to prescribers false information about the risks, benefits, and superiority of opioids for the long-term treatment of pain.

471. Further, St. Clair County only covers the cost of services, tests, and prescription drugs that are medically necessary, reasonably required, and prescribed for an FDA-approved use. Doctors, pharmacists, other health care providers, and/or other agents of the health plans and workers' compensation program expressly or impliedly certified to St. Clair County that opioids were medically necessary and reasonably required to treat chronic pain because they were influenced by the false and misleading statements disseminated by Defendants (or the medical Defendants made the misrepresentations themselves) about the risks, benefits, and superiority of opioids for chronic pain. Moreover, many of the prescriptions written by physicians or other health care providers and/or authorized by the health plans and workers' compensation program, and submitted to St. Clair County were for uses that were misbranded and/or for off-label uses not approved by the FDA.

472. The misrepresentations were material because if St. Clair County had known of the false statements disseminated by Defendants and that doctors, pharmacies, other health care providers, and/or the health plans and workers' compensation program certified and/or determined that opioids were medically necessary and reasonably required based on those false statements, St. Clair County would have refused to authorize payment for opioid prescriptions.

St. Clair County is a self-insured entity and directly covers the cost of prescription drugs and other medical services for St. Clair County employees and retirees.

473. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made false claims with the intent to induce the St. Clair County to approve and pay such false and fraudulent claims.

474. By virtue of the above-described acts, Defendants acted in concert with third party Front Groups and KOLs to make misleading statements about the risks, benefits, and superiority of opioids to treat chronic pain. Defendants were aware of the misleading nature of the misstatements and material omissions made by KOLs and Front Groups, and yet Defendants provided them substantial assistance and encouragement by helping them develop, refine and promote these misstatements and material omissions and distributing them to a broader audience. Defendants also substantially encouraged the dissemination of these misstatements and material omissions by providing the Front Groups and KOLs with funding and technical support for the shared purpose of issuing misleading, pro-opioid messaging. Defendants knew or should have known that these marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain and would result in the submission of false insurance claims for opioid prescriptions written to treat chronic pain.

475. By reason of Defendants' insurance fraud, St. Clair County has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

476. Because Defendants' unbranded marketing caused the doctors to prescribe and St. Clair County to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Defendants caused and are responsible for those costs and claims, as well.

WHEREFORE, Plaintiff, St. Clair County, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Four of the Complaint; (b) compelling Defendants to pay three times any money acquired as a result of Defendants' fraud; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (d) awarding St. Clair County such other, further, and different relief as this Honorable Court may deem just.

XIV. COUNT FIVE

UNJUST ENRICHMENT

VIOLATIONS OF THE COMMON LAW PROHIBITION ON UNJUST ENRICHMENT AGAINST ALL DEFENDANTS

477. Plaintiff, St. Clair County, realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

478. Defendants have unjustly retained a benefit to St. Clair County's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

479. By illegally and deceptively promoting opioids to treat chronic pain, directly, through their control of third parties, and by acting in concert with third parties, Defendants have unjustly enriched themselves at St. Clair County's expense. St. Clair County has made payments for opioid prescriptions, and Defendants benefited from those payments. Because of their deceptive promotion of opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and St. Clair County lacks a remedy provided by law.

480. By reason of Defendants' unlawful acts, St. Clair County has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, Plaintiff, St. Clair County, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Five of the Complaint; (b) compelling Defendants to disgorge all unjust enrichment to St. Clair County; and (c) awarding St. Clair County such other, further, and different relief as this Honorable Court may deem just.

Respectfully submitted,

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