IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CITY OF CHICAGO, a municipal corporation,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; DEPOMED, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC; f/k/a ACTAVIS PLC; ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.,

Defendants.

Case No. 14-cv-04361

Honorable Jorge L. Alonso

SECOND AMENDED COMPLAINT*

JURY TRIAL DEMANDED

***Redacted Pursuant to Confidentiality Agreements and November 6, 2014 Order**

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Plaintiff City of Chicago ("the City"), by its attorney, Stephen R. Patton, Corporation Counsel of the City, files this Second Amended Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma Inc.; the Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.;[1] Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Depomed, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan plc f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively, "Defendants"). The City 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 health-care 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

[1] Pursuant to this Court's May 8, 2015 Memorandum Opinion and Order,dismissing this entity for lack of personal jurisdiction, and without waiver of the City's right to appeal that decision, the Complaint no longer names Teva Pharmaceutical Industries, Ltd. as a Defendant.

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.[2, 3]

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.[4]

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.[5] Like heroin, prescription opioids work by binding to receptors on the

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

[3] 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.

[4] 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).

[5] 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 may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by

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 Sections V.B.1 and V.C.2; (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids, as described in Section V.B.2; (c) recruiting prescribing physicians as paid speakers, as

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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.

a means of both securing those physicians' future "brand loyalty" and extending their reach to the physicians' peers, as described in Section V.B.2; (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 Section V.C.2; 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 Section V.C.2.

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 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. 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.

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, 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 is projected to reach $15.3 billion by 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 one doctor told the City: "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."[6] 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. One Defendant'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 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, 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

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

even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

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.

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."[7]

19. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on the City and local agencies that address heroin use and addiction. 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. Chicago ranks first in the nation in

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

emergency room visits for heroin overdoses. 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 addiction.

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 people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.[8]

21. Countless Chicagoans 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 Chicago 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. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

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[8] 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.

22. Defendants' actions are not permitted or excused by the fact that their labels (with the exception of Cephalon's labels for Fentora and Actiq) 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 Defendants' causal role broken by the involvement of doctors. 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. Defendants targeted not only pain specialists, but also primary care physicians (PCPs), nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements. 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. 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 local, state, and common law, as laid out below.

- Municipal Code of Chicago ("MCC") § 2-25-090, in that Defendants engaged in fraudulent and deceptive acts and practices in their promotion of opioids to treat chronic pain, and/or engaged in conduct that violates the Illinois Consumer

Fraud and Deceptive Business Practices Act and/or the Uniform Deceptive Trade Practices Act.

- MCC § 2-25-090, in that Defendants engaged in unfair acts or practices, including the oppressive and unscrupulous promotion of opioids to treat chronic pain, in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act.

- MCC § 4-276-470, in that Defendants employed deception, fraud, false pretense, false promise or misrepresentation, or concealed, suppressed or omitted material facts with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise.

- MCC § 1-21-010, in that Defendants knowingly made false statements of material fact to the City in violation of any statute, ordinance or regulation, or knowingly made a false statement of material fact to the city in connection with any application, report, affidavit, oath, or attestation, including a statement of material fact made in connection with a bid, proposal, contract or economic disclosure statement or affidavit.

- MCC § 1-22-020, in that Defendants knowingly presented or caused to be presented to the City false or fraudulent claims for payment or approval; knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the City; and/or conspired to defraud the City by getting false or fraudulent claims allowed or paid.

- MCC § 1-20-020, in that Defendants caused the City or its agents to incur costs in order to provide services reasonably related to Defendants' violation of any federal, state or local law, and/or Defendants failed to correct conditions which violate any federal, state or local law that Defendants were under a legal duty to correct.

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

- The common law prohibition against civil conspiracy, in that 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 Defendants have unjustly retained a benefit to the City's detriment, and Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

25. To redress and punish these violations, the City seeks a judgment requiring 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, and (g) any other relief to which the City may be entitled. The City also requests that the Court enjoin Defendants' unlawful promotion of opioids and order them to correct their misrepresentations.

II. PARTIES

A. Plaintiff.

26. Plaintiff is the City of Chicago, a municipal corporation organized and existing under the laws of the State of Illinois. The Corporation Counsel has the authority to "[a]ppear for and protect the rights and interests of the city in all actions, suits and proceedings brought by or against it or any city officer, board or department." MCC § 2-60-020.

27. Pursuant to its authority under the Chicago false claims ordinance, MCC § 1-22-050, the Corporation Counsel conducted a more than year-long investigation into the marketing of opioids for chronic pain by these Defendants and other entities and concluded that Defendants engaged in a pattern and practice of conduct violating state and local law and that the impact of their conduct on public health and law enforcement warranted immediate action. The Commissioner of the Department of Business Affairs and Consumer Protection also requested

that the Corporation Counsel bring an action for injunctive and equitable relief, pursuant to the Chicago consumer fraud ordinance. MCC § 2-25-090, *et seq*.

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 and in Chicago, including the following:

(a) OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist[9] 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 inadequate." Prior to April 2014,[10] 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

[9] 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.

[10] 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 "[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.

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

30. OxyContin is Purdue's largest-selling opioid, in both Chicago and 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. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

33. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. (Teva Ltd."), an Israeli corporation. Teva USA is a Delaware corporation with its principal place of business in Pennsylvania.

34. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva USA conducts Teva Ltd.'s sales and marketing activities for Cephalon in the United States and has done so since Teva Ltd.'s October 2011 acquisition of Cephalon. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Chicago, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. (Teva USA and Cephalon, Inc. collectively are referred to herein as "Cephalon.")

35. Cephalon has been in the business of manufacturing, selling, and distributing the following opioids, nationally and in Chicago:

(a) Actiq (fentanyl citrate) is a Schedule II opioid agonist lozenge (lollipop) first approved in 1998 and indicated for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

(b) Fentora (fentanyl citrate) is a Schedule II opioid agonist buccal tablet (similar to plugs of smokeless tobacco) first approved in 2006 and indicated for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

36. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful promotion to cancer patients experiencing pain. The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug must be prescribed solely to cancer patients. In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million in fines, damages, and penalties.

37. Teva USA is also in the business of selling generic opioids, nationally and in Chicago, including a generic form of OxyContin from 2005 through 2009.

38. On September 29, 2008, Cephalon entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The agreement, *inter alia*, required Cephalon to send doctors a letter advising them of the settlement terms and giving them a means to report questionable conduct of its sales representatives; disclose payments to doctors on its web site; and regularly certify that the company has an effective compliance program.

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

40. Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs in Chicago and the rest of the nation, including Duragesic (fentanyl), which is a Schedule II opioid agonist transdermal patch first approved in 1990 and indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

41. Until January 2015, Janssen also developed, marketed, and sold Nucynta and Nucynta ER:

(a) Nucynta ER (tapentadol extended release) is a Schedule II opioid agonist tablet first approved in 2011 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, Nucynta ER was indicated for the "management of moderate to severe chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." The DPN indication was added in August 2012.

(b) Nucynta (tapentadol) is a Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older."

42. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

43. DEPOMED, INC. ("Depomed") is a California corporation with its principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system (CNS) conditions. Depomed develops, markets, and sells prescription drugs in Chicago and nationally. Depomed acquired the rights to Nucynta and Nucynta ER for $1.05 billion from Janssen pursuant to a January 15, 2015 Asset Purchase Agreement. This agreement closed on April 2, 2015.[11]

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

[11] The City has listed Depomed as a Defendant for the purpose of ensuring that the City can obtain appropriate injunctive relief as to Nucynta and Nucynta ER.

45. Endo develops, markets, and sells prescription drugs, including the following opioids, in Chicago and nationally:

(a) Opana ER (oxymorphone hydrochloride extended release) is a Schedule II opioid agonist tablet first approved in 2006 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, Opana ER was indicated for the "relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time."

(b) Opana (oxymorphone hydrochloride) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "relief of moderate to severe acute pain where the use of an opioid is appropriate."

(c) Percodan (oxycodone hydrochloride and aspirin) is a Schedule II opioid agonist tablet first approved in 1950 and first marketed by Endo in 2004 and indicated for the "management of moderate to moderately severe pain."

(d) Percocet (oxycodone hydrochloride and acetaminophen) is a Schedule II opioid agonist tablet first approved in 1999 and first marketed by Endo in 2006 and indicated for the "relief of moderate to moderately severe pain." [12]

46. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it alone accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, nationally and in Chicago, both itself and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

[12] In addition, Endo marketed Zydone (hydrocodone bitartrate and acetaminophen), a Schedule III opioid agonist tablet indicated for the "relief of moderate to moderately severe pain," from 1998 through 2013. The FDA's website indicates this product is currently discontinued, but it appears on Endo's own website. The City paid for 110 Endo Zydone prescriptions from July 18, 2005 through March 4, 2013.

47. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in March 2015. Prior to that, WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. as of January 2013 and then to Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter collectively are referred to as "Actavis.")

48. Actavis engages in the business of marketing and selling opioids in Chicago and across the country, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Kadian (morphine sulfate extended release) is a Schedule II opioid agonist capsule first approved in 1996 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, Kadian 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." Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

III. JURISDICTION AND VENUE

49. This civil action was originally filed in the Circuit Court of Cook County, Illinois. It was removed by Defendants to the United States District Court for the Northern District of Illinois and the City did not seek remand. Jurisdiction is proper in the Northern District of Illinois pursuant to 28 U.S.C. § 1332.

50. 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.

51. Venue as to each Defendant is proper in this court under 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the Eastern Division of the Northern District of Illinois.

IV. JURY DEMAND

52. The City demands a jury trial pursuant to Federal Rule of Civil Procedure 38.

V. FACTUAL ALLEGATIONS

A. The Science behind Pain Medicine.

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

53. 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.

54. 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.

55. 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.

56. 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.

57. 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."[13] The City's workers' compensation program and health benefit plans have expended approximately $2.4 million on addiction treatment services from May 2013 to May 2015 alone, on top of the City's provision of grants to drug treatment centers for services including the treatment of opioid addiction.

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

59. 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

[13] 745 ILCS 35/2.

may persist for months after a complete withdrawal from opioids, depending on how long opioids were used.

60. 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."[14] 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.

61. 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 high."[15] 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.

62. 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

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[14] 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.

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

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.

63. 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."[16] 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.

64. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[17]

65. 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 below, not in Defendants' marketing).[18] 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.

66. 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, Janssen's Nucynta ER and Duragesic, Endo's

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[16] 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).

[17] Joseph A. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care 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).

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

Opana ER, and Actavis's Kadian are all 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." Cephalon's Actiq and Fentora are particularly fast-acting drugs that are explicitly indicated only for use in conjunction with continuous opioid therapy. 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.

67. 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."[19]

68. 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."[20] The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death."[21] The FDA required that—going forward—opioid makers of long-acting formulations clearly communicate these risks in their labels (defined, as noted in Section V.C.1, to include promotional materials disseminated by or on behalf of the manufacturer of the drug).

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[19] 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.

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

[21] *Id*.

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***."[22]

69. 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.

70. Despite the fact that opioids now are routinely prescribed, there never has been evidence of their safety and efficacy for long-term use. Defendants always have been aware of these gaps in knowledge. While promoting opioids to treat chronic pain, 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.

71. 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.[23] 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 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,

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[22] *Id.* at 7 (emphasis in original).

[23] 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).

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).

72. 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."[24] 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.

73. Endo's 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%).

74. 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.

[24] 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).

75. 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."[25]

76. 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.

77. 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.

78. 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 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

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

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.

79. Before 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.

80. 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.

81. 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.

82. 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."[26]

83. 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.*[27]

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."[28]

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

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

[28] *Id.*

84. 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."[29] Defendants changed that perception.

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

85. Defendants' direct marketing proceeded on two tracks, serving two related purposes. First, 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, 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. 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.

86. Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. Defendants' advertising budgets peaked in 2011, when they collectively spent more than $14 million on medical journal advertising of opioids, nearly triple what they

[29] 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).

spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.[30]

87. As described in Sections V.D and V.E below, 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 below, are unsubstantiated and contradicted in the medical literature.

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

88. Each Defendant 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, 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. [redacted]

[30] 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.

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

90. [redacted] 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.

91. Defendants' sales representatives have visited hundreds of thousands of doctors, including thousands of visits to Chicago 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.

92. As described in more detail in Section V.E below, each Defendant 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.

93. Besides carefully training their sales representatives, 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 Defendants gauge physicians' perceptions of, and willingness to prescribe, a particular Defendant's drugs. As described below in Section V.B.4, data obtained by the City, 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 and in Chicago.

94. In addition to making sales calls, Defendants' detailers also identified doctors to serve, for payment, on Defendants' speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. Defendants almost always select physicians who are "product loyalists," since one question they will be asked is whether they prescribe the drug themselves. Endo, for instance, sought to use [redacted]—including high prescribers of its drugs—as local thought leaders to market Opana ER to primary care doctors. 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.

95. 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. [redacted] Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Defendants also track the prescribing of event attendees, [redacted] It would make little sense for Defendants to devote significant resources to programs that did not increase their sales.

96. 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. [redacted] 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 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 Defendants greater freedom in the messages they present.

97. Defendants devoted massive resources to these direct sales contacts with prescribers. In 2014, Defendants collectively spent $168 million on detailing branded opioids to physicians nationwide. This figure includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. The total figure is more than double Defendants' collective spending on detailing in 2000. Detailers' role in Defendants' overall promotional efforts was also carefully calibrated; [redacted]

98. 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,[31] and face-to-face detailing has the highest influence on intent to prescribe. 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 Defendants' drugs.

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

99. Defendants guided their efforts to expand opioid prescribing through comprehensive marketing and business plans for each drug. These documents, based on the

[31] *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 a 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).

companies' extensive market research, laid out ambitious plans to bring in new prescribers and increase overall prescribing of Defendants' opioids.

a. Targeting categories of prescribers

100. Defendants targeted, by zip codes and other local boundaries, individual health care providers for detailing. 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.

101. Collectively, Defendants' marketing plans 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, Defendants also targeted increasing numbers and types of prescribers for marketing.

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

103. The expanded market also included internists and general practitioners who were low- to mid-volume prescribers. [redacted]

[redacted]

b. Increasing "direct to consumer" marketing

104. Defendants knew that physicians were more likely to prescribe their branded medications when patients asked for those medications. [redacted] 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 to, as Endo put it, "[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss."

105. 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. [redacted]

c. Differentiating each brand

106. 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, Defendants faced

increasing pushback from the medical community and regulators based on the growing problems of opioid addiction and abuse. Both market conditions prompted 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 Purdue and other competitors.

107. [redacted] Pressure to stand out among other drugs resulted in Defendants identifying marketing themes that thereafter were reflected in Defendants' deceptive and harmful messages to physicians and consumers, as described in greater detail in Sections V.D and V.E below [redacted]

d. Moving beyond office visits

108. 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." 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 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 Chicago Using the Same Strategies and Messages They Employed Nationwide.

109. As one of the United States' largest cities, and the regional hub of the Midwest, Chicago is a focus of Defendants' marketing efforts. Chicago and the Midwest 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. Defendants also perceived Chicago and Illinois as receptive to their marketing messages, [redacted]

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

111. 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 above in Section V.B.2, Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide desks, and supervisors rode along with them periodically to both check on their performance and compliance.

112. As they did nationwide, Defendants extensively tracked the prescribing behavior of Chicago-area 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. Providers' prescribing volume was ranked and sorted into deciles.

113. This information allowed Defendants to target, within each sales territory, prescribers who could have the biggest sales impact. Indeed, one Chicago pain specialist, Prescriber NN, who estimates that he writes 600-700 opioid prescriptions each month for the treatment of long-term chronic pain, observed that detailers see him often because he is "big money for these people." Tracking prescribing behavior also enabled Defendants to zero in on trends; Actavis, for example, identified on a monthly basis the prescribers with the greatest increases and decreases in prescriptions written.

114. 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' marketing campaigns in Chicago.

115. These misrepresentations are reflected in the accounts of Chicago prescribers whom the City interviewed. As set forth below in Sections V.E, these prescribers were on the receiving end of Defendants' misleading messaging via detailing visits; CMEs; small-group speaker programs; dinners, and other meals; branded advertisements; and unbranded promotional materials funneled through third parties. These deceptive and unfair messages include the unfounded and untrue claims described in Section V.D 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.

116. Such misrepresentations also are captured in the verbatim sales message recall data obtained by the City. To gain insight into detailing messaging, the City 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."

117. Surveyed Midwestern health care providers often reported that 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, Defendants' representatives also repeatedly claimed or implied that their drugs had minimal or low abuse potential; were safer than other pain medications; and, in the case of Cephalon's Actiq and Fentora, were appropriate for off-label uses. Individual Defendants' misrepresentations contained in that data are described below in Section V.E[32]

[32] As also set forth in that section, many of the misrepresentations reported in the Midwestern verbatim data and in the City's interviews with Chicago-area prescribers can be traced back to sales training materials produced to the City by Defendants. However, the City does not have access to all of the materials on which Defendants' sales representatives were trained. Upon information and belief—based on the careful instruction and monitoring sales representatives receive to ensure that they deliver only

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

118. In addition to their direct marketing efforts, Defendants used unbranded, third-party marketing, which they deployed as part of their national marketing strategies for their branded drugs. Each Defendant 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, 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, 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.

119. 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.[33] 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,

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company-approved messages—Defendants' sales representatives received corporate training on each of the deceptive statements reported by prescribers herein.

[33] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

120. 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."[34] "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended."[35] 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.[36] "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.[37] Thus, Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.

121. 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."[38] Promotion

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[34] 21 U.S.C. §§ 352.

[35] 21 C.F.R. § 201.5.

[36] 21 U.S.C. § 321(m).

[37] *See id.*

[38] FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, May 2009, at 14.

that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

122. 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 cannot be supported by the results of the study."[39] 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."[40]

123. 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.[41] 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.

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[39] 21 C.F.R. § 99.101(a)(4).

[40] 21 C.F.R. § 202.1(e)(6)(ii).

[41] *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").

124. The Chicago Consumer Fraud and False Claim ordinances reflect the same 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. Defendants Deployed Front Groups and Doctors to Disseminate Unbranded Information on Their Behalf.

125. Drug companies market both directly and indirectly, using third party validators (such as scientists, physicians, or patient or professional organizations) that appear to be 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. [42]

126. 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,

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

drug companies can sidestep the extensive regulatory framework, described in Section V.C.1, governing branded communications.

127. 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 Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside of FDA oversight. Through unbranded materials, Defendants presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Defendants' branded marketing materials and drug labels and with Defendants' own knowledge of the risks, benefits and advantages of opioids. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

128. Even where such unbranded messages were channeled through third-party vehicles, 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)(l)(2).[43] As described below and in Section V.E,

[43] 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.

Defendants' sales representatives distributed third-party marketing material that was deceptive to Defendants' target audiences. Defendants are responsible for these materials.

129. Moreover, Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that 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[44] with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

130. 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. 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.

131. The third-party publications 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 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.

132. By acting through third parties, Defendants were able to both avoid FDA scrutiny and give the false appearance that the messages reflected the views of independent third parties.

[44] 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.

Later, Defendants would cite to these sources as "independent" corroboration of their own statements. As one physician adviser to 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—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.

133. As part of a strategic marketing scheme, 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

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

135. Pro-opioid doctors have been at the hub of 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. Defendants were able to exert control of each of these modalities through their KOLs.

136. In return, the KOLs' association with 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.

137. Although some KOLs initially may have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.[45] 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.

138. Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, 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

[45] 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.

Defendants, Russell Portenoy, 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, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

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

140. 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. From 2000 on, Cephalon, for instance, has paid doctors more than $4.5 million for programs relating to its opioids.

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

142. 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 above in Section V.B.2. 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 Defendants, all the while causing harm to Chicago prescribers and patients.

i. *Russell Portenoy*

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

144. 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.

145. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcast in Chicago and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[46]

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

146. 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."[47] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[48]

ii. *Lynn Webster*

147. 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.[49] He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

148. Dr. Webster had 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

[47] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012.

[48] *Id*.

[49] 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.

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 Endo, Janssen, and Purdue. 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 Chicago doctors.

149. 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." As noted below in Section V.E.3, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, as described below in Section V.D.4, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[50]

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

b. "Research" That Lacked Supporting Evidence

150. Rather than find a way to actually test the safety and efficacy of opioids for long-term use, Defendants led everyone to believe that they already had. 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.

151. To accomplish this, Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals. Defendants' internal documents reveal plans to submit research papers and "studies" to long lists of journals, [redacted]

152. Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. The plans for these 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 Defendants' marketing departments and with Defendants' marketing and public relations consultants. 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 Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

153. 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 Endo.[51] 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, reproduced in full below, 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.)

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

[51] 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.

154. 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 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.

155. Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, 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.

156. 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 Section V.C.1. 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

157. 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 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, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

i. *FSMB*

158. 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.

159. 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."

160. 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 Chicago physicians.

161. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies,

including Endo and Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors).

162. 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."

163. 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.

164. 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.

ii. *AAPM/APS Guidelines*

165. AAPM and the APS are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013 (with AAPM receiving over $2 million).

[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.

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]

166. 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 Janssen, Cephalon, Endo, and Purdue.

167. 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 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 treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited

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

[54] *Id.*

732 times in academic literature, were disseminated in Chicago during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

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

iii. *American Geriatrics Society*

169. 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.

170. AGS contracted with Defendants Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. These Defendants were 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 Defendants including

[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.

Endo and Purdue beginning July 15, 2009. Internal 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. Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

171. 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 Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in 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*

172. The extent of 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

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

controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting 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]

173. 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]

174. 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 review:

> 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

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[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.

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

d. Continuing Medical Education

175. 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.

176. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, 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 Defendants' deceptions.

177. In all, 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

[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.

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.

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

179. Dozens of CMEs that were available to and attended or reviewed by Chicago doctors during the relevant time period did not live up to the AMA's standards.

180. The influence of 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-

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

funded, making clear the difficulty health care providers have in screening and accounting for source bias.[61]

181. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, Defendants could expect messages to be favorable to them, as these organizations were otherwise dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy, as described in Section V.C.2.a. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measured the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

e. Unbranded Patient Education

182. 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] [redacted]

[redacted]

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

[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).

[redacted]" Recognizing this fact, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

183. 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

184. As noted above, Defendants Cephalon, Endo, Janssen, and Purdue entered into arrangements with numerous organizations to promote opioids. These organizations depend upon Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting 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 Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. 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.

185. 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. While many of these non-Chicago-based organizations refused to cooperate with the City's investigatory subpoenas,

some of the available evidence demonstrating how Defendants controlled their allied Front Groups is laid out below.

i. *American Pain Foundation*

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

187. 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 Section V.C.4.b, 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 Chicagoans.

188. 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.

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

board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

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

191. 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.

192. 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.

193. The same drug company made general grants, but even then it directed how APF used them. In response to a 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?"

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

195. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[64]

ii. *The American Academy of Pain Medicine*

196. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed in Section V.C.2.c.ii, and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

197. 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.

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

Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event. [redacted]

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

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

[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.

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

200. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, 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.

201. 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 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 Chicago prescribers and patients.

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

203. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); 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 Defendants.

204. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA 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 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 below in Section V.E, 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. Defendants Targeted Vulnerable and Lucrative Populations.

a. The Elderly

205. 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 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. Defendants' targeted marketing to the elderly and the absence of cautionary language in their promotional materials

[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.

flies in the face of scientific evidence and their own labels, and creates a heightened risk of serious injury to elderly patients.

206. 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, Endo, and Janssen 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.

207. 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, 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

208. Veterans, too, are suffering greatly from the effects of 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 overdoses—double the rate of the civilian population.

209. The City has a substantial population of veterans who must cope with the consequences of overprescribing opioids. The Jesse Brown Veterans Affairs Medical Center, which serves Chicago residents who are veterans, saw dramatic increases in their rates of prescribing opioids. In addition, at least one doctor interviewed by the City of Chicago described the pressure to prescribe opioids in the facility and the high rates of addiction. The City also has a policy to promote the hiring of veterans, and these employees are then covered by the City's health plans and workers' compensation programs.

210. Opioids are particularly dangerous to 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, 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.

211. *Exit Wounds*, a 2009 publication sponsored by Purdue, distributed by APF with grants from Janssen and Endo, 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.

212. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose the risk that opioids may cause fatal interactions with benzodiazapines, 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, Endo, and Janssen. Yet, Janssen, 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 Defendants' opioids.

213. 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 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*.

[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.

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

214. 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, 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.

215. As described in greater detail below in Sections V.D.1-7, there are seven primary misleading and unfounded representations. 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.

216. In addition to these misstatements, Purdue purveyed an eighth deception—laid out in detail below in Section V.D.8—that OxyContin provides a full 12 hours of pain relief.

217. Exacerbating each of these misrepresentations and deceptions was the collective effort of 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. Defendants and Their Third-Party Allies Misrepresented that Opioids Improve Function.

218. 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 quality of life could be overcome by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

219. 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 injuries does not cause patients to return to work or physical activity.[71] Indeed, one Defendant's

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[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(11) 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.

[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.

own internal marketing plans characterized functional improvement claims as "aspirational." Another acknowledged in 2012 that "[s]ignificant investment in clinical data [was] needed" to establish opioids' effect on mitigating quality of life issues, like social isolation.

220. As laid out below in Section V.D.7, 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. Defendants often omitted these adverse effects from their publications, as well as omitting certain risks of drug interactions.

221. Yet each of the following statements by Defendants, which are further discussed, by Defendant, in Section V.E, suggests that the long-term use of opioids improve patients' function and quality of life, and that scientific evidence supports this claim.

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "***most*** chronic benign pain patients do have ***markedly improved ability to function*** when maintained on chronic opioid therapy." (Emphasis added.) b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function. c. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and cause patients to enjoy their lives." The FDA warned Actavis such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[72] d. Actavis sales representatives told Chicago prescribers that prescribing Actavis's opioids would improve their patients' ability to function and improve their quality of life.

[72] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18. 2010), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm.

Cephalon	e. Cephalon 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." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists. f. Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids when used properly "give [pain patients] a quality of life we deserve." The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the publication is currently available online. g. Cephalon sponsored a CME written by key opinion leader Dr. Lynn Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007, through December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. h. Cephalon sales representatives told Chicago prescribers that opioids would increase patients' ability to function and improve their quality of life.

Endo	i. Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. j. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taugh that chronic opioid therapy has been "shown to reduce pain and improve depressive symtoms and cognitive functioning." k. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.[73] l. Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007). This book 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." m. Endo provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *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. n. Endo sales representatives told Chicago prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

[73] FDA regulations require that warnings or limitations be given equal prominence in disclosure, and failure to do so constitutes "misbranding" of the product. 21 C.F.R. § 202.1(e)(3); *see also* 21 U.S.C. § 331(a).

Janssen	o. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative backing for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population. p. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying her experience would be representative. This video is still available today on youtube.com. q. Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *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. r. Janssen sales representatives told Chicago prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

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. 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* (2009), 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 Chicago 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.

222. The fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. To reach chronic pain patients, 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 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.

223. Through their well-funded, comprehensive marketing efforts, 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. 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 Defendants' own labels—compelled disclosure.

224. Further, in addition to falsely claiming opioids had low addiction risk or omitting disclosure of the risk of addiction altogether, 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, Defendants used code words that conveyed to prescribers that their opioid was less prone to abuse and addiction. For instance, sales representatives for Actavis, Endo, Janssen, and 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, Endo actively promoted its reformulated Opana ER on the basis that it was "designed to be crush-resistant," suggesting both

(a) that Endo had succeeded in making the drug harder to adulterate, and (b) that it was less addictive, in consequence. In fact, however, Endo knew that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER" and that Opana ER could still be ground and cut into small pieces by those looking to abuse the drug. In the same vein, Janssen denied that Nucynta ER was an opioid and claimed that it was not addictive, and 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.

225. 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."

226. 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%,[74] abuse averages between 21% and 29% and addiction between 8% and 12%.[75] These estimates are well in line with Purdue's own studies, showing that between 8%

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

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

and 13% of OxyContin patients became addicted, but on which Purdue chose not to rely, citing instead the Porter-Jick letter.

227. The FDA has found as well that 20% of opioid patients use two or more pharmacies, 26% obtain opioids from two or more prescribers, and 16.5% seek early refills—all potential "red flags" for abuse or addiction.[76] 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.[77]

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

229. 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. Examples of these misrepresentations are laid out below, and further discussed, by Defendant, in Section V.E:

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[76] 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.

[77] 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*.

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of addiction. b. Actavis caused a patient education brochure to be distributed in 2007 that claimed addiction is possible, but it is "less likely if you have never had an addiction problem." Although the term "less likely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. c. Kadian sales representatives told Chicago prescribers that Kadian was "steady state" and had extended release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused. d. Kadian sales representatives told Chicago prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused—and thereby less addictive—than other opioids. e. In discussions with Chicago prescribers, Kadian sales representatives omitted any discussion of addiction risks related to Actavis's drugs.
Cephalon	f. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which claims, among other things, that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." g. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. h. In discussions with Chicago prescribers, Cephalon sales representatives omitted any discussion of addiction risks related to Cephalon's drugs.
Endo	i. Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence. j. Endo's advertisements for the 2012 reformulation of Opana ER claimed it was *designed to be crush resistant*, in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse" and Endo's "post-marketing data submitted are insufficient to support any conclusion about

	the overall or route-specific rates of abuse." Further, Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Opana ER was less subject to abuse. k. Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. l. Endo sponsored a website, PainAction.com, which stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." m. Endo sponsored CMEs published by APF's NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult* and *Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients[,]" which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients. n. Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." o. Endo distributed a patient education pamphlet edited by key opinion leader Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue. p. Endo 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 there is no such evidence. Endo 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 their completion.

	q. Endo sales representatives told Chicago 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. r. Endo provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught 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 that the risk is so low as not to be a worry. s. In discussions with Chicago prescribers, Endo sales representatives omitted discussion of addiction risks related to Endo's drugs.
Janssen	t. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a "myth" that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." Although the term "rarely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use is not a problem. u. Janssen 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." The study supporting this assertion does not analyze addiction rates by age and, as already noted, addiction remains a significant risk for elderly patients. Janssen 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 their completion. v. Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught 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 the risk is so low as not to be a worry. w. Janssen currently runs a website, *Prescriberesponsibly.com* (last modified July 2, 2015), which claims that concerns about opioid addiction are "overstated."

	x. [redacted] y. Janssen sales representatives told Chicago 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. z. Janssen sales representatives told Chicago prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen's drugs. In truth, however, as set out in Nucynta's FDA-mandated label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit." aa. Janssen sales representatives falsely told a Midwestern orthopedic surgeon in 2013 that Duragesic had anti-abuse properties when it had none. bb. Janssen's sales representatives told Chicago prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug. cc. In discussions with Chicago prescribers, Janssen sales representatives omitted discussion of addiction risks related to Janssen's drugs.
Purdue	dd. 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.[78] 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. ee. 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

[78] Purdue itself submitted briefing materials in October 2010 to a meeting of the FDA's Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee in which it stated that OxyContin was used non-medically by injection 4-17% of the time.

	"misconceptions about opioid addiction." ff. 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. gg. 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."[79] 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. hh. 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 their completion. ii. 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. jj. Purdue sales representatives told Chicago 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. kk. Purdue sales representatives told Chicago 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. ll. Advertisements that Purdue sent to Chicago prescribers stated that OxyContin ER was less likely to be favored by addicts, and, therefore, less

[79] Watson, Controlled-release oxycodone, *supra*.

	likely to be abused or diverted, or result in addiction. mm. In discussions with Chicago prescribers, Purdue sales representatives omitted discussion of addiction risks related to Purdue's drugs.

230. In addition to denying or minimizing the risk of addiction and abuse generally, and as laid out in Section V.E, 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, 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. Endo also asserted in particular that, because a reformulation of Opana ER was (or was designed to be) abuse-deterrent or tamper-resistant, patients were less likely to become addicted to them. Defendants had no evidence to support any of these claims, which, by FDA regulation, must be based on head-to-head trials;[80] the claims also were false and misleading in that they misrepresented the risks of both the particular drug and opioids as a class.

231. Further, rather than honestly disclose the risk of addiction, 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, 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). Defendants and their third-party allies claimed that purportedly overblown worries

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

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

232. For example, Janssen's website, *Let's Talk Pain*, 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 abusive 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."

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

234. 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, 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.

235. There 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.

236. 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, such as use of risk assessment instruments, opioid management plans, patient education, 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."[81] 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.

237. 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.

238. As described below, and in Section V.E, each Defendant 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[82] 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.

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

[82] 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.

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.[83] 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 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 Chicago prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction.

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

239. 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 Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and

[83] *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.

"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."[84]

240. Each of the publications and statements below, which are further discussed, by Defendant, in Section V.E, falsely states or suggests that the concept of "pseudoaddiction" is substantiated by scientific evidence and accurately describes the condition of patients who only need, and should be treated with, more opioids:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction."
Cephalon	b. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction. Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.
Endo	c. Endo distributed copies of a book by KOL Dr. Lynn Webster entitled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as pseudoaddiction and thus, increasing the dose *in most cases . . . should be the clinician's first response.*" (emphasis added). d. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."

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

Janssen	e. Janssen's website, *Let's Talk Pain*, stated from 2009 through 2011 that "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated*" and "[p]seudoaddiction is *different from true addiction* because such behaviors can be resolved with effective pain management." (emphasis added).
Purdue	f. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." g. Purdue distributed to physicians at least as of November 2006, and posted on its unbranded website, *Partners Against Pain*, a pamphlet copyrighted 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct including "illicit drug use and deception" it defined as indicative of pseudoaddiction or untreated pain. It also states: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when *pain is undertreated*. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be *distinguished from true addiction* in that the behaviors resolve when the pain is effectively treated." (Emphasis added.) h. Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name, "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction. Purdue also spent over $100,000 to support distribution of the book. i. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which states: "Pseudo-addiction describes patient behaviors that may occur when *pain is undertreated*. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." (Emphasis added.)

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

241. 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.

242. In an effort to underplay the risk and impact of addiction, 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.

243. 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.

244. Each of the publications and statements below, which are further discussed, by Defendant, in Section V.E, falsely states or suggests that withdrawal from opioids was not a problem and they should not be hesitant about prescribing or using opioids:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis's sales representative training claimed opioid withdrawal would take only a week, even in addicted patients.
Endo	b. A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.

Janssen	c. [redacted] d. Janssen sales representatives told Chicago prescribers that patients on Janssen's drugs were less susceptible to withdrawal than those on other opioids.
Purdue	e. 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. f. Purdue sales representatives told Chicago prescribers that the effects of withdrawal from opioid use can be successfully managed. g. Purdue sales representatives told Chicago prescribers that the potential for withdrawal on Butrans was low due to Butrans's low potency and its extended release mechanism.

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

245. 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.

246. 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. Each of 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.

247. 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.

248. Each of the following claims, which are further discussed, by Defendant, in Section V.E, suggests that high-dose opioid therapy is safe:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing

	doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis's opioid, Kadian.
Cephalon	b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed. c. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations. d. Cephalon sales representatives assured Chicago prescribers that opioids were safe, even at high doses.
Endo	e. Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," and once that occurs, further dose increases would not occur. Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it. f. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief."
Janssen	g. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."
Purdue	h. 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. i. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinitely high ones, which suggested that high dose opioids are safe and appropriate and did not disclose the risks from high dose opioids. This publication is still available online. j. 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. k. 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. l. Purdue sales representatives told Chicago 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. Defendants and Their Third-Party Allies Deceptively Omitted or Minimized Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment.

249. 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. 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;"[85] 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).[86]

250. Despite these serious risks, 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. Defendants and their third-party allies described over-the-counter NSAIDs as life-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 not addiction, overdose, or death). Compared with NSAIDs, opioids are responsible for roughly four times as many fatalities annually.

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

[86] 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]."

251. As with the preceding misrepresentations in Sections V.D.1-6, 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.

252. Each of the following, which are further discussed, by Defendant, in Section V.E, reflects Defendants' deceptive claims and omissions about the risks of opioids, including in comparison to NSAIDs:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs. b. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, in older persons. c. Kadian sales representatives told Chicago prescribers that NSAIDs were more toxic than opioids.
Cephalon	d. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught 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 attributed 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. e. Cephalon sales representatives told Chicago prescribers that NSAIDs were more toxic than Cephalon's opioids
Endo	f. Endo distributed a "case study" to prescribers titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. The study cites an example, meant to be representative, of a patient "with a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years), and recommends treating with opioids instead. g. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer called "Pain: Opioid Therapy." This publication

	included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. h. Endo provided grants to APF to distribute *Exit Wounds* (2009), which omitted 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. i. Endo sales representatives told Chicago prescribers that NSAIDs were more toxic than opioids.
Janssen	j. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation. k. Janssen sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines. Janssen's label for Duragesic, however, states that use with benzoidazepines "may cause respiratory depression, [low blood pressure], and profound sedation or potentially result in coma. *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. l. Janssen sales representatives told Chicago prescribers that Nucynta was not an opioid, making it a good chice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is an opioid and has the same effects as other opioids.
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. APF distributed copies of *Exit Wounds* to a non-profit in Chicago. *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 Chicago prescribers that NSAIDs were more toxic than opioids.

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

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

254. 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 following chart, which was, upon information and belief, adapted from Purdue's own sales materials:[87]

[87] Jim Edwards, "*How Purdue Used Misleading Charts to Hide 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 dose is no longer marketed. Purdue's promotional materials in the past displayed a logarithmic scale, which gave the misleading impression the concentration remained constant.

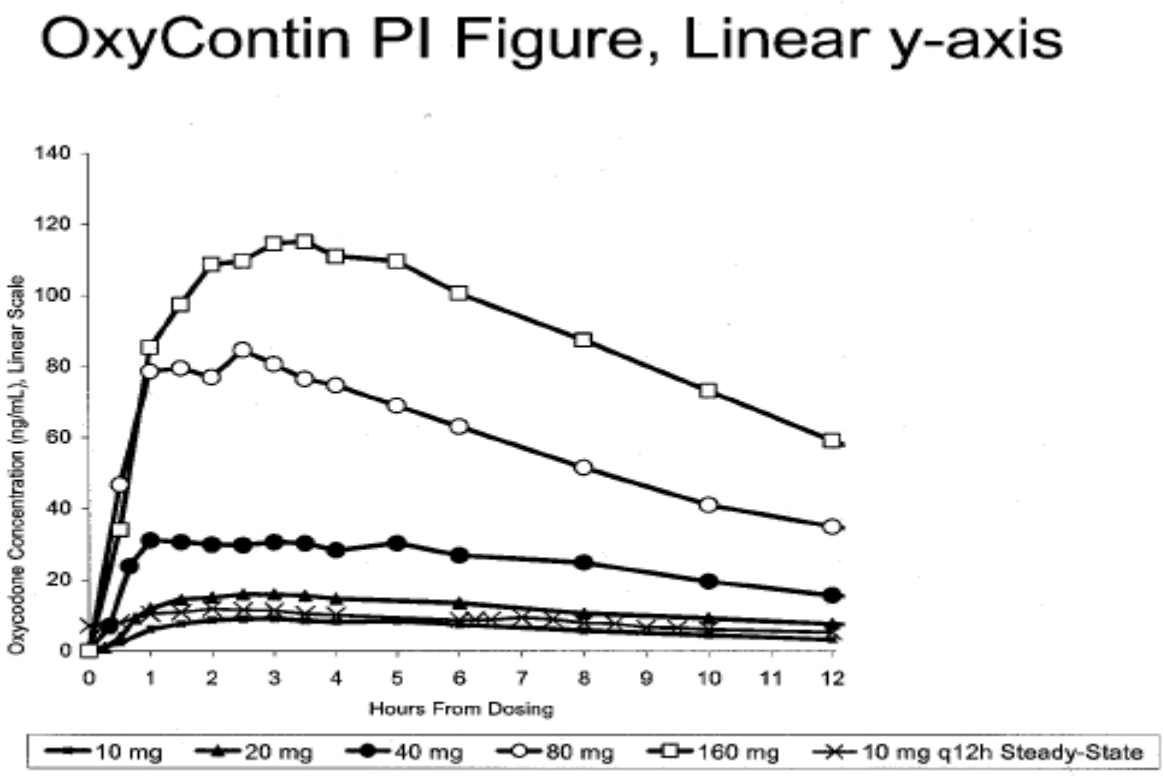

Figure 1

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.

255. 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.

256. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full 12 hours. [redacted]

[redacted]

257. More recently, other Purdue advertisements also emphasized "Q12h" (meaning twice-daily) dosing, as discussed in Section V.E.5. 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.

258. 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.[88] 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 contrast to OxyContin. [redacted] Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

259. Purdue's failure to disclose the prevalence of end-of-dose failure meant that prescribers in Chicago 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 increasing the dose or prescribing "rescue" opioids, which has the same effect as increasing the amount of opioids prescribed to a patient, as described above in Section V.D.6.[89, 90]

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

[89] 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"

E. Each Defendant Engaged in Deceptive Marketing, Both Branded and Unbranded, that Targeted and Reached Chicago Prescribers.

260. 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 Chicago prescribers and patients, with the intent of distorting their views on the risks, benefits, and superiority of opioids for treatment of chronic pain.

261. Defendants engaged in their deceptive marketing campaign, both nationwide and in Chicago, using a number of strategies. Defendants trained their sales forces and recruited physician speakers to deliver these deceptive messages and omissions, and they in turn conveyed them to prescribers. 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 Defendants' drugs, these materials are considered "labeling" within the meaning of 21 C.F.R. § 1.3(a), which means Defendants are liable for their content.

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medication appear in publications Purdue sponsored such as APF's *A Policymaker's Guide* (2011) and the 2013 CME *Overview of Pain Management Options*.

[90] The Connecticut Attorney General's office filed a citizens' petition with the FDA on January 27, 2004, requesting that the OxyContin label be amended with a warning not to prescribe the drug more than twice daily as a means of compensating for end-of-dose failure. The FDA denied this request on September 11, 2008. The FDA found that the state had failed to present sufficient evidence that more frequent dosing caused adverse outcomes, but the FDA did not challenge the Connecticut finding that end-of-dose failure of OxyContin was prevalent. Indeed, the FDA found that end-of-dose failure affected a "substantial" number of chronic pain patients prescribed OxyContin.

262. As described below, the City has located a number of Chicago-area prescribers who received Defendants' misrepresentations. Each of the misrepresentations received by these doctors—as well as other misrepresentations outlined above in Section V.D—constitutes an integral piece of a centrally directed marketing strategy to change medical perceptions regarding the use of opioids to treat chronic pain. Defendants were aware of each of these misrepresentations, and Defendants approved of them and oversaw their dissemination at the national, corporate level.[91]

1. Actavis

263. As described below, Actavis promoted its branded opioid, Kadian, through a highly deceptive marketing campaign that it carried out principally through its sales force and recruited physician speakers. As internal documents indicate, this campaign rested on a series of misrepresentations and omissions regarding the risks, benefits, and superiority of opioids, and indeed incorporated each of the types of deceptive messages described above in Section V.D.1-7. Based on the highly coordinated and uniform nature of Actavis's marketing, and as confirmed by both verbatim message data and prescriber interviews, Actavis conveyed these deceptive messages to Chicago prescribers. Actavis did so with the intent that Chicago prescribers and/or consumers would rely on the messages in choosing to use opioids to treat chronic pain.[92]

[91] In some instances, Chicago prescribers reported receiving Defendants' misrepresentations but failed to write prescriptions for Defendants' drugs paid for by the City. Such instances nevertheless represent misstatements made by Defendants in connection with trade or commerce in Chicago with the intent that these prescribers rely on those misrepresentations. Further, it is plausible—if not likely—that these prescribers wrote prescriptions for Chicago consumers that were funded by another third-party payor or by Chicago consumers themselves.

[92] 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.

a. Actavis's Deceptive Direct Marketing

264. To help devise its marketing strategy for Kadian, Actavis commissioned a report from one of its consultants in January 2005 about barriers to market entry. The report concluded that two major challenges facing opioid manufacturers in 2005 were (i) overcoming "concerns regarding the safety and tolerability" of opioids, and (ii) the fact that "physicians have been trained to evaluate the supporting data before changing their respective practice behavior." To do that, the report advocated a "[p]ublication strategy based on placing in the literature key data that influence members of the target audience" with an "emphasis . . . on ensuring that the message is believable and relevant to the needs of the target audience." This would entail the creation of "effective copy points . . . backed by published references" and "developing and placing publications that demonstrate [the] efficacy [of opioids] and [their] safety/positive side effect profile." According to the report, this would allow physicians to "reach[] a mental agreement" and change their "practice behavior" without having first evaluated supporting data—of which Actavis (and other Defendants) had none.

265. The consulting firm predicted that this manufactured body of literature "w[ould], in turn, provide greater support for the promotional message and add credibility to the brand's advocates" based on "either actual or ***perceived*** 'scientific exchange'" in relevant medical literature. (emphasis added). [redacted]

[redacted] In short, Actavis knew exactly what each study would show—and how that study would fit into its marketing plan—before it was published. [redacted]

266. To ensure that messages based on this science reached individual physicians, Actavis deployed sales representatives, or detailers, to visit prescribers in Chicago and across the country. At the peak of Actavis's promotional efforts in 2011, the company spent $6.7 million on detailing.

267. [redacted]

268. Actavis also planned to promote Kadian by presenting at conferences of organizations where it believed it could reach a high concentration of pain specialists. Its choice of conferences also was influenced by the host's past support of opioids. For example, Actavis documents show that Actavis presented papers concerning Kadian at an annual meeting of AGS because AGS's guidelines "support the use of opioids."

269. Actavis targeted prescribers using both its sales force and recruited physician speakers, as described below.

i. *Actavis's Deceptive Sales Training*

270. Actavis's sales representatives targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales

representatives were critical in delivering Actavis's marketing strategies and talking points to individual prescribers.

271. Actavis's strategy and pattern of deceptive marketing is evident in its internal training materials. [redacted]

272. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality, as described above in Section V.D.1, available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids [redacted] Actavis failed to explain to its

sales representatives and, through them, to doctors the greater risks associated with opioids at high doses, which are described in Section V.D.6 above.

273. Further, the 2010 sales training module highlighted the risks of alternate pain medications without providing a comparable discussion of the risks of opioids, painting the erroneous and misleading impression that opioids are safer. Specifically, the document claimed that [redacted] By contrast, the corresponding section related to opioids neglects to include a *single* side effect or risk associated with the use of opioids, including from long-term use.

274. This sales training module also severely downplayed the main risk associated with Kadian and other opioids—addiction. [redacted] This falsely suggests that few patients will become addicted, that only those with a prior history of abuse are at risk of opioid addiction, and that doctors can screen for those patients and safely prescribe to others. To the contrary, as described above in Section V.D.2, opioid addiction will affect a significant population of patients; while patients with a history of abuse may be more prone to addiction, all patients are at risk, and doctors may not be able to identify, or safely prescribe to, patients at greater risk.

275. [redacted]

[redacted]

276. Further, the sales training neglected to disclose that no risk-screening tools related to opioids have ever been scientifically validated. As noted in Section V.D.3, the AHRQ recently issued an Evidence Report that could identify "[n]o study" that had evaluated the effectiveness of various risk mitigation strategies—including the types of patient screening implied in Actavis's sales training—on outcomes related to overdose, addiction, abuse or misuse.

277. The sales training module also directed representatives to counsel doctors to be on the lookout for the signs of "[p]seudoaddiction," [redacted] However, as described above in Section V.D.4, the concept of "pseudoaddiction" is unsubstantiated and meant to mislead doctors and patients about the risks and signs of addiction.

278. [redacted]

279. [redacted] but Actavis sales representatives were passing deceptive messages on to prescribers even before then. A July 2010 "Dear Doctor" letter issued by the FDA indicated that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and

minimized serious risks associated with [Kadian]." Certain risks that were misrepresented included the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid agonists have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion." The FDA also took issue with an advertisement for misrepresenting Kadian's ability to help patients "live with less pain and get adequate rest with less medication," when the supporting study did not represent "substantial evidence or substantial clinical experience."

280. Actavis's documents also indicate that the company continued to deceptively market its drugs after 2010. [redacted]

281. [redacted]

282. Finally, the internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines with doctors during detailing visits. As discussed above in Section

V.C.2.c.ii, these guidelines deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories.

ii. *Actavis's Deceptive Speakers Training*

283. Actavis also increasingly relied on speakers—physicians whom Actavis recruited to market opioids to their peers—to convey similar marketing messages. [redacted]

284. A training program for Actavis speakers included training on many of the same messages found in the [redacted] as decribed below. The deceptive messages in Actavis's speakers' training are concerning for two reasons: (a) the doctors who participated in the training were themselves prescribing doctors, and the training was meant to increase their prescriptions of Kadian; and (b) these doctors were trained, paid, and directed to deliver these messages to other doctors who would write prescriptions of Kadian.

285. Consistent with the training for sales representatives, Actavis's speakers' training falsely minimized the risk of addiction posed by long-term opioid use. [redacted] In recommending the use of these screening tools, the speakers' training neglected to disclose that none of them has been scientifically validated.

286. The speakers' training also made reference to "pseudoaddiction" [redacted] By portraying the risks in this manner, the speakers' training presentation deceptively gave doctors a false sense of security regarding the types of patients who can become addicted to opioids and the types of behaviors these patients exhibit.

287. The speakers' training downplayed the risks of opioids, while focusing on the risks of competing analgesics like NSAIDs [redacted] As a result, the training exaggerated the risks of

NSAIDs, both absolutely and relative to opioids, to make opioids appear to be a more attractive first-line treatment for chronic pain.

288. The speakers' training also misrepresented the risks associated with increased doses of opioids. [redacted]

b. Actavis's Deceptive Statements to Chicago Prescribers and Patients

289. The misleading messages and training materials Actavis provided to its sales force and speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, without complete and accurate information about the risks, benefits, and alternatives. This deception was national in scope and included Chicago. As described in Section V.B.2 above, Actavis's nationwide messages reached Chicago prescribers in a number of ways. For example, they were carried into Chicago by Actavis's sales representatives during detailing visits as well as made available to Chicago patients and prescribers through websites and ads, including ads in prominent medical journals. They have also been delivered to Chicago prescribers by Actavis's paid speakers, who were required by Actavis policy and by FDA regulations to stay true to Actavis's nationwide messaging.

290. Once trained, Actavis's sales representatives and speakers were directed to, and did, visit potential prescribers in Chicago, as elsewhere, to deliver their deceptive messages. These contacts are demonstrated by Actavis's substantial effort in tracking the habits of

individual Chicago physicians in prescribing Kadian, and by the direct evidence of Actavis detailing Chicago prescribers.

291. [redacted]

292. Actavis tracked, in substantial detail, the prescribing behavior of Chicago area physicians [redacted]

293. [redacted][93] [redacted]

294. The experiences of specific prescribers confirm both that Actavis's national marketing campaign included the misrepresentations described above in Sections V.D and V.E.1, and that the company disseminated these same misrepresentations to Chicago prescribers and consumers. In particular, these prescriber accounts reflect that Actavis detailers omitted or minimized the risk of opioid addiction; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

93 [redacted]

295. A survey of a sample of Midwestern physicians, who reported the "verbatim" messages that they retained from detailing visits and other promotional activity, documented that Kadian sales representatives promoted Kadian as being less addictive than other Schedule II opioids at least between 2006 and 2008. In specific instances in 2007 and 2008, these sales representatives also made these claims to nurse practitioners. Additionally, Kadian sales representatives told a Midwestern orthopedic surgeon in 2006 that Kadian improved patients' sleep (a promise of improved function) and told a Midwestern rheumatologist that Kadian was "safer than NSAIDs."

296. In addition, the City has interviewed a number of Chicago-area prescribers who reported that they were detailed by Actavis sales representatives and heard similar claims, as well as other messages described in Sections V.D. and V.E.1.[94] In each instance, Actavis intended that the prescriber rely on these messages. Most of these physicians did, in fact, prescribe Actavis's opioids. As specified below and in Exhibit A.1, most of them wrote prescriptions for Actavis opioids that were paid for by the City's health plans:[95]

a. Chicago Prescriber B, an anesthesiologist, sees opioid drug company representatives on a regular basis, and he has met with representatives from Actavis. These representatives pushed the message that "steady-state" drugs have less potential for abuse. Opioid manufacturers, including Actavis, have told him that opioids improved patient function and

[94] The City's interviews with prescribers, described here and elsewhere in the Complaint, focused on the period 2006 to the present. Prescribers, however, cannot always recall with precision when particular detailing visits took place. Defendants, on the other hand, closely track their sales representatives' detailing visits through call notes and other documentation, and are in a much better position to know these dates than the City.

[95] The claim figures set forth here, and similar claim figures in the parts of Section V.E relating to the other Defendants, reflect prescribing activity reported in claims to a single third-party payor, the City's health plans. On information and belief, in most instances these figures reflect but a small fraction of the opioid prescriptions written by each prescriber for treatment of the chronic pain of Chicago-area residents.

quality of life. Prescriber B relies on the information he receives from drug company representatives because his busy practice prevents him from having the time to conduct the research himself. For the period June 3, 2005 – June 29, 2015, the City health plan paid $176,510.98 in claims for opioids prescribed by Prescriber B, including $34,029.61 in Defendants' drugs (368 prescriptions) and $26,979.75 for Actavis's opioids in particular (252 prescriptions).

b. 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, including Kadian representatives, told Prescriber D that their drugs were "steady state," which he interpreted to mean that they were less addictive. For the period June 6, 2005 – August 11, 2012, the City health plans paid $61,651.12 in claims for opioids prescribed by Prescriber D, including $59,566.89 in Defendants' drugs (624 prescriptions) and $11,297.89 for Actavis's opioids in particular (425 prescriptions).

c. Chicago Prescriber E, an anesthesiologist and pain specialist, explained that he received visits from sales representatives from all Defendants, including Kadian representatives, until a few years ago. Representatives from Actavis never discussed addiction with him other than to promote Kadian as tamper-proof and more difficult to abuse. Prescriber E also attended a dinner at which a heavy Kadian prescriber talked about the benefits of using the drug.[96] For the period October 23, 2006 – May 12, 2014, the City health plans paid $23,114.17 in claims for opioids prescribed by Prescriber E, including $15,638.46 in Defendants' drugs (107 prescriptions) and $3,954.62 for Actavis's opioids in particular (68 prescriptions).

d. Chicago Prescriber F, a headache specialist, who sees patients on the City's health plans, recalls being detailed by Kadian representatives from 2005 to 2007. Prescriber F explained that Kadian representatives told him that Kadian is less addicting than other opioids due to its extended release mechanism, a proposition he believes to be true. For the period December 8,

[96] Prescriber C, as well as Prescriber H below, attended talks presented by Actavis speakers. These talks would have followed the same deceptive talking points covered in Actavis's speaker training, as described above in Section V.E.1a.ii.

2006 – June 4, 2015, the City health plans paid $2,434.76 in claims for opioids prescribed by Prescriber F, including $450.05 in Defendants' drugs (3 prescriptions) and $377.51 for Actavis's opioids in particular (2 prescriptions).

e. Chicago Prescriber G indicated that he was visited by sales representatives from all Defendants, including Actavis. He recalled that he was never warned about the risk of addiction. According to Prescriber G, opioid sales representatives—including Kadian representatives—told him that opioids would increase patients' ability to complete activities of daily living and that patients could be managed to avoid addiction. These representatives also told him that patients can be screened to mitigate addiction risks. For the period November 16, 2009 – June 18, 2015, the City health plans paid $23,794.71 in claims for opioids prescribed by Prescriber G, including $23,399.66 in Defendants' drugs (75 prescriptions).

f. Chicago Prescriber H, a Chicago physician, was detailed many times by Kadian sales representatives. These representatives never discussed the risk of addiction with him. Prescriber H attended a speaker event sponsored by Actavis. For the period January 19, 2010 – April 23, 2012, the City health plans paid $68.70 in claims for opioids prescribed by Prescriber H, including $68.70 in Defendants' drugs (3 prescriptions) and $15.89 for Actavis's opioids in particular (1 prescription).

g. Chicago Prescriber I recalled being detailed by Kadian representatives every few months. Prescriber I recalls being told by his Kadian representative that, if the capsule was opened, its contents could not be dissolved in water, which he believes was intended to imply that Kadian was less likely to be abused—and thereby less likely to lead to addiction—than other opioids. Sales representatives, including Kadian representatives, never informed Prescriber I about the risk of addiction. For the period July 6, 2011 – May 17, 2012, the City health plans paid $1,018.13 in claims for opioids prescribed by Prescriber I, including $1005.18 in Defendants' drugs (4 prescriptions) and $211.48 for Actavis's opioids in particular (1 prescription).

h. Chicago Prescriber J, a nurse practitioner, indicated that she was visited (or sat in on visits) by sales representatives from Defendants Purdue, Cephalon, Janssen, and Actavis. She could not recall drug representatives from these Defendants, including Kadian representatives, ever mentioning the risks of addiction associated with opioid use. For the period February

> 22, 2012 – May 25, 2015, the City health plans paid $5,253.22 in claims for opioids prescribed by Prescriber J, including $2,706.06 in Defendants' drugs (39 prescriptions) and $1,252.08 for Actavis's opioids in particular (20 prescriptions).

297. These accounts reflect specific examples of instances in which Actavis's sales representatives made the misrepresentations outlined above in Sections V.D and V.E.1 directly to Chicago prescribers. They are not an exhaustive list. Many physicians are difficult to reach given their patient schedules, and some are reluctant to be interviewed about their prescribing decisions. Nevertheless, based on the nationwide and uniform character of Actavis's marketing campaign, these examples support the inference that Actavis sales representatives made similar misstatements to the other Chicago-area prescribers they detailed.

2. Cephalon

298. At the heart of Cephalon's deceptive promotional efforts was a concerted and sustained effort to expand the market for its branded opioids, Actiq and Fentora, far beyond their FDA-approved use in opioid-tolerant cancer patients. Trading on their rapid-onset formulation, Cephalon touted its opioids as the answer to "breakthrough pain"—a term its own KOL allies planted in the medical literature—whether cancer pain or not. Cephalon promoted this message through its sales force, paid physician speakers, advertisements, and CMEs, even after the FDA issued the company warnings and rejected an expanded drug indication.

299. Even as it promoted Actiq and Fentora off-label, Cephalon also purveyed many of the deceptive messages described above in Section V.D. It did so both directly—through detailing visits and speaker programs—and through the publications and CMEs of its third-party partners. These messages included misleading claims about functional improvement, addiction risk, pseudoaddiction, and the safety of alternatives to opioids.

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

a. Cephalon's Deceptive Direct Marketing

301. Like the other Defendants, Cephalon directly engaged in misleading and deceptive marketing of its opioids through its sales force and branded advertisements. These messages were centrally formulated and intended to reach prescribers nationwide, including those practicing in the Chicago area. Cephalon also spent the money necessary to aggressively promote its opioid drugs, setting aside $20 million to market Fentora in 2009 alone.

i. *Cephalon's Fraudulent Off-Label Marketing of Actiq and Fentora*

302. Chief among Cephalon's direct marketing efforts was its campaign to deceptively promote its opioids for off-label uses. Cephalon reaps significant revenue from selling its opioids for treatment of chronic non-cancer pain. However, neither of its two opioid drugs—Actiq or Fentora—is approved for this purpose. Instead, both have indications that are very clearly and narrowly defined to limit their use to a particular form of cancer pain. Despite this restriction and in order to claim its piece of the broader chronic non-cancer pain market, Cephalon deceptively and unlawfully marketed Actiq and then Fentora for patients and uses for which they were not safe, effective, or allowed, causing prescriptions to be written and paid and, grievously, patients to be injured and die. As described below in Section V.E.2.c, Cephalon's

efforts to expand the market for its drugs beyond cancer pain extended to Chicago prescribers, few of whom were oncologists and at least one of whom was surprised to have received Cephalon's sales pitches because he ran a "headache clinic."

(a) Cephalon launched its fraudulent marketing scheme for Actiq

303. Cephalon's Actiq is a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate."[97]

304. Actiq is appropriately used only to treat "breakthrough" cancer pain that cannot be controlled by other medications. Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain. Actiq is a rapid-onset drug that takes effect within 10-15 minutes but lasts only a short time. It is also an extremely strong drug, considered to be at least 80 times more powerful than morphine. Fentanyl, a key ingredient in Actiq, has been linked to fatal respiratory complications in patients. Actiq is not safe in any dose for patients who are not opioid tolerant, that is, patients who have taken specific doses of opioids for a week or longer and whose systems have acclimated to the drugs.

305. In 1998, the FDA approved Actiq "***ONLY*** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[98] (Emphasis in FDA document). Because of Actiq's dangers, wider, off-label uses—as the FDA label makes clear—are not permitted:

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[97] *See* John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs*, Wall St. J., Nov. 3, 2006.

[98] FDA Approval Letter for NDA 20-747 (Nov. 4, 1998) at 5, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.

> This product ***must not*** be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason ACTIQ is contraindicated in the management of acute or postoperative pain.[99]

306. Actiq and Fentora are thus intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Unlike other drugs, as to which off-label uses are permitted but cannot be promoted by the drug maker, Actiq and Fentora are so potent that off-label use for opioid naïve patients is barred by the FDA, as their labels make clear.

307. Notwithstanding the drug's extreme potency and related dangers and the FDA's explicit limitations, Cephalon actively promoted Actiq for chronic non-cancer pain—an unapproved, off-label use. Cephalon marketed Actiq as appropriate for the treatment of various conditions including back pain, headaches, pain associated with sports-related injuries, and other conditions not associated with cancer for which it was not approved, appropriate, or safe.

308. Actiq's initial sales counted in the tens of millions of dollars, corresponding to its limited patient population. But by 2005, Actiq sales reached $412 million, making it Cephalon's second-highest selling drug. As a result of Cephalon's deceptive, unlawful marketing, sales exceeded $500 million by 2006.

(b) October 1, 2006—Cephalon fraudulently marketed Actiq's successor drug, Fentora

309. Actiq was set to lose its patent protection in September 2006. To replace the revenue stream that would be lost once generic competitors came to market, Cephalon purchased

[99] Actiq Drug Label, July 2011. The 1998 version does not substantively differ: "Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contra-indicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients." (Emphasis in original).

a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug Application ("NDA") to the FDA for approval. Like Actiq, Fentora is an extremely powerful and rapid-onset opioid. It is administered by placing a tablet in the mouth until it disintegrates and is absorbed by the mucous membrane that lines the inside of the mouth.

310. On September 25, 2006, the FDA approved Fentora, like Actiq, only for the treatment of breakthrough cancer pain in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Fentora's unusually strong and detailed black box warning label—the most serious medication warning required by the FDA—makes clear that, among other things:

> Fatal respiratory depression has occurred in patients treated with FENTORA, including following use in opioid non-tolerant patients and improper dosing. The substitution of FENTORA for any other fentanyl product may result in fatal overdose.
>
> Due to the risk of respiratory depression, FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients.[100]

311. When Cephalon launched Fentora on October 1, 2006, it picked up the playbook it developed for Actiq and simply substituted in Fentora. Cephalon immediately shifted 100 general pain sales representatives from selling Actiq to selling Fentora to the very same physicians for uses that would necessarily and predictably be off-label. Cephalon's marketing of Actiq therefore "primed the market" for Fentora. Cephalon had trained numerous KOLs to lead promotional programs for Fentora, typically including off-label uses for the drug. Cephalon billed Fentora as a major advance that offered a significant upgrade in the treatment of breakthrough pain generally—not breakthrough cancer pain in particular—from Actiq.

[100] Fentora Drug Label, February 2013, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021947s008lbl.pdf

Cephalon also developed a plan in 2007 to target elderly chronic pain patients, via a multi-city tour with stops at AARP events, YMCAs, and senior living facilities.

312. On February 12, 2007, only four months after the launch, Cephalon CEO Frank Baldino told investors:

> [W]e've been extremely pleased to retain a substantial portion, roughly 75% of the rapid onset opioid market. We executed our transition strategy and the results in our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come.[101]

313. On May 1, 2007, just seven months after Fentora's launch, Cephalon's then-Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts that Fentora's reach would exceed even Actiq's. He described the company's successful and "aggressive" launch of Fentora that was persuading physicians to prescribe Fentora for ever broader uses. He identified two "major opportunities"—treating breakthrough cancer pain and:

> The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain. . . .
>
> . . . .
>
> We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication. . . . [opioids are] widely used in the treatment of . . . non-cancer patients . . . .
>
> . . . .
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.

[101] *See Cephalon Q4 2006 Earnings Call Transcript,* Seeking Alpha (February 12, 2007, 8:48 PM EST) at 5, http://seekingalpha.com/article/26813-cephalon-q4-2006-earnings-call-transcript.

> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[102]

(c) September 2007—Reports of death and serious side effects led the FDA to issue a public health warning for Fentora

314. On September 10, 2007, Cephalon sent letters to doctors warning of deaths and other "serious adverse events" connected with the use of Fentora and indicating that "[t]hese deaths occurred as a result of improper patient selection (*e.g.*, use in opioid non-tolerant patients), improper dosing, and/or improper product substitution."[103] The warning did not mention Cephalon's deliberate role in the "improper patient selection."

315. Two weeks later, the FDA issued its own Public Health Advisory. The FDA emphasized, once again, that Fentora should be prescribed only for approved conditions and that dose guidelines should be carefully followed. The FDA Advisory made clear that several Fentora-related deaths had occurred in patients who were prescribed the drug for off-label uses. The FDA Advisory warned that Fentora should not be used for any off-label conditions,

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[102] *See Cephalon Q1 2007 Earnings Call Transcript,* Seeking Alpha (May 1, 2007, 8:48 PM EST) at 23, http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript?page=1.

[103] Letter from Jeffrey M. Dayno, M.D., Vice President, Medical Services, Cephalon, Inc. to Healthcare Providers (Sept. 10, 2007), http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMed icalProducts/UCM154439.pdf.

including migraines, post-operative pain, or pain due to injury, and that it should be given only to patients who have developed opioid tolerance. The Advisory reiterated that because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.[104]

316. Cephalon's off-label marketing continued notwithstanding the regulatory scrutiny. Cephalon's 2008 internal audit of its Sales & Marketing Compliance Programs concluded that marketing and tactical documents, as written, may be construed to promote off-label uses. The same report acknowledged that Cephalon lacked a process to confirm that speakers' program participants were following Cephalon's written, formal policies prohibiting off-label promotion, and that "non-compliant [Cephalon Speaker Programs] may be taking place." Moreover, the report acknowledged that Cephalon's "call universe" may include "inappropriate prescribers"—prescribers who had nothing to do with cancer pain.

(d) May 6, 2008—The FDA rejected Cephalon's request for expanded approval of Fentora

317. Cephalon filed a supplemental new drug application, ("sNDA"), asking the FDA to approve Fentora for the treatment of non-cancer breakthrough pain. Cephalon admitted that Fentora already had been heavily prescribed for non-cancer pain, but argued that such widespread use demonstrated why Fentora should be approved for these wider uses.[105] Cephalon's application also conceded that "[t]o date, no medication has been systematically

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[104] FDA Public Health Advisory, *Important Information for the Safe Use of Fentora (fentanyl buccal tablets*) (Sept. 26, 2007), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.

[105] *See Fentora CII: Advisory Committee Briefing Document,* U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008), http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf.

evaluated in clinical studies or approved by the FDA for the management of [breakthrough pain] in patients with chronic persistent non-cancer-related pain." *Id.*

318. In response to Cephalon's application, the FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.[106] By a vote of 17-3, the relevant Advisory Committee—a panel of outside experts—voted against recommending approval of Cephalon's sNDA for Fentora, citing the potential harm from broader use. On September 15, 2008, the FDA denied Cephalon's application and requested, in light of Fentora's already off-label use, that Cephalon implement and demonstrate the effectiveness of proposed enhancements to Fentora's Risk Management Program. In December 2008, the FDA followed that up with a formal request directing Cephalon to submit a Risk Evaluation and Mitigation Strategy for Fentora.

(e) March 26, 2009—the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") warned Cephalon about its misleading advertising of Fentora

319. Undeterred by the rejection of its sNDA, Cephalon continued to use its general pain sales force to promote Fentora off-label to pain specialists as an upgrade over Actiq for the treatment of non-cancer breakthrough pain. Deceptively and especially dangerously, Cephalon also continued to promote Fentora for use by all cancer patients suffering breakthrough cancer pain, and not simply those who were opioid tolerant.

320. On March 26, 2009, DDMAC issued a Warning Letter to Cephalon, telling Cephalon that its promotional materials for Fentora amounted to deceptive, off-label promotion

[106] *See* Yoo Jung Chang & Lauren Lee, *Review of Fentora and Actiq Adverse Events from the Adverse Event Reporting System ("AERS") Database*, U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008), http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDAcorepresentations.ppt#289,1 (last visited Aug. 17, 2010).

of the drug.[107] Specifically, the Warning Letter asserted that a sponsored link on Google and other search engines for Fentora, which said "[l]earn about treating breakthrough pain in patients with cancer,"[108] was improper because it "misleadingly broaden[ed] the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora therapy . . . when this is not the case."

321. DDMAC emphasized that Fentora's label was limited to cancer patients with breakthrough pain **"*who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.*"** (Emphasis in original). DDMAC explained that the advertisement was "especially concerning given that Fentora **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids." (Emphasis in original). DDMAC also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate **any** risk information associated with the use" of the drug. (Emphasis in original).

(f) Cephalon continues to knowingly, deceptively, and illegally promote Fentora for off-label uses

322. Cephalon's own market research studies confirm that its Fentora promotions were not focused on the physicians who treat breakthrough cancer pain. Cephalon commissioned

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[107] Letter from Michael Sauers, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, to Carole S. Marchione, Senior Director and Group Leader, Regulatory Affairs (March 26, 2009), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM166238.pdf.

[108] Screen shots of the sponsored link are available here: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166240.pdf.

several market research studies to determine whether oncologists provided an "adequate" market potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

323. [redacted]

324. [redacted]

[redacted]

325. [redacted]"[109] [redacted]

326. Cephalon was well aware that physicians were prescribing Fentora for off-label uses. [redacted]

[109] [redacted]

[redacted]

327. [redacted]

328. Cephalon also was aware that its detailing had an impact on prescription rates. [redacted]

329. [redacted]

[redacted]

330. [redacted]

331. In 2011, Cephalon wrote and copyrighted an article titled "2011 Special Report: An Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA®) and Oral Transmucosal Fentanyl Citrate (ACTIQ®)" that was published in *Pain Medicine News*. The article promoted Cephalon's drugs for off-label uses by stating that the "judicious use of opioids can facilitate effective and safe management of chronic pain" and noted that Fentora "has been shown to be effective in treatment of [break through pain] associated with multiple causes of pain," not just cancer.

ii. *Cephalon's Misrepresentation of the Risks Associated with the Use of Opioids for the Long-Term Treatment of Chronic Pain*

332. Cephalon's conduct in marketing Actiq and Fentora for chronic non-cancer pain, despite their clear (and deadly) risks and unproved benefits, was an extension, and reaped the benefits, of Cephalon's generally deceptive promotion of opioids for chronic pain.

333. [redacted] As described above in Section V.D.1, there is no scientific evidence corroborating a link between chronic opioid therapy and increased functionality, and any suggestion of such a link is, in fact, false.

334. [redacted]

335. Along with its deploying its sales representatives, Cephalon also used speakers bureaus to help reach prescribers. The following [redacted] used by Cephalon in connection with developing a speakers bureau program in 2010, reflects how the company viewed each treating

physician as a vehicle to generate prescriptions—whether written by that physician directly or caused indirectly by his or her influence over other physicians:

336. Having determined that speakers were an effective way to reach prescribers, Cephalon set to work ensuring that its speakers would disseminate its misleading messages.

337.

[redacted]

338. Working with FSMB, Cephalon also trained its speakers to turn 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 instead that they would be punished if they failed to prescribe opioids to their patients with pain. Through this messaging, Cephalon aimed to normalize the prescribing of opioids for chronic pain and failed to acknowledge the serious risks of long-term opioid use and its inappropriateness as a front-line treatment for pain.

[redacted]

339. Finally, Cephalon also developed a guidebook called *Opioid Medications and REMS: A Patient's Guide*, which deceptively minimized the risks of addiction from the long-term use of opioids. Specifically, the guidebook claimed that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids," which, as described in Section V.D.2, is dangerously false. Cephalon distributed the guidebook broadly, and it was available to and intended to reach prescribers in Chicago.

340. The misleading messages and materials Cephalon provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, without complete and accurate information about the risks, benefits, and

alternatives. This deception was national in scope and included Chicago. As described above in Section V.B, Cephalon's nationwide messages would have reached Chicago prescribers in a number of ways. For example, they were delivered in Chicago by Cephalon's sales representatives in detailing visits and made available to Chicago patients and prescribers through websites and ads, including ads in prominent medical journals. They have also been delivered to Chicago prescribers by Cephalon's paid speakers, who were required by Cephalon policy to stay true to the company's nationwide messaging.

b. Cephalon's Deceptive Third-Party Statements

341. Like the other Defendants, Cephalon also relied on third parties to disseminate its messages through deceptive publications and presentations. By funding, developing and reviewing the content of, and distributing and facilitating the distribution of these messages, Cephalon exercised editorial control over them. Cephalon, in some instances, used its sales force to directly distribute certain publications by these Front Groups and KOLs, rendering those publications "labeling" within the meaning of § 21 C.F.R. § 1.3(a) and making Cephalon responsible for their contents. Cephalon also deployed its KOLs as speakers for talks and CMEs to selected groups of prescribers.

342. [redacted]

343. Cephalon's relationships with several such Front Groups and KOLs—and the misleading and deceptive publications and presentations those relationships generated—are described below.

i. *FSMB – Responsible Opioid Prescribing*

344. In 2007, for example, Cephalon sponsored and distributed through its sales representatives FSMB's *Responsible Opioid Prescribing*, which was drafted by "Medical Writer X," whose work for Janssen is described below in Section V.E.4. Medical Writer X was frequently hired by a consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Medical Writer X's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

345. *Responsible Opioid Prescribing* was a signature piece of Medical Writer X's work and contained a number of deceptive statements. This publication claimed that because pain had a negative impact on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve function." However, as described in Section V.D.1 above, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction.

346. *Responsible Opioid Prescribing* also misrepresented the likelihood of addiction by mischaracterizing drug-seeking behavior as "pseudoaddiction." It explained that "requesting drugs by name," engaging in "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding were all signs of "pseudoaddiction" and are likely the effects of undertreated pain, rather than true addiction. As described in Section V.D.4 above, there is no scientific evidence to support the concept of pseudoaddiction, and any suggestion that addictive behavior masquerades as "pseudoaddiction" is false.

347. Cephalon spent $150,000 to purchase copies of *Responsible Opioid Prescribing* in bulk. It then used its sales force to distribute these copies to 10,000 prescribers and 5,000

pharmacists nationwide. These were available to and intended to reach prescribers and pharmacists in Chicago.

ii. *APF – Treatment Options: A Guide for People Living with Pain*

348. Cephalon also exercised considerable control over the Front Group APF, which published and disseminated many of the most egregious falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, are described in detail below.

349. Documents indicate that Cephalon provided APF with substantial assistance in publishing deceptive information regarding the risks associated with the use of opioids for chronic pain. An April 3, 2008 Fentora Assessment Strategy Tactics Team Meeting presentation outlines Cephalon's strategy to prepare for a meeting at which the FDA Advisory Committee would consider expanding the indication of Fentora to include chronic, non-cancer pain. Cephalon prepared by "reaching out to third-party organizations, KOLs, and patients to provide context and, where appropriate, encourage related activity." First among the Front Groups listed was APF.

350. Cephalon was among the drug companies that worked with APF to persuade the Institute of Medicine of the National Academies (IOM) on issues related to chronic opioid therapy. APF President Will Rowe circulated a document to Cephalon and other drug company personnel that contained key message points and suggested that they "[c]onsider using this document in your communications with the members of the IOM Committee." According to Rowe, recipients should "consider this a working document which you can add to or subtract from." Rowe also advised that, if recipients "have an ally on that Committee," they should "consider sharing this document with that person."

351. Cephalon personnel responded enthusiastically, with Cephalon's Associate Director for Alliance Development stating her belief that "the document does a good job of bringing together many important ideas." Cephalon reviewed and directed changes to this document, with the Cephalon Associate Director thanking Rowe "for incorporating the points we had raised." The close collaboration between Cephalon and APF on this project demonstrates their agreement to work collaboratively to promote the use of opioids as an appropriate treatment for chronic pain.

352. Cephalon's influence over APF's activities was so pervasive that APF's President, Will Rowe, even reached out to Defendants—including Cephalon—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.

353. Cephalon also sponsored APF's *Treatment Options: A Guide for People Living with Pain*, starting in 2007. It is rife with misrepresentations regarding the risks, benefits, and superiority of opioids.

354. For example, *Treatment Options* deceptively asserts 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." As described above in Section V.D.1, there is no scientific evidence corroborating that statement, and such statements are, in fact, false because available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in life activities like work.

355. *Treatment Options* also claims that addiction is rare and is evident from patients' conduct in self-escalating their doses, seeking opioids from multiple doctors, or stealing the drugs. *Treatment Options* further minimizes the risk of addiction by claiming that it can be

avoided through the use of screening tools, like "opioid agreements," which can "ensure [that patients] take the opioid as prescribed." Nowhere does *Treatment Options* explain to patients and prescribers that neither "opioid agreements" nor any other screening tools have been scientifically validated to decrease the risks of addiction, and the publication's assurances to the contrary are false and deceptive as described above in Section V.D.2-3.

356. *Treatment Options* also promotes the use of opioids to treat chronic pain by painting a misleading picture of the risks of alternate treatments, most particularly NSAIDs. *Treatment Options* notes that NSAIDs can be dangerous at high doses, and attributes 10,000 to 20,000 deaths a year annually to NSAID overdose. According to *Treatment Options*, NSAIDs are different from opioids because opioids have "no ceiling dose," which is beneficial since some patients "need" larger doses of painkillers than they are currently prescribed. These claims misleadingly suggest that opioids are safe even at high doses and omit important information regarding the risks of high-dose opioids, as discussed above in Section V.D.6.

357. Additionally, *Treatment Options* warns that the risks associated with NSAID use increase if NSAIDs are "taken for more than a period of months," but deceptively omits any similar warning about the risks associated with the long-term use of opioids. As discussed above in Section V.D.7, this presentation paints a misleading picture of the risks and benefits of opioids compared with alternate treatments.

358. APF distributed 17,200 copies of *Treatment Options* in 2007 alone. It is currently available online and was intended to reach Chicago prescribers and pharmacists. As described below in Section V.E.2.c, it was attended by at least one Chicago physician, Prescriber G.

iii. *Key Opinion Leaders and Misleading Science*

359. Cephalon also knew that its misleading messages would be more likely to be believed by prescribers if they were corroborated by seemingly neutral scientific support.

[redacted]

360. [redacted] With funding from Cephalon, for example, Dr. Portenoy wrote an article that purported to expand the definition of breakthrough cancer pain to non-cancer indications, vastly expanding the marketing potential of Cephalon's Fentora. The article was published in the nationally circulated *Journal of Pain* in 2006 and helped drive a surge in Fentora prescriptions.

361. The concept of "breakthrough pain" ultimately formed the sole basis for the central theme of promotional messages Cephalon cited to support the approval and marketing of Actiq and Fentora, rapid-acting opioids which begin to work very quickly but last only briefly. Neither of these drugs had a natural place in the treatment of chronic pain before Cephalon's marketing campaign changed medical practice. A recent literature survey of articles describing

non-cancer breakthrough pain calls into question the validity of the concept, suggesting it was not a distinct pain condition but a hypothesis to justify greater dosing of opioids. In other words, Cephalon conjured the science of breakthrough pain in order to sell its drugs.

362. As one scholar has pointed out, references to breakthrough pain in articles published on the MEDLINE bibliographic database spiked in 1998 and again in 2006.[110] These spikes coincide with FDA's approval of Actiq and Fentora.

363. Cephalon also bolstered supportive studies with supportive key opinion leaders.

[redacted] All told, Cephalon has paid doctors more than $4.5 million for programs relating to its opioids since 2000.

iv. *Misleading Continuing Medical Education*

364. Cephalon developed sophisticated plans for the deployment of its KOLs, broken down by sub-type and specialty, to reach targeted groups of prescribers through CMEs.

365. [redacted]

[110] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut , Georgetown U. Med. Ctr. (June 25, 2010), *available at* pharmedout.galacticrealms.com/Fugh-BermanPrescription forConflict6-25-10.pdf.

[redacted] Cephalon used the CME programs it sponsored to deceptively portray the risks related to the use of opioids to treat chronic non-cancer pain and promote the off-label use of Actiq and Fentora.

366. In 2007 and 2008, Cephalon sponsored three CMEs that each positioned Actiq and Fentora, and only Actiq and Fentora, as "rapid onset opioids" that would provide effective analgesia within the time period during which "breakthrough pain" was at its peak intensity. Although the CMEs used only the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME knew it referred only to Actiq or Fentora.

367. The CMEs each taught attendees that there was no sound basis for the distinction between cancer and non-cancer "breakthrough pain," and one instructed patients that Actiq and Fentora were commonly used in non-cancer patients, thus effectively endorsing this use. *Optimizing Opioid Treatment for Breakthrough Pain*, offered online by Medscape, LLC from September 28, 2007, through December 15, 2008, was prepared by KOL Dr. Lynn R. Webster and M. Beth Dove. It recommends prescribing a "short-acting opioid" (e.g., morphine, hydromorphone, oxycodone) "when pain can be anticipated," or a rapid-onset opioid when it cannot. The only examples of rapid-onset opioids then on the market were oral transmucosal fentanyl citrate (*i.e.*, Actiq) or fentanyl effervescent buccal tablet (*i.e.*, Fentora): "Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients *and are*

frequently prescribed to treat [breakthrough pain] in noncancer patients as well." (Emphasis added).

368. *Optimizing Opioid Treatment for Breakthrough Pain* not only deceptively promoted Cephalon's drugs for off-label use, but also misleadingly portrayed the risks, benefits, and superiority of opioids for the treatment of chronic pain. For example, the CME misrepresented that Actiq and Fentora would help patients regain functionality by advising that they improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. The CME also minimized the risks associated with increased opioid doses by explaining that NSAIDs were less effective than opioids for the treatment of breakthrough pain because of their dose limitations, without disclosing the heightened risk of adverse events on high-dose opioids.

369. [redacted] Around the same time, Dr. Webster was receiving nearly $2 million in funding from Cephalon.

370. *Optimizing Opioid Treatment for Breakthrough Pain* was available online and was intended to reach Chicago prescribers. As described below in Section V.E.2.c, it was attended by at least three Chicago physicians, Prescriber G, Prescriber O, and Prescriber P.

371. Cephalon similarly used an educational grant to sponsor the CME *Breakthrough Pain: Improving Recognition and Management*, which was offered online between March 31, 2008, and March 31, 2009, by Medscape, LLC. The direct result of Cephalon's funding was a purportedly educational document that echoed Cephalon's marketing messages: the CME deceptively omitted Actiq's and Fentora's tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like Cephalon's *Optimizing Opioid Treatment* CME, taught that Actiq and Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. This CME was available online and was intended to reach Chicago prescribers.

372. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski and Michael J. Brennan, M.D. Cephalon paid to have this CME published in a supplement of Pain Medicine News in 2009. It instructed prescribers that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility," and recommended dispensing "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," *i.e.*, Actiq, and "fentanyl buccal tablet," *i.e.*, Fentora, including in patients with chronic non-cancer pain. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines, that she served on

Cephalon's speakers bureau.[111] Dr. Fine also received funding from Cephalon for consulting services.

373. *Opioid-Based Management of Persistent and Breakthrough Pain* was available to and was intended to reach Chicago prescribers. As described below in Section V.E.2.c, it was attended by at least two Chicago physicians, Prescriber O and Prescriber P.

374. Cephalon's control over the content of these CMEs is apparent based on its advance knowledge of their content. A December 2005 Cephalon launch plan set forth key "supporting messages" to position Fentora for its product launch. Among them was the proposition that "15-minute onset of action addresses the unpredictable urgency of BTP." Years later, the same marketing messages reappeared in the Cephalon-sponsored CMEs described above. Echoing the Cephalon launch plan, *Optimizing Opioid Treatment for Breakthrough Pain* stated that "[t]he unpredictability of BTP will strongly influence the choice of treatment" and that Fentora "delivers an onset of analgesia that is similar to [Actiq] at ≤ 15 minutes." Similarly, *Opioid-Based Management of Persistent and Breakthrough Pain* defined "breakthrough pain" as "unpredictable," over a table describing both cancer and non-cancer "breakthrough pain."

375. Cephalon tracked the effectiveness of its deceptive marketing through third parties, demonstrating that Cephalon not only planned for but depended upon their activities as a key element of its marketing strategy. [redacted]

[111] As described in Section V.C.2.c.ii above, 14 of 21 panel members who drafted the AAPM/APS Guidelines received support from Janssen, Cephalon, Endo, and Purdue.

[redacted]

c. Cephalons's Deceptive Statements to Chicago Prescribers and Patients

376. Cephalon used various measures to disseminate its deceptive statements regarding the risks of off-label use of Actiq and Fentora and the risks, benefits, and superiority of opioids to Chicago patients and prescribers.

377. Cephalon targeted Chicago prescribers by recruiting them for its speakers bureaus for Actiq and Fentora [redacted] Based on the uniform and nationwide character of Cephalon's marketing and Cephalon's own speaker training materials, each of these speakers attended Cephalon's speaker's training, was instructed to disseminate the misrepresentations outlined above, and did disseminate those misrepresentations in Chicago.

378. Cephalon's speakers regularly held talks for Chicago prescribers—Cephalon sponsored more than [redacted] such events in Chicago and its surrounding areas between [redacted] These talks would have followed the same deceptive talking points covered in Cephalon's speakers' training.

379. Cephalon also targeted Chicago prescribers through the use of its sales force. In planning for the launch of Fentora, two sales representatives scheduled 10 events at various Chicago offices and restaurants, meeting with 151 prescribers in Chicago through speakers

bureau programs and dinners during the fourth quarter of 2006. Cephalon spent over $200,000 on these meetings, many of which were with prescribers who did not specialize in treating cancer patients. Given Fentora's sole indication for treating cancer pain in opioid-tolerant patients, these physicians were unlikely to prescribe the product for its approved, on-label use.

380. On October 3, 2006, Cephalon sales representatives hosted 17 Chicago prescribers for dinner at a cost of over $4,000. The next day, Cephalon sales representatives hosted five prescribers at the office of a respected physician specializing in neurology and general pain medicine at a cost of $750. The following day, Cephalon representatives treated 19 Chicago prescribers to a $3,500 dinner at an upscale Chicago restaurant. Many of the prescribers with whom Cephalon met did not have cancer-related specialties.

381. Given that Cephalon's own studies demonstrated that the overwhelming majority of oncologists diagnose and treat breakthrough cancer pain themselves, Cephalon knew the only purpose in its representatives meeting with these prescribers was to promote off-label use. Based on the uniform and nationwide character of Cephalon's marketing, Cephalon's deceptive messages would have been disseminated to Chicago prescribers by Cephalon's sales representatives during these events.

382. [redacted]

383. [redacted]

[redacted]

384. The experiences of specific prescribers confirm both that Cephalon's national marketing campaign included the misrepresentations described above in Sections V.D and V.E.2, and that the company disseminated these same misrepresentations to Chicago prescribers and consumers. In particular, these prescriber accounts reflect that Cephalon detailers omitted or minimized the risk of opioid addiction; overstated the benefits of opioids, including by making claims of improved function, and engaged in the off-label promotion of Cephalon's drugs for the treatment of chronic non-cancer pain.

385. A survey of a sample of Midwestern physicians, who reported the messages that they retained from detailing visits detailing visits and other promotional activity, documented that Cephalon's sales force disseminated the misleading statements described above. In 2006, for example, Cephalon sales representatives told a Midwestern general practitioner that Actiq was effective in "rapid relief of acute exacerbations of chronic pain." They told anesthesiologists in 2008 and 2009 that Actiq can be used for chronic back pain, and in 2014, they told an ob/gyn that Actiq was appropriate for use treating chronic pain. All told, at least ten ob/gyn physicians responded to the survey indicating they were detailed by representatives promoting Actiq or Fentora from 2014 and 2015.

386. In addition, the City has interviewed a number of Chicago-area prescribers who reported that they were detailed by Cephalon sales representatives and heard similar claims, as well as other messages described in Sections V.D. and V.E.2. In each instance, Cephalon

intended that the prescriber rely on these messages. Certain of these physicians did, in fact, prescribe Cephalon's opioids.

a. 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 Cephalon, 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. Prescriber C was detailed at two meals paid for by Cephalon to promote Fentora on May 23, 2014 and June 30, 2014.[112]

b. Chicago Prescriber F, a headache specialist, recalls being detailed heavily on Fentora and Actiq from 2010 to 2013. Prescriber FX believes that Cephalon sales personnel wanted him to prescribe for off-label use because they came to him many times to detail Actiq even though he runs a headache clinic and does not treat cancer patients. He has prescribed Actiq and Fentora.

c. Chicago Prescriber G, a pain specialist, indicated that he was visited by sales representatives from all Defendants, including Cephalon. Cephalon's representatives stated that Cephalon's opioids might find a place in his practice, even though he was not an oncologist. Prescriber G remembers receiving *Treatment Options*: He recalled that he was never warned about the risk of addiction. *A Guide for People Living with Pain* and *Opioid Based Management of Persistent and Breakthrough Pain*, described above in Section V.E.2.b.ii. In addition, opioid sales representatives—including representatives from Cephalon—told Prescriber G that opioids would increase patients' ability to complete activities of daily living and that patients could be managed to avoid addiction. These representatives also told him that patients can be screened to mitigate addiction risks.

[112] Under the Physician Payment Sunshine Act, passed as Section 6002 of the Affordable Care Act, pharmaceutical companies are required to disclose payments to prescribers and to teaching hospitals, as well as information about the nature, type, and purpose of the payments, for a period starting from August 2013. Data are available through December 2014 on the ProPublica.org website. *See* 42U.S.C. § 1320a-7g. Although Defendants also detailed nurse practitioners and physician assistants, the Act does not require the public disclosure of payments to these non-physician prescribers.

d. Chicago Prescriber E, an anesthesiologist and pain specialist, explained that he received visits from sales representatives from all Defendants, including Cephalon, until a few years ago. Representatives from Cephalon never discussed addiction with him.

e. Chicago Prescriber O, a physiatrist (doctor who specializes in rehabilitation) recalls attending the Cephalon-sponsored CMEs *Opioid Based Management of Persistent and Breakthrough Pain* and *Optimizing Opioid Treatment for Breakthrough Pain,* described above in Section V.E.2.b.iv. He was contacted at least 24 times by Cephalon sales representatives from 2006 to 2007.

f. Chicago Prescriber P, a physiatrist, also recalls attending, whether online or in person, *Opioid Based Management of Persistent and Breakthrough Pain*. He also recalled attending *Optimizing Opioid Treatment for Breakthrough Pain*, described above in Section V.E.2.b.iv. He has prescribed Actiq.

g. Chicago Prescriber Q recalls being visited by representatives from Cephalon. Prescriber Q indicated that none of the representatives discussed abuse, addiction, or overdoses, which were not part of the sales conversation.

h. Chicago Prescriber J, a nurse practitioner, indicated that she was visited (or sat in on visits) by sales representatives from Defendants Purdue, Cephalon, Janssen, and Actavis. Drug representatives from these Defendants, including Cephalon, never mentioned the risks of addiction associated with opioid use. For the period February 22, 2012 – May 25, 2015, the City health plans paid $5,253.22 in claims for opioids prescribed by Prescriber J, including $2,706.06 in Defendants' drugs (39 prescriptions).

387. These accounts reflect specific examples of instances in which Cephalon's sales representatives made the misrepresentations outlined above in Sections V.D and V.E.2 directly to Chicago prescribers. They are not an exhaustive list. Based on the nationwide and uniform character of Cephalon's marketing campaign, these examples support the inference that Cephalon sales representatives made similar misstatements to the other Chicago-area prescribers they detailed.

388. In particular, the degree to which Cephalon sales representatives promoted off-label use of Actiq and Fentora is evident in claims submitted to the City. In the City health plans' data, 219 prescriptions for Actiq and 66 prescriptions for Fentora were written for patients who did not have a documented cancer diagnosis at any time between June 1, 2005 and November 4, 2014, resulting in charges of $567,296.23. Of these prescriptions, 62 were written by prescribers on Cephalon's 2007 Fentora target list, Prescribers A, EE, FF, MM, and M, resulting in charges to the City of $78,188.99. An additional 42 prescriptions were written by prescribers whom Cephalon targeted and detailed in 2010, 2011, and 2013, Prescribers V and R, resulting in charges of $83,681.06. For Fentora alone, 47 of the 66 prescriptions were for patients (71%) who did not have a recorded cancer diagnosis, and $85,287.22 of the $113,783.10 in City health plan spending on these patients (75%) is attributable to these off-label prescriptions.

389. Cephalon knew that its Chicago sales force was effective in its work[redacted]

[redacted]

3. Endo

390. Endo promoted its opioids through the full array of marketing channels. The company deployed its sales representatives, paid physician speakers, journal supplements, and advertising in support of its branded opioids, principally Opana and Opana ER. Misleading claims about the purportedly lower abuse potential of Opana ER featured prominently in this campaign, but Endo also made many of the other deceptive statements and omissions described above in Section V.D. These included deceptive messages about functional improvement, addiction risk, pseudoaddiction, addiction screening tools, and the safety of alternatives to opioids.

391. At the same time, Endo also relied on a cast of third-party partners to promote the safety, efficacy, and superiority of opioids generally, through a combination of CMEs, websites, patient education pamphlets, and other publications. These materials echoed the misrepresentations described above, and also made deceptive statements about withdrawal symptoms and the safety of opioids at higher doses.

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

a. Endo's Deceptive Direct Marketing

393. Like the other Defendants, Endo used deceptive direct marketing to increase the sales of its dangerous opioids. As set forth below, Endo conveyed these deceptive messages in training of its sales force and recruited speakers, who in turn conveyed them to physicians; in a misleading journal supplement; and in unbranded advertising.

i. *Endo's Sales Force and Deceptive Sales Training*

394. Endo's promotion of Opana ER relied heavily on in-person marketing, including to Chicago prescribers. Endo had an aggressive detailing program, with its sales representatives making nearly 72,000 visits to prescribers nationwide to detail Opana ER in the first quarter of 2010 alone. Between 2007 and 2013, Endo spent between $3 million and $10 million each quarter to promote opioids through its sales force.

395. Endo's sales representatives, like those of the other Defendants, targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in transmitting Endo's marketing strategies and talking points to individual prescribers.

396. Endo specifically directed its sales force to target physicians who would prescribe its drugs to treat chronic pain. [redacted] Indeed, Endo sought to develop strategies that would be most persuasive to primary care doctors—strategies that sought to influence the prescribing behavior of primary care physicians through the use of subject matter experts. [redacted]

397. Endo trained its sales force to make a number of misrepresentations to physicians nationwide, including to physicians in Chicago. [redacted]

398. Endo knew that its marketing reached physicians —repeatedly—because it tracked their exposure. [redacted]

399. Endo was not only able to reach physicians through its marketing, but also successfully imparted its marketing messages. The company found its promotional materials tripled prescribers' ability to recall the sales message and doubled their willingness to prescribe Opana ER in the future. This was true of marketing that contained its deceptions.

400. [redacted] The Endo message that prescribers retained was a plain misrepresentation: that use of Opana ER was unlikely to lead to abuse and addiction. Although Opana ER always has been classified under Schedule II as a drug with a "high potential for abuse" and consistent with the pattern of misrepresentations described in Section

V.D.2, the largest single perceived advantage of Opana ER, according to a survey of 187 physicians who reported familiarity with the drug, was "perceived low abuse potential," cited by 15% of doctors as an advantage. As described in Section V.E.3.c below, low abuse potential was among the deceptive messages that Chicago prescribers received, and retained, from Endo sales representatives.

401. [redacted] however, [redacted] "Opana ER has an abuse liability similar to other opioid analgesics as stated in the [FDA-mandated] box warning." [redacted]

402. Nevertheless, Endo knew that its marketing was extremely effective in turning physicians into prescribers. Nationally, the physicians Endo targeted for in-person marketing represented approximately 84% of all prescriptions for Opana ER in the first quarter of 2010. Endo also observed that the prescribers its sales representatives visited wrote nearly three times as many prescriptions per month for Opana ER as those physicians who were not targeted for Endo's marketing—7.4 prescriptions per month versus 2.5. The most heavily targeted prescribers wrote nearly 30 prescriptions per month. [redacted]

403. More broadly, Endo's sales trainings and [redacted] demonstrate that its sales force was trained to provide prescribers with misleading information regarding the risks of

opioids when used to treat chronic pain. Foremost among these messages were misleading claims that the risks of addiction, diversion, and abuse associated with opioids—and Endo's products in particular—were low, and lower than other opioids.

(a) Endo's Sales Force Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy.

404. [redacted]

405. [redacted]

406. Endo's claims about the crush-resistant design of Opana ER also made their way to the company's press releases. A January 2013 article in *Pain Medicine News*, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to Chicago patients and prescribers.

407. Endo could only have promoted the crush resistance of Opana ER in order to persuade doctors that there was less risk of abuse, misuse, and diversion of the drug. As laid out below in Section V.E.3.c, that Endo was less addictive than other drugs was the precise message that Chicago prescribers took from Endo's marketing.

408. On May 10, 2013, however, the FDA warned Endo that there was no evidence that Opana ER's design "would provide a reduction in oral, intranasal, or intravenous abuse" and

that the post-marketing data Endo had submitted to the FDA "are insufficient to support any conclusion about the overall or route-specific rates of abuse." Even though it was rebuked by the FDA, Endo continued to market Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused.

409. Endo's sales training and the promotional materials distributed by its sales representatives also minimized the risk of addiction. For example, Endo circulated an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which implied to persons providing care to chronic pain patients that addiction was not a substantial concern by stating that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem." This program was downloadable from Endo's website and accessible to Chicago area prescribers.

410. [redacted]

411. [redacted]

[redacted]

(b) Endo's Sales Force Deceptively Implied that Chronic Opioid Therapy Would Improve Patients' Ability to Function.

412. In addition to their deceptive messages regarding addiction, Endo's promotional materials and sales trainings also misleadingly claimed that patients using opioids for the long-term treatment of chronic pain would experience improvements in their daily function. In reality, long-term opioid use has not been shown to and does not improve patients' function, and, in fact, often is accompanied by serious side effects that degrade function. [redacted]

413. Nevertheless, Endo distributed product advertisements that suggested that using Opana ER to treat chronic pain would allow patients to perform demanding tasks like work as a chef. One such advertisement states prominently on the front: [redacted]

414. [redacted]

415. [redacted]

416. [redacted]

417. [redacted]

(c) Endo's Sales Force Deceptively Presented the Risks and Benefits of Opioids To Make Them Appear Safer Than Other Analgesics

418. Endo further misled patients and prescribers by downplaying the risks of opioids in comparison to other pain relievers. For example, it distributed in Chicago and elsewhere a presentation titled *Case Challenges in Pain Management*: *Opioid Therapy for Chronic Pain*. This study held out as a representative example one patient who had taken NSAIDs for more than eight years and, as a result, developed "a massive upper gastrointestinal bleed." The presentation recommended treating this patient with opioids instead. By focusing on the adverse side effects of NSAIDs, while omitting discussion of serious side effects associated with opioids, this presentation misleadingly portrayed the comparative risks and benefits of these drugs.

419. [redacted]

ii. *Endo's Speakers Bureau Programs Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy*

420. In addition to its sales representatives' visits to doctors, Endo also used deceptive science and speaker programs to spread its deceptive messages.

421. Endo leaned heavily on its speakers' bureau programs. In 2008 alone, Endo spent nearly $4 million to promote up to 1,000 speakers programs around the country. In 2012, at least 13 speakers programs devoted to Opana ER took place in Illinois, up from 8 in 2011. [redacted] These programs were attended by sales representatives, which reveal their true purpose as marketing, rather than

educational, events. As described below in Section V.E.3.c, among Endo's speakers were several Chicago physicians.

422. Endo's internal reporting stated that the "return on investment" turned positive 8-12 weeks after such programs. [redacted]

423. These speakers bureau presentations included the very same misrepresentations Endo disseminated through its sales representatives. [redacted]

424. [redacted]

425. In 2009, Endo wrote a talk titled *The Role of Opana ER in the Management of Chronic Pain*, which was delivered by Chicago Prescriber M.[113] The talk included a slide titled "Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain," which cited the AAPM/APS Guidelines—and, as described above in Section V.C.2.c.ii, their accompanying misstatements regarding the likelihood of addiction (by claiming that addiction risks were manageable regardless of patients' past abuse histories) while omitting their disclaimer regarding the lack of supporting evidence in favor of that position. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

426. The misleading messages and materials Endo provided to its sales force and its speakers 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 Chicago. As described above in Section V.B.2, Endo's nationwide messages would have reached Chicago prescribers in a number of ways. For example, they were carried into Chicago by Endo's sales representatives during detailing visits as well as made available to Chicago patients and prescribers through websites and ads. They also have been delivered to Chicago prescribers by Endo's paid speakers, who were required by Endo policy and by FDA regulations to stay true to Endo's nationwide messaging.

iii. *Endo's Misleading Journal Supplement*

427. In 2007, Endo enlisted Chicago Prescriber M to write a supplement available for CME credit in the *Journal of Family Practice* that Endo paid to have published. It was called *Pain Management Dilemmas in Primary Care: Use of Opioids*, and it deceptively minimized the

[113] Prescriber M did not just work for Endo. He also gave paid promotional talks for opioid drugs manufactured by Janssen and Cephalon; appeared on a Purdue unbranded website; and taught at Purdue-funded CMEs, including several available in the Chicago area.

risk of addiction by emphasizing the effectiveness of screening tools. Specifically, it recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain. It also falsely claimed that, through the use of tools like toxicology screens, pill counts, and a "maximally structured approach," even patients at high risk of addiction could safely receive chronic opioid therapy. Endo distributed 96,000 copies of this CME nationwide, and it was available to and was intended to reach Chicago prescribers.

iv. *Endo's Deceptive Unbranded Advertising*

428. Endo also used unbranded advertisements to advance its goals. By electing to focus on unbranded marketing, Endo was able to make claims about the benefits of its opioids that the FDA would never allow in its branded materials. The chart below compares an Endo unbranded statement with one of Endo's FDA-regulated, branded statements:

Living with Someone with Chronic Pain (2009) **(Unbranded)**	**Opana ER Advertisement (2011/2012/2013)** **(Branded)**
Patient education material created by Endo	Endo advertisement
"Most health care providers who treat people with pain agree that **most people do not develop an addiction problem**."	"[C]ontains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit." "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

b. Endo's Deceptive Third-Party Statements

429. Endo's efforts were not limited to directly making misrepresentations through its marketing materials, its speakers, and its sales force. Endo believed that support for patient

advocacy and professional organizations would reinforce Endo's position as "the pain management company."

430. Prior to, but in contemplation of, the 2006 launch of Opana ER, Endo developed a "Public Stakeholder Strategy." Endo identified "tier one" advocates to assist in promoting the approval and acceptance of its new extended release opioid. Endo also intended to enlist the support of organizations that engage or have the potential to advocate for public policy that would be "favorable" to Schedule II opioids from a sales perspective. Endo sought to develop its relationships with these organizations through its funding. In 2008, Endo spent $1 million per year to attend conventions of these pro-opioid medical societies, including meetings of AAPM, APS, and the American Society of Pain Management Nursing ("ASPMN").

431. APF's ability to influence professional societies and other third parties is demonstrated by its approach in responding to a citizens' petition filed with the FDA by the Physicians for Responsible Opioid Prescribing (the "PROP Petition"). The PROP petition, filed by a group of prescribers who had become concerned with the rampant prescribing of opioids to treat chronic pain, asked the FDA to require dose and duration limitations on opioid use and to change the wording of the approved indication of various long-acting opioids to focus on the severity of the pain they are intended to treat.

432. The PROP Petition set off a flurry of activity at Endo. [redacted] These

communications reflected Endo's absolute confidence that the professional societies would support its position.

i. *APF*

433. One of the societies with which Endo worked most closely was APF. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC"). Endo was one of the APF's biggest financial supporters, and Endo provided more than half of the $10 million APF received from opioid manufacturers during its lifespan. [redacted]

434. Endo's influence over APF's activities was so pervasive that APF President Will Rowe even reached out to Defendants—including Endo—rather than his own staff to identify potential authors to answer an article critical of opioids that appeared in the *Archives of Internal Medicine* in 2011. Personnel from Defendants Purdue, Endo, Janssen, and Cephalon worked with Rowe to formulate APF's response. The response suggested by Defendants was the one that APF ultimately published.

435. Documents also indicate that Endo personnel were given advance notice of materials APF planned to publish on its website and provided an opportunity to comment on the content of those materials before they were published. For example, in early July of 2009, APF's Director of Strategic Development wrote to Endo personnel to give them advance notice of content that APF planned to be "putting . . . up on the website but it's not up yet." This Endo employee also reassured the sender that she "will not forward it to anyone at all" and promised that she would "'double delete it' from [her] inbox." In response, APF's Director of Strategic Development replied internally with only four words: "And where's the money?"

436. Nowhere was Endo's relationship with APF closer than with its sponsorship of the NIPC. Before being taken over by APF, the NIPC was sponsored by Professional Postgraduate Services, but that company was determined to be a "commercial interest" by the ACCME and could no longer serve as a sponsor. In response, Endo reached out to APF. An August 2009 document titled "A Proposal for the American Pain Foundation to Assume Sponsorship of the National Initiative on Pain Control," pointed out that "[f]or the past 9 years, the NIPC has been supported by unrestricted annual grants from Endo Pharmaceuticals, Inc." According to this document, APF's sponsorship of the NIPC "[o]ffers the APF a likely opportunity to generate new revenue, as Endo has earmarked substantial funding: $1.2 million in net revenue for 2010 to continue the NIPC." Further, sponsorship of the APF would "[p]rovide[] numerous synergies to disseminate patient education materials," including "[h]andouts to attendees at all live events to encourage physicians to drive their patients to a trusted source for pain education—the APF website."

437. A September 14, 2009 presentation to APF's board contained a materially similar discussion of NIPC sponsorship, emphasizing the financial benefit to APF from assuming the role of administering NIPC. The proposal "offer[ed] a solution to continue the development and implementation of the NIPC initiative as non-certified . . . yet independent education to physicians and healthcare professionals in the primary care setting, while providing the APF with a dependable, ongoing source of grant revenue." A number of benefits related to NIPC sponsorship were listed, but chief among them was "a likely opportunity [for APF] to generate new revenue, as Endo has earmarked substantial funding: $1.2 million in net revenue for 2010 to continue the NIPC."

438. [redacted] Endo emails indicate that Endo personnel reviewed the content created by NIPC and provided feedback.

439. Behind the scenes, Endo exercised substantial control over NIPC's work. Endo exerted its control over NIPC by funding NIPC and APF projects; developing, specifying, and reviewing content; and taking a substantial role in distribution of NIPC and APF materials, which in effect determined which messages were actually delivered to prescribers and consumers. As described below, Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

440. From 2007 until at least 2011, Endo also meticulously tracked the distribution of NIPC materials, demonstrating Endo's commercial interest in and access to NIPC's reach. Endo knew exactly how many participants viewed NIPC webinars and workshops and visited its website, *Painknowledge.com*. Endo not only knew how many people viewed NIPC's content, but what their backgrounds were (*e.g.*, primary care physicians or neurologists). Endo's access to and detailed understanding of the composition of the audience at these events demonstrates how deeply Endo was involved in NIPC's activities. Moreover, Endo tracked the activities of NIPC—ostensibly a third party—just as it tracked its own commercial activity.

441. Endo worked diligently to ensure that the NIPC materials it helped to develop would have the broadest possible distribution. [redacted]

[redacted]

442. In short, NIPC was a key piece of Endo's marketing strategy. Indeed, internal APF emails question whether it was worthwhile for APF to continue operating NIPC given that the NIPC's work was producing far more financial benefit for Endo than for APF. Specifically, after Endo approved a $244,337.40 grant request to APF to fund a series of NIPC eNewsletters, APF personnel viewed it as "[g]reat news," but cautioned that "the more I think about this whole thing, [Endo's] making a lot of money on this with still pretty slender margins on [APF's] end." APF's commitment to NIPC's "educational" mission did not figure at all in APF's consideration of the value of its work, nor was Endo's motive or benefit in doubt.

(a) Misleading Medical Education

443. NIPC distributed a series of eNewsletter CMEs focused on "key topic[s] surrounding the use of opioid therapy" and sponsored by Endo. These newsletters were edited by KOL Dr. Perry Fine and also listed several industry-backed KOLs, including Dr. Webster, as individual authors. Endo estimated that roughly 60,000 prescribers viewed each one, which were available to and would have included Chicago prescribers. Before-and-after surveys, summarized in the chart below, showed that prescriber comfort with prescribing opioids ranged from 27% to 62% before exposure to the CME, and from 76% to 92% afterwards:

Topic	Comfort level *prior to reading the article*	Comfort level *after reading the article*
Patient Selection and Initiation of Opioid Therapy as a Component of Pain Treatment	47%	87%
Informed Consent and Management Plans to Optimize Opioid Therapy for Chronic Pain	48%	81%
Risk Stratification and Evaluation of High-Risk Behaviors for Chronic Opioid Therapy	28%	76%
Integration of Nonpharmacologic and Multidisciplinary Therapies Into the Opioid Treatment Plan	42%	85%
Addressing Patients' Concerns Associated With Chronic Pain Treatment and Opioid Use	62%	92%
Opioid Therapy in Patients With a History of Substance Use Disorders	35%	85%
Urine Drug Testing: An Underused Tool	54%	86%
Appropriate Documentation of Opioid Therapy: The Emergence of the 4As and Trust and Verify as the Paradigm	44%	86%
Opioid Rotation	27%	92%
Discontinuing Opioid Therapy: Developing and Implementing an "Exit Strategy"	37%	90%

444. Endo documents made clear that the persuasive power of NIPC speakers was directly proportional to their perceived objectivity. Accordingly, Endo personnel directed that, when giving Endo-sponsored talks, NIPC faculty would not appear to be "Endo Speakers." Nevertheless, the two parties understood that Endo and NIPC shared a common "mission to educate physicians" and working "through the APF . . . [wa]s a great way to work out . . . problems that could have been there without the APF's participation and support."

445. The materials made available on and through NIPC included misrepresentations. For example, Endo worked with NIPC to sponsor a series of CMEs titled *Persistent Pain in the Older Patient* and *Persistent Pain in the Older Adult*. These CMEs misrepresented the prevalence of addiction by stating that opioids have "possibly less potential for abuse" in elderly patients than in younger patients, even though there is no evidence to support such an assertion. Moreover, whereas withdrawal symptoms are always a factor in discontinuing long-term opioid therapy, *Persistent Pain in the Older Adult* also misleadingly indicated that such symptoms can

be avoided entirely by tapering the patient's does by 10-20% per day for ten days. *Persistent Pain in the Older Patient*, for its part, made misleading claims that opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." NIPC webcast these CMEs from its own website, where they were available to and were intended to reach Chicago prescribers.

(b) Painknowledge.com

446. Working with NIPC enabled Endo to make a number of misleading statements through the NIPC's website, *Painknowledge.com*. Endo tracked visitors to *PainKnowledge.com* and used *Painknowledge.com* to broadcast notifications about additional NIPC programming that Endo helped to create.

447. APF made a grant request to Endo to create an online opioid "tool-kit" for NIPC and to promote NIPC's website, *Painknowledge.com*. In so doing, APF made clear that it planned to disseminate Defendants' misleading messaging. The grant request expressly indicated APF's intent to make misleading claims about functionality, noting: "Some of these people [in chronic pain] may be potential candidates for opioid analgesics, which can improve pain, function, and quality of life." Endo provided $747,517 to fund the project.

448. True to APF's word, *Painknowledge.com* misrepresented that opioid therapy for chronic pain would lead to improvements in patients' ability to function. Specifically, in 2009 the website instructed patients and prescribers that, with opioids, a patient's "level of function should improve" and that patients "may find [they] are now able to participate in activities of daily living, such as work and hobbies, that [they] were not able to enjoy when [their] pain was worse."

449. *Painknowledge.com* also deceptively minimized the risk of addiction by claiming that "[p]eople who take opioids as prescribed usually do not become addicted."

Painknowledge.com did not stop there. It deceptively portrayed opioids as safe at high doses and also misleadingly omitted serious risks, including the risks of addiction and death, from its description of the risks associated with the use of opioids to treat chronic pain.

450. Endo was the sole funder of *Painknowledge.com*, and it continued to provide that funding despite being aware of the website's misleading contents.

(c) *Exit Wounds*

451. Finally, Endo also sponsored APF's publication and distribution of *Exit Wounds*, a publication aimed at veterans that also contained a number of misleading statements about the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by "Medical Writer X," whose extensive work for Janssen is described below in Section V.E.4. Medical Writer X was frequently hired by a consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Medical Writer X's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

452. *Exit Wounds* is a textbook example of Medical Writer X's authorship on drug companies' behalf. The book misrepresented the functional benefits of opioids by stating that opioid medications "*increase* your level of functioning" (emphasis in original).

453. *Exit Wounds* also misrepresented that the risk of addiction associated with the use of opioids to treat chronic pain was low. It claimed 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."

454. Finally, *Exit Wounds* misrepresented the safety profile of using opioids to treat chronic pain by omitting key risks associated with their use. Specifically, it omitted warnings of

the risk of interactions between opioids and benzodiazepines—a warning sufficiently important to be included on Endo's FDA-required labels. *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—a particular risk for veterans.

455. As outlined above, Endo exercised dominance over APF and the projects it undertook in an effort to promote the use of opioids to treat chronic pain. In addition, as outlined above, Medical Writer X's work was being reviewed and approved by drug company representatives, motivating him to draft pro-opioid propaganda masquerading as science. Combined, these factors gave Endo considerable influence over the work of Medical Writer X and over APF. Further, by paying to distribute *Exit Wounds*, Endo endorsed and approved its contents.

ii. *Other Front Groups: FSMB, AAPM, and AGS*

456. In addition to its involvement with APF, Endo worked closely with other third-party Front Groups and KOLs to disseminate deceptive messages regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. As with certain APF publications, Endo in some instances used its sales force to directly distribute certain publications by these Front Groups and KOLs, making those publications "labeling" within the meaning of 21 C.F.R. § 1.3(a).

457. In 2007, Endo sponsored FSMB's *Responsible Opioid Prescribing*, which, as described in Section V.D, in various ways deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* was drafted by "Medical Writer X."

458. Endo spent $246,620 to help FSMB distribute *Responsible Opioid Prescribing*. [redacted] Based on the uniform and

nationwide character of Endo's marketing campaign, and the fact that Endo purchased these copies specifically to distribute them, these copies were distributed to physicians nationwide, including physicians in Chicago.

459. In December 2009, Endo also contracted with AGS to create a CME to promote the 2009 guidelines titled the *Pharmacological Management of Persistent Pain in Older Persons* with a $44,850 donation. As described in Section V.C.2.c.iii above, these guidelines misleadingly claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse," since 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 recommendation)" when in reality, opioid therapy was an appropriate treatment only for a subset of those patients, as Endo's FDA-mandated labels recognized.

460. AGS's grant request to Endo made explicit reference to the CME Endo was funding. Endo thus knew full well what content it was paying to distribute, and was in a position to evaluate that content to ensure it was accurate, substantiated, and balanced before deciding whether to invest in it. After having sponsored it, Endo's internal documents indicate that Endo's pharmaceutical sales representatives discussed the AGS guidelines with doctors during individual sales visits.

461. Endo also worked with AAPM, which it viewed internally as "Industry Friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications.

462. A talk written by Endo in 2009, approved by Endo's Medical Affairs Review Committee,[114] and given by a Chicago-area KOL, titled *The Role of Opana ER in the Management of Chronic Pain,* includes a slide titled *Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain.* That slide cites the AAPM/APS Guidelines, which contain a number of misstatements as outlined in Section V.C.2.c.ii above, while omitting their disclaimer regarding the lack of supporting evidence. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines. Furthermore, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

iii. *Key Opinion Leaders and Misleading Science*

463. Endo also sought to promote opioids for the treatment of chronic pain through the use of key opinion leaders and biased, misleading science.

464. Endo's 2010 publication plan for Opana ER identified a corporate goal of making Opana ER the second-leading branded product for the treatment of moderate-to-severe chronic pain (after OxyContin). Endo sought to achieve that goal by providing "clinical evidence for the use of Opana ER in chronic low back pain and osteoarthritis," and succeeded in having articles on this topic published.[115]

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[114] Although they were given slightly different names by each Defendant, each Defendant employed a committee that would review and approve materials for distribution. These committees included representatives from all relevant departments within Defendants' organizations, including the legal, compliance, medical affairs, and marketing departments. The task of these review committees was to scrutinize the marketing materials Defendants planned to distribute and to ensure that those materials were scientifically accurate and legally sound. Tellingly, these committees were called to review only materials that created a potential compliance issue for the company, an implicit recognition by Defendants that they ultimately would be responsible for the content under review.

[115] These studies suffered from the limitations common to the opioid literature—and worse. None of the comparison trials lasted longer than three weeks. Endo also commissioned a six-month, open label trial during which a full quarter of the patients failed to find a stable dose, and 17% of patients discontinued,

465. In the years that followed, Endo sponsored articles, authored by an Endo consultant and Endo employees, which argued that the metabolic pathways utilized by Opana ER made it less likely than other opioids to result in drug interactions in elderly low back and osteoarthritis pain patients. In 2010, Endo directed its publication manager to reach out to a list of consultants conducting an ongoing Endo-funded study, to assess their willingness to respond to an article[116] that Endo believed emphasized the risk of death from opioids, "without [] fair balance."[117]

466. [redacted] Although the FDA requires such speaker slide decks to reflect a "fair balance" of information on benefits and risks, Endo's slides reflected one-sided and deeply biased information. [redacted]

467. [redacted]

citing intolerable effects. In open label trials, subjects know which drug they are taking; such trials are not as rigorous as double-blind, controlled studies in which neither the patients nor the examiners know which drugs the patients are taking.

[116] Susan Okie, *A Flood of Opioids, a Rising Tide of Deaths*, 363 New Engl. J. Med. 1981 (2010), finding that opioid overdose deaths and opioid prescriptions both increased by roughly 10-fold from 1990 to 2007.

[117] Endo did manage to get a letter written by three of those researchers, which was not published.

[redacted][118]

468. [redacted] Nor did this acknowledged lack of support stop Endo from directing its sales representatives to tell prescribers that its drugs were less likely to be abused or less addictive than other opioids.

469. Endo also worked with various KOLs to disseminate various misleading statements about chronic opioid therapy. For example, Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding your Pain: Taking Oral Opioid Analgesics*. This pamphlet deceptively minimized the risks of addiction by stating that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems," implying that patients who are taking opioids for pain are not at risk of addiction.

[118] Andrea M. Trescot et al., *Opioids in the management of non-cancer pain: an update of American Society of the Interventional Pain Physicians*, Pain Physician 2008 Opioids Special Issue, S5-S2.

470. *Understanding your Pain: Taking Oral Opioid Analgesics* also misleadingly omitted any description of the increased risks posed by higher doses of opioid medication. Instead, in a Q&A format, the pamphlet asked "[i]f I take the opioid now, will it work later when I really need it?" and responded that "[t]he dose can be increased . . . [y]ou won't 'run out' of pain relief."

471. Dr. Portenoy received research support, consulting fees, and honoraria from Endo for editing *Understanding Your Pain* and other projects.

472. *Understanding Your Pain* was available on Endo's website during the time period of this Complaint and was intended to reach Chicago prescribers. As described below in Section V.E.3.c, at least one Chicago physician, Prescriber G, received this pamphlet from an Endo sales representative.

473. Endo similarly distributed a book written by Dr. Lynn Webster titled *Avoiding Opioid Abuse While Managing Pain*, which stated that in the face of signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."

474. A slide from an Opana ER business plan contemplated distribution of the book as part of Endo's efforts to "[i]ncrease the breadth and depth of the OPANA ER prescriber base via targeted promotion and educational programs." [redacted] The [redacted], shown below, demonstrates Endo's express incorporation of this book by a KOL into its marketing strategy:

[redacted]

475. [redacted] Based on the nationwide and uniform character of Endo's marketing, and the book's approval for distribution, this book was available to and was intended to reach Chicago prescribers.

c. Endo's Deceptive Statements to Chicago Prescribers and Patients

476. Endo also directed the dissemination of the misstatements described above to Chicago patients and prescribers, including through its sales force, speakers bureaus, CMEs, and the *Painknowledge.com* website.

477. Consistent with their training, Endo's sales representatives delivered all of these deceptive messages to Chicago prescribers. A former Endo sales representative, Sales Representative D, who marketed Opana and Opana ER for Endo in Chicago's southwest suburbs, including Joliet, Orland Park, and Tinley Park, spoke to the City about her training and sales practices. This sales representative marketed principally to internists. She never heard about the risks of long-term opioid use while working at Endo. As she explained, the risks of

long-term opioid use were not a focus of her training. She was familiar with the term pseudoaddiction, which she defined as patients who thought they were addicted but really were not. In her sales visits, she would dodge any questions about addiction, telling doctors that she lacked a document or data to talk about it.

478. Sales Representative D reported that Endo specifically targeted physicians who prescribed Vicodin and NSAIDs. She was trained to persuade them to prescribe Endo's drugs by discussing milder side effects associated with the drugs, like constipation and itching skin. She also frequently told doctors that prescribing Opana ER to their patients would improve patients' ability to function. Finally, this former sales representative recalls leaving copies of *Understanding Your Pain: Taking Oral Opioid Analgesics* with the prescribers she detailed. As described above in Section V.E.3.b.iii, this publication misleadingly implied that pain patients prescribed opioids would not become addicted.

479. Given that this sales representative was in the same sales region as Chicago (and subject to the same regional management as Chicago sales representatives), that her detailing reached Chicago suburbs, and that her messaging tracked Endo's deceptive sales training, her account offers insight into the misleading messages conveyed to prescribers in the Chicago area.

480. The experiences of specific prescribers confirm both that Endo's national marketing campaign included the misrepresentations described above in Sections V.D and V.E.3, and that the company disseminated these same misrepresentations to Chicago prescribers and consumers. In particular, these prescriber accounts reflect that Endo detailers omitted or minimized the risk of opioid addiction; claimed that Endo's drugs would be less problematic for patients because they were tamper resistant and "steady state;" claimed or implied that opioids

were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

481. A survey of a sample of Midwestern physicians, who reported the messages that they retained from detailing visits detailing visits and other promotional activity, documented that Endo promoted Opana ER as less addictive than other opioids. For example, Endo sales representatives told a Midwestern internal medicine doctor in 2008 that Opana ER had a "minimal" abuse potential," and in 2008 and 2011 told physicians that it has a "lower" abuse potential, presumably as compared to other opioids. Further, beginning in 2012, the survey reported that Endo sales representatives promoted the "Intac" formulation as being affirmatively crush resistant, despite FDA findings to the contrary. For example, Endo representatives told a pain specialist in 2012 that Opana ER was "tamper proof"; they told internal medicine doctors in 2013 and 2014 that Opana ER was "difficult to abuse." Endo sales representatives also claimed that the fact that Opana ER was a long-acting formulation made it less addicting, despite its Schedule II classification. Finally, Opana ER sales representatives told a Midwestern internist that sustained release had the properties of "hopefully avoiding addiction" in 2013.

482. In addition, the City has interviewed a number of Chicago-area prescribers who reported that they were detailed by Endo sales representatives and heard similar claims, as well as other messages described in Sections V.D and V.E.3. In each instance, Endo intended that the prescriber rely on these messages. Most of these physicians did, in fact, prescribe Endo's opioids. As specified below and in Exhibit A.3, most of them wrote prescriptions for Endo opioids that were paid for by the City's health plans:

a. 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 Endo, 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. Prescriber C was detailed at three meals paid for by Endo to promote Opana ER on April 14, 2014; May 27, 2014; and September 12, 2014.

b. Chicago Prescriber S, a nurse practitioner who is based in Indiana but writes opioid prescriptions to a number of employees covered by the City's health plans, recalls being visited frequently by drug representatives detailing Opana. According to Prescriber S, representatives from Defendants Janssen, Purdue, and Endo emphasized that opioids could help her patients regain function by becoming more physically active and returning to work. For the period July 20, 2005 – May 15, 2015, the City health plans paid $9,460.86 in claims for opioids prescribed by Chicago Prescriber S, including $5,990.96 in Defendants' drugs (43 prescriptions) and $807 for Endo's opioids in particular (3 prescriptions).

c. 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 D that their drugs were "steady state," which he interpreted to mean that they were less addictive. For the period June 6, 2005 – August 11, 2012, the City health plans paid $61,651.12 in claims for opioids prescribed by Prescriber D, including $59,566.89 in Defendants' drugs (624 prescriptions) and $5,707.28 for Endo's opioids in particular (20 prescriptions).

d. Chicago Prescriber G indicated that he was visited by sales representatives from all Defendants, including Endo. He recalls receiving some of the marketing materials described above, including a copy of *Understanding your Pain: Taking Oral Opioid Analgesics* that was given to him by an Endo sales representative. Prescriber G was never told about the risk of addiction. According to Prescriber G, opioid sales representatives—including Endo's—told him that opioids would increase patients' ability to complete activities of daily living and that patients could be managed to avoid addiction. These representatives also told him that patients can be screened to mitigate addiction risks. For the period August 21, 2007 – June 18, 2015, the City health plans paid $23,759.89 in

claims for opioids prescribed by Presciber G, including $23,299.81 in Defendants' drugs (84 prescriptions).

e. Chicago Prescriber E, an anesthesiologist and pain specialist, explained that he received visits from sales representatives from all Defendants, including Endo, until a few years ago. Representatives from Endo never discussed addiction with him. For the period October 23, 2006 – May 12, 2014, the City health plans paid $23,114.17 in claims for opioids prescribed by Prescriber E, including $15,638.46 in Defendants' drugs (107 prescriptions) and $15.03 for Endo's opioids in particular (2 prescriptions).

f. Chicago Prescriber F, a headache specialist, recalls being detailed by Endo sales representatives. Prescriber F explained that these sales representatives told him that Opana was less addicting than other opioids. For the period December 8, 2006 – June 4, 2015, the City health plans paid $3,737.07 in claims for opioids prescribed by Prescriber F, including $1,503.41 in Defendants' drugs (71 prescriptions) and $193.95 for Endo's opioids in particular (4 prescriptions).

g. Chicago Prescriber B, a Chicago anesthesiologist, sees opioid drug company representatives on a regular basis, and he has seen representatives from Endo. These representatives pushed the message that "steady-state" extended release drugs have less potential for abuse. Opioid manufacturers, including Endo, have told him that opioids improved patient function and quality of life. He relies on the information he receives from drug company representatives because he does not have the time to conduct his own research. For the period June 3, 2005 – June 29, 2015, the City health plans paid $176,510.98 in claims for opioids prescribed by Prescriber B, including $34,029.61 in Defendants' drugs (368 prescriptions) and $2,679.90 for Endo's opioids in particular (81 prescriptions).

h. 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 simply not part of the sales conversation." For the period March 25, 2011 – May 27, 2014, the City health plans paid $889.53 in claims for opioids prescribed by Prescriber Q, including $165.94 in Defendants' drugs (12 prescriptions).

i. Chicago Prescriber T indicated that he was visited by sales representatives from Defendants Purdue, Endo, and Janssen.

Endo's sales representatives told Prescriber T that Opana would improve his patients' ability to function and make it more likely that they could groom themselves, bathe, feed themselves, and conduct other daily activities. Endo representatives never mentioned the risks of addiction associated with Opana. For the period October 31, 2013 – October 3, 2014, the City health plans paid $3,238.31 in claims for opioids prescribed by Prescriber T, including $501.83 in Defendants' drugs (16 prescriptions) and $112.32 for Endo's opioids in particular (4 prescriptions).

j. Chicago Prescriber QQ, a Chicago-area anesthesiologist, has met with representatives from Endo within the last five years. Endo representatives told him that the delivery system of Opana ER made it tamper-resistant, which he interpreted to mean it is less likely to be diverted or misused. For the period December 21, 2007 to June 26, 2015, the City health plans paid $50,044.34 in claims for opioids prescribed by Prescriber QQ, including $42,170.47 in Defendants' drugs (340 prescriptions) and $20,995 for Endo's opioids in particular (72 prescriptions).

483. These accounts reflect specific examples of instances in which Endo's sales representatives made the misrepresentations outlined above in Sections V.D and V.E.3 directly to Chicago prescribers. They are not an exhaustive list. Based on the nationwide and uniform character of Endo's marketing campaign, these examples support the inference that Endo sales representatives made similar misstatements to the other Chicago-area prescribers they detailed.

484. Endo also entered into speaking engagements with Chicago-area prescribers, including Chicago Prescribers A and M. Prescriber A was the top prescriber of Opana ER paid for by the City's health plans. In the period June 26, 2007 to June 4, 2015 he wrote a total of 286 prescriptions for Opana ER to members of the City's health plans, resulting in $183,194.81 in costs to the City. Prescriber M likewise has been responsible for significant costs to the City. In the period August 29, 2007 to April 20, 2010 he wrote a total of 4 Opana ER prescriptions for City health plan members, causing the City to incur $1,146.21 in costs.

485. The speaker agreements between Endo and these doctors demonstrate the complete control that Endo exerts over the content of their presentations. [redacted]

486. Prescribers A and M were not alone. Endo documents indicate that Endo hired additional Chicago prescribers to speak on its behalf to Chicago-area doctors. [redacted]

487. [redacted] Moreover, these paid speaking engagements incentivized these prescribers to write prescriptions for Endo's opioids, because only doctors who wrote Endo prescriptions were considered for the role. Prescribers U and V wrote a total of 450 prescriptions of Opana ER to members of the City's health plans, resulting in $ 93,320.32 in costs to the City.

488. The importance of Chicago prescribers to Endo is also demonstrated by its solicitation of marketing advice from Chicago health professionals. [redacted]

[redacted]

[redacted] These physicians wrote a total of 28 prescriptions of Opana ER to members of the City's health plan, resulting in $8,475.90 in costs to the City.

489. Endo also directed misleading marketing to Chicago prescribers and patients through the APF/NIPC materials it sponsored, reviewed, and approved. For example, Endo hired a New York-based KOL to deliver the CME *Managing Persistent Pain in the Older Patient* on April 27, 2010 at the Westin Michigan Avenue in Chicago, with 54 attendees. As described above in Section V.E.3.b.i (a) above, this CME misrepresented the prevalence of addiction in older patients and made misleading claims that chronic opioid therapy would improve patients' ability to function. An email invitation to the event and other NIPC programs was sent to "all healthcare professionals" in APF's database.

490. Another CME, *Persistent Pain in the Older Adult*, was presented in Chicago by a Philadelphia, Pennsylvania-based KOL on Wednesday, May 18, 2011. This talk took place at the Marriott Chicago Downtown and was attended by 41 prescribers in Chicago. Like *Managing Persistent Pain in the Older Patient*, *Persistent Pain in the Older Adult* understated the risks of addiction. It also trivialized the risks associated with opioid withdrawal by stating that withdrawal symptoms can be eliminated entirely.

491. The significant response to *Painknowledge.com* also indicates that those websites were viewed by Chicago prescribers, who were exposed to the site's misleading information regarding the effect of opioids on patients' ability to function and the deceptive portrayal of the risks of opioids. As of September 14, 2010, *Painknowledge.com* had 10,426 registrants, 86,881

visits, 60,010 visitors, and 364,241 page views. Upon information and belief, based on the site's nationwide availability, among the site's visitors were Chicago-area patients and prescribers who were exposed to the site's misleading information regarding the effect of opioids on patients' ability to function and the deceptive portrayal of the risks of opioids.

492. Endo knew that the harms from its deceptive marketing would be felt in Chicago. It saw workers' compensation programs as a lucrative opportunity, and it promoted the use of opioids for chronic pain arising from work-related injuries, like chronic lower back pain. Endo developed plans to "[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss in those with pain; [with a] specific focus on high-risk employers and employees." In 2007, Endo planned to reach 5,000 workers' compensation carriers in order to ensure that Opana ER would be covered under disability insurance plans. Given that that the City of Chicago is one of the largest employers in Chicago, Endo knew or should have known that claims for its opioids would be paid for by the City's workers' compensation program.

4. Janssen

493. Janssen promoted its branded opioids, including Duragesic, Nucynta, and Nucynta ER, through its sales representatives and a particularly active speakers program. Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign. Janssen also conveyed other mispresentations as described in Section V.D, including that its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs.

494. Janssen supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain. These materials likewise made deceptive claims about addiction risk, safety at

higher doses, and the safety of alternative treatments. They also claimed that opioid treatment would result in functional improvement, and further masked the risk of addiction by promoting the concept of pseudoaddiction.

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

a. Janssen's Deceptive Direct Marketing

496. Janssen joined the other Defendants in propagating deceptive branded marketing that falsely minimized the risks and overstated the benefits associated with the long-term use of opioids to treat chronic pain. Like the other Defendants, Janssen sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed identically across the country. These sales representatives were critical in transmitting Janssen's marketing strategies and talking points to individual prescribers. In 2011, at the peak of its effort to promote Nucynta ER, Janssen spent more than $90 million on detailing.

497. Janssen's designs to increase sales through deceptive marketing are apparent on the face of its marketing plans. For example, although Janssen knew that there was no credible scientific evidence establishing that addiction rates were low among patients who used opioids to treat chronic pain, [redacted] there is no evidence that Nucynta is any less

addictive or prone to abuse than other opioids, or that the risk of addiction or abuse is low. Similarly, Janssen knew that there were severe symptoms associated with opioid withdrawal including, severe anxiety, nausea, vomiting, hallucinations, and delirium, but Janssen touted the ease with which patients could come off opioids.

i. *Janssen's Deceptive Sales Training*

498. [redacted] Janssen encouraged these sales representatives to maximize sales of Nucynta and meet their sales targets by relying on the false and misleading statements described above, including in Sections V.D.2 and V.D.5.

499. For example, Janssen's sales force was trained to trivialize addiction risk. [redacted]

500. [redacted]

[redacted]

501. [redacted]

502. [redacted]

503. [redacted]

504. During the very time Janssen was [redacted] it knew or should have known that, as laid out above in Section V.D.2, significant numbers of patients using opioids to treat chronic pain experienced issues with addiction. As laid out in Section V.D.5, [redacted]

505. The deceptive messages described above and in Section V.D.1-7 are confirmed by Janssen sales representatives. One former Janssen sales representative, Sales Representative E,

who was interviewed by the City and worked in Janssen's Midwest Region (the Regional Manager had offices in Naperville, Illinois) recalls selling Nucynta and Nucynta ER. Her compensation was directly tied to how many Nucynta and Nucynta ER prescriptions were written by the doctors who were listed on the quarterly call plan she received from her district manager and how many doctors or clinics in her assigned zip codes prescribed the drugs that she was asked to sell. This former sales representative stated that family practices and internal medicine doctors made up about 80% of the call plan targets for opioids; as noted above, these generalists are less knowledgeable about opioids and more likely to fall victim to sales representatives' misrepresentations.

506. Sales Representative E was instructed to push the envelope when selling Nucynta ER and stress that Nucynta ER didn't hit receptors like other opioids so it was less addictive and had fewer withdrawal issues. She also promoted Nucynta and Nucynta ER as a safer alternative to NSAIDs and, when discussing side effects related to Nucynta and Nucynta ER, she focused on nausea, itchy skin, and vomiting. She told physicians that they could prescribe higher doses of Nucynta ER because its mechanism works differently than other opioids. She also recalls telling prescribers that Janssen's opioids can improve their patients' ability to function in their lives, enabling them to get off workers' compensation or work pain-free. She also recalls being provided various books, articles, and pamphlets to provide as handouts to physicians.

507. This former sales representative also recalls that Janssen's Midwest region would hold regional "Plan of Action" meetings three times a year, usually at a hotel or conference facility in a northern suburb of Chicago. These meetings would include various presentations regarding the marketing of Janssen's drugs, including Nucynta and Nucynta ER. The Midwest region also held weekly Friday calls, which were used to make sure that everyone followed the

same strategy and talking points. Based on the uniform character of Janssen's marketing, Chicago sales representatives, who were in the same sales region, would have received the same sales training and made the same misrepresentations when detailing Chicago prescribers.

508. Another former Janssen sales representative, Sales Representative F, who also worked in Janssen's Midwest region, recalls Janssen using a number of KOLs in support of its efforts to sell Nucynta and Nucynta ER. Some of these KOLs were based in Chicago and participated in Janssen's speakers bureau. On information and belief, based on the uniform and nationwide character of Janssen's marketing, these speakers were trained to deliver the misleading messages described above in Section V.E.4.a.ii to prescribers in Chicago.

509. A third former Janssen sales representative, Representative G, whose territory included the suburbs northwest of Chicago, recalled selling Nucynta and Nucynta ER. She promoted Nucynta and Nucynta ER as safe and effective for the long-term treatment of chronic pain and told physicians that drugs like Tylenol kill the liver and that Nucynta and Nucynta ER were cleaner by comparison and did not attack the organs.

510. Finally, a fourth former Janssen sales representative, Sales Representative H, who also worked in Janssen's Midwest Region, recalls selling Nucynta and Nucynta ER. She recalls being trained to say that Nucynta and Nucynta ER did not offer the same euphoric feeling as other opioids. She also recalled referring prescribers to a Youtube video that asserted that Nucynta was more difficult to crush than other pills, making it less likely to be abused or diverted. Representative H believed that it was common for Janssen sales representatives to downplay the addictive nature of Nucynta and Nucynta ER.

511. The misleading messages and materials Janssen provided to its sales force 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 Chicago. As described above in Section V.B.2, Janssen's nationwide messages reached Chicago prescribers in a number of ways, including through its sales force in detailing visits, as well as through websites and ads. They also were delivered to Chicago prescribers by Janssen's paid speakers, who were required by Janssen policy and by FDA regulations to stay true to Janssen's nationwide messaging.

ii. *Janssen's Deceptive Speakers Bureau Programs*

512. Janssen did not stop at disseminating its misleading messages regarding chronic opioid therapy through its sales force. It also hired speakers to promote its drugs and trained them to make the very same misrepresentations made by its sales representatives.

513. Janssen's speakers worked from slide decks—which they were required to present—reflecting the deceptive information about the risks, benefits, and superiority of opioids outlined above. [redacted]

514. [redacted]

[redacted]

515. These speakers presentations were part of Janssen's nationwide marketing efforts. [redacted] Upon information and belief, a number of these events were available to and were intended to reach Chicago prescribers.

iii. *Janssen's Deceptive Unbranded Advertising*

516. Janssen was aware that its branded advertisements and speakers programs would face regulatory scrutiny that would not apply to its unbranded materials, so Janssen also engaged in direct, unbranded marketing.

517. One such unbranded project was Janssen's creation and maintenance of *Prescriberesponsibly.com* (last updated July 2, 2015), a website aimed at prescribers and patients that claims that concerns about opioid addiction are "overstated." A disclaimer at the bottom of the website states that the "site is published by Janssen Pharmaceuticals, Inc., which is solely responsible for its content." This website was available to and intended to reach Chicago prescribers and patients.

b. Janssen's Deceptive Third-Party Statements

518. Janssen's efforts were not limited to directly making misrepresentations through its sales force, speakers bureau, and website. To avoid regulatory constraints and give its efforts an appearance of independence and objectivity, Janssen obscured its involvement in certain of its

marketing activities by "collaborat[ing] with key patient advocacy organizations" to release misleading information about opioids.

i. *AAPM and AGS – Finding Relief: Pain Management for Older Adults*

519. Janssen worked with AAPM and AGS to create a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009). In doing so, Janssen contracted with a medical publishing firm, Conrad & Associates, LLC. The content was drafted by a writer ("Medical Writer X") hired by Conrad & Associates and funded by Janssen. These materials were reviewed, in detail, by Janssen's medical-legal review team, which conducted detailed reviews and gave him editorial feedback on his drafts, which was adopted in the published version.

520. Medical Writer X understood, without being explicitly told, that since his work was funded and reviewed by Janssen, the materials he was writing should aim to promote the sale of more drugs by overcoming the reluctance to prescribe or use opioids to treat chronic pain. He knew that the publication was undertaken in connection with the launch of a new drug and was part of its promotional effort. Medical Writer X knew of the drug company sponsoring the publication, and he would go to the company's website to learn about the drug being promoted. He also knew that his clients—including Janssen—would be most satisfied with his work if he emphasized that: (a) even when used long-term, opioids are safe and the risk of addiction is low; (b) opioids are effective for chronic pain; and (c) opioids are under-prescribed because doctors are hesitant, confused, or face other barriers.[119]

[119] Medical Writer X now acknowledges that the lists of adverse effects from chronic opioid use in the publications he authored, which excluded respiratory depression, overdose, and death and minimized addiction, were, "ridiculous" and "prime examples" of leaving out facts that the pharmaceutical company sponsors and KOLs knew at the time were true. His writings repeatedly described the risk of addiction as

521. *Finding Relief* is rife with the deceptive content described above in Sections V.D.2, V.D.6, and V.D.7. *Finding Relief* misrepresents that opioids increase function by featuring a man playing golf on the cover and listing examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The functional claims contained in *Finding Relief* are textbook examples of Defendants' use of third parties to disseminate messages the FDA would not allow them to say themselves. Compare, e.g.:

Branded Advertisement That Triggers an FDA Warning Letter (2008)[120]
Improvement in Daily Activities Includes: • Walking on a flat surface • Standing or sitting • Climbing stairs • Getting in and out of bed or bath • Ability to perform domestic duties.

with:

Seemingly Independent Publication: "Finding Relief: Pain Management for Older Adults"

low. Medical Writer X stated that he understood that the goal was to promote opioids and, as a result, discussing addiction would be "counterproductive."

[120] This advertisement drew an FDA Warning Letter dated March 24, 2008. Though the advertisement was by drug company King, it is used here to demonstrate the types of claims that the FDA regarded as unsupported.

(Final Authority, Janssen 2009):
Your recovery will be measured by how well you reach functional goals such as • Sleeping without waking from pain • Walking more, or with less pain • Climbing stairs with less pain • Returning to work • Enjoying recreational activities • Having sex • Sleeping in your own bed

522. *Finding Relief* also trivialized the risks of addiction describing a "myth" that opioids are addictive, and asserting as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."

523. *Finding Relief* further misrepresented that opioids were safe at high doses by listing dose limitations as "disadvantages" of other pain medicines but omitting any discussion of risks from increased doses of opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."

524. Finally, *Finding Relief* deceptively overstated the risks associated with alternative forms of treatment. It juxtaposes the advantages and disadvantages of NSAIDs on one page, with the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "increase[d] . . . risk of heart attack and stroke." Conversely, the only adverse effects of opioids listed by *Finding Relief*

are "upset stomach or sleepiness," which the brochure claims will go away, and constipation. The guide never mentions addiction, overdose, abuse, or other serious side effects of opioids.

525. Janssen was not merely a passive sponsor of *Finding Relief*. Instead, Janssen exercised control over its content and provided substantial assistance to AGS and AAPM to distribute it. [redacted]

526. AAPM, which is based in Chicago, purchased and distributed copies of *Finding Relief* to all of its members, including those who reside in its home city.

527. *Finding Relief's* author, Medical Writer X, later said it was clear, from his perch at the intersection of science and marketing, that the money paid by drug companies to the KOLs and professional and patient organizations with which he worked distorted the information provided to doctors and patients regarding opioids. The money behind these and many other "educational" efforts also, he believes, led to a widespread lack of skepticism on the part of leading physicians about the hazards of opioids. It also led these physicians to accept without adequate scrutiny published studies that, while being cited to support the safety of opioids, were, in fact, of such poor methodological quality that they would not normally be accepted as adequate scientific evidence.

ii. *AGS – Misleading Medical Education*

528. Janssen also worked with the AGS on another project—AGS's CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. As described above in Section V.C.2.c.iii, 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 recommendation)." Based on Janssen's control over AGS's *Finding Relief*, Janssen also would have exercised control over this project as well.

iii. *APF*

529. Janssen also worked with APF to carry out its deceptive marketing campaign. Documents obtained from one of Janssen's public relations firms, Ketchum, indicate that Janssen and the firm enlisted APF as part of an effort to [redacted] Janssen also drew on APF publications to corroborate claims in its own marketing materials and its sales training. Janssen personnel participated in a March 2011 call with APF's "Corporate Roundtable," in which they worked with APF and drug company personnel to develop strategies to promote chronic opioid therapy. In particular, APF personnel spoke with Janssen employees, who "shar[ed] expertise from within their company for [a] public awareness campaign."

530. Their joint work on the "Corporate Roundtable" demonstrates the close collaboration between Janssen and APF in promoting opioids for the treatment of chronic pain. APF President Will Rowe also reached out to Defendants—including Janssen—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. Additional examples of APF's collaboration with Janssen are laid out below:

(a) Let's Talk Pain

531. Most prominent among these efforts was the *Let's Talk Pain* website. Janssen sponsored *Let's Talk Pain* in 2009, acting in conjunction with APF, American Academy of Pain Management, and American Society of Pain Management Nursing, whose participation in the website Janssen financed and orchestrated.

532. Janssen exercised substantial control over the content of the *Let's Talk Pain* website. Janssen's internal communications always referred to *Let's Talk Pain* as promoting tapentadol, the molecule it sold as Nucynta and Nucynta ER.

533.

[redacted]

534. [redacted] Moreover, emails describing Janssen's review and approval rights related to *Let's Talk Pain* indicate that this right extended to "major changes and video additions."

535. As a 2009 Janssen memo conceded, "[t]he *Let's Talk Pain Coalition* is sponsored by PriCara, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc." and "[t]he Coalition and Pricara **maintain editorial control of all *Let's Talk Pain* materials and publications**" (emphasis added).

536. A 2011 Consulting Agreement between Janssen and one of APF's employees, relating to the dissemination of national survey data, demonstrates the near-total control Janssen

was empowered to exercise over APF in connection with the *Let's Talk Pain* website, including in requiring APF to circulate and post Janssen's promotional content. The agreement required APF to "participate in status calls between Janssen, APF, AAPM, ASPMN, and Ketchum as requested by Janssen" and required APF to "respond to requests to schedule status calls **within 48 hours** of the request" (emphasis in original). APF also was required to "[r]eview and provide feedback to media materials, including a press release, pitch email, a key messages document, and social media messages, **within one week** of receipt" (emphasis in original).

537. The agreement further required APF to provide a summary of the survey results in APF's PAIN MONITOR e-newsletter, post a link to the survey results on APF's Facebook page, send out tweets related to the survey, serve as a spokesperson available for media interviews, "[s]hare information with any media contacts with whom APF has existing relationships to promote the announcement of the national survey findings," identify at least two patient spokespersons to talk about the survey data, and include the survey results in "any future APF materials, as appropriate." Tellingly, "any ideas made or conceived by [APF] in connection with or during the performance" of the Agreement "shall be the property of, and belong to, [Janssen]."

538. Janssen also exercised its control over *Let's Talk Pain*. Janssen was able to update the *Let's Talk Pain* website to describe its corporate restructuring [redacted] Given its editorial control over the content of *Let's Talk Pain*, Janssen was at all times fully aware of—and fully involved in shaping—the website's content.[121]

[121] It bears noting that Janssen does not publicly identify its role in creating *Let's Talk Pain*'s content. Instead, *Let's Talk Pain* represents that "coalition members" develop the content that appears on the website and lists Janssen as the only sponsor of that coalition.

539. *Let's Talk Pain* contained a number of the misrepresentations outlined above in Sections V.D.1 and V.D.4.

540. For example, *Let's Talk Pain* misrepresented that the use of opioids for the treatment of chronic pain would lead patients to regain functionality. *Let's Talk Pain* featured an interview claiming that opioids were what allowed a patient to "continue to function." This video is still available today on YouTube.com and is accessible to Chicago prescribers and patients.

541. *Let's Talk Pain* in 2009 also promoted the concept of pseudoaddiction, which it described as patient behaviors that may occur when *pain is under-treated*" but differs "*from true addiction* because such behaviors can be resolved with effective pain management" (emphasis added). *Let's Talk Pain* was linked to by *the Chicago Tribune Blog* in 2008, where it was available to and was intended to reach Chicago patients and prescribers. The website was in fact viewed by a large number of Chicago readers; according to Internet analysis tools, the *Chicago Tribune* post was the second-leading driver of traffic to *Let's Talk Pain*.

(b) Exit Wounds

542. Janssen also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described above in Section V.D, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by "Medical Writer X." It is fully representative of his work on behalf of drug companies.

543. Janssen gave APF substantial assistance in distributing *Exit Wounds* in Chicago and throughout the nation by providing grant money and other resources.

544. APF mailed copies of *Exit Wounds* to the "Wounded Heroes Foundation" in Chicago. The Wounded Heroes Foundation is an organization designed to support the injured

men and women who have served the United States in Iraq, Afghanistan and around the world. Unfortunately, by distributing *Exit Wounds* to its members, it distributed Defendants' deceptive statements about the appropriateness of opioid therapy to treat chronic pain.

c. Janssen's Deceptive Statements to Chicago Prescribers and Patients

545. Janssen also directed the misstatements described above to Chicago patients and prescribers, including through CMEs, its sales force, and recruited physician speakers.

i. *Janssen's Deceptive Medical Education Programs in Chicago*

546. Janssen sponsored CMEs and talks attended by Chicago prescribers. From 2009 to 2013, Janssen spent over $195,000 on 103 speakers bureau programs in Cook County, retaining 27 different physicians as speakers (including four of the top six Nucynta prescribers in Chicago) who gave talks with more than 1,000 attendees. [redacted] One such program, "New Perspectives in the Management of Moderate to Severe Chronic Pain," which was given 33 times to Chicago prescribers over 2011 and 2012, [redacted]

547. Speakers on Janssen's bureau were among the more prolific prescribers of Janssen's opioids. PRESCRIBER R received $36,845 in payments from Johnson & Johnson from 2011-2013, and his prescriptions resulted in $8,546.37 in payments from the City between 2011 and 2015 for Janssen's opioids. PRESCRIBER CC received $8,250 in speaking fees for 2010, and his prescriptions resulted in $4,193.39 in claims from Nucynta and Nucynta ER.

These doctors were trained by Janssen and thus were exposed to the same misrepresentations disseminated to other doctors. Further, the benefits of speaking on behalf of Janssen gave them a powerful incentive to continue to prescribe Janssen's opioids.

548. [redacted] Based on the uniform and nationwide character of Janssen's marketing campaign, the speakers at these events would have delivered talks from slide decks provided by Janssen, consistent with the key deceptive messages described above in Section V.E.4.a.ii.

ii. *Janssen's Deceptive Detailing Practices in Chicago*

549. [redacted]

550. The experiences of specific prescribers confirm both that Janssen's national marketing campaign included the misrepresentations described above in Sections V.D and V.E.4, and that the company disseminated these same misrepresentations to Chicago prescribers and consumers. In particular, these prescriber accounts reflect that Janssen detailers claimed that

Nucynta was "not an opioid" because it worked on an "alternate receptor";[122] claimed that Janssen's drugs would be less problematic for patients because they had anti-abuse properties and were "steady state"; claimed that patients on Janssen's drugs were less susceptible to withdrawal; omitted or minimized the risk of opioid addiction; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

551. A survey of a sample of Midwestern physicians, who reported the messages that they retained from detailing visits detailing visits and other promotional activity, documented that Janssen sales representatives promoting Duragesic made claims to Midwestern prescribers that Duragesic improves physical function, at least from 2006 to 2010. They also misrepresented the likelihood of abuse associated with Janssen's drugs. For example, they falsely told a Midwestern orthopedic surgeon in 2013 that Duragesic had anti-abuse properties. The same survey indicates that, between 2009 and 2012, Nucynta and Nucynta ER sales representatives repeatedly promoted these drugs as less addictive than other opioids. For example, Janssen sales representatives described Nucynta as "not an opioid" to one Midwestern internist at least twice in 2010. Similarly, a sales representative told a Midwestern physician that Nucynta was "non-opioid yet opioid like" in 2011.

552. In addition, the City has interviewed a number of Chicago-area prescribers who reported that they were detailed by Janssen sales representatives and heard similar claims, as well as other messages described in Sections V.D and V.E.4. In each instance, Janssen intended that the prescriber rely on these messages. Most of these physicians did, in fact, prescribe

[122] The FDA-approved labels for both Nucynta and Nucynta ER describe the tapentadol molecule as an "opioid agonist and a Schedule II controlled substance that can be abused in a manner similar to other opioid agonists, legal or illicit."

Janssen's opioids. As specified below and in Exhibit A.4, most of them wrote prescriptions for Janssen opioids that were paid for by the City's health plans:

a. 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 Janssen, 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. Janssen's sales representatives also falsely stated that Nucynta was not being abused. Prescriber C was detailed at four meals paid for by Janssen on August 5, 2013; August 13, 2013; May 9, 2014; and July 21, 2014.[123]

b. Chicago Prescriber S, a nurse practitioner who is based in Indiana but wrote opioid prescriptions to a number of City employees, was visited frequently by Janssen representatives and was told by opioid sales representatives, including representatives from Janssen, that opioids would improve her patients' function, and allow them to be increasingly physically active and return to work. For the period July 20, 2005 – May 15, 2015, the City health plans paid $9,460.86 in claims for opioids prescribed by Prescriber S, including $5,990.96 in Defendants' drugs (43 prescriptions) and $4,319.63 for Janssen's opioids in particular (18 prescriptions).

c. 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. For the period June 6, 2005 – August 11, 2012, the City health plans paid $61,651.12 in claims for opioids prescribed by Prescriber D, including $59,566.89 in Defendants' drugs (624 prescriptions) and $215.49 for Janssen's opioids in particular (1 prescription).

[123] Pursuant to a 2010 Corporate Integrity Agreement with the Office of the Inspector General of the U.S. Department of Justice, the yearly value of payments by Johnson & Johnson to prescribers is made public, but without information about which particular drug was being promoted.

d. Chicago Prescriber G, who served on Janssen's speakers bureau from 2009 to 2012, indicated that he was visited by sales representatives from all Defendants, including Janssen. He recalled that he was never warned about the risk of addiction. According to Prescriber G, opioid sales representatives—including those employed by Defendant Janssen—represented that opioids would increase patients' ability to complete activities of daily living and that patients could be managed to avoid addiction. These representatives also told him that patients can be screened to mitigate addiction risks. For the period August 21, 2007 – June 18, 2015, the City health plans paid $23,759.89 in claims for opioids prescribed by Prescriber G, including $23,299.81 in Defendants' drugs (84 prescriptions) and $23,224.28 for Janssen's opioids in particular (74 prescriptions). This prescriber met with Janssen sales representatives over meals on five separate occasions from October 2013 through August 2014. Prescriber G also received $1,085 in unspecified speaking fees and for meals in 2011 from Johnson & Johnson, and $10,232 in speaking fees, meals, and travel in 2012.

e. Chicago Prescriber B, an anesthesiologist, sees opioid drug company representatives on a regular basis, and he has seen representatives from Janssen. These representatives pushed the message that "steady-state" drugs have less potential for abuse. Respresentatives from opioid manufacturers, including Janssen, have told him that opioids improved patient function and quality of life. He relies on the representations made by drug company representatives because he does not have the time to conduct his own research. For the period June 3, 2005 – June 29, 2015, the City health plans paid $176,510.98 in claims for opioids prescribed by Prescriber B, including $34,029.61 in Defendants' drugs (368 prescriptions) and $1,471.40 for Janssen's opioids in particular (12 prescriptions).

f. Chicago Prescriber H, a podiatrist, was aggressively detailed by Janssen sales representatives, who called on him once or twice a month. These representatives told Prescriber H that Janssen's drugs were less susceptible to withdrawal then their competitors and never discussed the risk of addiction. Janssen documents indicate that Prescriber H was detailed 57 times between March 2010 and December 2012. According to Janssen "call notes"—written notes by detailers reflecting their discussions with individual prescribers during sales visits—Prescriber H told a detailer that "if he doesn't have to worry about withdrawal problems . . . he would like to start a patient as soon as possible" on Nucynta. For the period July 11, 2008

– June 5, 2012, the City health plans paid $448.06 in claims for opioids prescribed by Prescriber H, including $424.20 in Defendants' drugs (12 prescriptions) and $380.29 for Janssen's opioids in particular (4 prescriptions).

g. Chicago Prescriber J, a nurse practitioner, indicated that she was visited (or sat in on visits) by sales representatives from Defendants Purdue, Cephalon, Janssen, and Actavis. Drug representatives from these Defendants, including Defendant Janssen, never mentioned the risks of addiction from opioid use. Janssen sales representatives also told Prescriber J that their drugs were "steady state." For the period February 22, 2012 – May 25, 2015, the City health plans paid $5,253.22 in claims for opioids prescribed by Prescriber J, including $2,706.06 in Defendants' drugs (39 prescriptions) and $259.93 for Janssen's opioids in particular (1 prescription).

h. 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. For the period September 3, 2008 – April 13, 2015, the City health plans paid $369.08 in claims for opioids prescribed by Prescriber Z, including $279.62 in Defendants' drugs (10 prescriptions) and $215.71 for Janssen's opioids in particular (1 prescription).

i. Chicago Prescriber AA indicated that she was visited by sales representatives from Defendant Janssen. She was detailed by this sales representative once a month for 6 months to a year. This sales representative marketed Nucynta to Prescriber AA, but not as an opioid. Instead, Prescriber AA was told that Nucynta was an alternative to opioid therapy and that it worked on an alternate receptor. This sales representative explained that Nucynta would be appropriate for chronic pain patients who were unable to continue opioid therapy due to excessive side effects. This sales representative also stated that Nucynta didn't have a risk of addiction, unlike opioids, and that it would improve her patients' function. For the period January 26, 2006 – June 10, 2015, the City health plans paid $673.32 in claims for opioids prescribed by Prescriber AA, including $314.61 in Defendants' drugs (54 prescriptions).

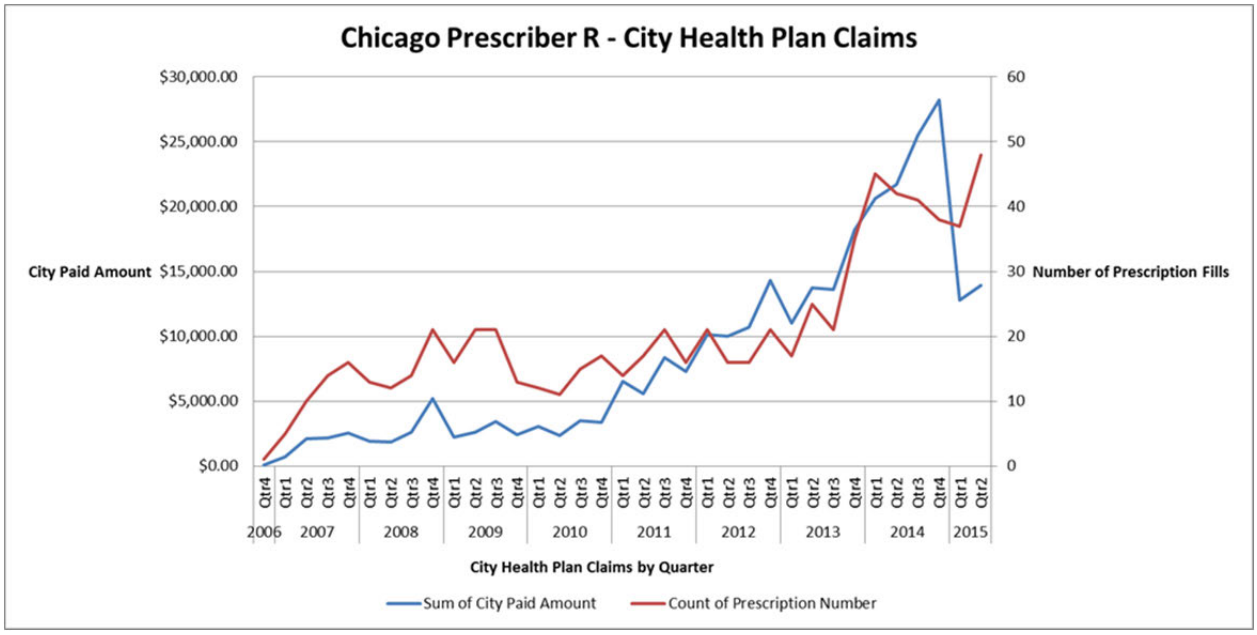
j. Chicago Prescriber T indicated that he was visited by sales representatives from Defendants Purdue, Endo, and Janssen. Janssen sales representatives told him that Nucynta would

improve his patients' ability to function. Janssen sales representatives never mentioned the risks of addiction associated with Janssen's drugs. For the period October 31, 2013 – October 3, 2014, the City health plans paid $3,238.31 in claims for opioids prescribed by Prescriber T, including $501.83 in Defendants' drugs (16 prescriptions).

k. Chicago Prescriber PP indicated that he was visited by sales representatives from Janssen. Janssen sales representatives told him that Nucynta would improve his patients' ability to function because once pain is under control, the patient can "get out and be more active." Janssen sales representatives also warned Prescriber PP about the risks of NSAIDs, which included gastrointenstinal bleeding, and suggested that Nucynta could be an appropriate option if NSAIDs did not work. For the period October 31, 2013 – October 3, 2014, the City health plans paid $3,238.31 in claims for opioids prescribed by Prescriber PP, including $501.83 in Defendants' drugs (16 prescriptions). He has prescribed Nucynta.

553. These accounts reflect specific examples of instances in which Janssen's sales representatives made the misrepresentations outlined above in Sections V.D and V.E.4 directly to Chicago prescribers. They are not an exhaustive list. Based on the nationwide and uniform character of Janssen's marketing campaign, these examples support the inference that Janssen sales representatives made similar misstatements to the other Chicago-area prescribers they detailed.

554. [redacted] Prescriber R is responsible for 732 claims paid by the City health plans from December 28, 2006 through June 23, 2005, for $294,383.44. Prescriber R's opioid prescribing has steadily increased over time, as shown below.



Of the 732 claims to the City, 45 claims totaling $11,159.26 reflect Janssen opioids. Prescriber R's prescribing of Nucynta was significantally higher overall, however; [redacted]

555. Prescriber R received significant funding from Janssen to promote Nucynta and Nucynta ER. Between 2011 and 2012, Prescriber R [redacted] His total funding from Janssen was $13,422 in 2011, $17,423 in 2012, $15,000 in 2013, and $8,777 in 2014.

556. Janssen also detailed a number of other prescribers who wrote prescriptions paid for by the City. Chicago Prescriber BB received 3 meals from Janssen on August 14, October 1, and November 4. 2013, which would have included talks by Janssen sales representatives. Three days after the third of these meetings, a patient filled a prescription from this doctor for Nucynta ER, which was the first part of a course of therapy eventually resulting in $3,923.74 in payments for that drug, and for short-acting Nucynta prescribed in tandem, for that patient alone. The patient previously had been prescribed generic Schedule III opioids.

557. While these individual doctors allow the City to describe, in retrospect, the link between Janssen's deceptive marketing and claims paid by the City, Janssen tracked this information on a real-time basis. [redacted]

5. Purdue

558. Purdue promoted its branded opioids—principally, Oxycontin, Butrans, and Hysingla—and opioids generally in a campaign that consistently mischarascterized 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.

559. 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 Chicago prescribers. The materials that Purdue generated in collaboration with third parties also were distributed or made available in Chicago. Purdue distributed these messages, or facilitated their distribution, in Chicago with the intent that Chicago prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Purdue's Deceptive Direct Marketing

560. Like the other Defendants, 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.

561. Purdue engaged in in-person marketing to doctors in Chicago and operated speakers bureau programs that included and targeted Chicago prescribers. [redacted] Like the other Defendants' detailers, Purdue sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed, identically, across the country. These sales representatives were critical in delivering Purdue's marketing strategies and talking points to individual prescribers.[124] Indeed, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines, which as discussed above in Section V.C.2.C.ii deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories, with doctors during individual sales visits.

562. 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

[124] 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.

through its sales force, from under $5 million in 2007 to more than $30 million by the end of 2014.

563. 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 above in Section V.D.8, Purdue has marketed its drug as effective for 12 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.

564. For example, [redacted]

565. Purdue advertisements that ran in 2005 and 2006 issues of the *Journal of Pain* depict a sample prescription for OxyContin with "Q12h" 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*.

566. 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."

567. As outlined above in Section V.D.8, 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. [redacted]

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

569. 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.

570. 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 [redacted] and the vignettes imply that an OxyContin prescription will help him 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).

571. 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.

572. 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 above in Section V.D.2, that OxyContin was used non-medically by injection less than 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.

573. *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.

574. *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 Chicago prescribers through its sales force.

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

576. 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.

577. *In the Face of Pain* was available nationally and was intended to reach Chicago prescribers.

578. Purdue also used its unbranded website *Partners Against Pain* to promote the same deceptive messages regarding risk of addiction that are described in Section V.D.2 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.

579. 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 Chicago. As described in Section V.B.2 above, Purdue's nationwide messages would have reached Chicago prescribers in a number of ways. For example, they were carried into Chicago by Purdue's sales representatives during detailing visits as well as made available to Chicago patients and prescribers through websites and ads, including ads in prominent medical journals. They would have also been delivered to Chicago 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

580. Purdue's efforts were not limited to making misrepresentations through its own sales force 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, like the other Defendants, 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

581. 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 detail below.

582. 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.

583. 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.

584. 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 "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."

585. 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."

586. 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*.

587. 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."

588. According to an Assurance of Voluntary Compliance ("AVC") entered into between the New York Attorney General and Purdue Pharma 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.

589. 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, 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 do 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 APF, which was Purdue." The

group meets regularly in-person and via teleconference and shares information through an email listserv.

590. 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 pharma 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.

591. In 2007, the PCF Education Subgroup, consisting of drug companies Purdue and Alpharma, 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*.

592. 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 Defendants 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.

593. 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."[125] 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. Purdue 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 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.

594. APF President Will Rowe reached out to Defendants—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.

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[125] *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 APF'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.

595. 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*

596. 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 that there were studies showing that the use of opioids for the long-term treatment of chronic pain could improve patients' ability to function.

597. 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."[126]

598. 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."

[126] 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).

599. 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 pseudo-addiction highlights the common, concerted effort behind Purdue's deceptive statements.

600. 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.

601. 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.

602. The *Policymaker's Guide* was posted online, and was available to and intended to reach Chicago 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 Chicago through its own sales force.

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

603. 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*.

604. *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."

605. Further, as outlined above in Section V.D.2, *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.

606. *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 doses 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.

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

(d) *Exit Wounds*

608. 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 above in Section V.D, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

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

610. 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*

611. 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*

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

613. 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.

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

614. 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 above in Section V.C.2.c.iii, 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 recommendation)."

615. 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 2009 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.

616. 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 Chicago prescribers. Indeed, internal documents of another Defendant, 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.[127]

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

617. 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. This CME was presented at various locations in the United States and, as described below in Section V.E.5.c, attended by at least one Chicago physician, Prescriber P.

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

618. 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

[127] As described above in Section V.C.2.c.ii, 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 Defendants). The webinar was available to and was intended to reach Chicago prescribers and, as described below in Section V.E.5.c, was attended by at least one Chicago physician, Prescriber P.

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

619. 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.

620. 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 Chicago prescribers.

(f) *Overview of Management Options*

621. 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 Russel 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 Chicago prescribers.

iii. *Purdue's Misleading Science*

622. 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.[128] 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.

[128] 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).

This article was placed in a prominent pain journal and has been cited 487 times.[129] While this 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 Chicago Prescribers and Patients

623. Purdue directed the dissemination of the misstatements described above to Chicago patients and prescribers through the Front Groups, KOLs, and publications described above, as well as through its substantial sales force in Chicago 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.

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

625. Likewise, the deceptive messages minimizing addiction were not only directed at Chicago patients and prescribers through the publications circulated above, but also were disseminated directly by Purdue's sales force. For example, 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.

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

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

627. The experiences of specific prescribers confirm both that Purdue's national marketing campaign included the misrepresentations described above in Sections V.D and V.E.5, and that the company disseminated these same misrepresentations to Chicago 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.

628. 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.

629. 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.

630. In addition, the City has 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 Sections V.D and V.E.5. In each instance, Purdue intended that the prescriber rely on these messages. Most of these physicians did, in fact, prescribe Purdue's opioids. As specified below and in Exhibit A.5, most of them wrote prescriptions for Purdue opioids that were paid for by the City's health plans:

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. For the period June 3, 2005 – June 29, 2015, the City health plans paid $176,510.98 in claims for opioids prescribed by Prescriber B, including $34,029.61 in Defendants' drugs (368 prescriptions) and $2,605.89 for Purdue's opioids in particular (14 prescriptions).

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 above in Section V.D.2. For the period January 6, 2006 – June 17, 2015, the City health plans paid $19,415.52 in claims for opioids prescribed by Prescriber P, including $6,279.26 in Defendants' drugs (219 prescriptions) and $145.08 for Purdue's opioids in particular (2 prescriptions).

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 employees covered by the City's health plans, recalls being visited by drug representatives detailing OxyContin and Burtrans. These representatives emphasized that opioids could help her patients regain function by becoming more physically active and returning to work. For the period July 20, 2005 – May 15, 2015, the City health plans paid $9,460.86 in claims for opioids prescribed by Prescriber S, including $5,990.96 in Defendants' drugs (43 prescriptions) and $385.31 for Purdue's opioids in particular (2 prescriptions).

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. For the period December 8, 2006 – June 4, 2015, the City health plans paid $3,737.07 in claims for opioids prescribed by Prescriber F, including $1,503.41 in Defendants' drugs (71 prescriptions) and $72.54 for Purdue's opioids in particular (1 prescription).

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. For the period June 6, 2005 – August 11, 2012, the City health plans paid $61,651.12 in claims for opioids prescribed by Prescriber D, including $59,566.89 in Defendants' drugs (624 prescriptions) and $39,256.33 for Purdue's opioids in particular (95 prescriptions).

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 representative 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. For the period August 21, 2007 – June 18, 2015, the City health plans paid $23,759.89 in claims for opioids prescribed by Prescriber G, including $23,299.81 in Defendants' drugs (84 prescriptions).

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. For the period October 23, 2006 – May 12, 2014, the City health plans paid $23,114.17 in claims for opioids prescribed by Prescriber E, including $15,638.46 in Defendants' drugs (107 prescriptions) and $11,601.26 for Purdue's opioids in particular (30 prescriptions).

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. Prescriber DD provided the City with a 2014 document a sales representative gave him, labeled "Retained visual aid – not for distribution." This visual aid prominently describes the product as "Every-12-hour OxyContin Tablets." Prescriber DD has written opioid prescriptions paid by the City in 2013 and 2014. For the period September 9, 2005 – June 27, 2015, the City health plans paid $10,975.67 in claims for opioids prescribed by Prescriber DD, including $10,636.52 in Defendants' drugs (154 prescriptions) and $8,079.65 for Purdue's opioids in particular (53 prescriptions).

j. Chicago Prescriber O recalled attending 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 above in Section V.D.2. For the period June 16, 2005 – June 11, 2015, the City health plans paid $24,385.60 in claims for opioids prescribed by Prescriber O, including $22,029.24 in Defendants' drugs (81 prescriptions) and $8,894.58 for Purdue's opioids in particular (32 prescriptions).

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 select patients appropriate for opioid therapy and manage addiction. For the period August 19, 2005 – February 13, 2015, the City health plans paid $42.14 in claims for opioids prescribed by Prescriber GG, including $8.70 in Defendants' drugs (2 prescriptions).

l. Chicago Prescriber J, a nurse practitioner, indicated that she was visited (or sat in on visits) by sales representatives from Defendants Purdue, Cephalon, Janssen, and Actavis. Drug representatives from these Defendants, including 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 was 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." For the period February 22, 2012 – May 25, 2015, the City health plans paid $5,253.22 in claims for opioids prescribed by Prescriber J, including $2,706.06 in Defendants' drugs (39 prescriptions) and $1,033.42 for Purdue's opioids in particular (5 prescriptions).

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. For the period September 3, 2008 – April 13, 2015, the City health plans paid $369.08 in claims for opioids prescribed by Prescriber Z, including $279.62 in Defendants' drugs (10 prescriptions).

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. For the period July 28, 2005 – June 13, 2015, the City health plans paid $2,689.04 in claims for opioids prescribed by Prescriber HH, including $2,689.04 in Defendants' drugs (117 prescriptions) and $956.27 for Purdue's opioids in particular (5 prescriptions).

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." For the period October 31, 2013 – October 3, 2014, the City health plans paid $3,238.31 in claims for opioids prescribed by Prescriber T, including $501.83 in Defendants' drugs (16 prescriptions) and $233.43 for Purdue's opioids in particular (1 prescription).

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. For the period December 21, 2007 to June 26, 2015, the City health plans paid $50,044.34 in claims for opioids prescribed by Prescriber QQ, including $42,170.47 in Defendants' drugs (340 prescriptions) and $13,402 for Purdue's opioids in particular (28 prescriptions).

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. For the period March 25, 2011 – May 27, 2014, the City health plans

> paid $889.53 in claims for opioids prescribed by Prescriber Q, including $165.94 in Defendants' drugs (12 prescriptions). Prescriber Q has prescribed OxyContin.

631. These accounts reflect specific examples of instances in which Purdue's sales representatives made the misrepresentations outlined above in Sections V.D and V.E.5 directly to Chicago prescribers. They are not an exhaustive list. 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 Chicago-area prescribers they detailed.

632. 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 Chicago Prescriber G, he was required to stick to the company-approved messaging during his speaking engagements. Chicago Presciber G characterized this district manager as a mercenary who would do whatever it took to sell Purdue's drug and told Chicago Presciber G that Purdue would spare no expense in furtherance of that goal.

F. The Result of Defendants' Fraudulent Scheme

633. Through their direct promotional efforts, along with those of the third-party Front Groups and KOLs they assisted and controlled, and whose seemingly objective materials they distributed, 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, Chicago doctors began prescribing opioids long-term to treat chronic pain—something most would never have considered prior to Defendants' campaign.

634. 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 Defendants' deceptive marketing on doctors' prescribing and patients' use of opioids is evidenced by: (a) the increase in opioid prescribing nationally in concert with Defendants' marketing; (b) the City's own increased spending on opioids resulting from Defendants' promotional spending; (c) interviews with Chicago prescribers, including those who prescribed opioids paid for by the City, who confirmed that they prescribed opioids based on deceptive marketing, patients' demand, and/or to continue opioids therapy begun by other doctors; (d) a representative sample of claims for opioids that were prescribed by physicians who were subject to Defendants' deceptive marketing, then paid for by the City's health plans and workers' compensation program; and (e) the consequences of opioid overprescription—including addiction, overdose, and death—that have been visited on Chicago and its residents, as confirmed by interviews with victims and addiction treatment programs.

1. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to the City of Chicago.

635. In the first instance, the City 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.

636. Defendants' marketing of opioids caused health care providers to prescribe and the City, through its health plans and workers' compensation program, to pay for prescriptions of opioids to treat chronic pain. Because of Defendants' unbranded marketing, health care

providers wrote and the City 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, the City is obligated to cover medically necessary and reasonably required care, it had no choice but to pay these false and fraudulent claims.

637. The fact that the City would pay for these ineligible prescriptions is both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy *so that* doctors would prescribe and government payors, such as the City of Chicago, 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

638. 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.

639. 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.[130]

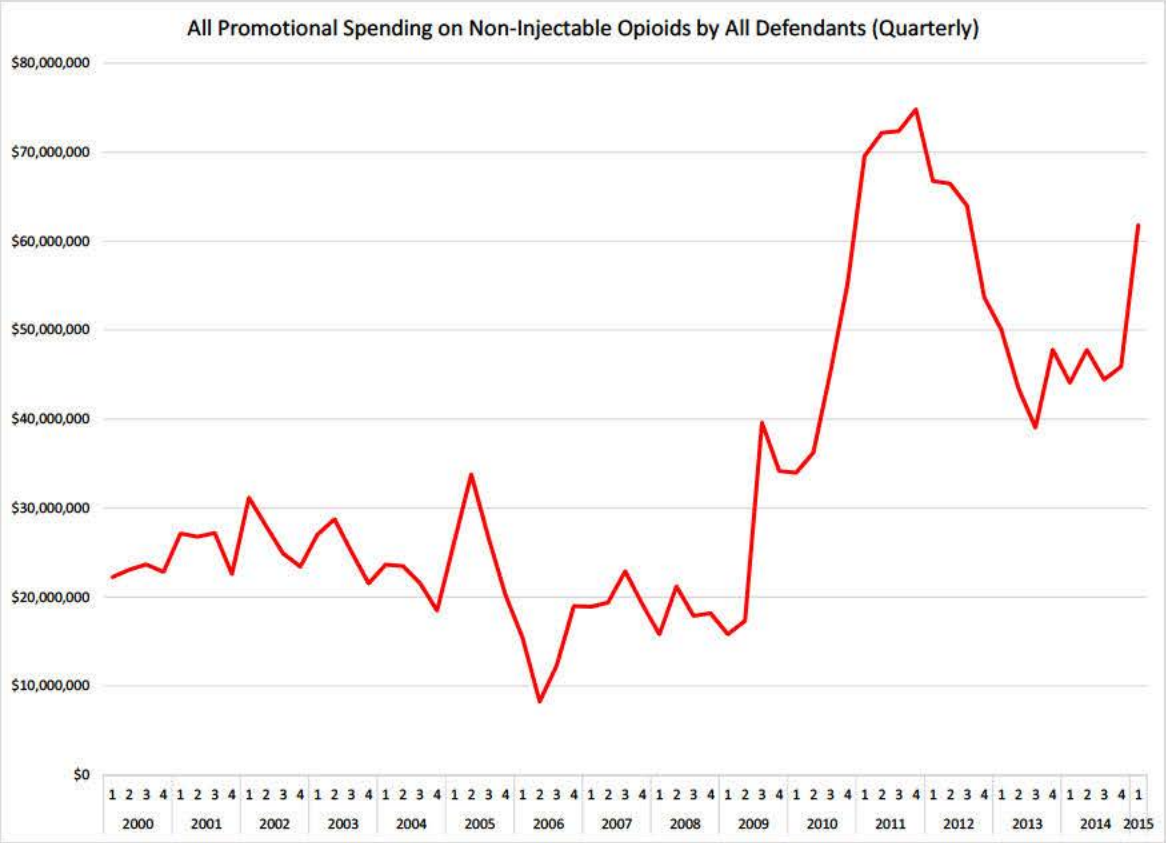
[130] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care 870 (2013).

640. 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."[131] 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.

641. This increase corresponds with, and was caused by, Defendants' massive marketing push. As reflected in the chart below, according to data obtained from a marketing research company, Defendants' spending nationwide on marketing of opioids—including all of the drugs at issue here—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 Defendants confronted increased concern regarding opioid addiction, abuse, and diversion, and as Janssen, which accounted for most of the spending reduction, prepared to sell its U.S. rights to Nucynta and Nucynta ER. Even so, Defendants still

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

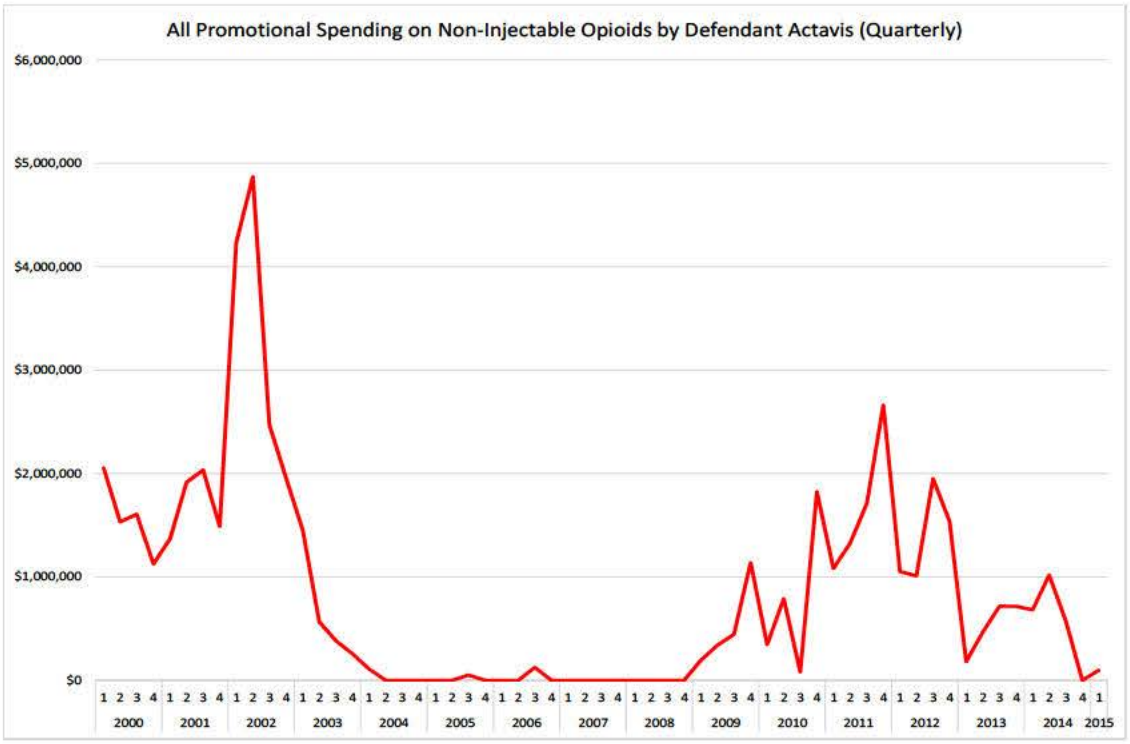
spend double what they spent in 2000 on opioid marketing.



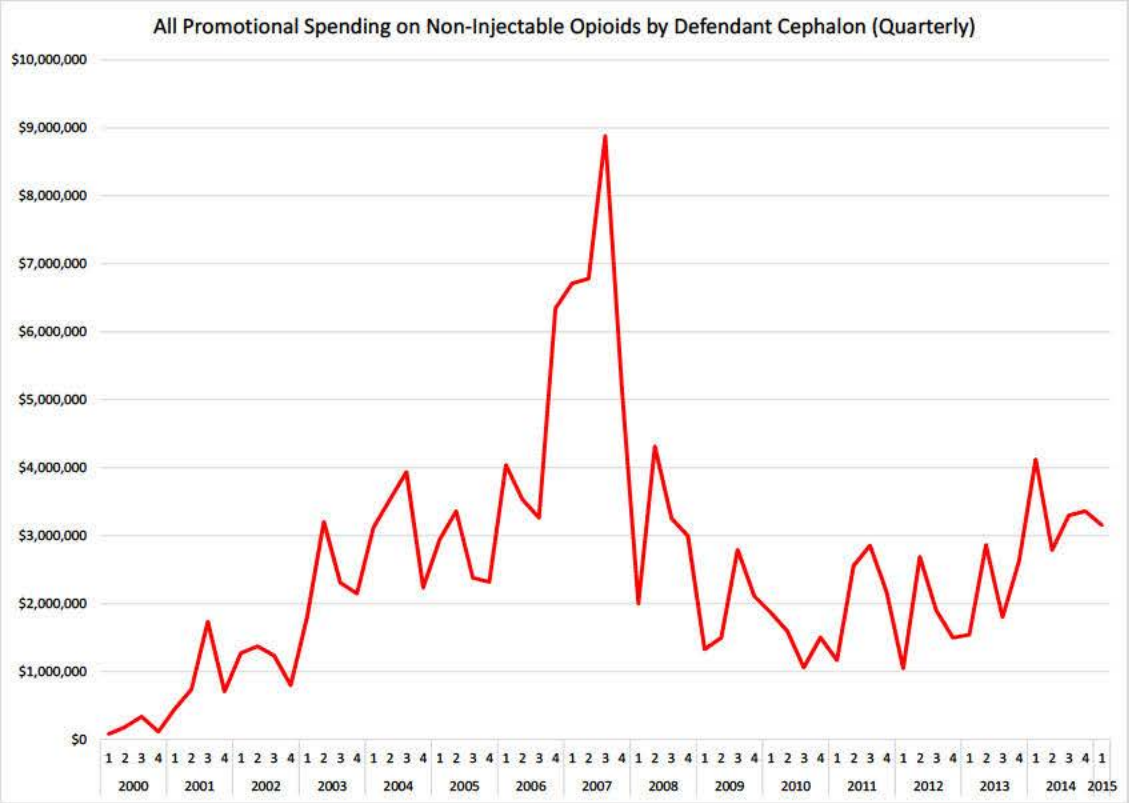
642. By far the largest component of this spending was opioid drugmakers' detailing visits to individual doctors, with total detailing expenditures more than doubling between 2000 and 2014 and now standing at $168 million annually.

643. Each Defendant's promotional spending reflects its participation in this marketing blitz. Between 2000 and 2011:

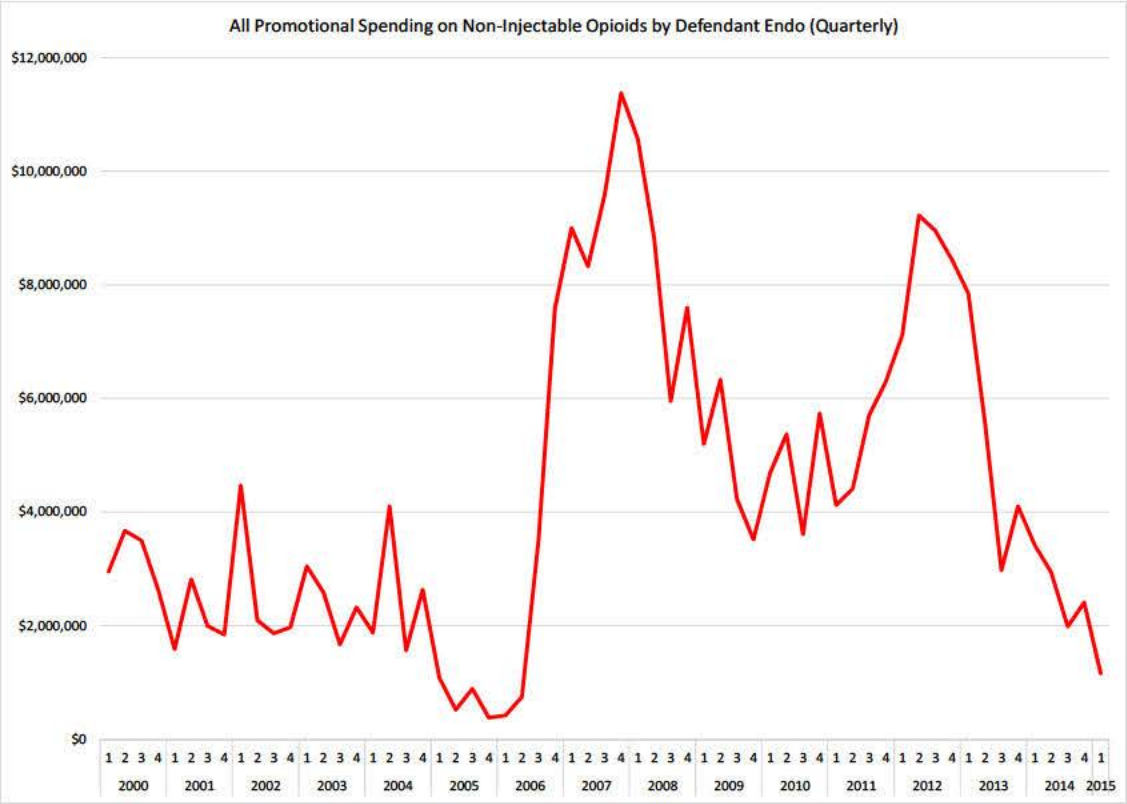
- Actavis's promotional spending, which was virtually non-existent in the 2004-2008 period, sharply rose beginning in 2009 to a quarterly peak of nearly $3 million at one point in 2011 (and nearly $7 million for the year), as shown below:



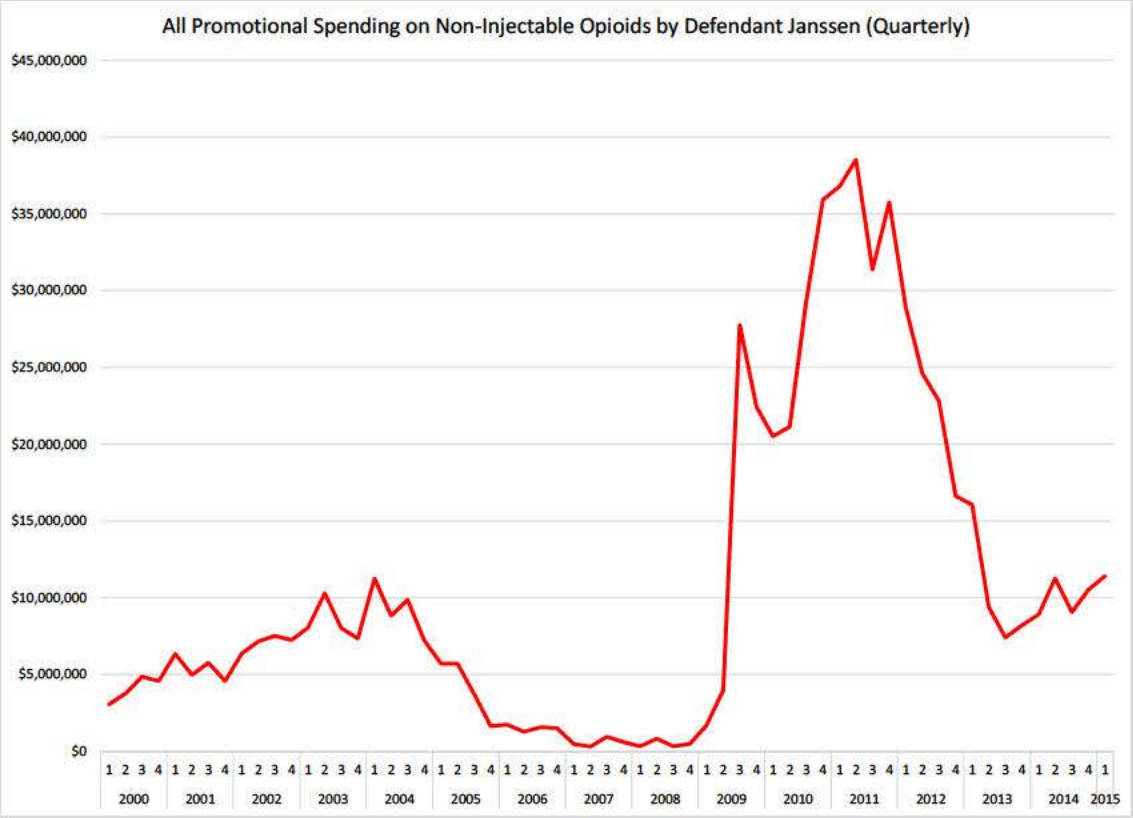
- Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown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



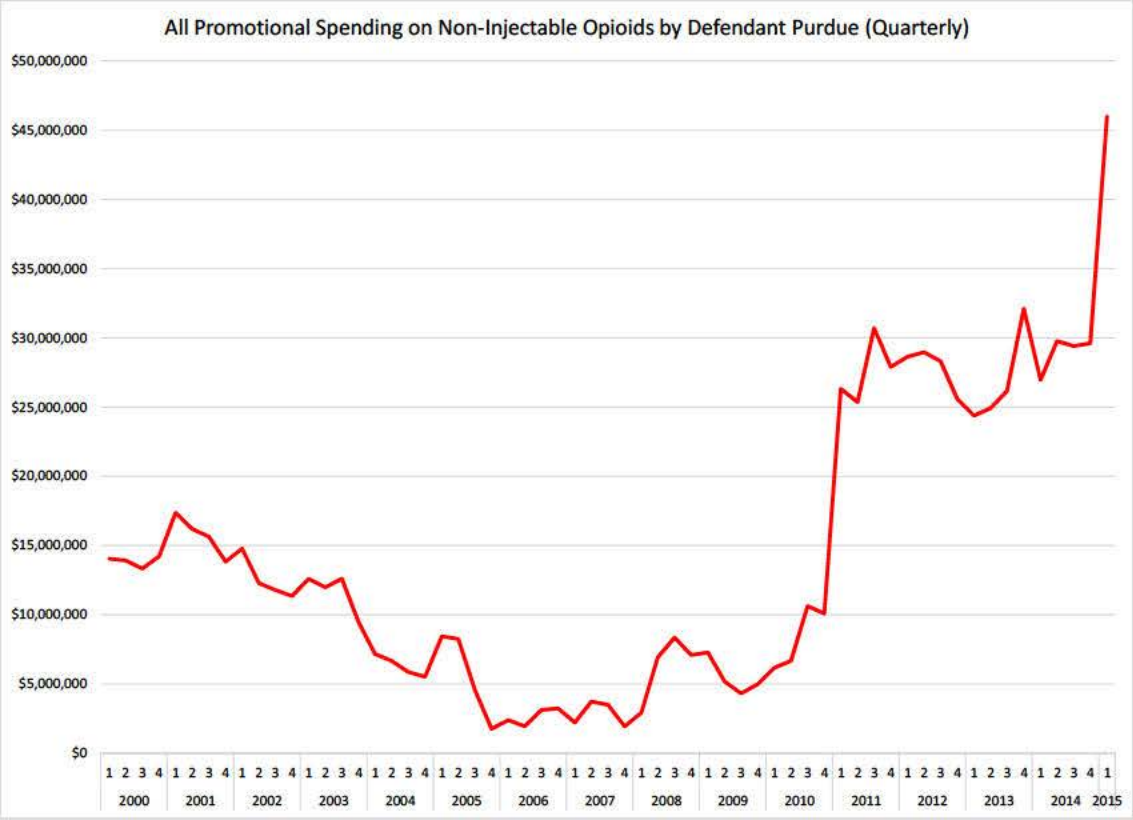
- Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly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



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



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



b. The City's Increased Spending on Opioids

644. Commensurate with Defendants' heavy promotion of opioids and the resultant, massive upswing in prescribing of opioids nationally, the City of Chicago 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*

645. The City provides comprehensive health care benefits, including prescription drugs coverage, to its employees and retirees. These benefits are provided under various health

plans that the City self-insures, including a preferred provider organization ("PPO") for employees, a health maintenance organization ("HMO") for employees, a plan that covers retirees who are not yet on Medicare, and a plan that provides supplemental coverage to those retirees who are on Medicare.

646. The prescription drug plan under the PPO is self-insured: the costs of prescription drugs are paid directly by the City. Throughout the relevant time period for this action, the PPO's prescription drug costs have been paid by the City.

647. The HMO's prescription drug coverage has been self-insured at various times throughout the relevant time period. Before July 2006, the City paid the premiums for the HMO plans, which in turn covered the cost of prescription drugs. Between July 2006 and December 2009, the City paid the premiums for an HMO plan to Unicare, which in turn covered the cost of prescription drugs. During that same time period, the City also had an HMO plan with Blue Cross/Blue Shield, which directly billed the City for prescription drugs. From January 2010 to December 2011, both HMO plans were operated by Blue Cross/Blue Shield, and the costs of prescriptions drugs were paid directly by the City. From January 2012 to December 2013, one HMO plan was offered and the City paid premiums to the HMO plan, which in turn covered the cost of prescription drugs. Since January 1, 2014, the City's prescription drug coverage under the HMO is once again self-insured and the City has been directly paying the costs of prescription drugs under the HMO. In times when the City was not self-insured or paying prescription drug costs directly, it was covering those costs indirectly through insurance premiums priced to account, in part, for the rising cost of Defendants' drugs.

648. Doctors submit claims directly to the City's applicable health plans 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 the City's self-insured health plans are filled by pharmacies, which submit claims for reimbursement to the City's pharmacy benefit manager.

649. The City'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.

650. Defendants caused doctors and pharmacies to submit, and the City 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 the City for chronic opioid therapy false.

651. The City'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 the City's plans. Under the plans, 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."

652. Doctors who care for City employees and retirees and their dependents are bound by the provider agreements that entitle them to participate in the City's health plans. These

agreements 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."

653. The City is obligated to pay for the medically necessary treatment of covered employees.

654. 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, and the various self-insured HMOs)—the health plans authorize payment from City funds.

655. 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."

656. Further, 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 Defendants' drugs did not accurately describe the risks associated with long-term use of their products, rendering them misbranded. Due to this misbranding, Defendants' opioids were not FDA-approved, within the meaning of the City's health plans, for the long-term treatment of chronic pain.

657. Moreover, Cephalon's Actiq and Fentora were specifically marketed for off-label, non-FDA-approved uses—*i.e.* for the treatment of non-cancer chronic pain, or in patients who

are not opioid tolerant. Physicians, in turn, wrote prescriptions for Fentora and for Actiq for non-FDA approved uses, causing the self-insured health plans to authorize, and the City to pay for, those prescriptions.

658. Alternatively, even to the extent that chronic opioid therapy is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Defendants' deceptive marketing. Defendants' marketing targeted and subverted every input physicians rely on in making prescribing decisions, from the medical literature to the patients themselves. Defendants' ability to seed—through deceptive and unfair conduct—medical practice that supported the use of opioids for chronic pain should not entitle them to profit from that conduct.

659. For each and all of the reasons laid out above, chronic opioid therapy and its attendant and consequential costs are not eligible for reimbursement through the City's health plans. The City would not have knowingly reimbursed claims for prescription drugs that were not eligible for coverage.

660. As a result of Defendants' deceptive marketing, Chicago 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 the City to incur additional costs.

661. Attached as Exhibits A.1-6 and B.1 are a representative sample of claims that each Defendant caused to be submitted to and paid by the City's health plans related to Defendants' opioid products.

662. In all, based on a preliminary review, the City spent more than $13.9 million for over 320,000 claims for opioids during this period.[132] This includes approximately $3.2 million for Purdue Schedule II and III opioids, $2 million for Actavis Schedule II and III opioids, $1.3 million for Endo Schedule II and III opioids, $464,000 for Janssen Schedule II and III opioids, and $1 million for Cephalon and Teva 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 City 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. Between May 2013 and May 2015, the health plans alone spent more than $2.3 million for the treatment of opioid abuse and dependency.

663. 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 Defendants' deceptive and unfair conduct. The vast majority of opioids paid for by the City's health benefits and workers compensation programs were for chronic pain, as shown in the figure below.[133] This is consistent with national data indicating that 87% of all opioids dispensed were to chronic pain patients using opioids long-term, whereas only 13% were for acute or cancer pain patients.

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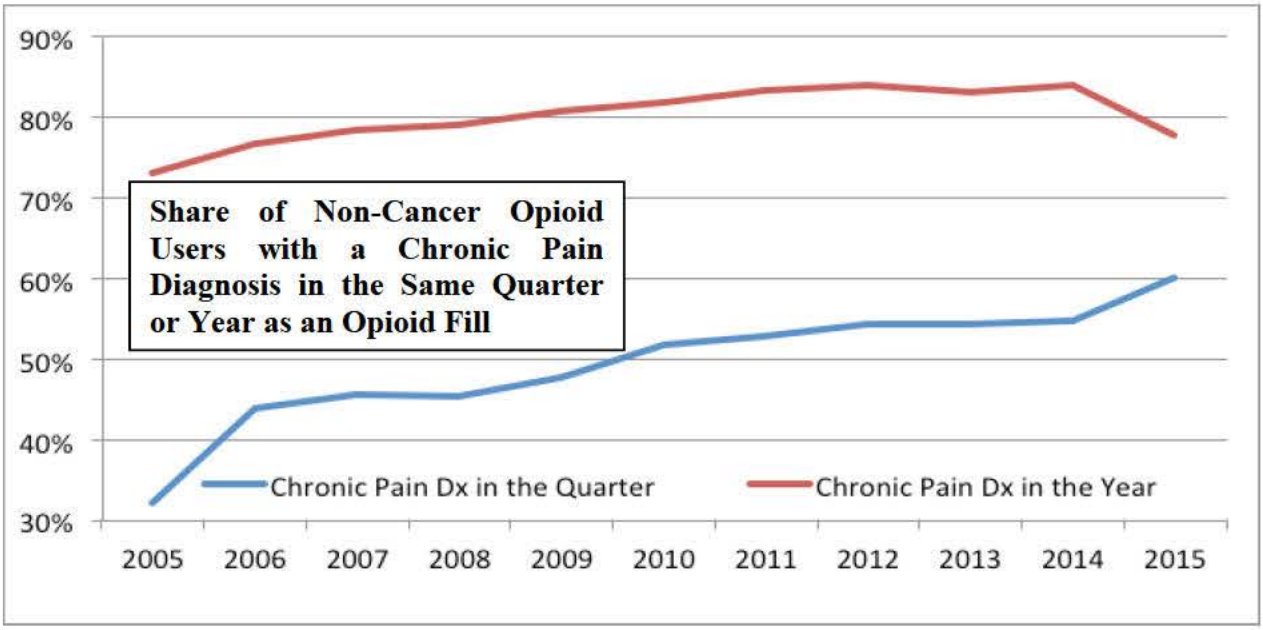
[132] The First Amended Complaint describes more than 400,000 claims for opioids in total. Some of those data did not reflect separate prescriptions or fills, but instead accounting adjustments.

[133] This analysis undercounts the number of Chicago health benefits and workers compensation patients using opioids for chronic pain, as it analyzes only those with chronic pain diagnoses in the same quarter or year as the opioid prescription. As the Complaint lays out, many chronic pain patients remain on opioids for years.



ii. *Workers' Compensation Program*

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

665. The City uses Coventry, a medical management vendor, to help manage medical benefits under the workers' compensation program. Doctors submit claims directly to the City's workers' compensation program for the costs associated with prescribing opioids, including office visits and toxicology screens for patients prescribed opioids. First Script is the pharmacy and drug utilization management program used by Coventry to manage prescriptions for the City's workers' compensation program.

666. The City'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.

667. Defendants caused doctors and pharmacies to submit, and the City 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 claims to the City for chronic opioid therapy false.

668. 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).

669. Similarly, Coventry's provider agreement limits covered, or reimbursable, services to services that are "Medically Necessary." Services and supplies meet this standard if they are determined to be (a) "[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"; (b) "[n]ecessary to

meet the health needs of the Member, improve physiological function and required for a reason other than improving appearance"; (c) "[c]onsistent in type, frequency and duration of treatment with scientifically-based guidelines of national medical research, professional medical specialty organizations or governmental agencies that are generally accepted as national authorities on the services, supplies, equipment or facilities for which coverage is requested"; and (d) "[c]onsistent with the diagnosis of the condition at issue."

670. 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 City funds.

671. The City's workers' compensation program is obligated to cover all "medically necessary" and "reasonably required" treatment arising from a compensable work-related injury.

672. 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).

673. Nevertheless, the amount of such prescriptions paid by workers 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.

674. In 2011, First Script prepared a Drug Trends Report, outlining pharmaceutical trends identified in its workers' compensation book of business. In this report, First Script explained that short-acting and long-acting opioids represent the two most-prescribed drug classes within its workers' compensation program, representing 37% of its drug spending, as

shown in the tables below. The report also noted: "The nation's liberal consumption of narcotic pain relievers continues to gain recognition for its detrimental impact on injured workers—particularly those treated for chronic pain—and their employers."

Top 10 Therapeutic Classes by Amount Billed–2010

Therapeutic Class	% Total Rx	% Total Billed
Analgesics, Narcotic Sustained-Release	6.0%	20.3%
Analgesics, Narcotic Short-Acting	30.2%	17.5%
Anticonvulsants	8.5%	10.6%
NSAIDs	11.1%	7.5%
Muscle Relaxants	10.3%	7.3%
Dermatological/Topical Preparations	3.6%	7.0%
Antidepressant Medications, Non-TCA	6.1%	6.7%
Sedative/Hypnotics	3.4%	3.5%
Antiulcer Medications	2.6%	3.2%
Antipsychotics	0.6%	2.0%
Top 10 Total	**82.4%**	**85.6%**
All Other Total	**17.6%**	**14.4%**

Top 10 Therapeutic Classes by Amount Billed–2011

Therapeutic Class	% Total Rx	% Total Billed
Analgesics, Narcotic Sustained-Release	5.7%	19.4%
Analgesics, Narcotic Short-Acting	29.8%	17.5%
Anticonvulsants	8.5%	10.7%
NSAIDs	11.9%	7.7%
Dermatological/Topical Preparations	3.9%	7.3%
Antidepressant Medications, Non-TCA	6.0%	6.8%
Muscle Relaxants	10.3%	6.7%
Antiulcer Medications	2.6%	3.3%
Sedative/Hypnotics	3.1%	3.1%
Antipsychotics	0.7%	2.3%
Top 10 Total	**82.5%**	**84.8%**
All Other Total	**17.5%**	**15.2%**

675. For 2010 and 2011, First Script also reviewed its claim data and put together the following two tables depicting the Top 10 Medications by Amount Billed in 2010 and 2011

throughout its network. As these tables show, Defendants' opioid products accounted for over 20% of total prescription spending by First Script's entire workers' compensation program in 2010 and nearly 19% in 2011.

Figure 9

Top 10 Medications by Amount Billed-2010

Medications	FS Rank	% Total Rx	% Total Billed
Oxycontin®	1	2.5%	10.5%
Lidoderm®	2	1.8%	4.9%
Vicodin®*	3	15.1%	4.7%
Percocet®*	4	4.9%	4.2%
Lyrica®	5	2.9%	4.2%
Celebrex®	6	2.6%	3.5%
Duragesic®*	7	1.1%	3.5%
Neurontin®*	8	3.2%	3.4%
Cymbalta®	9	1.8%	3.0%
Actiq®*	10	0.1%	1.9%
Top 10 Total		**36.0%**	**43.8%**
All Other Total		**64.0%**	**56.2%**

*Aggregate of brand and generic.

Figure 10

Top 10 Medications by Amount Billed-2011

Medications	FS Rank	% Total Rx	% Total Billed
Oxycontin®	1	2.1%	9.2%
Lidoderm®	2	1.8%	4.9%
Vicodin®*	3	15.0%	4.6%
Lyrica®	4	2.8%	4.4%
Percocet®*	5	4.9%	4.1%
Celebrex®	6	2.5%	3.5%
Neurontin®*	7	3.5%	3.5%
Cymbalta®	8	1.9%	3.3%
Duragesic®*	9	1.0%	3.2%
Opana® ER	10	0.5%	2.3%
Top 10 Total		**36.0%**	**43.0%**
All Other Total		**64.0%**	**57.0%**

*Aggregate of brand and generic.

676. Attached as Exhibits A.7 and B.2 are representative samples of claims for chronic pain conditions prescribed by marketing targets for Defendants' opioids paid through the City's

workers' compensation program between November 29, 2009 and June 26, 2015. In all, the City's workers' compensation program spent $1.98 million on opioids during this period. This includes approximately $287,000 for Purdue Schedule II and III opioids, $406,000 for Actavis Schedule II and III opioids, $265,000 for Endo Schedule II and III opioids, $163,000 for Janssen Schedule II and III opioids, and $363,000 for Cephalon and Teva Schedule II and III opioids. The balance reflects prescriptions that were also caused by Defendants' fraudulent marketing, including prescriptions for Defendants' generic opioid products and prescriptions for opioids from other manufacturers. These figures do not reflect the cost to the City 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.

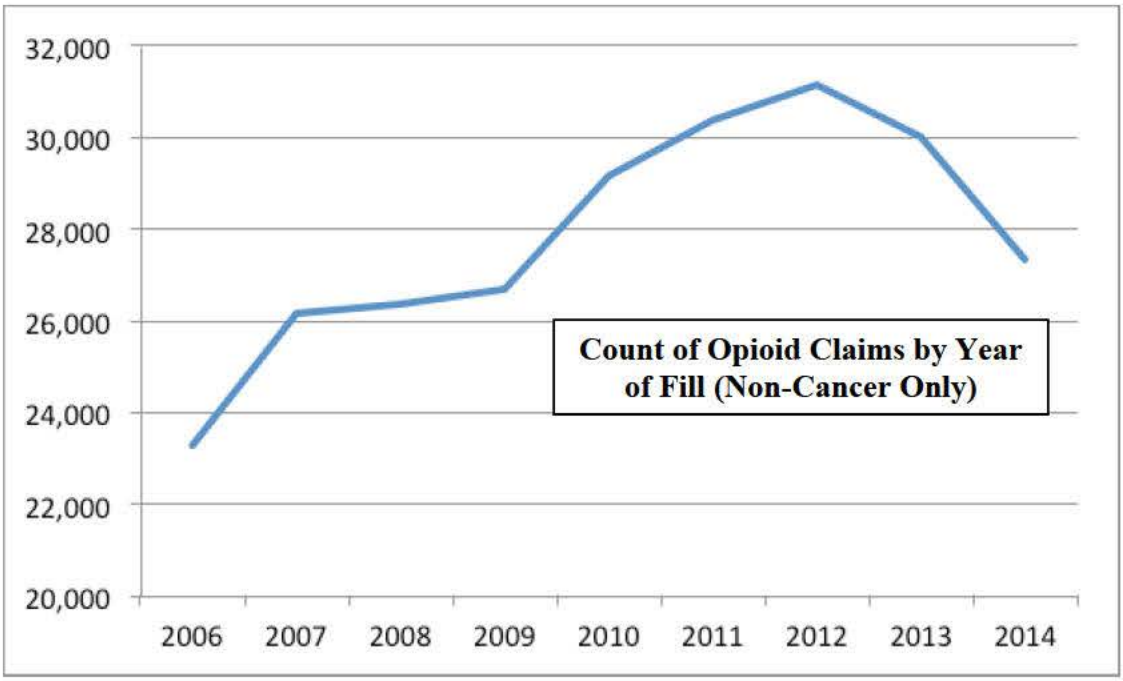
677. However, the costs of long-term opioid use are not limited to costs of opioid prescriptions. Long-term opioid use is accompanied by a host of consequential costs, including costs related to abuse, addiction, and death.

678. 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 Defendants' fraudulent scheme.

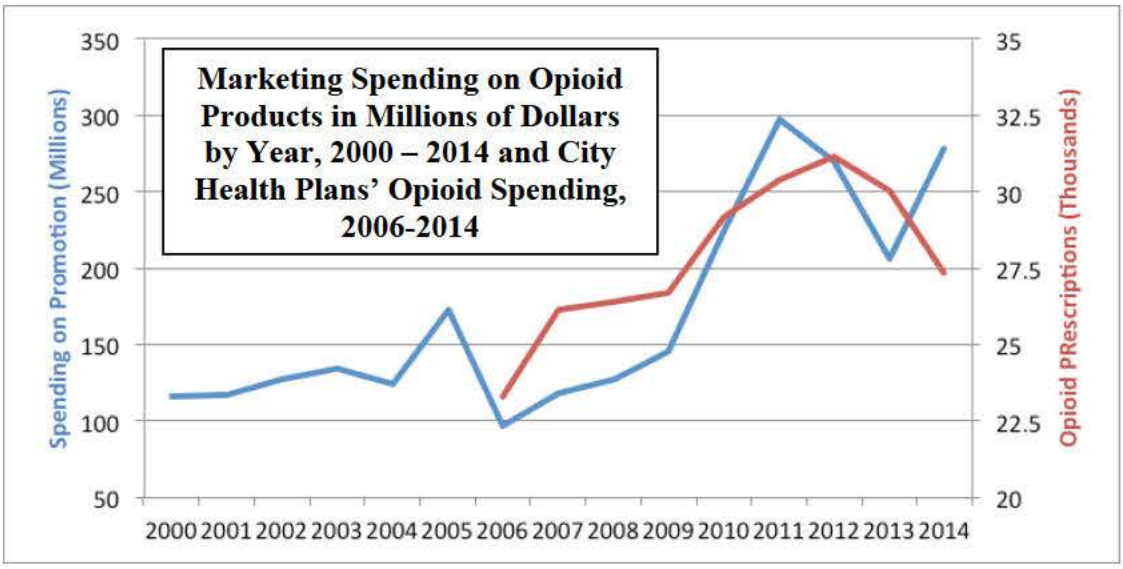
iii. *The City's Increased Costs Correlate With Defendants' Promotion.*

679. In 2006, the City health plans funded 27,768 opioid prescriptions (23,277 with patients with no cancer diagnosis in the year of the prescription). As shown below, by 2011, this number had increased, with the City health plans funding 33,990 prescriptions (30,377 non-cancer). Opioid prescribing peaked in 2012, ebbed in 2013, and exhibited an even sharper downward turn in late 2014 when the federal government reclassified one of the most popular

opioids—hydrocodone—as a more tightly controlled Schedule II opioid. As a result, the number of opioid prescriptions fell to 31,405 (27,317 non-cancer).



680. As shown below, the City's spending on opioids rose along with Defendants' spending to promote opioids. According to expert analysis performed for the City of data on Defendants' promotional spending, that spending had a direct impact on opioid use (and its consequences in abuse, addiction, and overdose) in Chicago. Every 10% increase in Defendants' promotional spending nationally is associated with a 4.8% increase in the volume of opioids covered by the City of Chicago's health benefits and workers compensation programs.



681. 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 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. Interviews with Chicago Prescribers

682. The connection between 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.

683. As described above, Defendants' marketing in Chicago took varied forms. Defendants heavily relied on speakers bureau programs, in which Chicago-area 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 Chicago physicians at Defendant-funded events. [redacted]

684. These speakers themselves responded to Defendants' marketing by prescribing opioids, comprising 7,480 prescriptions, representing $1.36 million, written by these physicians and paid for by the City's health plans in the period June 1, 2005 –June 28, 2015. This is roughly 10% of the the City health plans' total opioid spending.[134]

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

686. Defendants also targeted Chicago-area prescribers and potential prescribers for visits by the companies' sales representatives. As described above in Section V.E, Defendants carefully tracked the prescribing behavior of Chicago prescribers, targeting them by specialty, prescribing volume, and other criteria. [redacted] based on Defendants' actual detailing practices, they targeted many more. [redacted] These physicians, many of whom were visited numerous times in that period, responded to the marketing pitches by prescribing Defendants' opioids.

687. The City interviewed numerous Chicago doctors who prescribed opioids for chronic pain to Chicago consumers and City employees, and these interviews confirmed the influence of Defendants' deceptive marketing. These doctors relied on treatment guidelines or scientific articles, attended CMEs, were visited by drug representatives, and were trained by

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

doctors who provided 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 following are examples of Chicago-area physicians' experience with the consequences of Defendants' deceptive opioid marketing:

688. 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 above in Section V.E, Prescriber B reported that he talked with opioid manufacturers' sales representatives on a regular basis and that he has met with detailers from Actavis, Endo, Janssen, and Purdue.

689. 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.

690. 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.

691. For the period June 3, 2005 – June 29, 2015, the City health plans paid $176,510.98 in claims for opioids prescribed by Prescriber B, including $34,029.61 in Defendants' drugs (368 prescriptions).

692. Chicago Prescriber D is a family care physician in Melrose Park, Illinois, who has treated patients on the City's health plans. 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.

693. 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.

694. For the period June 6, 2005 – August 11, 2012, the City health plans paid $61,651.12 in claims for opioids prescribed by Prescriber D, including $59,566.89 in Defendants' drugs (624 prescriptions).

695. 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.

696. 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.

697. 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 succesful weaning takes six months to a year, depending on how long the patient was on the drugs.

698. 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.

699. 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.

700. As a result of 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.

701. 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.

702. The influence of Defendants' deceptive marketing in Chicago extends far beyond the physicians who were detailed by Defendants' sales representatives or attended their talks or CMEs, however. 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 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 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.

703. The following are examples of Chicago physicians who do not recall being exposed to Defendants' marketing but nevertheless prescribe opioids, albeit with reservations about their consequences:

704. 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.

705. 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. For the period October 31, 2005 to May 20, 2015 the City health plans paid $2,670.13 in claims (50 prescriptions) for opioids prescribed by Prescriber KK, including $2,316.61 in claims for OxyContin (10 prescriptions).

706. 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 the City's Health Plans and Workers' Compensation Program

707. The following represent a sample of patients who obtained prescriptions for opioids between 2007 and the present—prescriptions reimbursed by the City's health plans and its workers' compensation program. These patients used opioids for longer than 90 days and suffered from chronic pain conditions, such as osteoarthritis or low back pain, and, on that basis, were prescribed these drugs to treat chronic pain. Their chronic pain conditions are summarized, along with the number and dates of their opioid prescriptions.

708. As examples, the prescriptions below were medically unnecessary and ineligible for payment under the City's health plans and workers' compensation program because they were prescribed for medical conditions not appropriate for opioid therapy. These examples are drawn from patients who were prescribed opioids by health care providers who confirmed that they received the marketing messages described above in Section V.D. Because of Defendants' fraudulent, misleading, and unfair marketing, these claims were not—and could not have been—based on the prescribers' assessments of the risks and benefits of opioids to treat these patients' chronic pain:

a. Chicago Health Plan Patient A was diagnosed with back pain as early as 2005. This patient received 355 prescriptions from August 19, 2005 through June 6, 2015, incurring $67,053.58 in claims paid by the City health plans. These include 4

prescriptions for OxyContin from Chicago Prescriber O, who reported attending CMEs sponsored by Cephalon and Purdue, and 43 OxyContin prescriptions from Chicago Prescriber R, who was a member of the Janssen speakers bureau and a marketing target of Cephalon.

b. Chicago Health Plan Patient B received chronic opioid therapy from June 13, 2005 through June 25, 2015, and had separate diagnoses for back pain in 2011, 2013, and 2014, and joint pain in 2011. This patient received 15 prescriptions of Opana ER from Chicago Prescriber Y, who had acted as an adviser to Endo from June 2005 to September 2006. The patient also received 59 prescriptions for Kadian from this doctor (and two from another prescriber), 40 prescriptions of generic Actiq, 21 prescriptions for Actiq, and two prescriptions for Nucynta, as well as prescriptions for generic fentanyl. In total Patient B received 285 prescriptions for opioids, incurring $201,867.83 in charges to the City health plans.

c. Chicago Health Plan Patient C received opioids for a back pain diagnosis between June 11, 2005 and June 27, 2015. In total, this patient received 434 prescriptions resulting in $160,427.61 in charges to the City health plans. During this time, this patient received a total of 148 prescriptions for Opana ER, including 92 from Chicago Prescriber A, who was trained in Endo's speakers bureau.

d. Chicago Health Plan Patient D received opioids for pain conditions including back and joint pain between October 11, 2005 and February 11, 2014. In total, this patient received 189 opioid prescriptions, resulting in $25,995.34 in claims to the City health plans, of which $21,636.94 were for OxyContin. This patient received OxyContin prescriptions from members of the Endo, Janssen, and Cephalon speakers' bureaus, Chicago Prescribers V, OO, and M. Prescriber M who was a member of all three bureaus, wrote additional prescriptions for OxyContin and for Opana ER, along with prescriptions for fentanyl, oxycodone-acetaminophen, and hydrocodone-acetaminophen.

709. The following is a representative sample of claims submitted to the City's workers' compensation program:

e. Chicago Workers' Compensation Patient E received opioids for a claim arising from a condition of the joints in the lower leg. This patient received a total of 100 prescriptions for opioids from September 1, 2011 to June 20, 2015, for a total

cost to the City's workers' compensation plan of $21,031.17. These claims included 72 prescriptions for branded and generic OxyContin, one prescription for Opana ER, and 26 prescriptions for combination hydrocodone-acetaminophen. Three of these prescriptions for oxycodone were written by Chicago Prescriber E, who reported being detailed by sales representatives from all Defendants, none of whom discussed addiction risks with him.

f. Chicago Workers' Compensation Patient F received opioids for a claim arising from lower back pain. This patient received a total of 101 opioid prescriptions from January 6, 2010 to June 15, 2015, for a total cost to the City's workers compensation plan of $84,993.54. These claims include 44 prescriptions for Janssen's Duragesic patch; 4 claims for generic fentanyl patches, two of which were prescribed by Chicago Prescriber A who was trained in Endo's speaker's bureau; and 34 prescriptions for Actavis's Norco tablets. This patient's claims also include 2 prescriptions for Purdue's Butrans patch, 1 prescription for generic OxyContin, and prescriptions for hydromorphone tablets, hydrocodone-acetaminophen combinations, and morphine sulfate solution.

g. Chicago Workers' Compensation Patient G received opioids for claims arising from lower back pain. This patient received a total of 48 opioid prescriptions from October 7, 2010, through September 16, 2014, for a total cost to the City's Workers Compensation Plan of $6,317.72. The prescriptions include 5 prescriptions from Chicago Prescriber J, a nurse practitioner who reported being detailed by representatives from Purdue, Cephalon, Janssen, and Actavis. Prescriber J wrote this patient prescriptions for hydromorphone and methadone. The patient also received 1 prescription for Kadian, 4 prescriptions for Nucynta, and 3 prescriptions for Nucynta ER, along with other prescriptions for generic morphine, hydrocodone-acetaminophen, and oxycodone-acetaminophen.

h. Chicago Workers' Compensation Patient H received opioids for a claim arising from conditions including back pain, joint pain, and pain of psychological origin, from October 22, 2010 through June 9, 2015. This patient received a total of 91 opioids for a cost to the City's workers compensation plan of $42,153.30. These claims included 2 prescriptions for Fentora in 2010, and 2 prescriptions for Kadian in 2010. Additionally, in January 2011, this patient received treatment for opioid dependency, resulting in an additional $13,974.50 in expenses

> to the workers compensation plan. Subsequent to this treatment, this patient received 9 prescriptions for branded and generic morphine in 2013 and 2014 from Chicago Prescriber OO, a member of Janssen's speakers bureau.

2. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Chicago Consumers.

a. Increased Opioid Use Has Led to an Increase in Opioid Abuse, Addiction, and Death

710. 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."[135] 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.

711. 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 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.

712. 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

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

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).

713. Emergency room visits tied to opioid use likewise have sharply increased in Chicago. The U.S. Department of Health and Human Services estimated that in 2009 in Chicago, 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. Emergency department visits due to opioids increased 153 percent between 2004 and 2011. In 2009, over 1,200 emergency department visits involved patients who were illicitly using opioids.

714. Widespread opioid use and abuse in Chicago are problems even where they do not result in injury or death. According to addiction treatment programs interviewed by the City, opioid addiction is affecting residents of all ages, ethnicities, and socio-economic backgrounds in Chicago. Many addicts start with a legal opioid prescription—chronic back pain, fibromyalgia, or even dental pain—and do not realize they are addicted until they cannot stop taking the drugs.

715. These treatment programs told the City that many of their patients reported never being told by their doctor of the risk of addiction from opioids. The founder and director of one resource center explained that prescription pills are the primary gateway to heroin and that very few of the center's clients were addicted to heroin before they were addicted to pills. The center's clients have included individuals who became addicted to opioids by first using the drugs at issue here, including OxyContin, MS Contin, Dilaudid, Dilaudid-HP, Butrans, Opana, Opana ER, Percodan, and Percocet. More than 75% of the center's clients crossed over from opioids to heroin. Individuals typically increase their opioid doses as their tolerance builds, and then cross into snorting and/or shooting drugs. The center's clients who first received opioids

through prescriptions were initially prescribed opioids by a broad range of prescribers for a variety of ailments, including chronic pain. The prescribing doctors rarely discussed the risk of addiction with them.

716. The medical director of another treatment center also said many addicts in his program received no education from their prescribing physicians on addiction risk and consequently had "no clue" of the danger posed; they simply followed doctors' instructions. A counselor at another treatment center echoed that view, saying that many of the facility's patients did not know when they started on pharmaceutical opioids of the risk they might become addicted. A Chicago physician specializing in addiction treatment said a "minority" of his patients were warned of the risk of addiction by their prescribing physicians. Other physicians treating opioid addiction spoke of their patients feeling misled because they were not told of the risk they could become addicted to their prescription opioids. These patients note that they would have never started on opioids had they known what might follow.

717. A founder of another resource center, who estimates that the center sends 200 individuals per month to local in-patient treatment centers and supports over 200 individuals a week in recovery and support groups, similarly noted prescribers' failure to educate patients regarding the risks of addiction. The center's clients have included individuals who became addicted to opioids by first using lawfully obtained prescriptions for drugs at issue here, including OxyContin, MS Contin, Dilaudid, Fentora, Duragesic, Percocet, and Percodan. 80% of the center's clients cross over from opioids to heroin. And the rate of relapse for those individuals in recovery is high—an estimated 90 to 95%.

718. Those Chicago patients who spoke to the City echoed themes of not being warned and not being aware when they started that they could become addicted to opioids prescribed to them by their doctors.

719. In 2015, the top prescriber of opioids in the City, Prescriber A, transmitted Defendants' misrepresentations to a former runner and athletic trainer seeking treatment for pain. He told the patient that opioids would improve the quality of her life and that, by taking opioids, including Nucynta and Nucynta ER, she would be able to return to running and cycling. The doctor told this patient that she might be on opioids for the rest of her life but that they were necessary for her to lead the active life she had before the onset of her pain. When the patient asked the doctor about addiction, he brushed off her concerns.

720. One Chicago addiction treatment patient is a waitress who suffered a back injury on the job and saw a physician for the pain. The doctor prescribed 5 mg Norco, which worked for about a month. She told the doctor she needed more, and he increased the dose to 10 mg. He never warned her about the risk of addiction. She was taking two pills a day, but soon started taking four pills to get the same pain relief, and within a few months she was up to 10 pills per day. After about 5-6 months, the doctor cut her off – a story repeated by many patients whose addiction eventually became evident to their doctors. She turned to the street for more opioids, obtaining them through doctor-shopping, using aliases, going to an emergency room, or working through "someone who knew someone" who could get them. She has suffered severe withdrawal symptoms when she has attempted to kick the habit. She is now treated with daily methadone.

721. Another recovering addict in Chicago was prescribed opioids in 2012 after he slipped and hurt his back. He saw a pain specialist in Chicago, who prescribed Tramadol. His

primary care physician also prescribed opioids for his pain, including Norco and fentanyl. A nurse, he had some knowledge of addiction, but understood he would not get addicted if he took the medications as directed. While the opioids worked for a while, the pain returned, and he ended up increasing his dose, taking the drugs more often, or combining drugs. He was fired for appearing drunk on the job, which he attributed to all the medications he was taking. He did not realize he was addicted until he went through withdrawal. He has been in rehab since late 2013 and still craves opioids for his pain.

722. These glaring omissions, described consistently by counselors and patients, mirror and confirm Defendants' drug representatives' own widespread practice, as described above, of omitting any discussion of addiction from their sales presentations to physicians or in their "educational" materials.

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

723. By May 2014, Illinois had seventy-one Certified Opioid Treatment Programs, thirty-one of which are in the City of Chicago. 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.

724. 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.

725. The City's workers' compensation program and health benefit plans have expended approximately $2.4 million on addiction treatment services from May 2013 to May

2015. Additionally, claims data indicate that non-retirees covered by the City's health plans had 835 days of inpatient therapy between May 2013 and May 2015, causing these employees to miss work.

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

726. 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. Defendants' scheme supplies both ends of the 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."[136] It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

727. 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."[137]

728. 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 the

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

[137] Monifa Thomas, *supra*.

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."[138]

729. That reality holds in Chicago. According to addiction programs in Chicago, a typical course is addicts requesting more and more opioids from their doctors, who eventually cut them off. Many then doctor-shop for additional prescriptions, and when that source runs out, turn to the streets to buy opioids illicitly. A significant number become heroin addicts. Addiction treatment programs, whose patient populations vary, reported rates of patients who had switched from prescription opioids to heroin ranging from half to 95%. Those addicts who do reach treatment centers often do so when their health, jobs, families and relationships reach the breaking point or after turning to criminal activity such as prostitution and theft to sustain their addiction. Unfortunately, few are successful in getting and staying clean. Addiction treatment centers told the City that repeated relapse is common; one Chicago addiction center estimated that only 5-10% of its patients reach abstinence on a long-term basis.

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

730. While the use of opioids has taken an enormous toll on the City of Chicago and its residents, Defendants have realized blockbuster profits. In 2012, health care providers wrote 259

[138] 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.

million prescriptions for painkillers—roughly one prescription per American adult. Opioids generated $8 billion in revenue for drug companies just in 2010.

731. Financial information—where available—indicates that Defendants each 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. Defendants Fraudulently Concealed their Misrepresentations.

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

733. First, and most prominently, 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. Defendants purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

734. While 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. Defendants exerted their considerable influence on these promotional and "educational" materials.

735. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear that they were accurate, truthful, and supported by substantial scientific evidence. 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 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 the City.

736. Thus, while the opioid epidemic was evident, Defendants, in furtherance of their respective marketing strategies, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that the City now asserts. The City was not alerted to the existence and scope of Defendants industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

737. Through their public statements, marketing, and advertising, Defendants' deceptions deprived the City of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

VI. COUNT ONE

CONSUMER FRAUD—DECEPTIVE PRACTICES

VIOLATIONS OF MCC § 2-25-090 AGAINST ALL DEFENDANTS

738. The City 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.

739. MCC § 2-25-090 makes it unlawful for a business to "engage in any act of consumer fraud, unfair method of competition, or deceptive practice while conducting any trade or business in the city" including "[a]ny conduct constituting an unlawful practice under the Illinois Consumer Fraud and Deceptive Business Practices Act." The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2, makes unlawful, among other things,

"the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act.'"

740. Defendants have engaged in unlawful and deceptive business practices in violation of the Municipal Code as set forth above.

741. Defendants' practices as described in the Complaint are deceptive business practices that violate MCC § 2-25-090 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 the City.

742. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and/or by aiding and abetting third parties,[139] violated MCC § 2-25-090 by making and disseminating untrue, false, and misleading statements to Chicago 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 Chicago 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;

[139] Here and in the subsequent counts of the Complaint, the allegations that Defendants acted with and through third parties pertain to Defendants Cephalon, Endo, Janssen, and Purdue. The City does not allege that Actavis acted with or through third parties.

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.

743. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and by aiding and abetting third parties, also violated MCC § 2-25-090 by making statements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic pain. 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.

744. At all times relevant to this Complaint, 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.

745. 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, 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.

746. The third-party KOLs and Front Groups which 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. 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 assistance for the shared purpose of issuing misleading, pro-opioid messaging.

747. In sum, 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 Defendants made, controlled, and

disseminated deceptive marketing themselves, Defendants also are independently liable for the deceptive activity of third parties.

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

749. As a direct result of the foregoing acts and practices, 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 MCC § 2-25-090 as described in this Complaint.

750. By reason of Defendants' unlawful acts, Chicago consumers have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

751. Because Defendants' unbranded marketing caused the doctors to prescribe and the City 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, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count One of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the MCC § 2-25-090; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' consumer fraud and deceptive practices; (d) compelling Defendants to pay civil penalties up to $10,000 per violation pursuant to § 2-25-0909(f) for each day the violations occurred; (e) compelling Defendants to disgorge their ill-gotten profits; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

VII. COUNT TWO

CONSUMER FRAUD—UNFAIR PRACTICES

VIOLATIONS OF 815 ILCS 505/2 AND MCC § 2-25-090 AGAINST ALL DEFENDANTS

752. The City 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.

753. The MCC § 2-25-090 makes it unlawful for a business to "engage in any act of consumer fraud, unfair method of competition, or deceptive practice while conducting any trade or business in the city," including "any conduct constituting an unlawful practice under the Illinois Consumer Fraud and Deceptive Business Practices Act." The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2, makes unlawful, among other things, "[u]nfair . . . acts or practices."

754. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and/or by aiding and abetting third parties, violated the Illinois Consumer Fraud and Deceptive Business Practices Act—and therefore MCC § 2-25-090—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 Chicago consumers that is not outweighed by any countervailing benefits to consumers or competition.

755. 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 decreased 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;

g. Promoting their opioids for off-label uses in the case of Cephalon, by marketing Actiq and Fentora for treatment of non-cancer pain and/or for use in non-opioid-tolerant patients; and

756. Defendants engaged in these practices both directly and through the KOLs and Front Groups that they controlled and/or which they aided and abetted. Defendants were aware of the unfair conduct of the KOLs and Front Groups, and yet Defendants provided them substantial assistance and encouragement by helping them engage in the unfair practices. 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.

757. 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."[140] Nevertheless, by engaging in the conduct alleged above, 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. 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.

758. 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, 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. 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 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 Defendants' unlawful conduct.

759. Finally, Defendants' conduct has caused substantial, indeed grievous, injury to Chicago consumers. The staggering rates of opioid use, abuse, and addiction resulting from

[140] 745 ILCS 35/2.

Defendants' marketing efforts have caused substantial injury to Chicago residents, including, but not limited to:

a. Upwards of 30% of all adults have used opioids, with the vast majority of the use stemming from prescribing for chronic pain conditions.

b. A substantial number of Chicago 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 or death and sometimes an unrecoverable toll on their health, work, and family.

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

d. Chicagoans 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. Chicago 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. 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. 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.

760. The profound injuries to Chicago consumers are not outweighed by any countervailing benefits to consumers or competition since there is no benefit from the deceptive marketing of these narcotic drugs. Moreover, no public policy justifies Defendants' conduct in overstating the benefits, denying or downplaying the risks, and misrepresenting the superiority of opioids for chronic pain, which deprived Chicago 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), Chicago consumers could not reasonably have avoided their injuries.

761. By reason of Defendants' unlawful acts, Chicago consumers and the City have been damaged and continue to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Two of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the MCC § 2-25-090; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' consumer fraud and unfair practices; (d) compelling Defendants to pay civil penalties up to $10,000 per violation pursuant to § 2-25-0909(f) for each day the violations occurred; (e) compelling Defendants to disgorge their ill-gotten profits; (f)

compelling Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

VIII. COUNT THREE

MISREPRESENTATIONS IN CONNECTION WITH SALE OR ADVERTISEMENT OF MERCHANDISE

VIOLATIONS OF MCC § 4-276-470 AGAINST ALL DEFENDANTS

762. The City 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.

763. Section 4–276–470(1) of the MCC states:

> It shall be [unlawful] for any person to act, use or employ any deception, fraud, false pretense, false promise or misrepresentation, or to conceal, suppress or omit any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale . . . or advertisement of any merchandise . . . .

764. Defendants' practices, as described in the Complaint, violate MCC § 4-276-470(1) because the practices were intended to deceive doctors, consumers, and other health care payors and occurred in connection with the sale or advertisement of any merchandise.

765. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and by aiding and abetting third parties, violated MCC § 4-276-470(1) by making and disseminating deceptions and misrepresentations 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 in order to promote the sale and use of opioids to treat chronic pain.

766. Defendants knew at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or

misleading and failed to disclose material risks and were therefore likely to deceive prescribers, consumers, and other health care payors. In addition, 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.

767. Defendants repeatedly failed to disclose material facts about the risks of opioids. Such material omissions, which are deceptive and misleading in their own right, render even Defendants' seemingly truthful statements about opioids untrue, false, and misleading. In omitting and concealing these material facts, Defendants intended to cause Chicago prescribers, consumers, and other payors of opioid prescriptions to rely on those omissions and concealments.

768. Defendants also engaged in the fraudulent conduct described above by acting in concert with third party Front Groups and KOLs to make false statements about Defendants' drugs' suitability for the treatment of chronic pain. Defendants were aware of the misleading nature of the statements 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.

769. All of this conduct, separately and collectively, was intended to deceive Chicago consumers who used or paid for opioids for chronic pain; Chicago prescribers who prescribed opioids for chronic pain; and other payors, including the City, that purchased, or covered the purchase of, opioids for chronic pain.

770. As a direct result of the foregoing acts and practices, 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 MCC § 4-276-470(1) as described in this Complaint.

771. By reason of Defendants' unlawful acts, Chicago consumers and the City have been damaged and continue to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Three of the Complaint; (b) compelling Defendants to pay civil penalties up to $2,000 per violation pursuant to § 4-276-480 for each day the violations occurred; and (c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

IX. COUNT FOUR

FALSE STATEMENTS TO THE CITY

VIOLATIONS OF MCC § 1-21-010, *ET SEQ.* AGAINST ALL DEFENDANTS

772. The City 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.

773. Section 1-21-010(a) of the MCC provides, in pertinent part:

> Any person who knowingly makes a false statement of material fact to the city in violation of any statute, ordinance or regulation, or who knowingly makes a false statement of material fact to the city in connection with any application, report, affidavit, oath, or attestation, including a statement of material fact made in connection with a bid, proposal, contract or economic disclosure statement or affidavit, is liable to the city for a civil penalty of not less than $500.00 and not more than $1,000.00, plus up to three times the amount of damages which the city sustains because of the person's violation of this section. A person who violates this section shall also be liable for the city's litigation and collection costs and attorney's fees. The penalties imposed by this section shall be in addition to any other penalty provided for in the municipal code.

774. Section 1-21-010(d) of the MCC provides, in pertinent part, that:

> For the purposes of Chapter 1-21 of this Code, a person knowingly makes a false statement of material fact when that person (i) makes a statement of material fact with actual knowledge that the statement was false, or (ii) makes a statement of material fact with knowledge of facts or information that would cause a reasonable person to be aware that the statement was false when it was made, or (iii) signs, certifies, attests, submits or otherwise provides assurances, or causes any other person to sign, certify, attest, submit or otherwise provide assurances, that a statement of material fact is true or accurate in deliberate ignorance or reckless disregard of the truth or falsity of the statement. For purposes of this section, a person who fails to make a reasonable investigation to determine the accuracy, truthfulness or completeness of any material fact acts in deliberate ignorance or reckless disregard of the truth or falsity of the material fact.

775. Subsection 1-21-020 of the MCC provides, in pertinent part, that:

> Any person who aids, abets, incites, compels or coerces the doing of any act prohibited by this chapter shall be liable to the city for the same penalties for the violation.

776. Defendants' practices, as described in the Complaint, violated Section 1-21-010(a) of the MCC. Defendants have incited or caused others to submit false statements of material fact to the City. Through their scheme to illegally and deceptively promote opioids in an effort to further opioids sales, Defendants aided, abetted, incited, or caused doctors, pharmacists, other health care providers, and/or agents of the City's health plans and workers' compensation program to sign, certify, attest, submit or otherwise provide assurances, expressly or impliedly, that opioids to treat chronic pain were medically necessary and reasonably required because they were influenced by Defendants' and third parties' false and misleading statements about the risks, benefits, and superiority of opioids for chronic pain. Opioids, however, are not "medically necessary" or "reasonably required" to treat chronic pain.

777. Defendants' conduct was in deliberate ignorance or reckless disregard of the truth or falsity of the statements submitted by doctors, pharmacists, other health care providers, and/or

agents of the City's health plans and workers' compensation program. As described in the Complaint, Defendants promoted opioids with the purpose and effect of expanding their use to chronic pain—*i.e.* beyond what is medically necessary and reasonably required. In addition, Defendants knew, deliberately ignored, or recklessly disregarded that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

778. Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the City's health plans and workers' compensation program for payment. The City only covers the cost of prescription drugs that are medically necessary or reasonably required. Doctors, pharmacists, other health care providers, and/or other agents of the health plans and workers' compensation program expressly or impliedly certified to the City 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 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 the City were for uses that were misbranded and/or not otherwise approved by the FDA.

779. Defendants knew, deliberately ignored, or recklessly disregarded that, as a natural consequence of their actions, governments such as the City would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Defendants' fraud. Indeed, Defendants acted to maximize their reimbursements from these third party payors.

780. If the City had known of the false statements Defendants have incited or caused others to submit—*i.e.*, that agents of the health plans and workers' compensation program were certifying and/or determining that opioids were "medically necessary" and "reasonably required"—the City would have refused to authorize payment for opioid prescriptions.

781. By reason of Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Since 2005, the City has spent more than $13.9 million to pay for more than 320,000 prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

782. Because Defendants' unbranded marketing caused the doctors to prescribe and the City 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, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Four of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the MCC § 1-21-010 and/or 1-21-020; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' false statements; (d) compelling Defendants to pay civil penalties up to $1,000 for each false statement made to the City that Defendants aided, abetted, incited, or caused; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

X. COUNT FIVE

FALSE CLAIMS

VIOLATIONS OF MCC § 1-22-020 AGAINST ALL DEFENDANTS

783. The City 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.

784. Section 1-22-020 of the MCC is violated when any person

> (1) knowingly presents, or causes to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the city; [or] (3) conspires to defraud the city by getting a false or fraudulent claim allowed or paid.

785. Section 1-22-010 of the MCC defines a claim as:

> any request or demand, whether under a contract or otherwise, for money or property which is made by a city contractor, grantee, or other recipient if the city is the source of any portion of the money or property which is requested or demanded, or if the city will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

786. Defendants' practices, as described in the Complaint, violated Section 1-22-020 of the MCC. Defendants, through their deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used a false statement to get a false or fraudulent claim for payment or approval by the City.

787. Defendants knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of getting insurers and self-insurers, such as the City's health plans and workers' compensation program, to pay for opioids for long-term treatment of chronic pain. In addition,

Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

788. Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the City's health plans and workers' compensation program for payment. The City only covers the cost of prescription drugs that are medically necessary or reasonably required. Doctors, pharmacists, other health care providers, and/or other agents of the health plans and workers' compensation program expressly or impliedly certified to the City 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 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 the City were for uses that were misbranded and/or not otherwise approved by the FDA.

789. Defendants knew or should have known that, as a natural consequence of their actions, governments such as the City would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Defendants' fraud. Indeed, Defendants acted to maximize their reimbursements from these third party payors.

790. Defendants' misrepresentations were material because if the City had known of the false statements disseminated by Defendants and their third-party allies and that doctors, pharmacists, other health care providers, and/or other agents of the health plans or workers' compensation program were certifying and/or determining that opioids were medically necessary

and reasonably required, the City would have refused to authorize payment for opioid prescriptions to treat chronic pain.

791. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the City.

792. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City to approve and pay such false and fraudulent claims.

793. To the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Defendants' deceptive marketing.

794. The City, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal business practices.

795. By reason of Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Since 2005, the City has spent more than $13.9 million to pay for more than 320,000 prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

796. Each Defendant is responsible for the claims submitted and the amount the City spent on its opioids.

797. Because Defendants' unbranded marketing caused the doctors to prescribe and the City 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, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Five of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the MCC § 1-21-020; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' false statements; (d) compelling Defendants to pay civil penalties up to $10,000 for each false or fraudulent claim Defendants caused to be presented to an official or employee of the City for payment or approval; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XI. COUNT SIX

CONSPIRACY TO DEFRAUD BY GETTING FALSE OR FRAUDULENT CLAIMS PAID OR APPROVED BY THE CITY

VIOLATIONS OF MCC § 1-22-020 AGAINST DEFENDANTS CEPHALON, ENDO, JANSSEN, AND PURDUE

798. The City 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.

799. Section 1-22-020 of the MCC is violated when any person:

> (1) knowingly presents, or causes to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the city; [or] (3) conspires to defraud the city by getting a false or fraudulent claim allowed or paid.

800. Defendants' practices, as described in the Complaint, violated Section 1-22-020 of the MCC. Each Defendant conspired with KOLs and Front Groups to defraud the City by getting false or fraudulent claims allowed or paid, as part of a comprehensive scheme to illegally and deceptively promote opioids in an effort to further opioids sales.

801. Defendants Cephalon, Endo, Janssen, and Purdue, 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 to prescribers and consumers. Each of these Defendants enlisted KOLs and Front Groups to make and disseminate these deceptive statements in furtherance of a common strategy to increase opioid sales, and each of these Defendants—along with the KOLs and Front Groups with which each of them conspired—knew that the statements they made and disseminated served this purpose.

802. By engaging in the conduct described in this Complaint, Defendant Cephalon agreed with Front Groups FSMB and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with FSMB and APF, Cephalon provided support for FSMB's and APF's deceptive statements promoting opioids and FSMB and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Cephalon's drugs. *Responsible Opioid Prescribing* (Cephalon and FSMB) and *Treatment Options: A Guide for People Living with Pain* (Cephalon and APF) are publications that contained a number of deceptive statements about opioids as outlined in Sections V.D and V.E.2 above. They are products of these conspiracies, and the collaboration between Cephalon and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

803. By engaging in the conduct described in this Complaint, Defendant Endo agreed with Front Groups APF, NIPC, AGS and FSMB that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, NIPC, AGS and FSMB, Endo provided support for APF, NIPC, AGS and FSMB's deceptive statements

promoting opioids and APF, NIPC, AGS and FSMB used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Endo's drugs. *Persistent Pain in the Older Adult* (Endo, APF, and NIPC), *Persistent Pain in the Older Patient* (Endo, APF, and NIPC), *Painknowledge.com* (Endo, APF, and NIPC), *Exit Wounds* (Endo and APF); *Pharmacological Management of Persistent Pain in Older Persons* (Endo and AGS), and *Responsible Opioid Prescribing* (Endo and FSMB) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined in Sections V.D and V.E.3 above. They are products of these conspiracies, and the collaboration between Endo and each of these entities in creating and disseminating these publications, CMEs, and websites is further evidence of each conspiracy's existence.

804. By engaging in the conduct described in this Complaint, Defendant Janssen agreed with Front Groups AAPM, AGS, and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with AAPM, AGS, and APF, Janssen provided support for AAPM, AGS, and APF's deceptive statements promoting opioids, and AAPM, AGS, and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Janssen's drugs. *Finding Relief: Pain Management for Older Adults* (Janssen, AAPM, and AGS), a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Janssen and AGS), the *Let's Talk Pain* website (Janssen and APF), and *Exit Wounds* (Janssen and APF) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined in Sections V.D and V.E.4 above. They are products of these conspiracies and the collaboration between Janssen and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

805. By engaging in the conduct described in this Complaint, Defendant Purdue 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 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),[141] *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 Sections V.D and V.E.5 above. They are products of these conspiracies, and the collaboration between Purdue and each of these entities in creating and disseminating these publications, CMEs, and websites is further evidence of each conspiracy's existence.

806. As outlined in Section V.E above, Defendants Cephalon, Endo, Janssen, and Purdue Defendants 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-

[141] 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 the risks, benefits, and superiority of opioid therapy for chronic pain.

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

807. Because of these schemes, prescribers wrote prescriptions for opioids to treat chronic pain that were submitted to the City's health plans and workers' compensation program for payment, which only cover the cost of medically necessary or reasonably required prescriptions and those that are prescribed for FDA approved uses. Doctors, pharmacists, other health care providers, and/or other agents of the health plans and workers' compensation program expressly or impliedly certified to the City 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 Cephalon, Endo, Janssen, and Purdue and their respective co-conspirators 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 the City were for uses that were misbranded and/or otherwise for off-label uses not approved by the FDA.

808. Defendants Cephalon, Endo, Janssen, and Purdue and each of their co-conspirators knew or should have known that, as a natural consequence of their actions, governments such as the City would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Defendants' fraud.

809. These Defendants' misrepresentations were material because if the City had known of the false statements disseminated by Defendants Cephalon, Endo, Janssen, and Purdue and their co-conspirators in support of opioids, and known that doctors, pharmacies, other health care providers, and/or the health plans or workers' compensation program were certifying and/or determining that opioids were medically necessary and reasonably required based on those false statements, the City would have refused to authorize payment for opioid prescriptions.

810. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the City.

811. By virtue of the above-described acts, Defendants Cephalon, Endo, Janssen, and Purdue, and the KOLs and Front Groups with which they allied, conspired to defraud the City by getting a false or fraudulent claim allowed or paid.

812. Alternatively, to the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Defendants' deceptive marketing.

813. The City, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

814. By reason of Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Since 2005, the City has spent more than $13.9 million to pay for over 320,000 prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

815. Each Defendant is responsible for the claims submitted and the amount the City spent on its opioids.

816. Because Defendants' unbranded marketing caused the doctors to prescribe and the City 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, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants Cephalon, Endo, Janssen, and Purdue on Count Six of the Complaint; (b) enjoining these Defendants from performing or proposing to perform any acts in violation of the MCC § 1-21-020; (c) compelling these Defendants to pay restitution of any money acquired as a result of the false statements disseminated by them and their respective co-conspirators; (d) compelling these Defendants to pay civil penalties up to $10,000 for each instance they made or used false records and statements and caused false statements and records to be used to get a false or fraudulent claim paid or approved by the City; (e) compelling these Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling these Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XII. COUNT SEVEN

RECOVERY OF CITY COSTS OF PROVIDING SERVICES

VIOLATIONS OF MCC § 1-20-020 AGAINST ALL DEFENDANTS

817. The City 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.

818. Section 1-20-020 of the MCC provides, in pertinent part:

> Any person who causes the city or its agents to incur costs in order to provide services reasonably related to such person's violation of

> any federal, state or local law, or such person's failure to correct conditions which violate any federal, state or local law when such person was under a legal duty to do so, shall be liable to the city for those costs. This liability shall be collectible in the same manner as any other personal liability.

819. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and/or by acting in concert with third parties, participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

a. Violating, or aiding and abetting in the violation of, MCC § 2-25-090 by making and disseminating untrue, false, or misleading statements 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 in order to promote the sale and use of opioids to treat chronic pain;

b. Violating, or aiding and abetting in the violation of, MCC § 2-25-090 by engaging in unfair acts or practices, including the deceptive, oppressive, and unscrupulous promotion of opioids to treat chronic pain, in violation of the Illinois Consumer Fraud and Deceptive Business Act;

c. Violating, or aiding and abetting in the violation of, MCC § 4-276-470 by making and disseminating deceptions and misrepresentations to promote the sale and use of opioids to treat chronic pain, or by causing untrue, false, or misleading statements about opioids to be made or disseminated in order to promote the sale and use of opioids to treat chronic pain;

d. Violating MCC § 1-21-010 by illegally and deceptively promoting opioids to further opioid sales, and thereby aiding, abetting, inciting, or causing doctors, pharmacists, other health care providers, and/or agents of the City's health plans and workers' compensation program to sign, certify, attest, submit or otherwise provide assurances, expressly or impliedly, 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 about the risks, benefits, and superiority of opioids for chronic pain;

e. Violating MCC § 1-22-020 by illegally and deceptively promoting opioids to further opioid sales, and thereby aiding, abetting, inciting, or causing doctors, pharmacists, other health care providers, and/or agents of the City's health plans and

workers' compensation program to present false or fraudulent claims 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 about the risks, benefits, and superiority of opioids for chronic pain. Through this same conduct, Defendants also knowingly used or caused to be used false statements to get a false or fraudulent claim for payment approved by the City;

f. Violating MCC § 1-20-020 by ***conspiring*** to illegally and deceptively promote opioids to further opioid sales, and thereby aiding, abetting, inciting, or causing doctors, pharmacists, other health care providers, and/or agents of the City's health plans and workers' compensation program to present false or fraudulent claims 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 about the risks, benefits, and superiority of opioids for chronic pain. Through this same conduct, Defendants also ***conspired*** to knowingly use or cause to be used false statements to get a false or fraudulent claim for payment approved by the City;

g. Violating, or aiding and abetting in the violation, of 720 ILCS § 5/17-10.5 by illegally and deceptively promoting opioids to further opioid sales, and thereby knowingly causing doctors, pharmacists, other health care providers, and/or agents of the City's health plans and workers' compensation program to present false claims to the City's health plans and workers' compensation program, which are self-insured, and knowingly obtaining or causing to be obtained through deception the property of the City in payments for those false claims;

h. Violating 21 U.S.C. § 331(a) and 21 U.S.C. § 352 by making and disseminating false and misleading statements about the risks, benefits, and superiority of opioids for chronic pain in labels and other written, printed, or graphic matter accompanying their drugs, or causing such statements to be made; and

i. Violating the common law of the state of Illinois by engaging in a civil conspiracy to deceptively promote opioids to treat chronic pain and by unjustly enriching themselves at the City's expense.

820. Defendants have known at all times relevant to this Second Amended Complaint that their statements (and those statements made by the KOLs and third party Front Group they directed and assisted) were false and misleading. Defendants also knew that their misrepresentations would be "reasonably related to" unnecessary opioid prescriptions being written, and that a large number of these prescriptions would be ultimately paid for by the City.

821. Moreover, Defendants knew that their drugs were much more harmful then they, or the third parties they acted in concert with, represented and that their conduct would cause substantial harm to the City and its residents. Accordingly, Defendants created conditions that violate the legal provisions outlined above and were under a legal duty to correct those conditions, but failed to do so.

822. The City, through its health plans as well as other expenditures, has incurred costs reasonably related to Defendants' violations of federal, state, or local laws, and/or failure to correct conditions that violate those laws. These costs include the costs of unnecessary opioid prescriptions as well as the costs associated with providing services to consumers impacted by Defendants' deceptive marketing.

823. The City's health plans have paid costs that include, but are not limited to, the costs immediately associated with prescribing opioids for chronic pain, such as doctors' visits, toxicology screens to monitor patients' drug-taking, drugs and other treatment to address the adverse effects of opioids (including addiction), and the prescriptions themselves. In terms of prescription costs alone, since 2005 the City spent more than $13.9 million for more than 320,000 claims for opioids during this period.

824. The City's health plans have also paid costs imposed by long-term opioid use, abuse, and addiction, such as hospitalizations for opioid overdoses, drug treatment for

individuals addicted to opioids, intensive care for infants born addicted to opioids, long-term disability, and more. The City's workers' compensation program and health benefit plans have expended approximately $2.4 million on addiction treatment services from May 2013 to May 2015. Claims data indicate that non-retirees covered by the City's health plans had 835 days of inpatient therapy between May 2013 and May 2015, causing these employees to miss work, with corresponding costs to the City.

825. Defendants' conduct has also imposed costs on the City beyond those incurred by its health and workers compensation plans. These include costs of providing emergency services in response to opioid-related deaths, overdoses, addiction, and other injury; costs of funding addiction treatment, such as the prescription of additional drugs like buprenorphine/naloxone and naltrexone; and other costs attendant to the epidemic of opioid use and abuse in the City.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Seven of the Complaint; (b) compelling Defendants to pay the costs the City incurred that were reasonably related to Defendants' violations of federal, state, or local law; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (d) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XIII. COUNT EIGHT

INSURANCE FRAUD

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

826. The City 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.

827. 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.

828. 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.

829. 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 the City's health plans and workers' compensation program, which are self-insured; and (b) knowingly obtained or caused to be obtained through deception the property of the City in payments for those false claims. Defendants' scheme caused prescribers to write prescriptions for opioids to treat chronic pain that were presented to the City's health plans and workers' compensation program for payment. Therefore, each claim for reimbursement to the City 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.

830. Further, the City 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 the City 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 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 the City were for uses that were misbranded and/or for off-label uses not approved by the FDA.

831. The misrepresentations were material because if the City 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, the City would have refused to authorize payment for opioid prescriptions. The City is a self-insured entity and directly covers the cost of prescription drugs and other medical services for City employees and retirees.

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

833. 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.

834. By reason of Defendants' insurance fraud, the City has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Since 2005, the City has spent more than $13.9 million to pay for more than 320,000 prescriptions and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic pain.

835. Because Defendants' unbranded marketing caused the doctors to prescribe and the City 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, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Eight 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 the City such other, further, and different relief as this Honorable Court may deem just.

XIV. COUNT NINE

CIVIL CONSPIRACY

VIOLATIONS OF THE COMMON LAW PROHIBITION AGAINST CIVIL CONSPIRACY AGAINST DEFENDANTS CEPHALON, ENDO, JANSSEN, AND PURDUE

836. The City 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.

837. Defendants Cephalon, Endo, Janssen, and Purdue each conspired with various KOLs and Front Groups to commit unlawful acts or lawful acts in an unlawful manner. Defendants Cephalon, Endo, Janssen, and Purdue, and the various KOLs and Front Groups with which each of them was 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 Cephalon, Endo, Janssen, and Purdue enlisted various KOLs and Front Groups to make and disseminate these statements in furtherance of their common strategy to increase opioid sales, and Defendants Cephalon, Endo, Janssen, and Purdue—along with the KOLs and Front Groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

838. By engaging in the conduct described in this Complaint, Defendant Cephalon agreed with Front Groups FSMB and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with FSMB and APF, Cephalon provided support for FSMB's and APF's deceptive statements promoting opioids and FSMB and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Cephalon's drugs. *Responsible Opioid Prescribing* (Cephalon and FSMB) and *Treatment Options: A Guide for People Living with Pain* (Cephalon and APF) are publications that contained a number of deceptive statements about opioids as outlined in

Sections V.D and V.E.2 above. They are products of these conspiracies, and the collaboration between Cephalon and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

839. By engaging in the conduct described in this Complaint, Defendant Endo agreed with Front Groups APF, NIPC, AGS and FSMB that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, NIPC, AGS and FSMB, Endo provided support for APF, NIPC, AGS and FSMB's deceptive statements promoting opioids and APF, NIPC, AGS and FSMB used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Endo's drugs. *Persistent Pain in the Older Adult* (Endo, APF, and NIPC), *Persistent Pain in the Older Patient* (Endo, APF, and NIPC), *Painknowledge.com* (Endo, APF, and NIPC), *Exit Wounds* (Endo and APF); *Pharmacological Management of Persistent Pain in Older Persons* (Endo and AGS), and *Responsible Opioid Prescribing* (Endo and FSMB) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined in Sections V.D and V.E.3 above. They are products of these conspiracies, and the collaboration between Endo and each of these entities in creating and disseminating these publications, CMEs, and websites is further evidence of each conspiracy's existence.

840. By engaging in the conduct described in this Complaint, Defendant Janssen agreed with Front Groups AAPM, AGS, and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with AAPM, AGS, and APF, Janssen provided support for AAPM, AGS, and APF's deceptive statements promoting opioids and Conrad & Associates LLC, Medical Writer X, AAPM, AGS, and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would

benefit Janssen's drugs. *Finding Relief: Pain Management for Older Adults* (Janssen, AAPM, and AGS), a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Janssen and AGS), the *Let's Talk Pain* website (Janssen and APF), and *Exit Wounds* (Janssen and APF) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined in Sections V.D and V.E.4 above. They are products of these conspiracies and the collaboration between Janssen and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

841. By engaging in the conduct described in this Complaint, Defendant Purdue 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 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),[142] *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 Sections V.D and V.E.5 above. They are products of these conspiracies, and the collaboration between Purdue and each of these entities in creating and

[142] 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.

disseminating these publications, CMEs, and websites is further evidence of each conspiracy's existence.

842. 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. These Defendants and third parties nevertheless agreed to misrepresent the risks, benefits, and superiority of using opioids to Chicago patients and prescribers in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

843. As outlined in Section V.E above, Defendants Cephalon, Endo, Janssen, and Purdue 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 Defendants did not directly disseminate or control the content of these misleading statements, they are liable for conspiring with the third parties who did.

844. 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 MCC § 2-25-090;

b. violating, aiding and abetting in the violation, or causing the violation of MCC § 4-276-470;

c. violating MCC § 1-21-010;

d. violating MCC § 1-22-020;

e. violating MCC § 1-20-020;

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

g. violating 21 U.S.C. § 331(a); and

h. committing common law unjust enrichment.

845. By reason of Defendants' unlawful acts, the City 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.

846. Because Defendants' marketing caused doctors and other health care providers to prescribe and the City 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, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants Cephalon, Endo, Janssen, and Purdue on Count Nine of the Complaint; (b) compelling these Defendants to pay the City's direct and consequential damages; and (c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XV. COUNT TEN

UNJUST ENRICHMENT

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

847. The City 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.

848. Defendants have unjustly retained a benefit to the City's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

849. 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 the City's expense. The City 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 the City lacks a remedy provided by law.

850. By reason of Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

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

DATED: August 26, 2015.

Respectfully submitted,

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Exhibit A1

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Exhibit A2

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Exhibit A3

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Exhibit A4

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Exhibit A5

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Exhibit A6

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Exhibit A7

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Exhibit B1

FILED UNDER SEAL

Exhibit B2

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