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 PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ACTAVIS PLC; ACTAVIS, INC.; WATSON, PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.,

Defendants.

Case No. 14-cv-04361

Honorable Elaine E. Bucklo

FIRST AMENDED COMPLAINT*

JURY TRIAL DEMANDED

*Redacted Pursuant to November 6, 2014 Order

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Plaintiff City of Chicago ("City"), by its attorney, Stephen R. Patton, Corporation Counsel of the City, for its First Amended Complaint against defendants Purdue Pharma L.P., Purdue Pharma Inc., the Purdue Frederick Company, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. k/n/a Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. k/n/a Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Actavis plc, Actavis, Inc., Watson Pharmaceuticals, Inc. k/n/a Actavis, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively, "Defendants"), 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. When marketing a drug, a pharmaceutical manufacturer must tell the truth, which means ensuring that its marketing claims are supported by science and medical experience. Defendants broke these simple rules.

3. By the 1990s, Defendants had the ability to cheaply produce massive quantities of opium-like painkillers ("opioids"), but the market was small. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. They knew—and had known for years—that, except as a last resort, opioids were

too addictive and too debilitating for long-term use for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as "chronic pain").

4. Defendants also knew—and had known for years—that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly increasing the risk of significant side effects and addiction.[1] [2]

5. 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.

6. 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.[3] Like heroin, prescription opioids work by binding to receptors on the

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[1] *See, e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, *in* 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

[2] The authoritative Diagnostic and Statistical Manual of Mental Disorders, (5th ed. 2013) ("DSM-V") classifies addiction as a spectrum of "substance use disorders" that range 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 abuse disorders.

[3] 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 a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829.

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.

7. 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 for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches.

8. Defendants, through a common, sophisticated, and highly deceptive 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. They spent millions of dollars: (a) developing and disseminating seemingly truthful scientific and educational materials that misrepresented the risks, benefits, and superiority of opioids used long-term to treat chronic pain as described in Section V.C.2; (b) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs"), to draft misleading studies, conduct 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 (chronic opioid therapy is

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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.

the prescribing of opioids to treat chronic pain) as described in Section V.C.2.a; and (c) 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 urged doctors to prescribe and patients to use opioids long-term to treat chronic pain as described in Sections V.C.2.d and V.C.2.e. These "educational" efforts, 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 non-cancer pain outweighed the risks and that opioids could be used safely by most patients.

9. Working individually, collectively, 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 known—that opioids are addictive drugs, unsafe in most circumstances for long-term use—was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids. 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; and (c) overstated their superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives. There was, and is, no reliable scientific evidence to support Defendants' marketing claims, and there was, and is, a wealth of scientific evidence to the contrary. Defendants also deceptively marketed the drugs for indications and benefits that were outside of the drugs' labels.

10. Even Defendants' KOLs initially were very cautious about whether opioids were safe and effective to treat chronic non-cancer 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 long-term use of opioids to treat chronic non-cancer pain, Defendants continue to disseminate their false and misleading marketing claims to this day.

11. Defendants' efforts were wildly successful. The United States is now awash in opioids. In 2010, 254 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits result in the prescription of an opioid (nearly double the rate in 2000).[4] 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.[5] Together, opioids generated $8 billion in revenue for drug companies in 2012.[6]

12. Roughly 87% of opioids consumed are used to treat chronic pain[7]—a prescribing practice doctors previously considered not just ineffective, but even reckless given the substantial risk of addiction chronic opioid use creates. Among patients taking opioids for 90

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[4] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States*, 2000-2010, 51(10) Med. Care 870-78 (2013).

[5] Laxmaiah Manchikanti et al., *Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective*, 13 Pain Physician 401-435 (2010).

[6] Barry Meier & Bill Marsh, *The Surging Cost of the Opioid Economy*, N.Y. Times (June 22, 2013).

[7] Michael Von Korff, Group Health Res. Inst., *The Epidemiology of Use of Analgesics for Chronic Pain*, Presentation to the FDA (2012), *available at* http://www.fda.gov/downloads/Drugs/NewsEvents/UCM308128.pdf.

days or more, two-thirds of those followed for 4.8 years were still taking opioids at the end of this period.[8]

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. 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."[9] Prescription opioid use contributed to 16,651 overdose deaths nationally in 2010;[10] 16,917 in 2011; and 16,007 in 2012.[11] 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 the emergency room. 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

[8] Bradley C. Martin, et al, *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) J. Gen. Internal Med. 1450-1457 (2011).

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

[10] CDC, *Opioids drive continued increase in drug overdose deaths*, February 20, 2013, *available at*: http://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html.

[11] Evan Johnson, *Prescription Pill Deaths Down, Heroin Deaths on the Rise*, WBIR-TV (October 15, 2014), *available at*: http://www.wbir.com/story/news/local/2014/10/15/prescription-pill-deaths-down-heroin-death-on-the-rise/17326519/.

room.[12] But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

15. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors.

16. 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.

17. According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in the past year, and adolescents are abusing opioids in alarming numbers.[13] 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."[14]

18. 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. Chicago ranks first in the nation in emergency room visits for heroin overdoses.[15] 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

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[12] SAMHSA, *Metro Brief Chicago: Drug-Related Emergency Dep't Visits in Metro. Areas*, U.S. Dep't of Health & Human Servs. (2009).

[13] CDC, *Prescription Painkiller Overdoses in the US*, (Nov. 2011), *available at* http://www.cdc.gov/vitalsigns/painkilleroverdoses/.

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

[15] Natalie Moore, *Heroin: It's Cheap, It's Available and It's Dangerous Business*, WBEZ 91.5 (Dec. 4, 2013), http://www.wbez.org/news/heroin-its-cheap-its-available-and-its-dangerous-business-109304.

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.

19. 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.[16]

20. 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 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.

21. 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

[16] 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.

license to misrepresent the risks, benefits, or superiority of opioids. Indeed, what makes Defendants' effort particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly-addictive controlled substances. Defendants deceptively 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.

22. 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 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.

23. Defendants' course of conduct, individually and collectively, 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, unfair, and deceptive acts and practices, including misleading advertising in their promotion of opioids to treat chronic non-cancer 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 § 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 prohibition against common law fraud, in that Defendants made false statements of material fact that they knew were false to induce the City to act; the City relied on Defendants' false statements, relied on others who relied on Defendants' false statements, or both; and was damaged as a result.

- 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.

In addition, principles of subrogation, expressly reserved by the City in its health plan benefit documents, entitle it to recover for the damages suffered by employees participating in its health plan.

24. 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 order Defendants to cease their unlawful promotion of opioids and to correct their misrepresentations.

II. PARTIES

A. Plaintiff

25. 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.

26. 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

27. 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").

28. 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[17] tablet first approved 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,[18] OxyContin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

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

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

(d) Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the "relief of

[17] An opioid agonist is a drug that activates the opioid receptors in the brain, typically the mu-opioid receptor.

[18] The labels for OxyContin and other long-acting opioids were amended in response to a 2012 citizen's petition by doctors. The changes were intended to clarify the existing obligation to "make an individualized assessment of patient needs." The doctors 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), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf.

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."

29. 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 its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

30. 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.

31. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

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

33. Teva Ltd., Teva USA, and Cepahlon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Chicago, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards, distributed in Chicago, indicating Teva Ltd. would be responsible for covering certain co-pay costs. Through interrelated operations like these, Teva Ltd. operates in Chicago and the rest of the United States through its subsidiaries Cephalon and Teva USA. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. collectively are referred to herein as "Cephalon.")

34. 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 already receiving and who are tolerant to

> around-the-clock opioid therapy for their underlying persistent cancer pain."

35. 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 plead 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.

36. Cephalon also 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; to disclose payments to doctors on its web site; and to regularly certify that the company has an effective compliance program.

37. 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'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'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.")

38. Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs in Chicago and the rest of the nation, including the following:

(a) Duragesic (fentanyl) 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."

(b) 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 serve chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." The DPN indication was added in August 2012.

(c) 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."

39. Duragesic is the largest selling opioid of the group. Sales of Janssen's opioids collectively commanded between $1.3 billion in revenue in 2009 and $1.2 billion in 2012—a total of $4.7 billion dollars over the four-year period.

40. 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.")

41. Endo develops, markets, and sells prescription drugs, including the following opioids, in Chicago and nationally:[19]

(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."

42. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana yielded revenue of $1.16 billion from 2008 and 2012, and it alone accounted for 10% of Endo's total revenue in 2012.

43. ACTAVIS PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. WATSON PHARMACEUTICALS, INC.

[19] 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 of Chicago paid for 136 Endo Zydone prescriptions from December 13, 2007 through March 4, 2013.

acquired Actavis, Inc. in October 2012 and the combined company name was changed 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 ACTAVIS, INC. (f/k/a Watson Pharmaceuticals, Inc.), a Nevada Corporation with its principal place of business in Parsippany, New Jersey. ACTAVIS PHARMA, 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 Actavis plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Actavis plc exercises control over these marketing and sales efforts and profits from the sale of Actavis products ultimately inure to its benefit. (Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, and Watson Laboratories, Inc. hereinafter collectively are referred to as "Actavis.")

44. Actavis engaged in the business of marketing and selling opioids in Chicago and across the country, including the branded drug Kadian, 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

45. 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.

46. 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.

47. 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

48. 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 Effect Treatment of Chronic Pain Hinges on Informed Risk Management

49. 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 risk of prescribing opioids against the relative benefits that may be expected during the course of treatment against the risks and benefits of alternatives.

50. This bedrock principle of full disclosure is particularly important in the context of chronic opioid therapy because of the risk that patients who use the drugs long-term will develop tolerance that requires increasingly higher doses. At higher doses, opioids pose increasingly higher risks and adverse effects; patients become physically and psychologically dependent on the drugs and find it difficult to manage or terminate their use.

51. 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 change. 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. Known and Substantial Risks Associated with the Use of Opioids

52. 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.[20] 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,[21] and many

[20] *See* Jane Ballantyne & Jianren Mao, *Opioid Therapy for Chronic Pain*, 349 New Eng. J. Med. 1943-53 (2003).

[21] Substance Abuse and Mental Health Services Administration, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs,* Treatment Improvement Protocol (TIP Series), No. 43 (2005), *available at*: http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf.

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.

53. Opioids have been regulated 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, which may slow breathing to fatal levels.

54. Most patients with more than a few weeks of opioid therapy will experience withdrawal symptoms if opioids are discontinued (commonly referred to as "dependence").[22] Once dependent, a patient experiences deeply unpleasant symptoms when his or her current dose of opioids loses effect and is not promptly replaced with a new dose. Among the symptoms reported in connection with opioid withdrawal are: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months, or even years, after a complete withdrawal from opioids, depending on how long opioids were used.[23]

55. Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, has explained the effect of opioids as akin to "hijacking the brain's reward system," which in turn convinces a user that "the drug is needed to stay alive."[24] A patient's fear of the unpleasant effects of discontinuing opioids combined with the negative

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[22] Richard A. Deyo et al., *Opioids for Back Pain Patients: Primary Care Prescribing Patterns and Use of Services*, 24 J. Am. Bd. Of Fam. Prac. 725 (2011).

[23] *See* Jane Ballantyne, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain With Opioids*, 21(5) Pain Clinical Updates (Dec. 2013).

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

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.[25]

56. 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 dosage amounts that are considered to be "frighteningly high."[26] 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.[27]

57. 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.[28] 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

[25] *See* Mary Jeanne Kreek et al., *Pharmacotherapy of Addictions,* 1(9) Nature Reviews: Drug Discovery 710-26 (Sept. 2002). (Describing counter-adaptive drug-induced changes that prompt "continued drug use through negative reinforcement mechanisms."); Ballantyne, *New Addiction Criteria*, *supra*.

[26] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med., 1422-1424 (Sept. 13, 2010).

[27] 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); *see also* Laxmaiah Manchikanti et al., *American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 Pain Physician S1-S66 (2012).

[28] Kate M. Dunn et al., *Opioid prescriptions for chronic pain and overdose: a cohort study*, 152(2) Annals of Internal Med., 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.

to analgesic effects. Accordingly, the practice of continuously escalating dosages to match pain tolerance can, in fact, lead to over-dose even where opioids are taken as recommended.[29]

58. 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."[30] 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.[31]

59. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with addiction.[32]

60. Each of these risks and adverse effects—dependence, tolerance, and addiction—are fully disclosed in the labels for each of Defendants' opioids (though, as described below, not in Defendants' marketing).[33] 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, if at all.

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[29] *See* Laxmaiah Manchikanti et al., *Opioid Epidemic in the United States*, 15 Pain Physician ES9-ES38 (2012) (60% of opioid overdoses prescribed within guidelines).

[30] 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 (Feb. 1, 2006).

[31] Jane Ballantyne, *Opioid Dependence vs. Addiction: A Distinction without a Difference?*, Archives of Internal Med. (Aug. 13, 2012).

[32] 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 1776-82 (Oct. 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 185-94 (July-Sept. 2011).

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

61. Opioids vary by duration. Long-acting opioids are designed to be taken once or twice daily and provide continuous opioid therapy for, in general, 12 hours. Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's 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. 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. The FDA has required extended release and long-acting opioids to adopt "Risk Evaluation Mitigation Strateg[ies]" on the basis they present "a serious public health crisis of addiction, overdose, and death."[34] In 1998, Purdue's OxyContin FDA label taught that it was less addictive than short-acting opioids, but this claim was removed by 2001. 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." Defendants promoted the idea that pain should be treated first by taking long-acting opioids continuously and short-acting, rapid-onset opioids on top of that.

62. 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

[34] FDA, Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids (Aug. 2014), *available at* http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm.

addiction, overdone, and even death."[35] The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death."[36] 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). 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***."[37]

63. 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 Continuous Opioid Use are Unproven and Contradicted.

64. Despite the fact that opioids are routinely prescribed, there never has been evidence of their 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.

[35] 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).

[36] *Id*.

[37] *Id* (Emphasis in original).

65. 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.[38] 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.[39] In fact, a 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.[40]

66. On the contrary, evidence exists to show 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.[41] Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."[42]

67. 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%).

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

[39] Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23(4) Clin J. Pain 303-306 (2007); Roger Chou et al., *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147-159 (2009).

[40] Meredith Noble et al., *Long-term opioid management for chronic noncancer pain (Review)*, 1 Cochrane Database of Systematic Reviews (2010).

[41] Andrea D. Furlan, Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects, 174(11) Can. Med. Ass'n J. 1589-1594(2006).

[42] *Id*. 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 940-47 (2012).

68. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, posttraumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.[43]

69. As a pain specialist noted in an article titled, *Are We Making Pain Patients Worse?*, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[44]

70. 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.[45] 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. Partly, this is due to addiction and other side effects.[46]

71. As many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches.[47] Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment

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[43] Richard A. Deyo et al., *Opioids for Back Pain Patients: Primary Care Prescribing Patterns and Use of Services*, 24 J. Am. Bd. Of Fam. Prac.717-27 (2011).

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

[45] Luis E. Chaparro et al., *Opioids Compared to Placebo or Other Treatments for Chronic Low-Back Pain*, 8 Cochrane Database of Systematic Reviews (Aug. 27, 2013).

[46] Jeffrey Dersh et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine 2219-27 (Sept. 15, 2008).

[47] Dawn C. Buse, *Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study*, 52 Headache: The J. of Head & Face Pain 18-36 (Jan. 2012).

(MIDAS), and had higher rates of depression, compared to non-opioid users.[48] 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.[49]

72. The lack of evidence for the efficacy of opioid use long-term has been well-documented 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.[50] Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription increased the risk that the patient would be on work disability one year later.[51] A prescription for opioids as the first treatment for a workplace injury doubled the average length of the claim.[52]

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

73. 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

[48] *News Briefs—Opioid Treatment of Migraine is Associated with Multiple Risks*, Nat'l Headache Found. (June 2012), *available at* http://www.headaches.org/sites/default/files/uploaded_files/News_to_Know1/pdf2/NHF_News_to_Know_June_20121.pdf.

[49] *Press Kits—Migraine Patients Taking Addictive Or Non Approved FDA Migraine Treatment*, Nat'l Headache Found. (May 15, 2007), *available at* http://www.headaches.org/press/NHF_Press_Kits/Press Press_Kits/Press_Kits_ _Migraine_Patients_Taking_Addictive_Or_Non_Approved_FDA_Migraine_ Treatments.

[50] Jeffrey A. White, *et al.*, *The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan*, 54(8) J. of Occupational & Environ. Med. 948-953 (2012).

[51] Gary M. Franklin et al., *Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries: The Disability Risk Identification Study Cohort*, 33(2) *Spine* 199-204 (2008).

[52] Dongchun Wang, et al., *Longer-Term Use of Opioids*, Workers Comp. Res. Inst. (Oct. 2012).

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.

74. 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.

75. Studies and articles from the 1970s and 1980s made clear the reasons to avoid opioids.[53] 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, 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 noncancer pain.[54]

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[53] *See*, *e.g.*, Randal D. France et al., *Long-term use of narcotic analgesics in chronic pain*, 19(12) Soc. Sci. Med. 1379 (1984); Maruta T et al., *Drug abuse and dependency in patients with chronic pain*, 54(4) Mayo Clinic Proc. 241 (1979); Judith A. Turner et al., *Drug utilization pattern in chronic pain patients*, 12(4) Pain 357 (Apr. 1982); Scott L. McNairy et al., *Prescription medication dependence and neuropsychologic function*, 18(2) Pain 169 (Feb. 1984).

[54] R.G. Black, *The clinical syndrome of chronic pain*, Pain, Discomfort & Humanitarian Care 207-209 (L.K.Y. Ng and J.J. Bonica eds. 1980). In addition, very few pharmacies routinely carried oral opioids. Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain*" 1 Progress in Pain Res. & Mgmt. 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

76. For example, 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."[55]

77. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers from 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.*[56]

According to Portenoy, these 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."[57]

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[55] Russell K. Portenoy& Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, Pain. 171-186 (1986).

[56] Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain*, *supra*, (emphasis added).

[57] *Id.*

78. Thus, 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."[58] Defendants changed that.

B. Defendants' Plan to Change Prescribers Habits

1. Defendants Are In the Business of Influencing Prescriber Habits and Generating Claims for Payment

79. Defendants have extensive experience in influencing prescriber and patient habits to generate prescriptions, claims for payment, and profits. That is the core of Defendants' sales functions and how they make money.

80. Defendants, therefore, were intimately aware of the chain of events that would be required to generate prescriptions, and they knew that these prescriptions would result in claims that the City, along with other health care providers, would ultimately pay. Defendants understood that their aim was to persuade patients to request, and doctors to write, more opioid prescriptions. Defendants also understood that they would not get paid for these prescriptions until they were approved by an insurance provider or paid for by the patients themselves.

81. Defendants' goal of increasing revenue by promoting the prescription of, and reimbursement for, opioids for chronic pain could not be achieved without an increase in the number of claims submitted to healthcare payors such as the City.

2. Defendants Planned to Change Prescriber Habits Through the Calculated Release of False, Misleading, and Unsupported Information

82. To cause more prescriptions to be written, submitted, and paid, Defendants knew that they had to convince doctors and patients that the benefits of chronic opioid therapy

[58] Igor Kissin, *Long-Term Opioid Treatment of Chronic Nonmalignant Pain*, 6 J. Pain Research 513, 514 (2013) (quoting Loeser JD, *Five crises in pain management*, Pain Clinical Updates, 2012, 20(1):1-4).

outweighed the risks and that use of opioids for chronic pain was medically appropriate. Defendants needed, in other words, to persuade physicians to let go of their long-held apprehensions about prescribing opioids, and instead to prescribe opioids in doses and for durations previously known to be highly risky and often detrimental.

83. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, Defendants instead sought to distort medical and public *perception* of existing scientific data.

84. Among the documents produced by Defendants during the City's year-long investigation was a report prepared by an outside consultant to the pharmaceutical industry. As the report, written in January 2005, explained, "[m]ost institutional and practice guidelines recommend[ed] a stepwise approach to treating pain, beginning with acetaminophen, a [NSAID], or cyclooxygenase-2 ("COX-2") inhibitor to treat mild to moderate pain; progressing to 'weak' opioids or combination products [] to treat moderate pain" and then progressing to stronger opioids or combination products when "moderate to severe pain or other pain that has not responded to earlier interventions."

85. The report, prepared for Actavis, further highlighted two major challenges facing opioid manufacturers in 2005: (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."

86. The proposed solution to these problems was to create "effective copy points . . . backed by published references"—*i.e.*, the "developing and placing [of] publications that demonstrate [opioids'] efficacy and [their] safety/positive side effect profile in order to enhance the existing body of literature," thus allowing a physician to "reach[] a mental agreement" and

change his "practice behavior" without having first evaluated supporting data—of which Defendants had none.

87. 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 [where unsupported by data] ***perceived*** 'scientific exchange'" in relevant medical literature (emphasis added).[59]

88. Therefore, the ultimate goal was to overcome the lack of ***actual*** scientific basis supporting Actavis' claims by creating the ***perception*** of scientific exchange in medical literature through studies—commissioned by Defendants—that did nothing more than discuss and ***cite*** other studies that came to the same unsupported conclusions—and were also funded by Actavis and other Defendants.

89. Defendants, marshalling similar help from other consultants and public relations firms, developed and executed a common strategy to reverse the long-settled understanding of the risks and benefits of chronic opioid therapy. In fact, every Defendant sought the guidance and expertise of the consulting firm referenced above. Indeed, the sales force for at least one Defendant's opioid brand was comprised entirely of employees of the aforementioned firm "from reps to upper management."

90. As explained more fully in Section V.C.2 below, Defendants, collectively and individually, poured vast sums of money into generating articles, CMEs, and other "educational" materials, conducting sales visits to individual doctors, and supporting a network of professional

[59] An Endo planning document echoed the words of Actavis' consultant, referring to promotion of "scientific exchange" by placing favorable claims in academic literature.

societies and advocacy groups, all of which worked to—and did—create a new but phony consensus supporting the long-term use of opioids.

91. Defendants' money produced the results they sought. As explained more fully in Section V.F below, doctors began prescribing, patients began using, and payors, including the City, began paying for massive amounts of opioids.

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

1. Regulations Limit Branded Promotion to the Information—Including All Warnings—Provided on Each Drug's FDA-Approved Label

92. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. A drug company's promotion must be: (a) consistent with prescribing information; (b) not include false or misleading statements or material omissions; (c) fairly balance the drug's benefits and risks; and (d) be supported by "substantial" scientific evidence.[60] The regulatory framework governing the marketing of drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

93. 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."[61] "Adequate directions for use" are directions "under which the layman can use a drug safely and

[60] 21 U.S.C. § 352(a); 21 CFR §§ 1.21(a); 202.1(e)(3), 202.1(e)(6).

[61] 21 U.S.C. §§ 352(a)-(c).

for the purposes for which it is intended."[62] The label is defined to include all explanatory material accompanying the label.[63] The term "accompanying" is interpreted broadly to include promotional materials—posters, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.[64] Thus, Defendants' promotional materials—brochures, websites, and books, for example—are part of their drugs' labels. A drug that is misbranded is, effectively, not approved by the FDA for the use for which it has been misbranded.

94. It is 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."[65] Drug companies also 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."[66]

95. 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.[67]

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[62] 21 CFR § 201.5.

[63] 21 U.S.C. §§ 321(k), (m).

[64] *See* 21 U.S.C. § 321(m).

[65] 21 CFR § 99.101(a)(4).

[66] 21 CFR § 202.1(e)(6)(ii).

[67] *See* 21 CFR § 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 CFR § 314.70(c)(2) (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").

96. While promotional materials for prescription drugs 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.

97. The Chicago Consumer Fraud and False Claim ordinances reflect the same judgment that drug companies, like other businesses, have a duty to deal honestly with consumers, government, and other payors who purchase and use their products. Non-binding guidance of the FDA makes clear, as well, that patient awareness communications that fall outside of the drug's labels still must be "clear and accurate," and that the FDA is not alone responsible for ensuring compliance with this requirement.[68]

2. Defendants Deployed Front Groups and Doctors to Disseminate "Unbranded" Information on Their Behalf in Order to Evade Consumer Protection Laws

98. Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unbranded marketing materials—materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, Defendants presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on

[68] U.S. Dep't of Health & Human Servs., Guidance for Industry, 'Help-Seeking' and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (Jan. 2004).

Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

99. Even where such unbranded messages were channeled through third-party vehicles, Defendants adopted these messages as their own when they cited to, relied on, edited, approved, and distributed their deceptive messages and claims.

100. For example, drug companies have been admonished for making functional claims in FDA-reviewed branded materials, presumably 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. Compare, e.g.:

Branded Advertisement That Triggers an FDA Warning Letter (2008)[69]
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.

[69] 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.

with:

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

101. When disseminating information through third parties, Defendants did not include the warnings and instructions mandated by their FDA-required drug labels to ensure that the risks and uses of opioids were fully disclosed.

102. Defendants generally avoided using branded advertisements to spread misleading claims about addictiveness. The example below compares two Endo-controlled unbranded statements with Endo's branded statement:

Pain: Opioid Therapy (2009) **(Unbranded)**	**Living with Someone with Chronic Pain (2009)** **(Unbranded)**	**Opana ER Advertisement (2011/2012/2013)** **(Branded)**
Purported National Initiative on Pain Control publication funded by Endo	Patient education material created by Endo	Endo advertisement
"People who take opioids **as prescribed usually do not become addicted**."	"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**."

103. 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. Later, Defendants would cite to these sources as "independent" corroboration of their own statements. Further, 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 would with first party, drug company pieces.

104. Thus, to avoid regulatory scrutiny and gain legitimacy, Defendants created, supported, and directed a network of Front Groups to collectively promote the treatment of chronic pain using opioid products over other alternatives.

105. Defendants provided the funding that created or sustained Front Groups whose leaders and employees understood that their organizations were dependent upon Defendants' support. Without Defendants' funding, many of the Front Groups would cease to operate.

106. Defendants' marketing plans expressly contemplated "[m]essage-driven supportive tactics"—as this term was used in a 2005 Actavis internal document—which

involved, among other things, using financial influence to disseminate Defendants' promotional messages through supposedly independent medical literature.

107. Defendant Janssen sought to promote its Nucynta ER drug by "collaborat[ing] with key patient advocacy organizations," and Defendant Endo argued that support for patient advocacy and professional organizations would reinforce Endo's position as "the pain management company."

108. Defendants also used their influence to get their sales messaging disseminated through ostensibly neutral publications. For example, Janssen and Teva contracted with a medical publishing firm, Conrad & Associates, LLC in 2009 and 2013 to produce unbranded pamphlets and DVDs on opioids aimed at the general public. The materials listed professional groups, such as the American College of Physicians ("ACP"), as partners, though the content was drafted by a writer ("Medical Writer X") hired by Conrad & Associates and funded by the drug company sponsor. These materials were reviewed, in detail, by Janssen and Teva's compliance staff, who edited and approved the language.

109. Medical Writer X also wrote numerous other opioid-related publications, including books aimed at prescribers, pamphlets and books for patients, and CMEs. The American Pain Foundation, described in Section V.C.2.g, and KOLs lent their names to, advised on, and reviewed and approved the publications. So did the Defendants themselves. Medical Writer X worked directly with Defendants' medical-legal review teams who conducted detailed reviews and gave editorial feedback on his drafts.

110. While working with Medical Writer X for publications in 2007 by the Federation of State Medical Boards ("FSMB") and in 2009 by APF, APF and KOLs provided him with guidance and background materials for his writing to rely upon. These background materials

overstated the benefits of chronic opioid therapy, downplayed the risks, and over-emphasized the benefits of the drugs. APF and KOLs also reviewed and approved Medical Writer X's work.

111. Medical Writer X understood, without being explicitly told, that since his work was funded and reviewed by Defendants, the materials he was writing should aim to promote the sale of more drugs by overcoming the reluctance to prescribe or use opioids treat chronic pain. He also knew that his clients 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.

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

113. None of the KOLs or Front Groups who reviewed Medical Writer X's work suggested that he had failed to accurately portray the risks and benefits of opioids for treating chronic pain. It was clear to Medical Writer X, 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. While Defendants sometimes took direct control of Medical Writer X's work—when their medical/legal review teams edited it in detail—it was through their indirect impact on the doctors and Front Groups who guided and oversaw his work that they exerted their widest and most insidious influence.

114. Defendants' influence over this single ghostwriter is one example of the way in which they influenced medical and popular understanding of opioids writ large. More generally, and as part of a strategic marketing scheme, Defendants spread and validated their deceptive messages through the following vehicles: (a) sponsorship of KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) sponsorship of patient-advocacy and professional organizations, both directly and through the KOLs who served in leadership roles; (c) sponsorship, approval, and dissemination of published materials created by these organizations; (d) CMEs; and (e) treatment guidelines.

a. Defendants Spoke through KOLs:

115. Defendants cultivated a small circle of doctors who, upon information and belief, were selected solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. And, as they rose, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals.

116. 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 potision) 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.

117. 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.

118. 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 non-cancer pain.[70] 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.

119. Defendants cited and promoted favorable studies or articles by these KOLs. They did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy. Some KOLs have even gone on to become direct employees and

[70] 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.

executives of Defendants, like Dr. David Haddox, Purdue's Vice President of Risk Management, or Dr. Bradley Galer, Endo's former Chief Medical Officer.[71]

120. 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. They 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, paid doctors over $4.5 million for programs relating to its opioids.

121. Cephalon and Endo, and upon information and belief, other Defendants, developed sophisticated plans for the deployment of KOLs, broken down by sub-type and specialty. They planned to utilize KOLs through the expected economic life of their products, from launch to peak sales to preparation for generic entry and transitioning to a successor drug.

122. 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. Endo's internal documents approving one Chicago-area physician for "KOL status" cited positively his membership in the American Academy of Pain Medicine ("AAPM"), the American Pain Society ("APS"), and service as a professional advisor

[71] Once a Purdue employee, Dr. Haddox's public statements became increasingly outrageous. He has been quoted as saying "If you are taking OxyContin for legitimate pain, you have nothing to worry about . . . . If I gave you a stalk of celery and you ate that, it would be healthy for you. But if you put it in a blender and tried to shoot it into your veins, it would not be good." Roger Alford, *Deadly OxyContin Abuse Expected to Spread in the U.S.*, Charleston Gazette & Daily Mail (Feb. 9, 2001). And, "A lot of these people say, 'Well, I was taking the medicine like my doctor told me to,' and then they start taking more and more and more[.] I don't see where that's my problem." Chris Kahn, *Lawsuits accuse OxyContin Maker*, Phila. Inquirer, July 27, 2001. Both of these statements were made in 2001, a year after Dr. Haddox was chosen to head up Purdue's task force responding to media reports of OxyContin abuse and diversion. *See* Paul Tough, *The Alchemy of OxyContin: From Pain Relief to Drug Addiction*, N.Y. Times Mag., July 29, 2001.

to the American Chronic Pain Association ("ACPA"), a small Front Group in California. Endo also relied on past work for *other* drug companies, observing this same doctor had served as "a consultant and speaker for many pharmaceutical development advisory boards and speaker boards," including for Endo, Janssen, and Purdue. This doctor, in fact, gave paid promotional talks for opioid drugs manufactured by Defendants Janssen, Endo, and Cephalon; appeared on a Purdue unbranded website; and taught at Endo- and Purdue-funded CMEs, including several available in the Chicago area.

123. The marketing through KOLs was not limited to nationally-prominent physicians. Endo, for instance, sought to use specialists in pain medicine—including, on information and belief, high prescribers of its drugs - as local thought leaders to market Opana ER to primary care doctors. This strategy both rewarded friendly doctors and gave them a platform to reach other Doctors and bring them into the fold.

124. KOLs are particularly important to Defendants because Defendants know that doctors rely heavily and more uncritically on their peers than drug company sources. The following [redacted], used by Defendant Cephalon to develop a speakers bureau program in 2010, is one example of how Defendants 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:

i. Russell Portenoy

125. Dr. Russell Portenoy, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who 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. Dr. Portenoy edited an Endo-funded advertising supplement to AAPM's *Pain Medicine* journal concerning Opana ER, which Endo distributed to doctors through its paid sales representatives, including, on information and belief, to prescribers in Chicago. With funding from Cephalon, 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.[72]

[72] Russell K. Portenoy, *Prevalence and characteristics of breakthrough pain in opioid-treated patients with chronic noncancer pain*, 7(8) J. Pain 583-91 (2006). A recent literature survey of articles describing

126. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the APS/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.

127. 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 that "[a]ddiction, 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."[73]

128. 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" in which he 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."[74] Portenoy candidly stated "[d]id I teach about

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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. Laxmaiah Manchikanti et al., *Breakthrough Pain in Chronic Non-Cancer Pain: Fact, Fiction, or Abuse,* 14 Pain PhysicianE101-E117 (2011).

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

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

pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[75]

ii. Lynn Webster

129. 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. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo/Portenoy 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).

130. 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 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 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

[75] *Id*.

patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to doctors in Chicago during the relevant period.

131. 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*." Endo distributed this book to general practitioners, including on information and belief, to doctors in Chicago to "[i]ncrease the breadth and depth of the Opana ER prescriber base[.]" Years later, Dr. Webster reversed himself, acknowledging that "[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."[76]

b. Using "Research" That Lacked Supporting Evidence

132. Rather than finding 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 be relied upon by physicians,

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

patients and payors. Instead, this "literature" was marketing material focused on persuading doctors and the public of the efficacy and safety of opioids.[77]

133. As laid out in their elaborate go-to-market strategies, Defendants sought specifically to create "effective copy points backed by published references"—instead of data—that could serve to create the false perception that the medical community had changed its opinion based upon clinical data, when in reality, a few doctors supported by Defendants had seeded a trail of medical publications asserting unsupported claims mirroring those set forth in Defendants' marketing messages.

134. 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, including back-up options and last resort, "fast-track" application journals that it could use if the pending paper was rejected everywhere else.

135. The placement of supporting literature in academic journals was closely tied to drug companies' overall marketing objectives. In planning, preparing and eventually disseminating a "key message platform," Defendants did not prioritize science or the well-being of patients, but instead "prioritize[ed] ***what should be said, to whom, and when***." 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

[77] *See*, *e.g.*, Matthew S. Wieman et al., *Safety and efficacy of oxymorphone extended release for chronic low back pain in patients with comorbidities*, 11(4) The J. of Pain S48 (Apr. 2010) (funded by Endo); John Sasaki et al., *Opioids in non-cancer pain: Kadian®(morphine sulfate sustained release-capsules) is effective and safe for elderly patients with chronic, non-malignant, moderate/severe pain: The KRONUS-MSP trial*, 5(3) The J. of Pain S76 (Apr. 2004) (cited by Actavis in marketing).

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' third party marketing consultants.

136. Cephalon, for example, caused the term "breakthrough pain"—a term it seeded in the medical literature—to be used in articles published by practitioners and clinicians it supported. 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.

137. As one scholar has pointed out, references to the breakthrough pain in articles published on the MEDLINE bibliographic database spiked in 1998 and again in 2006. [78] These spikes coincide with the FDA's approval of Actiq and Fentora.

138. 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.[79]

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[78] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010), *available at* www.pharmedout.org/Fugh-BermanPrescriptionforconflict6-25-10.pdf. Cephalon's engagement of Dr. Portenoy to write an article describing non-cancer breakthrough pain in 2006 drove part of this surge. *See* Russell K. Portenoy, *Prevalence and characteristics of breakthrough pain in opioid-treated patients with chronic noncancer pain*, 7(8) J. Pain 583 (Aug. 2006).

[79] These studies suffered from the limitations common to the opioid literature. None of the comparison trials lasted longer than three weeks, however. Alan Kivitz et al., *A 2-week, multicenter, randomized,*

139. In the years that followed, Endo sponsored articles, authored by an Endo consultant and Endo employees, which pressed the case for a drug that is metabolized in the unique manner of Opana ER in elderly low back and osteoarthritis pain patients.[80]

140. Endo also contracted with other publishers to create glossy reprints and pocket guides of selected articles that sales representatives distributed to doctors, ensuring that the research Endo itself developed reached prescribers.

141. Defendants' influence was not limited to the subject of the article, nor was it always disclosed. For example, another Endo publication plan indicated that Endo was able to find an author, a former employee of an Endo contractor, willing to "develop a manuscript based on provided bullet points."

142. 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

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double-blind, placebo-controlled, dose-ranging, phase III trial comparing the efficacy of oxymorphone extended release and placebo in adults with pain associated with osteoarthritis of the hip or knee, 28(3) Clinical Therapeutics 352 (Mar. 2006); Alan K. Matsumoto et al., *Oxymorphone Extended-Release Tablets Relieve Moderate to Severe Pain and Improve Physical Function in Osteoarthritis: Results of a Randomized, Double-Blind, Placebo- And Active-Controlled Phase III Trial,* 6(5) *Pain Med*. 357 (Oct. 2005). Endo also commissioned a six-month, open label trial. Richard Rauck et al., *Titration with oxymorphone extended release to achieve effective long-term pain relief and improve tolerability in opioid-naive patients with moderate to severe pain*, 9(7) Pain Med. 777 (Oct. 2008). In the open label trial, a full quarter of the patients failed to find a stable dose, and 17% of patients discontinued citing intolerable effects.

[80] Joseph V. Pergolizzi et al., *Prevalence of Exposure to Potential CYP450 Pharmacokinetic Drug-Drug Interactions among Patients with Chronic Low Back Pain Taking Opioids*, 11(3) Pain Practice 230 (May/June 2011), first pub. online Aug. 26, 2010; Joseph V. Pergolizzi et al., *Exposure to Potential CYP450 Pharmacokinetic Drug–Drug Interactions among Osteoarthritis Patients: Incremental Risk of Multiple Prescriptions*, 11(4) Pain Practice 325 (2011), first pub. online Dec. 28, 2010. See also, Joseph V. Pergolizzi et al., *An open-label pharmacokinetic study of oxymorphone extended release in the presence of naltrexone in the older adult*, 8(6) J. of Opioid Mgmt. 383 (2012) ("The results of the current study of an ER formulation revealed no pharmacokinetic features that would preclude dosing in the elderly.").

New England Journal of Medicine: J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Engl. J. Med. 123 (Jan. 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.[81] 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.

143. 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 are

[81] 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.

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.

144. 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.

145. For example, 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[82] that Endo believed emphasized the risk of death from opioids, "without [] fair balance."[83]

146. Three studies funded by Purdue demonstrate the different ways Defendants treat favorable versus unfavorable studies. In 1998, Purdue funded two articles by a headache specialist, Dr. Lawrence Robbins in Chicago, which showed that between 8 and 13% of the patients he studied became addicted to opioids.[84] 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 was cited a mere 11 times. Purdue also funded a study of

[82] 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.

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

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

OxyContin in diabetic neuropathy patients, which was published in 2003. The article reached back to the 1980 Porter-Jick Letter as the only evidence for its claim that OxyContin was not commonly addictive, though OxyContin did not exist at the time the Porter-Jick Letter was written and would not be launched for another 16 years. This article, unlike the other two, appears in a prominent pain journal and has been cited 487 times.[85] While these articles were drafted over a decade ago, they continue to be relied upon to further the misrepresentations that opioids are not addictive.

147. Defendants' strategies—first, to plant and promote supportive literature, while burying unfavorable evidence, 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, distort the truth regarding the risks and benefits of opioids for chronic pain relief and distorted prescribing patterns as a result. The entire time, Defendants knew their marketing and "educational" materials were not supported by substantial scientific evidence, excluded contrary evidence or information about their drugs' risks and benefits, and presented conclusions that clearly cannot be supported by the results of the study.

c. Defendants' Marketing Plans Contemplated Acting Through Third Party Organizations

148. Defendants pursued a common networked strategy of engaging favorable professional and patient advocacy organizations and doctors. Defendants supported the same KOLs, who also would serve as board members of the Front Groups Defendants supported.

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

These organizations, in turn, sponsor conferences and provide fora that allow informal, off-the-record collaboration between the Front Groups and Defendants.

149. Defendants, internally, saw themselves as able to direct the Front Groups and understood that they could enlist these entities in their marketing plans. For example, in 2012, when confronted with efforts to narrow the indications of Endo's Opana ER and impose a maximum dose and duration of use, Endo representatives understood that responses from "an external source would be most impactful" and suggested responding "through our professional society affiliations." Another executive agreed that "the societies are better placed to make a medical case than Endo." Endo's planning and deliberation left no doubt of its ability to enlist its Front Groups to protect the company's economic interests. Upon information and belief, other Defendants viewed and used Front Groups in the same manner.

150. Defendants strategically chose third party organizations that could be relied upon to be supportive. Actavis developed a plan 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. Actavis documents show that Actavis presented papers concerning Kadian at an annual meeting of the American Geriatrics Society ("AGS") because AGS's guidelines "support the use of opioids."

151. 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 spending. In 2008, Endo spent $1 million per year

to attend conventions of "tier one" and "tier two" medical societies, including meetings of AAPM, APS, and the American Society of Pain Management Nursing ("ASPMN").

152. Janssen, too, sought to promote its Nucynta and Nucynta ER by allying with medical and pain care organizations. Janssen enlisted the support of the American Pain Foundation, AAPM, and ASPMN through a coalition known as *Let's Talk Pain*. Janssen's internal communications always referred to *Let's Talk Pain* as promoting tapentadol, the molecule it sold as Nucynta and Nucynta ER. Internally, Janssen regarded this project part of Nucynta's launch.

153. Purdue's plans involved contracting with APF on specific projects under a Master Consulting Agreement that gave Purdue—but not APF—the right to end any project (and, thus, APF's funding) for any reason. This relationship is described in greater detail in Section V.C.2.g.

154. [redacted]

d. Treatment Guidelines

155. 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

156. 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 receives a relatively small percentage of its overall income from Defendants, but it finances opioid- and pain-specific programs through grants from these companies.[86]

157. 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 only that opioids could be appropriate in limited cases or after other treatments had failed, but also 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 discussed addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

158. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing,* also make these same claims, which were, on information and belief, circulated to Chicago physicians.

159. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue. Other backers are organizations that

[86] For example, FSMB entered into an agreement with one drug company to purchase bulk copies of the 2007 publication *Responsible Opioid Prescribing* in order to finance distribution of the book by two Southern state medical boards.

were supported themselves by Defendants.[87] Endo provided $286,620 to support the book, Purdue $150,000, and Cephalon $150,000. 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).

160. 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 earned approximately $250,000 in revenue and commissions from their sale. The FSMB website describes the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

161. Drug companies relied on FSMB guidelines to convey the message that "under-treatment of pain" would result in official discipline, but not 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. [redacted]

162. 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

[87] These include numerous Front Groups and other advocates, including AAPM, APF, ASPMN, the Center for Practical Bioethics, the National Pain Foundation ("NPF"), and the Pain & Policy Studies Group ("PPSG").

therapy as a first choice after the failure of over the counter medication and has heightened the addiction and risk warnings.

ii. AAPM/APS Guidelines

163. AAPM and the APS, which are professional medical societies—each of which received substantial funding from Defendants from 2009 to 2013 (with AAPM receiving over $2 million)—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.[88] 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, and was taken down only after a doctor complained.[89]

164. 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.

165. 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 drug companies, including Defendants, made

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

[89] They are still available online elsewhere.

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 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*.

166. Upon information and belief, Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them. For example, a talk prepared by Endo in 2009 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*, which cites the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of supporting evidence. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

iii. AGS

167. 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") ("2002 AGS Guidelines") and 2009 ("Pharmacological Management of Persistent Pain in Older Persons") ("2009 AGS Guidelines"). The 2009 AGS Guidelines were distributed broadly through earmarked support from Endo, Purdue, and Janssen, and 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."[90] 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.

168. According to one news report, AGS received $344,000 in funding from opioid makers since 2009.[91] 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, that 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

169. 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 controlled substance abuse and may, in fact, be facilitating it."[92] ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in

[90] Pharmacological Management of Persistent Pain in Older Persons, 57 J. Am. Geriatrics Society 1332 (Aug. 2009), *available at* http://www.americangeriatrics.org/files/documents/2009_Guideline.pdf.

[91] John Fauber & Ellen Gabler, *supra*.

[92] Laxmaiah Manchikanti et al., *American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 Pain Physician S1-S66 (2012).

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."[93]

170. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommends 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.[94]

171. *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 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

[93] Laxmaiah Manchikanti, *et al.*, *American Society of Interventional Pain Physicians (ASIPP*) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance*, 15 Pain Physician S67-S116 (2012).

[94] *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.

> consent and opioid management plans . . .; and treatment of patients with chronic noncancer pain at higher risk for drug abuse or misuse.[95]

e. Continuing Medical Education

172. 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 are typically delivered by KOLs who are highly-respected in their fields and are thought to reflect their medical expertise, they can be especially influential with doctors.

173. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation.[96] 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.

174. 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

[95] 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.

[96] *See* Lisa M. Schwartz & Steven Woloshin, *Medical Communication Companies and Continuing Medical Education: Clouding the Sunshine?* 310(23) J. of the Am. Med. Ass'n 2507, 2507 (Dec. 18, 2013).

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.

175. 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 should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[97]

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

177. 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

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

other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty providers have in screening and accounting for source bias.[98]

178. 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.g.

179. For example, Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. This CME was available online for Chicago physicians, and others, to view during the relevant time period. The program was edited by Dr. Perry Fine—a doctor who also received funding from Cephalon for consulting services. *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.

180. 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

[98] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010), www.pharmedout.org/Fugh-BermanPrescriptionforconflict6-25-10.pdf.

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.

181. 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.

182. For example, Endo, through APF, funded a series of eNewsletter CMEs focused on a "key topic surrounding the use of opioid therapy" to be distributed by the National Initiative on Pain Control. These newsletters were edited by the same Dr. Fine who made *Path of Patient* and listed several industry-backed KOLs, including Dr. Webster, as individual authors. Endo estimated that roughly 60,000 prescribers viewed each one. 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%

183. CME sponsorships were smart investments for Defendants—both in content and reach. Having gained influence over a doctor's prescribing habits, they were able to provide from her entire patient base.

f. Unbranded Patient Education

184. Pharmaceutical industry marketing experts see direct-to-consumer advertising as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[99] Evidence also demonstrates that physicians are willing to accede to patient demands for a particular drug—even for opioids and for conditions for which they are not generally recommended. Recognizing this, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

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

185. 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, such as Janssen's *Finding Relief: Pain Management in Older Adults*, and Endo's patient brochures, which the drug companies left with doctors.

186. Direct-to-consumer marketing is often undertaken in conjunction with the assistance of third party groups. Endo, for example, funded the *Painknowledge.org* website, which was an APF program. Representatives of APF (including Dr. Fine), and Front Groups ACPA and AAPM, among others (such as Dr. Webster), appear on Purdue's patient-directed website *Inthefaceofpain.com* as "Voices of Hope." Janssen funded, assembled, and directed a coalition of seemingly neutral Front Groups for its *Let's Talk Pain* website, made up of APF, AAPM, and ASPMN. Janssen also engaged the participation of AGS and AAPM for the *Finding Relief: Pain Management in Older Adults* book and the DVD produced by Conrad & Associates described above. Each of these examples includes misrepresentations. Purdue's *Inthefaceofpain.com* promotes opioids as safe and effective to patients at high risk of addiction; Endo's *Painknowledge.org* referred to pseudoaddiction and promoted chronic opioid therapy for chronic pain as improving patient function and minimizing addiction risk; Janssen's publications also taught that opioids improve function and that addiction was rare. In so doing, they presented an unbalanced treatment of opioid risk compared with alternative therapies for chronic pain.

187. Defendants' influence was not restricted to ongoing medical education. Defendants' efforts to redirect medical literature and doctors' practice affected the teaching and

training of medical students, as well, creating new generations of doctors who misunderstood the risks, benefits, and role of chronic opioid therapy.

g. Defendants' Use of Front Groups

188. As explained earlier (*see* Section V.C.2), 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 support chronic opioid therapy, but 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 opioids to treat chronic pain. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties. Their funding did, in fact, ensure such supportive messages.

189. Several representative examples are highlighted below, but there are others, too, such as APS, AGS, FSMB, ACPA, and 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 these Front Groups is laid out below.

i. American Pain Foundation

190. 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.

191. 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, described in Section V.C.4; 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 in Chicago.

192. In addition to the KOLs discussed above 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.

193. 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; and 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.

194. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners against Pain* and Janssen's *Let's Talk Pain*. APF 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." 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."

195. Defendants were well-served by APF. For instance, at a July 2007 hearing before the Senate Judiciary Committee "evaluating the propriety and adequacy of the OxyContin criminal settlement," APF aggressively defended Purdue, repeatedly denying that patients were prescribed opioids abuse or became addicted to the drugs. APF's testimony falsely described addiction as a "rare problem" for chronic pain patients and asserted that "the scientific evidence suggests that addiction to opioids 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."[100]

196. APF was willing to echo Defendants' misrepresentations in exchange for support, and Defendants rewarded it with funding. For example, APF made a grant request to Endo to create an online opioid "tool-kit" for the National Initiative on Pain Control and offered to promote painknowledge.org. This demonstrated APF's willingness to assist with Defendants' marketing efforts; the grant request noted: "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 the project, which included a few of Defendants' key misrepresentations:

[100] *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement:* Hearing before the Committee on the Judiciary, U.S. Senate, 110th Cong. (July 31, 2007) (Statement of James Campbell, M.D.).

After starting opioid therapy . . .

- Your level of function should improve
- Your sleep may improve
- People who take opioids as prescribed usually do not become addicted.

197. In practice, APF operated in close collaboration with opioid makers. Documents provided by an entity that participated in communications and meetings with these groups and with Defendants, reveal close personal connections between Defendants' personnel and employees of APF. 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 the projects they themselves conceived.

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

199. The *Reporter's Guide*, which, on information and belief, was distributed in Chicago and available online, deceptively dismissed the risk of addiction from long-term use of opioids as the result of confusion: "[p]ain is woefully undertreated for a variety of reasons, including[] misconceptions about opioid addiction."

200. APF's *Reporter's Guide* also mischaracterized the scientific evidence on which it relied; it cited a 2006 study, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, for the proposition that "long-acting opioids in particular are effective in improving daily function, psychological health, [and] overall health-related quality of life[.]" The study's real (and scientifically supported) conclusion is very different: "For

functional outcomes, the other analgesics were significantly more effective than were opioids."[101]

201. Ultimately the *Reporter's Guide* not only fails to disclose the unfavorable finding of the cited study, but actually sets forth claims that lead a reader to conclude the opposite.

202. 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?"

203. The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Defendants. Further, the fact that one drug company was able to direct APF demonstrates that Defendants could and did exercise similar control.

204. APF was so conditioned in its role as opioid advocate that it sometimes did not even need industry prompting. On its own initiative, APF sought to respond to an article that appeared in the *Archives of Internal Medicine* in 2011.[102] The author of that publication noted that long-acting opioids carry higher risks of overdose and that opioid therapy may persist over years, resulting in higher doses. She concluded by offering her opinion that the risks of chronic opioid therapy outweigh the benefits. APF's Rowe turned not to doctors or researchers, but to Defendants Purdue, Endo, Janssen, and Cephalon to identify potential authors to draft an answer. Janssen responded, expressing a plan to conference with APF "and partners," presumably the other drug firms copied on the e-mail, to plan the response.

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[101] Furlan, *supra*.

[102] Deborah Grady et al., *Opioids for Chronic Pain,* 171(16) Archives of Internal Med. 1426, 1426 (Sept. 12, 2011).

205. APF's lack of independence did not stop Defendants from promoting APF as a neutral source and an authority for Defendants' own claims. Janssen, for example, drew on APF publications to corroborate claims in marketing materials and even its sales training, and Endo cited numerous APF publications as resources in a patient education pamphlet. APF personnel also appeared as "patient advocates" on Purdue's *Inthefaceofpain.com*.

ii. The American Academy of Pain Medicine

206. 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.d, and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

207. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 a year (on top of other funding) to participate. The benefits include 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 resorts. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

208. 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 at 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 President, Dr. Scott Fishman, stated he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[103]

209. Endo co-sponsored a CME offered by AAPM in 2012 called the *Safe Opioid Prescriber Course* (upon information and belief, available for CME credit and accessed by doctors in Chicago), and its sales representatives distributed to doctors a special supplement of AAPM's journal, *Pain Medicine,* paid for by Endo, edited by Dr. Portenoy, and containing favorable articles on Opana ER.

210. AAPM also partnered with Janssen and AGS on a 2009 non-branded patient education program entitled *Finding Relief: Pain Management for Older Adults*. This publication, which bore the AAPM logo on the front, was reviewed and approved by Janssen compliance staff and distributed by Janssen sales representatives, including, upon information and belief, in Chicago.

211. 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.

212. Defendants supported, controlled, and were assisted by other Front Groups, including, for example, ACPA, to which they gave substantial sums between 2007 and 2013 (the majority of which was from Purdue), and the American Academy of Pain Management, which

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

received similar amounts from Defendants over the same time period. Both were significantly involved in educational and advocacy efforts that furthered Defendants' marketing.

3. Defendants Acted Collectively in their Own Self-Interest in the Creation, Promotion and Control of Unbranded Marketing

213. 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.

214. Because Defendants relied upon unbranded promotional vehicles for their efforts, each Defendant had an incentive to cooperate with the plan since increasing the overall market for opioids would benefit them all. *See*, *e.g.*, Section V.C.3.

215. Because Defendants' individual efforts to boost the sales and revenue for their own products depend largely on a change in perception of the risks and benefits of long-term use of opioids generally, it would have made little sense for Defendants to compete in the creation of marketing that could not, by law, promote their own products.

216. Moreover, no Defendant has any incentive to come forward with information that might contradict the false, misleading, and unsupported claims required to successfully promote opioids for chronic pain. Indeed, the success of Defendants' plan required all Defendants to maintain similar positions with regard to the risks and benefits of their various opioid drugs.

217. Defendants have acted through and worked 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.

218. At conferences hosted by the Front Groups supported by Defendants, Defendants were able to meet and communicate about common approaches to messaging and marketing their

products. Defendants also were members of corporate roundtables sponsored by these same organizations, which provided additional opportunities to meet and discuss common activities.

219. In addition, Defendants openly worked together to promote opioids through the 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."

220. 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.

221. Upon information and belief, PCF was and continues to be run not by APF but by Defendant Purdue's in-house lobbyist, Burt Rosen. The group meets regularly in-person and via teleconference. There also is an email listserv that is used to share information.

222. 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 in education. Upon information and belief, their messages were adopted by the full PCF membership and were reflected in programs like *Let's Talk Pain*, the National Initiative on

Patient Education (put together by Endo and APF), and in industry run-websites like Purdue's *In the Face of Pain*.

223. In 2009, the FDA notified manufacturers that, pursuant to FDA guidelines, it would require a Risk Evaluation and Mitigation Strategy ("REMS") for Long-acting Opioids to more clearly communicate the risks of opioids to prescribers and patients.[104] 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. Defendants, along with their Front Groups, worked through the PCF to ensure that, although it was mandatory for drug companies to fund these CMEs related to opioid risks, 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.[105] With a push from PCF, they were not.

224. PCF also developed and disseminated its own "consensus recommendations" for the REMS. 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

[104] *See* FDA Information by Drug Class, Background on Opioid REMS, http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm187975.htm (last visited Oct. 19, 2014).

[105] Demonstrating their common marketing purpose and effort, one drug company noted in an email with Janssen, Purdue, and Endo about the survey, "it will take everything all of us have to keep them prescribing anything at all."

the management of pain and should not introduce new barriers[.]"[106] Defendants' collaborative activities through PCF to limit the reach and manage the message of the REMS enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

4. Defendants Developed Plans to Target Vulnerable and Lucrative Populations

a. Workers' Compensation

225. Defendant Endo, in particular, saw workers' compensation programs as a lucrative opportunity, and 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."

226. Endo allocated $85,000 in 2007 to reach 5,000 workers' compensation carriers in order to ensure that Opana ER would be covered under disability insurance plans.

227. Endo also trains its sales representatives that lower back pain is responsible for nearly 20% of workers' compensation claims. Branded advertising by Defendants Endo, Purdue, and Actavis has targeted back pain in particular, and, as a result, would have affected the use of opioids by workers' compensation claimants.

228. Endo was right about the potential size of the workers' compensation market. Due in large part to Defendants fraudulent promotion of chronic opioid therapy, the spending of workers' compensation programs on opioids has skyrocketed. A study by the National Council on Compensation Insurance ("NCCI") concluded that, in 2011, approximately 38% of pharmacy

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

costs in workers' compensation are for opioids and opioid combinations, amounting to approximately $1.4 billion.[107]

b. Elderly

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

230. In their effort to reach elderly patients experiencing pain associated with arthritis and other aging-related conditions, Purdue partnered with AGS to publicize the treatment guidelines, discussed at Section V.C.2.d, and education materials focused on elderly patients, including, upon information and belief, to doctors and patients in Chicago.

231. Defendants Endo and Janssen have targeted this population by launching branded advertising, supporting unbranded patient education, and publishing reprints of journal articles all promoting the use of opioids to treat osteoarthritis.

232. *Finding Relief: Pain Management for Older Adults*, a 2009 publication sponsored, approved, and distributed by Janssen repeated the same unsubstantiated, deceptive statements

[107] Workers' Compensation 2012 Issues Report at 27, NCCI (Mar. 2012), https://www.ncci.com/Documents/IR_2012.pdf.

that opioids are "rarely addictive" and increase patients' function, allowing them to get back to work or participate in recreational activities.

233. 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 which Purdue, Endo, and Janssen publicized, for example, 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.[108]

234. 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.[109] 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. Based on anecdotal evidence, many of these elderly patients started on opioids for chronic back pain or arthritis.

c. Veterans

235. 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.[110] Further, one-third of veterans prescribed opioids as of 2012 remained on take-home

[108] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee Journal-Sentinel / Medpage Today (May 30, 2012).

[109] *Id*.

[110] American-Statesman Investigative Team, *Prescription drug abuse, overdoses haunt veterans seeking relief from physical, mental pain*, Austin American-Statesman (Sept. 29, 2012).

opioids for more than 90 days.[111] 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.[112]

236. 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.

237. Opioids are particularly dangerous to veterans. According to a study published last year in the Journal of American Medicine, veterans returning from Iraq and Afghanistan prescribed opioids have 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.[113] Yet, according to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs benzodiazepines were also prescribed benzodiazepines.[114] 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.

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[111] Bill Briggs, *VA Docs Defied Opiate Rules in Treating Vets, Audit Finds*, NBC News (May 15, 2014).

[112] American-Statesman Investigative Team, *supra*.

[113] Seal, Association of Mental Health Disorders, *supra.*

[114] Briggs, *supra*.

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

239. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose the risk that opioids may cause fatal interactions with benzodiazapines taken by a significant number of veterans. 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.

240. The deceptive nature of *Exit Wounds* is made 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 are disclosed in *Exit Wounds*.

241. The City of Chicago amended its Personnel Rules, effective November 18, 2010, to include provisions to promote the hiring of veterans for City jobs. Veterans hired by the City, including those hired as a result of this initiative, would be covered by the City's workers' compensation program and health benefits plans.

D. Why Defendants Claims Are Misleading

242. Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused the deceptive materials and information described below, *inter alia,* to be placed into the marketplace, including to patients and prescribers in Chicago. These promotional messages were intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

243. Moreover, Defendants did not disclose to prescribers, patients or the public that evidence in support of its promotional claims was inconclusive, non-existent or unavailable. Rather, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence.

244. There are eight primary misleading and unfounded representations, laid out in greater detail below. Defendants:

- 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 it "pseudoaddiction"

- falsely claimed withdrawal is easily managed
- misrepresented the greater dangers from higher doses of opioids
- deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs

245. Underlying each of Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants' collective effort 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."[115]

1. Defendants Misrepresented that Opioids Improve Function

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

[115] 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).

247. Each of the following further suggests that its claims are corroborated by scientific evidence. Yet, as the FDA acknowledged in September 2013, "FDA is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[116]

Actavis	a. Actavis trained its sales representatives in 2010 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. Actavis further trained its sales representatives in 2010 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 non-cancer 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 "[w]e 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."[117]

[116] 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).

[117] 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/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm.

Cephalon	d. Cephalon sponsored the Federation of State Medical Boards' *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. ("While significant pain worsens function, relieving pain should reverse that effect and improve function," p.33). *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Cephalon also purchased $150,000 in bulk copies of the book and distributed it by its pain sales force to 10,000 prescribers and 5,000 pharmacists. e. 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. The American Pain Foundation distributed 17,200 copies in one year alone, according to its 2007 annual report, and it is currently available online. f. Cephalon sponsored a CME written by key opinion leader Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007, through December 15, 2008. The CME taught that Cephalon's Actiq and Fentora drugs improve patients quality of life and allow for more activities when taken in conjunction with long-acting opioids.
Endo	g. Endo sponsored a website, painknowledge.com, through the American Pain Foundation, 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." h. Endo distributed product advertisements that claimed that use of Opana ER to treat chronic non-cancer pain would allow patients to perform demanding tasks like construction work or work as a chef. These advertisements also described the Opana ER indication without including the "moderate to severe pain" qualification in the boldfaced portions of the ads. i. Endo spent $246,620 to buy copies of the Federation of State Medical Boards' *Responsible Opioid Prescribing* (2007) for distribution by Endo's sales force. This book taught that relief of pain itself improved patients' function. ("While significant pain worsens function, relieving pain should reverse that effect and improve function," p.33). *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."

Janssen	j. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which was distributed by its sales force. 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. k. Janssen sponsored a website, *Let's Talk Pain* in 2009, acting in conjunction with the American Pain Foundation, 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. l. 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 certain anti-anxiety medicines called benzodiazepines would increase fatality risk.

Purdue	m. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients each with pain conditions persisting over several months and recommending OxyContin for each. The ads did not disclose the absence of evidence that OxyContin is effective long-term. n. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that 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," with the implication these studies presented claims of long-term improvement 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. o. Purdue sponsored APF'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 NSAIDs 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 it is currently available online. p. Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans 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 certain anti-anxiety medicines called benzodiazepines would increase fatality risk. q. Purdue sponsored the Federation of State Medical Boards' *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. ("While significant pain worsens function, relieving pain should reverse that effect and improve function," p.33). *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.

2. Defendants Concealed the Truth About How Opioids Lead to Addiction

248. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. To reach chronic pain patients, Defendants 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 posed a nearly insurmountable challenge.

249. Through their well-funded, comprehensive marketing efforts, Defendants were able to do it, despite the well-settled historical understanding and clear evidence that opioids taken long-term are addictive.

250. Defendants: (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.

251. 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 to develop when opioids are prescribed for pain, doctors would prescribe opioids to more patients. For example, one publication exclusively sponsored by Purdue claimed that opioids are not prescribed often enough because of "misconceptions about opioid addiction." *A Policymaker's Guide to Understanding Pain & Its Management* (APF 2011).

252. 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:

Actavis	a. Actavis trained its sales representatives in 2010 that long-acting opioids were less likely to produce addiction than short-acting opioids, though 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 addition 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 it is so low as not to be a worry.
Cephalon	c. 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." d. 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.
Endo	e. Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence. f. Endo's advertisements for the a 2012 reformulation of Opana ER claimed they were *designed to be crush resistant*, in a way that conveyed that they were less difficult to abuse. 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[.]" Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Endo had succeeded. g. Endo sponsored a website, painknowledge.com, through APF, 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 it 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. h. 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." i. Endo sponsored a CME published by APF's National Initiative of Pain Control, of which Endo was the sole funder, entitled *Persistent Pain in the Older Adult*. This CME claimed that opioids have "possibly less potential for abuse than in younger patients[,]" which lacks evidentiary support. j. Endo distributed an education pamphlet with the Endo logo entitled *Living*

	with Someone with Chronic Pain, which alleged that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." This statement and the pamphlet inaccurately minimized the risk of addiction. k. Endo distributed a patient education pamphlet edited by key opinion leader Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics,* which was available during the relevant time period. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems. This implies that patients prescribed opioids will not become addicted, which is unsupported and untrue. l. Endo contracted with the American Geriatrics Society 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.
Janssen	m. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which was distributed by its sales force. 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 it 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. n. Janssen contracted with the American Geriatrics Society 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. o. 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 it is so low as not to be a worry. p. Janssen currently runs a website, *Prescriberesponsibly.com* (last updated August 18, 2014), which claims that concerns about opioid addiction are

	"overstated."
Purdue	q. 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.[118] 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. r. 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.[119] This publication is still available online. This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction[,]" proposing an overt link between Purdue's deceptions and increased prescribing. s. Purdue 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. t. 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."[120] The study relied only on a 1981 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 it is so low as not to be a worry. u. Purdue contracted with the American Geriatrics Society 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

[118] 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 only 4-17% of the time.

[119] In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.

[120] Watson, Controlled-release oxycodone, supra.

	addicted to opioids. v. Purdue sponsored APF's *Exit Wounds* (2009), which taught 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 it is so low as not to be a worry.

253. Rather than honestly disclose the risk of addiction, Defendants 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 claim that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. The Purdue- and Cephalon-funded *Treatment Options* guide states "[d]espite the great benefits of opioids, they are often underused." Another APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, laments that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include . . . misconceptions about opioid addiction."[121] The Purdue Guide further alleges that resulting regulatory constraints (like the FDA's REMS) have a "chilling effect" on prescribing and that abuse of opioids "jeopardize effective pain management by impeding patient access to opioids."

[121] This claim also appeared in a 2009 publication by APF, *A Reporter's Guide*. APF sought funding from Purdue for the *Policymaker's Guide* by representing to Purdue it would "repurpose" the guide, so Purdue would have known this claim would be included.

254. *Let's Talk Pain*, sponsored by Janssen, likewise warns 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, "[b]ecause 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."

255. 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 Misrepresent that Addiction Risk Can Be Managed

256. 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 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.

257. There are three fundamental flaws in Defendants' assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that screening works to substantially limit the risk 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. Third, there is no reliable scientific evidence that patients without these red flags can take opioids long-term without significant danger of addiction.

258. 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."[122] Furthermore, attempts to treat high-risk patients, like 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.[123]

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

[123] Michael Von Korff et al., Long-term opioid therapy reconsidered, 155(5) Annals Internal Med. 325 (Sept. 2011); Laxmaiah Manchikanti et al., American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chornic Non-Cancer Pain: Part I—Evidence Assessment, 15 Pain Physician S1 (2012).

259. Each of the following was created with the expectation that, by instructing patients and prescribers that screening tools can identify patients predisposed to addiction, doctors will feel more comfortable prescribing opioids to their patients and patients will feel more comfortable starting on opioid therapy for chronic pain. Patients deemed low risk will receive opioids, and patients deemed high risk will also receive opioids, just with more frequent visits and urine-screens that payors, including the City of Chicago, must reimburse.

260. As described below, each Defendant claimed that the risks of addiction could be avoided or managed, without scientific support for such claims

Actavis	a. Actavis trained its sales representatives in 2010 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 available for continuing education credit in the *Journal of Family Practice* written by a Chicago-based doctor who became a member of Endo's speakers bureau in 2010. This publication, entitled *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 taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. According to Endo's internal planning documents, it distributed 96,000 copies of this reprint nationwide.

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" is "at odds with" best medical practices.[124] e. Purdue sponsored a 2012 CME program taught by a Chicago-based key opinion leader entitled *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, entitled *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."

4. Defendants Create Confusion Through The Use Of Misleading Terms Like "Pseudoaddiction"

261. Each of the following misrepresentations was developed and disseminated with the 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 in opioid therapy for chronic pain by Dr. Russell Portenoy, who consulted for Defendants 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 "true addiction," as if patients could not experience both.

[124] *See In the Face of Pain Fact Sheet: Providing Access to Pain Treatment*, Purdue Pharma L.P. (2013), www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf.

262. Each of these publications and statements below falsely states or suggests that the concept of "pseudoaddiction" is substantiated by scientific evidence:

Actavis	a. Actavis trained its sales force in 2010 to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction."
Cephalon	b. Cephalon sponsored the Federation of State Medical Boards' *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 purchased $150,000 in bulk copies of the book and distributed it by 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 being to "Increase 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*." d. Endo spent $246,620 to buy copies of the Federation of State Medical Boards' *Responsible Opioid Prescribing* (2007) for distribution by Endo's sales force. This book 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."
Janssen	e. Janssen sponsored a website, *Let's Talk Pain* in 2009, which stated "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . Pseudoaddiction is *different from true addiction* because such behaviors can be resolved with effective pain management." (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." Purdue did not mention that the author who first proposed this description became a Purdue Vice President and did not disclose the lack of evidence for pseudoaddiction.[125]

[125] J. David Haddox & David E. Weissman, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) Pain 363 (Mar. 1989).

	g. Purdue's unbranded website, Partners Against Pain.com posted a pamphlet in 2005 and upon information and belief circulated after 2007 titled, *Clinical Issues in Opioid Prescribing*, which included a list of conduct including "illicit drug use and deception" it defined as indicative of pseudoaddiction / untreated pain. It also states that "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 addition* in that the behaviors resolve when the pain is effectively treated. h. Purdue sponsored the Federation of State Medical Boards' *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*, "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."

5. Defendants Claimed Withdrawal is Simply Managed

263. In an effort to underplay the risk and impact of addiction, Defendants frequently claim that while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed by gradually tapering patients' dosage to avoid the adverse effects of withdrawal. Defendants fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—an adverse effect that also makes it less likely that patients will be able to stop using the drugs.

264. Each of the following claims, none of which is corroborated by scientific evidence, was made to persuade doctors and patients that withdrawal from opioids was not a problem and they should not be hesitant about prescribing or using opioids:

Actavis	a. Actavis trained its sales force in 2010 that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis' sales representative training claimed opioid withdrawal can take a week, even in addicted patients.
Endo	b. A CME sponsored by Endo entitled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering dose by 10-20% per day for ten days.
Purdue	c. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence and 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.

6. Defendants Misrepresented that Increased Doses Pose No Significant Additional Risks

265. Defendants 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 was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses.

266. Defendants' claims were made with the expectation that, by instructing patients and prescribers that patients could remain on the same dose indefinitely, doctors would not be dissuaded from starting patients on opioids or increasing their doses during treatment, and that doctors would not discontinue their patients' treatment as doses escalate.

267. Each of the following claims suggests it was were corroborated by scientific evidence, which was not the case:

Actavis	a. Actavis taught its sales representatives in 2010 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 tool to induce them to switch to Actavis' opioid, Kadian. b. Actavis created a patient brochure for Kadian (2007), which stated that "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." This advertisement falsely teaches patients that opioid doses can be increased indefinitely and is unrelated to addiction by definition.
Cephalon	c. 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. d. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered 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.
Endo	e. Endo sponsored a website, painknowledge.com, through APF, 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. f. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics,* which was available during the time period of this complaint from Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased . . . You won't 'run out' of pain relief." g. Endo was a "corporate member" of the American Society of Pain Educators, which claimed in its Winter 2011 Newsletter, "What's left when the pain gets really bad? More morphine." It then falsely claimed that dose increases will not be necessary for most patients.
Janssen	h. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and

	approved and which was distributed by its sales force. 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	i. Purdue's *In the Face of Pain* website, along with initiatives of APF, promote 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 exerts undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands.[126] j. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinite ones, but did not disclose the risks from high dose opioids. This publication is still available online. k. Purdue 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 attributes 10,000 to 20,000 deaths annually to NSAID overdose when the figure was closer to 3,200.[127] The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. l. Purdue was a "corporate member" of the American Society of Pain Educators, which claimed in its Winter 2011 Newsletter, "What's left when the pain gets really bad? More morphine." It then falsely claimed that dose increases will not be necessary for most patients. m. 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.

[126] 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 Med. Care.294-99 (2014).

[127] Robert E. Tarone et al., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

7. Defendants Deceptively Omit or Minimize Adverse Effects Opioids and Overstate the Risks of Alternative Forms of Pain Treatment

268. Each of the following misrepresentations was created with the expectation that, by omitting known risks of chronic opioid therapy and emphasizing or exaggerating risks of competing products, prescribers and patients would be more likely to choose opioids. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression.

269. Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[128] hormonal dysfunction;[129] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[130] neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); potentially fatal interactions with alcohol or benzodiazapines, which are used to treat post-traumatic stress disorder and anxiety. Post-traumatic stress disorder and anxiety also often accompany chronic pain symptoms.[131]

270. Each of the following was also created with the expectation that prescribers would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

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[128] Letter from Bob A. Rappaport, *supra.*

[129] H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001).

[130] See Bernhard M. Kuschel, The risk of fall injury in relation to commonly prescribed medications among older people—a Swedish case-control study, Eur. J. Pub. H. (July 31, 2014).

[131] 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 940-47 (2012).

271. Each of the following further suggests that its claims are corroborated by scientific evidence:

Actavis	a. Actavis trained its sales representatives 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.
Cephalon	c. 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 attributes 10,000 to 20,000 deaths annually to NSAID overdose when the figure is closer to 3,200.[132] *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.
Endo	d. Endo distributed a "case study" to prescribers in Chicago and elsewhere entitled, *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. e. Endo sponsored a website, painknowledge.com, through APF, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. f. Endo provided grants to APF to distribute *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and certain anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder 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.
Purdue	g. Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk

[132] Tarone, *supra.*

	of interactions between opioids and certain anti-anxiety medicines called benzodiazepines. *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. h. Purdue 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 attributes 10,000 to 20,000 deaths annually to NSAID overdose when the figure is closer to 3,200. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. i. 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.
Janssen	j. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009). This publication describes the advantages and disadvantages of NSAIDs on one page, but 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.

272. As a result of Defendants' campaign of deception, promoting opioids at the expense of other drugs, 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.[133]

E. Defendants, in Promoting their Branded Products, Also Misled Prescribers

273. Defendants worked together to build the chronic pain market, they worked separately to claim their share of that market. Each Defendant promoted opioids for chronic pain through "detailers," or sales representatives, and small group speaker programs to reach out to individual prescribers in Chicago. By establishing close relationships with doctors, Defendants 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. .

274. Defendants developed sophisticated plans to select doctors for sales visits based on the doctors' 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 allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and spread the misinformation and materials described above. Sales representatives also identify doctors to attend programs with speakers and meals paid for by Defendants.

[133] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,* 51(10) Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. *See also* John N. Mafi et al., *Worsening Trends in the Management and Treatment of Back Pain,* 173(17) J. of the Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

1. Actavis

275. Actavis's 2010 sales training, for instance, included lessons that chronic opioid therapy caused most patients to have a "markedly improved ability to function," that Kadian was less liable to be abused than short-acting opioids, that signs of addiction really reflect "pseudoaddiction," and that, with orderly dose reductions, withdrawal symptoms abate within seven days. Actavis also supplied its representatives with talking points to use when doctors raise concerns about the abuse potential of Kadian. These talking points emphasize that the doctor can avoid abuse by making "proper assessment" of the patient and using "proper prescribing practices." Actavis engaged in in-person marketing to Chicago physicians, and would have conveyed these misrepresentations to them.

2. Endo

276. Endo's promotion of Opana ER also relied heavily on in-person marketing, including to Chicago doctors. Endo had an aggressive detailing program and its sales representatives made 72,000 visits to prescribers in one year alone. The prescribers 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 doctors they visited wrote nearly three times as many prescriptions per month for Opana ER—7.4 prescriptions per month versus 2.5. The most heavily targeted prescribers wrote nearly *30* prescriptions per month.

277. Endo tracked, in detail, the impact of its sales representatives' visits. When it rolled out certain materials, the company found they tripled prescribers' ability to recall the sales message and doubled their willingness to prescribe Opana ER in the future. Prescribers' "retained" message is a plain misrepresentation: that Opana ER was less likely to lead to abuse and addiction. Though Opana ER always has been classified under Schedule II as a drug with a "high potential for abuse," 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, compared with 6% who cited "abuse potential" as a disadvantage.

278. Endo also used speaker programs, featuring KOLs, to spread its deceptive messages. 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 events took place in Illinois, just devoted to Opana ER, up from 8 in 2011. These programs were attended by sales representatives, which reveal their true purpose as marketing, rather than educational, events. In that vein, Endo's internal reporting stated that the return on investment—presumably, the number of new prescriptions generated—turned positive between 8-12 weeks after the program.

3. Janssen

279. Defendant Janssen also directly marketed chronic opioid therapy to Chicago prescribers. [redacted] From 2009 to 2013, Janssen spent $195,888.70 on 103 speakers bureau programs in Cook County, retaining 27 different physicians as speakers (including four of the top six Nucynta prescribers in Chicago), reaching over 1,000 prescribers. [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, falsely promoted Nucynta ER as having "long-term" safety and efficacy.

280. [redacted]

the FDA concluded that two studies submitted by Janssen concerning osteoarthritis did not demonstrate efficacy, a fact that was shared with Janssen in 2010, but that Janssen did not disclose to prescribers.

4. Purdue

281. Purdue also engaged in in-person marketing to doctors in Chicago and operated speakers bureau programs that included Chicago prescribers. Purdue marketed to doctors who it believed were prescribing not to treat pain, but to fuel abuse and addiction.

282. Purdue's sales representatives have maintained a database since 2002 with a list of 1,800 doctors suspected of inappropriately prescribing its drugs. This database, according to a news report in the *Los Angeles Times*, was whittled down from 3,200 doctors reported as suspicious by Purdue's sales representatives (conduct so egregious that the sales representatives forewent the chance to earn commissions on the doctors' prescriptions).[134]

283. Rather than report these doctors (as Purdue is legally obligated to do), or even stop marketing to them, Purdue used the list to persuade the FDA of the high rates of diversion of the original, non-tamper resistant OxyContin so that the FDA would not permit generic copies of the drug—the same OxyContin that Purdue promoted as less addictive—as it was too subject to abuse.[135]

284. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in the *Los Angeles Times* article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." Instead, on information and belief, Purdue continued to

[134] Scott Glover & Lisa Girion, OxyContin Maker Closely Guards Its List of Suspect Doctors, L.A. Times, Aug. 11, 2013.

[135] *Id*.

profit from the prescriptions of these suspicious prescribers. Psychologist, researcher, and Stanford University professor Keith Humphreys noted, "[t]hose doctors are a gold mine for Purdue. And the whole time they're taking the money, knowing that something is wrong, and not telling anyone until it gives them a market advantage to do so. That is really disgusting."[136]

5. Cephalon

285. Cephalon also used speakers programs to promote Fentora. Cephalon spent $6 million on these programs in 2007, comprising 21% of its Fentora promotional budget the year the drug was launched. Cephalon spent another $2.5 million on advisory boards, which allowed Cephalon to build a relationship with KOLs, soliciting their views and advice and giving them a stake in the company and in the drug.

286. In planning for the launch of Fentora, Cephalon met with 151 prescribers in Chicago through speakers bureau programs and through dinners, which were initiated by invitations by sales representatives. 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, described below, these physicians were unlikely to prescribe the product for its approved, on-label use.

287. For example, on October 3, 2006, Cephalon sales representatives hosted 17 Chicago prescribers for dinner at a cost of over $4,000. And, the next day, Cephalon sales representatives hosted 5 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. Though Fentora's FDA-approved indications do not include treatment for non-cancer

[136] *Id.*

chronic pain, many of the prescribers with whom Cephalon met did not have cancer-related specialties.

a. Cephalon's Fraudulent Marketing of Actiq and Fentora

288. Cephalon also engaged in a distinct effort to market its opioids for chronic non-cancer pain despite having labels that specifically limited their use to cancer pain in opioid-tolerant individuals. As a result of its successful marketing efforts, 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.

289. Cephalon also sponsored organizations like APF and publications like its *Treatment Options: A Guide for People Living with Pain* (2007), as a precursor to off-label marketing. Cephalon understood that marketing of Fentora for breakthrough pain in chronic non-cancer pain could only be possible by first promoting the notion that continuous opioid therapy through long-acting drugs was the most appropriate course of therapy for chronic non-cancer pain.

i. Cephalon launched its fraudulent marketing scheme of Actiq

290. 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."[137]

291. 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 dosages of opioids for a week or longer and whose systems have acclimated to the drugs.

292. 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."[138] (Emphasis in FDA document.) Because of Actiq's dangers, wider, off-label uses—as the FDA label makes clear—are not permitted:

> 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 in patients not on a chronic regimen

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

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

> of opioids. For this reason ACTIQ is contraindicated in the management of acute or postoperative pain.[139]

293. 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, where off-label uses are permitted but cannot be promoted by the drug maker, Actiq and Fentora are so potent that off-label use to opioid naïve patients is strictly forbidden.

294. 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.

295. 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.

ii. October 1, 2006—Cephalon fraudulently marketed Actiq's successor drug, Fentora

296. 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 a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug

[139] Actiq Drug Label, December 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."

Application ("NDA") to the FDA for approval. Like Actiq, Fentora is an extremely powerful 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. Like Actiq, Fentora is a rapid onset opioid.

297. 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.[140]

298. 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.

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

299. On February 12, 2007, only five 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.[141]

300. 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%.
>
> 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.

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

> 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.[142]

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

301. 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."[143] The warning did not mention Cephalon's deliberate role in the "improper patient selection."

302. Two weeks later, the FDA issued its own Public Health Advisory. The FDA emphasized, once again, that Fentora only should be prescribed for approved conditions and that dosage 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 use. The FDA Advisory warned that Fentora should not be used for any off-label conditions, 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

[142] *See Cephalon Q1 2007 Earnings Call Transcript,* Seeking Alpha (May 1, 2007, 8:48 PM EST), http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript?page=2.

[143] Letter from Jeffrey M. Dayno, M.D., Vice President, Medical Services, Cephalon, Inc., dated Sept. 10, 2007, *available at* http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM154439.pdf.

contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.[144]

i. Cephalon sponsored CMEs used to promote the off-label use of Actiq and Fentora—2007-2008, in spite of the FDA warnings

303. Cephalon also used the CME programs it sponsored to promote the off-label use of their Actiq and Fentora. In 2007 and 2008, Cephalon sponsored three CMEs available to Chicago physicians 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 only use the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME would know to prescribe Actiq or Fentora.

304. 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 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*

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

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

305. Similarly, *Breakthrough Pain: Improving Recognition and Management*, offered between March 31, 2008, and March 31, 2009, by Medscape, LLC completely omitted Actiq's and Fentora's tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like the "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.

306. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, *Opioid-Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski and Michael J. Brennan, M.D. This CME was published in a paid supplement of Pain Medicine News in 2009. They instructed their audience, "Clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility," and recommend 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 specifically in patients with chronic non-cancer pain.

307. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines that she served on Cephalon's speakers bureau. Dr. Fine and Dr. Webster also received funding from Cephalon for consulting services, and, upon information and belief, Drs. Fine and Webster receive funding from other opioid manufacturers, too.

ii. May 6, 2008—The FDA rejected Cephalon's request for expanded approval of Fentora

308. 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.[145] Cephalon's application also conceded that "[t]o date, no medication has been systematically 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.*

309. In response to Cephalon's application, the FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.[146] 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 its 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.

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[145] *See Fentora CII: Advisory Committee Briefing Document,* U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (Apr. 4, 2008), http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf.

[146] *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 .

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

310. 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.

311. On March 26, 2009, the DDMAC issued a Warning Letter to Cephalon,[147] telling Cephalon that its promotional materials for Fentora amounted to deceptive, off-label promotion of the drug. Specifically, the Warning Letter asserted that a sponsored link on Google and other search engines for Fentora, which said "Learn about treating breakthrough pain in patients with cancer"[148] 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." 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

[147] Letter from Michael Sauers to Carole S. Marchione (March 26, 2009), *available at* : http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM166238.pdf.

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

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.)

c. Cephalon continues to knowingly, deceptively, and illegally promote Fentora for off-label uses

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

313. [redacted]

[redacted]

314. [redacted]"[149] [redacted]

315. Cephalon closely tracked prescribing rates of doctors by specialty, and it has put four different Chicago prescribers on its speakers bureaus for Actiq and Fentora. In the fourth

149 [redacted]

quarter of 2006, in preparation for the launch of Fentora, two sales representatives scheduled 10 events at various Chicago offices and restaurants, reaching 151 attendees, at a cost of over $200,000. Upon information and belief, its sales representatives have detailed Chicago Fentora prescribers, and it has distributed payment vouchers to cover co-pay costs to Chicago area pain management doctors who would be less likely to treat cancer patients than the oncologists themselves.

316. [redacted]

317. [redacted]

318. 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 of, and reaped the benefits of, Cephalon's generally deceptive promotion of opioids for chronic non-cancer pain.

F. The Result of Defendants' Fraudulent Scheme

319. Using misleading and unsupported, yet seemingly authentic medical literature and education programs and patient and professional organizations, Defendants accomplished exactly what they set out to do: changing the risk-benefit assessments and standard of care for Chicago doctors 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.

320. But for the misleading information disseminated by Defendants, doctors would not have prescribed opioids long-term to address chronic pain. In addition, these prescriptions never would have been deemed "medically necessary" and "reasonably required" by doctors and thus would not have been prescribed.

321. It is unusual for doctors to acknowledge having been swayed by a drug company's marketing. As learned professionals, they believe—genuinely—that they respond to scientific evidence, not other forms of persuasion. Nevertheless, numerous studies suggest that marketing can impact doctors' prescribing habits.[150] So does the fact that drug companies,

[150] Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 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 Health Affairs 1014 (June 2004) (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 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 its sales force and trebling of annual sales calls).

including these Defendants, spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment.

322. 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, as laid out in Section V.F.1.c; (b) the City's own increased spending on opioids over the same time period, as laid out in Section V.F.1.d; (c) interviews with Chicago doctors, including doctors 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; and (d) a representative sample of claims of opioids prescribed for chronic pain and paid for by the City's health plans and workers' compensation program.

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

323. In the first instance, the City was damaged directly, through its payments of false claims for chronic opioid therapy through (a) its self-insured health care plans and (b) its workers' compensation program.

324. Defendants' marketing of opioids caused doctors to prescribe and the City, through its health plans and workers' compensation program, to pay for prescriptions of opioids to treat chronic pain. Defendants' unbranded marketing caused doctors to write and the City to pay 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 based on 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.

325. 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 that these prescriptions, in fact, would not work and would be damaging to patients.

a. Health Care Plans

326. 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.

327. 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 paid by the City.

328. 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.

329. 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.

330. 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.

331. 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 and benefits 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 opioids long-term to treat chronic pain. Each—or any—of these factors made claims to the City for chronic opioid therapy false.

332. 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."

333. Similarly, doctors 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."

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

335. 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.

336. 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."

337. 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. FDA regulations provide that a drug is misbranded "if its labeling is false or misleading in any particular."[151] "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.[152] "In determining whether the labeling . . . [is] misleading there shall be taken into account (among other things) not only representations made or suggested . . . but also the extent to which the labeling fails to reveal facts material in the light of such representation or material with respect to the consequences which may result from the use" of the drug.[153] 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.

338. Moreover, Cephalon's Fentora was specifically marketed for off-label non-FDA-approved uses. Physicians, in turn, wrote prescriptions for Fentora for non-FDA approved uses, causing the self-insured health plans to authorize, and the City to pay for, those prescriptions.

339. 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

[151] 21 U.S.C. §352(a).

[152] 21 U.S.C. § 321(m).

[153] 21 U.S.C. §321(n).

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 fraud—medical practice that supported the use of opioids for chronic pain should not entitle them to profit from that fraud.

340. 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.

341. 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, addiction treatment, and long-term disability, among others, which caused the City to incur additional costs. For example, claims data indicates that Chicago employees on opioids missed 1,300 days of work due to inpatient treatment between March 2011 and February 2014.

342. Attached as Exhibit A is a representative sample of claims that Defendants caused to be submitted to and paid by the City's health plans related to Defendants' opioid products. Exhibit A includes 795 of the more than 22,000 claims relating to Defendants' branded opioids with at least three months of consecutive opioid prescriptions paid by the City between January 2007 and June 2014. In all, the City spent more than $9.5 million for over 400,000 claims for opioids during this period. This includes $2,807,735.36 for Purdue branded Schedule II and III opioids, $171,179.67 for Actavis branded Schedule II and III opioids, $696,479.75 for Endo branded Schedule II and III opioids, $319,952.78 for Janssen branded Schedule II and III opioids, and $152,346.34 for Cephalon branded Schedule II and III opioids.

The balance includes prescriptions that also were 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.

343. 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' fraudulent scheme. As a 2008 presentation to the FDA by the Group Health Research Institute demonstrated, 87% of all opioids dispensed were to chronic pain patients using opioids long-term, whereas only 13% were for acute or cancer pain patients.[154] Upon information and belief, approximately 87% of the opioid doses that the City has paid for through its health plans have been for ineligible uses.

344. 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. Between March 2011 and February 2014, the health plans spent nearly $2 million for treatment related to opioid addiction alone.

b. Workers' Compensation Program

345. 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

[154] *See* Von Korff, *supra*; *see also* Endo Presentation, "Opana Field Advisory Board," Chicago, IL, Oct. 5-6, 2008: non-cancer pain diagnosis for long-acting opioids 84.5% in 2008, and 91.8% of Opana ER prescriptions.

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.

346. 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.

347. 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.

348. 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 and benefits 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.

349. The Illinois Workers' Compensation Act requires employers to pay for "all the necessary first aid, medical and surgical services, and all necessary medical 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). Due to the undisclosed risks related to long-term opioid use, Defendants' products were incapable of being "reasonably required" to cure the effects of any workplace injuries involving chronic pain.

350. Coventry's provider agreement limits covered, or reimbursable, services to services that are "Medically Necessary." "Medically Necessary" is defined, *inter alia,* as services and supplies determined to be "Medically 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;" "[n]ecessary to meet the health needs of the Member, improve physiological function and required for a reason other than improving appearance;" and "[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*, finally, "[c]onsistent with the diagnosis of the condition at issue."

351. For claimants covered by the City's workers' compensation program, an addendum to the provider agreement indicates that it does not preempt state or federal laws or regulations pertaining to workers' compensation. But the state laws pertaining to workers' compensation are in accord, since the Illinois Workers' Compensation Act only requires employers to pay for "all the necessary first aid, medical and surgical services, and all necessary

medical 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).

352. 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.

353. The City's workers' compensation program is obligated to cover all "medically necessary" and "reasonably required" treatment arising from a compensable work-related injury.

354. As described above, though, the use of opioids to treat chronic pain is not "medically necessary" or "reasonably required" in that their risks do not 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).

355. 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. The report also noted that: "[t]he 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%**

356. 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.

357. Attached as Exhibit B is a representative sample of claims for prescriptions of at least three months' supply of Defendants' branded opioids paid through the City's workers' compensation program between January 7, 2009 and June 3, 2014. In all, the City's workers' compensation program spent $3.125 million on opioids during this period. This includes $264,782.32 for Purdue branded Schedule II and III opioids, $9,592.34 for Actavis branded

Schedule II and III opioids, $228,869.29 for Endo branded Schedule II and III opioids, $136,957.18 for Janssen branded Schedule II and III opioids, and $715,323.16 for Cephalon branded 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.

358. 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. Between August 21, 2008 and April 8, 2014, the City paid $846,112 through its workers' compensation program for treatment related to opioid addiction alone.

359. 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. As a 2008 presentation to the FDA by the Group Health Research Institute demonstrated, 87% of all opioids dispensed were to chronic pain patients using opioids long-term, whereas only 13% were for acute or cancer pain patients.[155] Upon information and belief, approximately 87% of the opioid fills that the City has paid for through its workers' compensation program have been for ineligible uses.

[155] *See* Von Korff, *supra*; *see also* Endo Presentation, "Opana Field Advisory Board," Chicago, IL, Oct. 5-6, 2008: non-cancer pain diagnosis for long-acting opioids 84.5% in 2008, and 91.8% of Opana ER prescriptions.

c. Increase in Opioid Prescribing Nationally

360. Defendants' scheme worked. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide. During 2009, they wrote 83 million more.[156]

361. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids."[157] Indeed, "[o]pioids are the most common means of treatment for chronic pain."[158] From 1980 to 2000, opioid prescription for chronic pain visits doubled. This is the result not of an epidemic of pain, but an epidemic of prescribing.[159] 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***.[160] 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

[156] *See* Laura Governale, *Outpatient Prescription Opioid Utilization in the U.S., Years 200—2009,* FDA (July 22, 2009), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM220950.pdf.

[157] Marie N. Stagnitti, Statistical Brief #235: Trends in Outpatient Prescription Analgesics Utilization and Expenditures for the U.S. Civilian Noninstitutionalized Population, 1996 and 2006, MEPS Agency for Healthcare Research and Quality, Fig. 6 (Feb. 2009).

[158] Deborah Grady et al., *Opioids for Chronic Pain,* 171 Archives of Internal Med. 1426, 1426 (Sept. 12, 2011), Matthew Daubresse et al., *Ambulatory Diagnosis & Treatment of Nonmalignant Pain in the U.S., 2000-2010,* 51(10) Med. Care 870 (Oct. 2013) (increase in opioid prescriptions from 11.3% to 19.6% from 2000 to 2010).

[159] Margaret A. Caudill-Slosberg et al., Office Visits and Analgesic Prescriptions for Musculoskeletal Pain in the U.S. 1980 v. 2000, 109 Pain 514 (2004).

[160] Daubresse, *supra.*

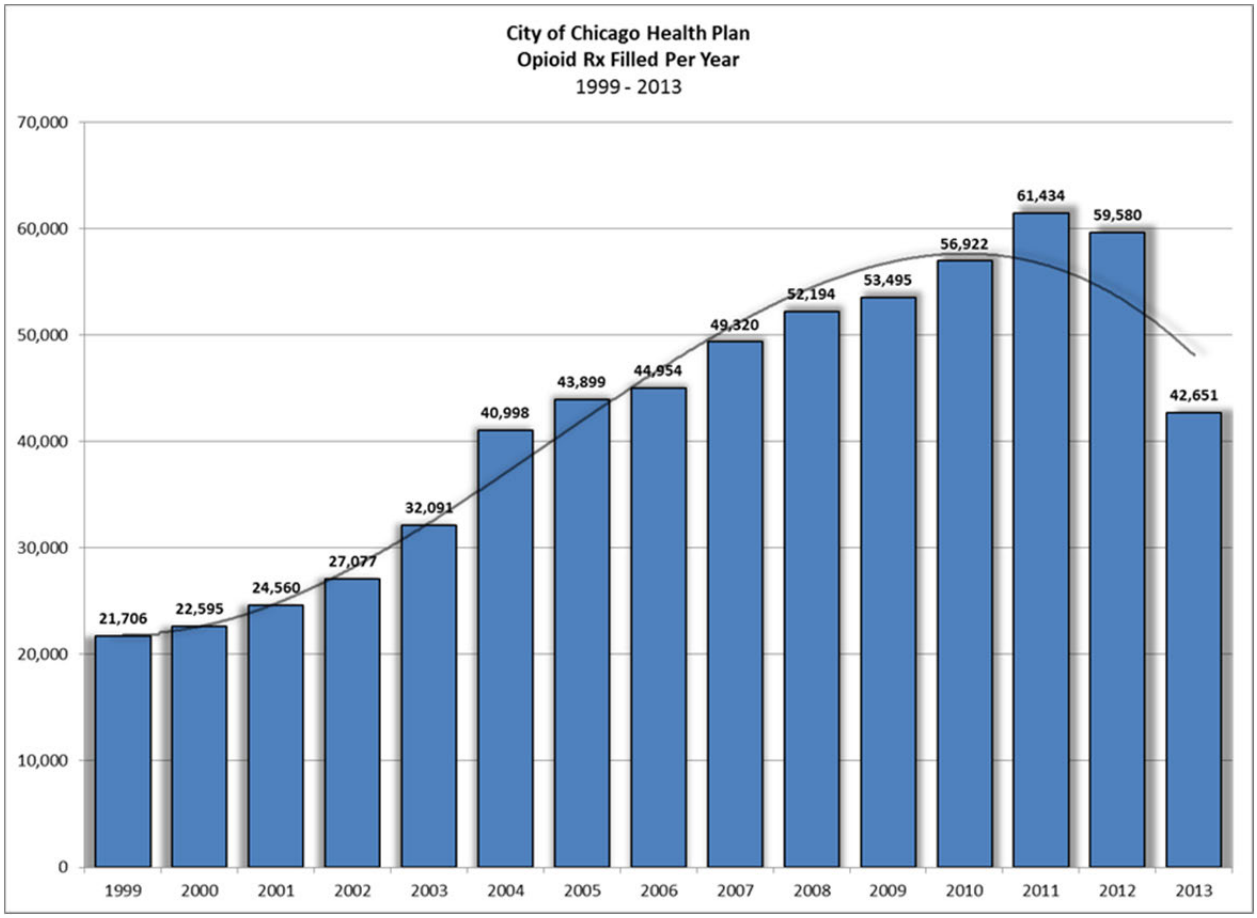
acetaminophen declined and referrals to physical therapy remained steady.[161] This increase corresponds with, and was caused by, Defendants' marketing push.

d. The City's Increased Spending on Opioids

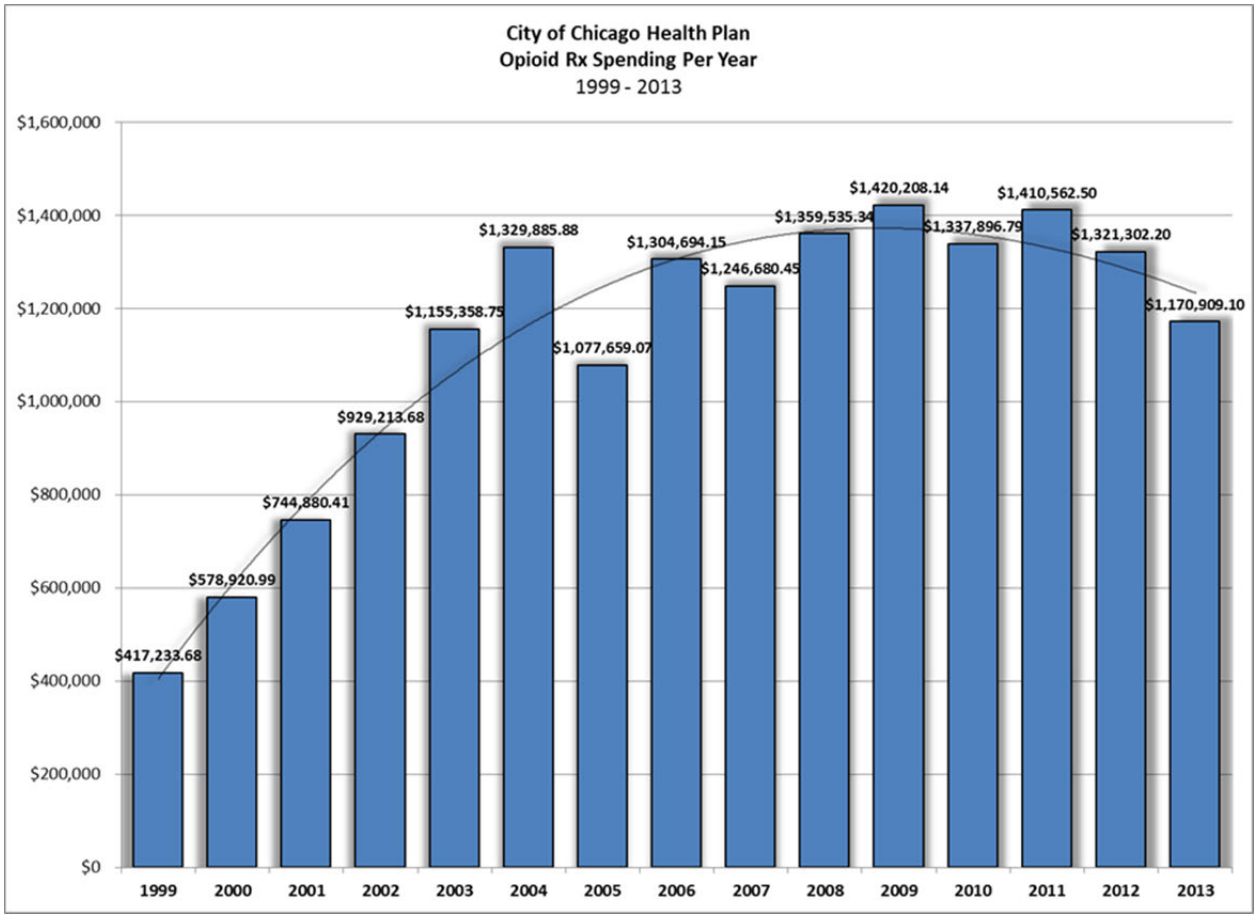
362. In addition to the massive upswing in prescribing of opioids nationally over the relevant time period, the City of Chicago saw its own spending on opioids increase dramatically.

363. The rate at which opioids were prescribed in Chicago consistently increased as Defendants' fraudulent marketing began to achieve its desired effect. In 2003, the City health plans funded 32,091 opioid prescriptions. By 2011, however, this number had almost doubled, with the City health plans funding 61,434 prescriptions. However, by 2013, as the real data regarding rates of opioid addiction, overdose, and death became more widely known (despite Defendants' best efforts), the number of opioid prescriptions fell to 42,651.

[161] Mafi, *supra*.



364. Predictably, the City's spending on opioids rose along with the number of opioid prescriptions. In 2003, the city spent $1.16 million on opioid prescriptions, which increased to an average of nearly $1.4 million during the years 2009 to 2011. As more accurate information about the risks relating to opioid use was made available to patients and prescribers, the City's total cost fell to $1.2 million in 2013.



e. Interviews with Chicago Doctors

365. The City interviewed numerous Chicago doctors who prescribed opioids for chronic pain to Chicago consumers and City employees and 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 doctors who had internalized 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.

366. Chicago Doctor A, an anesthesiologist, reported that he talked with opioid makers' sales representatives "all the time." Most of the time, they would tell him that new formulations of their opioids make the drugs "impossible" to be abused. He also has been told by drug representatives that opioids improve patients' function. He has attended, and continues to attend, CMEs on the use of opioids for chronic pain. He knows that the programs may be biased, but relies on the information because he has no time to research the issue on his own. For the same reason, he has used the AAPM/APS treatment guidelines. However, information regarding the epidemic of opioid abuse and addiction has caused him to reign in his prescribing in recent years. As a representative example, 681 opioid prescriptions written by Doctor A and paid for by the City's health plans are attached as Exhibit C. Documents uncovered by the City during its investigation indicate that at least two Defendants, Actavis and Janssen, identified Chicago Doctor A as a marketing "target" and tracked his prescribing habits.

367. Chicago Doctor B 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 by another doctor, typically by their primary care physician. He noted, further, that many of the patients he observed take opioids for more than a year.

368. Though Chicago Doctor B observed that most patients eventually begin to self-escalate their dosage, 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. Chicago Doctor B described this view as engrained in the curriculum.

369. Based on his own clinical experience and research, Chicago Doctor B does not now believe that opioids are medically appropriate for chronic pain as a first-line treatment, but reluctantly prescribed opioids to patients to try to taper them off the drugs. Chicago Doctor B described opioids as a "one way train:" patients almost always require escalating doses and it is very hard to end opioid therapy. He noted that weaning a patient off of opioids is "easier said than done;" "if successful," the process takes 6 months to year, depending on how long they were on the drugs.

370. Chicago Doctor B 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.

371. Chicago Doctor C, who works in the Hospital Medicine Department at the University of Chicago and has worked with veterans seeking treatment for pain, described prescribing of opioids for chronic pain as "unfortunate." He explained, based on his clinical experience and observations, that opioids are taken for "much, much" longer than is safe or necessary. Chicago Doctor C based his opinion on the well-known 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.

372. Chicago Doctor C 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. He noted that once a patient has been on opioids for chronic pain, they experience even worse pain when they come off the drugs.

373. As a result of Defendants' conduct, Chicago Doctor C learned that opioids are the most appropriate treatment for chronic pain. Chicago Doctor C also observed other providers using opioids for chronic pain and found support for their opioid use in medical literature he had read. Chicago Doctor C specifically pointed to the AAPM/APS Guidelines as one source of his support for his opinions about opioids. The Guidelines, Chicago Doctor C explained, made him more willing to prescribe opioid 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.

374. In the last two years, the prevalence of opioid abuse and addiction changed Chicago Doctor C's views on the use of opioids. Chicago Doctor C explained that the institution at which he works has similarly experienced a change in practice as to the proper way to treat chronic pain. Chicago Doctor C's opinion changed after he observed that chronic opioid therapy was not helping his patients, and rather that their addictions were decreasing their quality of life. The main problem, he noted, is that patients came in with "high expectations" of successful, long-lasting pain relief through opioids. Many had been using opioids for years and were addicted prior to coming to him for treatment. Chicago Doctor C found it astonishing that most of his patients were initially not aware of the substantial risk of addiction that accompanies long-term use of opioids.

375. Chicago Doctor C also observed that doctors often feel their hands are tied because their patients come to them already on opioids for chronic pain. He inherited many of his patients from a psychiatrist in Chicago who prescribed "gobs and gobs" of opioids. If he was not willing to prescribe more opioids, he might lose the patients (and the chance to provide better care) or face negative reviews. As a result, Chicago Doctor C feels that he has had to prescribe

opioids when he did not believe it appropriate. He reports that he was "definitely misled" about using opioids to treat chronic pain.

376. Finally, Chicago Doctor D recalled being visited by sales representatives promoting opioids. He noted that they undersell the risks and adverse effects from long-term use of opioids and do not talk about addiction. Patients he treated who have taken opioids long-term—even elderly patients—frequently experience psychological dependence and crave the drugs. In his experience, opioids cause more dysfunction than improved function.

377. Chicago Doctor D observed that patients who were referred to him while undergoing chronic opioid therapy, frequently stopped experiencing pain once they were taken off opioids.

378. Further, KOLs who served on the speakers bureaus of Cephalon, Endo, and Janssen have written more than 1,500 Schedule II and III opioid prescriptions for chronic pain between 2007 and the present paid for by the City's health plans. As laid out in Section V.C.2.a, these doctors were paid and trained by Defendants to assist in marketing opioids to treat chronic pain.

f. Examples of Opioid-Related Claims Paid by the City's Health Plans and Workers' Compensation Program

379. 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.

380. 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. Because of Defendants' fraudulent 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. Patient 1 sought treatment for general osteoarthritis and joint pain of the shoulder and leg at the University of Chicago. This patient was prescribed Hydrocodone/Acetaminophen by a handful of doctors in Chicago, including Chicago Doctor E, who practices internal and geriatric medicine.

   Records maintained by the health plans indicate that 26 claims were submitted for opioid prescriptions for Patient 1 between April, 2009 and August, 2014 for a total cost of $38.39. These claims were paid by the health plans.

b. Patient 2 sought treatment for chronic pain syndrome, rheumatoid arthritis, and various back-related conditions (such as disc degeneration) from a handful of medical service providers. This patient also received treatment for drug abuse and drug withdrawal. Patient 2 was prescribed a number of opioids, including OxyContin, Opana ER, Oxycodone, and Hydrocodone/Acetaminophen by a handful of doctors in Chicago, including Chicago Doctor F, who practices as an orthopedic surgeon.

   Records maintained by the health plans indicate that 197 claims were submitted for opioid prescriptions for Patient 2 between January, 2007 and August, 2013 for a total cost of $50,199.37. These claims were paid by the health plans.

c. Patient 3 sought treatment for chronic pain and for joint pain for multiple joints and cervical disc degeneration. This patient was prescribed a number of opioids, including OxyContin, Oxycodone, Fentanyl, and Opana ER by a handful of doctors in Chicago, including Chicago Doctor G, who practices as an anesthesiologist.

   Records maintained by the health plans indicate that 647 claims were submitted for opioid prescriptions for Patient 3 between January 11, 2007 and August, 2014 for a total cost of $121,129.48. These claims were paid by the health plans.

d. Patient 4 sought treatment for cervical and lumbar disk degeneration and similar conditions. This patient was prescribed a number of opioids, including

Oxycodone, Hydrocodone/Acetaminophen, and Morphine ER by a handful of doctors in Chicago, including Chicago-area Doctor H, an arthritis specialist.

Records maintained by the health plans indicate that 354 claims were submitted for opioid prescriptions for Patient 4 between January, 2007 and August, 2014 for a total cost of $3,921.65. These claims were paid by the health plans.

e. Patient 5 sought treatment for shoulder joint pain, and lumbar pain. This patient was prescribed a number of opioids, including OxyContin, Oxycodone, and Hydrocodone/Acetaminophen by a handful of doctors in Chicago, including Chicago Doctor I who practices orthopedic surgery.

Records maintained by the health plans indicate that 30 claims were submitted for opioid prescriptions for Patient 5 between March, 2009 and April, 2014 for a total cost of $82.45. These claims were paid by the health plans.

381. The following is a representative sample of claims submitted to the City's workers' compensation program:

a. Patient 6 sought treatment for pain in the neck and shoulder. This patient was prescribed Hydrocodone/Acetaminophen by several Chicago and Chicago area doctors, including Doctor J, an anesthesiologist.

Records maintained by the workers' compensation program indicate that 40 claims were submitted for opioid prescriptions for Patient 6 between March, 2011 and August, 2014 for a total cost of $1,129.01. These claims were paid by the workers' compensation program.

b. Patient 7 sought treatment back pain and spinal stenosis. This patient was prescribed Hydrocodone/Acetaminophen and Oxycodone/Acetaminophen by Chicago doctors, including Chicago Doctor K, an anesthesiologist.

Records maintained by the workers' compensation program indicate that 55 claims were submitted for opioid prescriptions for Patient 7 between July, 2008 and September, 2014 for a total cost of $7,604.07. These claims were paid by the workers' compensation program.

c. Patient 8 sought treatment for conditions including osteoarthritis. This patient was prescribed Hydrocodone/Acetaminophen and Vicodin, by Chicago and Chicago area doctors, including Doctor K, an anesthesiologist.

Records maintained by the workers' compensation program indicate that 92 claims were submitted for opioid prescriptions for Patient 8 between October, 2006 and September, 2014 for a total cost of $4,719.61. These claims were paid by the workers' compensation program.

d. Patient 9 sought treatment for back pain, among various conditions. This patient was prescribed Opana ER, Opana, MS Contin, Exalgo, Oxycodone, Oxycontin-Acetaminophen, Oxymorphone, and Morphine Sulfate by several Chicago area doctors.

Records maintained by the workers' compensation program indicate that 121 claims were submitted for opioid prescriptions for Patient 14 between March, 2008 and September, 2014 for a total cost of $90,095.89. These claims were paid by the workers' compensation program.

e. Patient 10 sought treatment for various back-related conditions. This patient was prescribed OxyContin, Hydrocodone/Acetaminophen, Oxycodone/Acetaminophen, Hydromorphone, and Morphine Sulfate by several Chicago area doctors.

Records maintained by the workers' compensation program indicate that 114 claims were submitted for opioid prescriptions for Patient 10 between February, 2008 and September, 2014 for a total cost of $58,405.86. These claims were paid by the workers' compensation program.

f. Patient 11 sought treatment for back pain and joint pain. This patient was prescribed Nucynta, Nucynta ER, and Oxycodone/Acetaminophen by Chicago physicians, including Doctor L, an internist, and Doctor M, a sports medicine doctor.

Records maintained by the workers' compensation program indicate that 83 claims were submitted for opioid prescriptions for Patient 11 between March, 2010 and December, 2013 for a total cost of $15,625.10. These claims were paid by the workers' compensation program.

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

a. Increased Opioid Use Has Led to an Increase in Opioid Abuse, Addiction, and Death

382. 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.[162] "Deaths from opioid overdose have risen steadily since 1990 in parallel with increasing prescription of these drugs."[163] 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.[164] More Americans have died from opioid overdoses than in the Vietnam War.[165]

383. 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.[166] 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.[167] In 2009, there were more than twice as many deaths from prescription opioid overdoses (15,597) than from cocaine (4,350) and heroin (3,278) put together.

384. 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

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[162] Theodore J. Cicero et al., Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States, 16(8) Pharmacoepidemiology and Drug Safety, 827 (2007).

[163] Grady, *supra* at 1426.

[164] CDC, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers*, 62 Morbidity & Mortality Wkly. 537 (July 5, 2013), www.cdc.gov/mmwr/preview/mmwrhtml/mm6226a3.htm.

[165] Gary M Franklin, *Opioids for Chronic Noncancer Pain: A Position Paper of the American Academy of Neurology*, 83(14) Neurology 1277-1284.

[166] Fran Lowry, *Doctors Have 'Knowledge Gaps' About Opioid Abuse*, Medscape (May 6, 2014), available at http://www.medscape.com/viewarticle/824702.

[167] *CDC Grand Rounds: Prescription Drug Overdoses, a U.S. Epidemic*, Ctrs. for Disease Control & Prevention (Jan. 13, 2012), www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm.

795 non-medical users.[168] Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).[169]

385. Again, the City of Chicago has also borne the costs of widespread opioid use. 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.[170] In 2009, over 1,200 emergency department visits involved patients who were illicitly using opioids.[171]

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

386. By May 2014, Illinois had seventy-one Certified Opioid Treatment Programs, thirty-one of which are in the City of Chicago.[172] By way of contrast, Tennessee, whose opioid epidemic is among the worst in the nation, has only twelve.[173] These treatment programs, by all reports, do not even begin to meet the need for services.

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[168] Wilson M. Compton, *Prescription Drug Abuse: It's Not What the Doctor Ordered*, Nat'l Inst. On Drug Abuse, (May 3, 2013), www.apa.org/about/gr/science/spin/2013/05/prescription-drug-abuse.pdf.

[169] *America's Addition to Opioids: Heroin and Prescription Drug Abuse: Hearing Before the Caucus on International Narcotics Control U.S. Senate,* 113th Cong. (May 14, 2014) (statement of Michael P. Botticelli, Acting Director, Office of Nat'l Drug Control Policy)

[170] SAMHSA, *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*, HHS Pub. No. (SMA) 13-4760 (May 2013).

[171] SAMHSA, *Metro Brief Chicago: Drug-Related Emergency Dep't Visits in Metro. Areas*, U.S. Dep't of Health & Human Servs. (2009).

[172] SAMHSA, *Opioid Treatment Program Directory,* U.S. Dep't of Health & Human Servs. http://dpt2.samhsa.gov/treatment/directory.aspx.

[173] *Id.*

387. 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.[174]

388. The City's workers' compensation program and health benefit plans have expended nearly $3 million on addiction treatment services over a three-year period alone.

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

389. 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 "substantial increases in the nonmedical use of opioids is a predictable adverse effect of substantial increases in the extent of prescriptive use."[175] It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.[176]

390. 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

[174] Katz, *Opioids: After Thousands of Years, supra*.

[175] G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308(18) The Journal of the Am. Med. Ass'n, 1865-1866 (Nov. 14, 2012).

[176] Katz, *Opioids: After Thousands of Years, supra,* ("It is now clear that opioid prescribing, however well-intentioned, is directly or indirectly a major driver of prescription opioid abuse").

the Chicago field division of the DEA, "Street gangs, too, have become increasingly involved in prescription drug diversion."[177]

391. 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 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.[178] 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."[179]

392. That reality holds in Chicago. According to addiction programs in Chicago, opioid addiction is affecting all demographics of the City—all ages, ethnicities, and socio-economic backgrounds. Many of those addicted to opioids who seek treatment in Chicago treatment centers started with a prescription obtained to treat pain, liked how opioids made them feel, and stayed on them. Even though these pills were prescribed, unwitting patients become addicted. They request more opioids from their doctors, who often eventually cut them off. Many then doctor shop for additional prescriptions, and when that source runs out, to the streets to buy opioids illicitly. A significant number will become heroin addicts. Those who do reach treatment centers often do so when their health, jobs, families and relationships reach the

[177] Monifa Thomas, *supra*.

[178] NPR Staff, *With Rise of Painkiller Abuse, A Closer Look At Heroin*, NPR (Nov. 2, 2013), www.npr.org/2013/11/02/242594489/with-rise-of-painkiller-abuse-a-closer-look-at-heroin.

[179] 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.

breaking point. Those who seek treatment often do so after a precipitating life event—either losing a job or being confronted by family—or after turning to criminal activity such as prostitution and theft to sustain their addiction. Unfortunately, few are successful in getting and staying clean. Chicago addiction centers estimate only 5-10% of their patients reach abstinence on a long-term basis.

3. Defendants Fraudulent Marketing Has Led to Record Profits

393. Defendants' marketing has achieved its aim and caused an explosion of opioid use in the United States.

394. 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 million prescriptions for painkillers—roughly one prescription per American adult.[180] Opioids generated $8 billion in revenue for drug companies just in 2010.[181]

395. 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.[182] In 2010, Research Firm Frost & Sullivan projected an increase to $15.3 billion in overall revenue from opioid sales by 2016.[183]

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[180] *CDC Vital Signs, Opioid Painkiller Prescribing*, CDC (July 2014), *available at* http://www.cdc.gov/vitalsigns/opioid-prescribing/.

[181] Barry Meier & Bill Marsh, *The Surging Cost of the Opioid Economy*, New York Times (June 22, 2013), *available at* http://www.nytimes.com/interactive/2013/06/23/sunday-review/the-soaring-cost-of-the-opioid-economy.html?_r=0.

[182] Katherin Eban, *Purdue Pharma's Painful Medicine*, Fortune Magazine (November 9, 2011), *available at* http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/.

[183] Frost & Sullivan, *U.S. Opioid Pain Management Market* (July 12, 2010), *available at* http://www.frost.com/prod/servlet/report-brochure.pag?id=N72F-01-00-00-00.

4. Defendants Fraudulently Concealed their Misrepresentations

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

397. 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.

398. 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 through their funding of and relationship with KOLs and Front Groups, both directly and through their public relations companies, pursuant to sophisticated publication plans.

399. 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.

400. 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 assert. 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.

401. 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

VIOLATIONS OF MCC § 2-25-090 AGAINST ALL DEFENDANTS

402. 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.

403. 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, 735 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' . . ."

404. Defendants have engaged in unlawful, deceptive, and unfair business practices in violation of the Municipal Code as set forth above.

405. 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.

406. At all times relevant to this Complaint, Defendants, directly or indirectly, violated MCC § 2-25-090 by making and disseminating untrue, false, and misleading statements to promote the sale and use of opioids to treat chronic non-cancer 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 non-cancer pain.

407. At all times relevant to this Complaint, Defendants, directly or indirectly, 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 non-cancer pain.

408. Defendant Purdue made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained misleading statements;

b. Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the ability of opioids to improve function long-term, and the evidence supporting the efficacy of opioids long-term, for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Purdue's own unbranded publications and on Internet sites Purdue operated;

d. Distributing brochures to doctors, patients, and law enforcement officials that included misleading statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing and assisting in the distribution of publications that promoted the misleading concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and

dose-dependent risks of opioids versus non-steroidal anti-inflammatory drugs;

g. Providing significant financial support to pro-opioid key opinion leader doctors, who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing necessary financial support to pro-opioid pain organizations that made untrue, false, and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained false, misleading and untrue statements concerning the use of opioids to treat chronic non-cancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids effective for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans in sponsoring and disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to Chicago hospital doctors and staff while purportedly educating them on new pain standards created by JCAHO;

q. Making untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain to Chicago prescribers through in-person detailing; and

r. Withholding from Chicago and Illinois law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

409. Defendant Endo made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained misleading statements;

b. Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the ability of opioids to improve function long-term, and the evidence supporting the efficacy of opioids long-term, for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high-risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on Internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus non-steroidal anti-inflammatory drugs;

g. Providing significant financial support to pro-opioid KOLs, who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing necessary financial support to pro-opioid pain organizations—including over $5 million to the organization responsible for many of the most egregious misrepresentations—that made untrue, false and

misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

j. Endorsing and assisting in the distribution of CMEs containing untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained false, misleading and untrue statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids effective for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain to Chicago prescribers through in-person detailing, speakers bureau events, and advisory boards.

410. Defendant Janssen made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained misleading statements;

b. Directly disseminating misleading statements through Internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious, and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus non-steroidal anti-inflammatory drugs;

f. Providing significant financial support to pro-opioid KOLs, who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population which contained false and misleading statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained false, misleading and untrue statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans in sponsoring and disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain to Chicago prescribers through in-person detailing and speakers bureau events.

411. Defendant Cephalon made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained misleading statements;

b. Sponsoring and assisting in the distribution of publications that promoted the misleading concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid key opinion leader doctors, who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

e. Providing necessary financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing untrue, false and misleading statements concerning the unsafe, off-label use of Cephalon's rapid-onset opioids;

h. Directing its marketing to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs serving chronic paint patients for off-label use of Cephalon's rapid-onset opioids;

i. Making untrue, false and misleading statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to Chicago prescribers

through in-person detailing and speakers bureau events, when such uses are off-label and unsafe; and

j. Making untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain to Chicago prescribers through in-person detailing and speakers bureau events.

412. Defendant Actavis made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

a. Instructing its sales force to make false, misleading and untrue statements to doctors concerning the ability of opioids to improve function long-term, in the treatment of chronic, non-cancer pain;

b. Instructing its sales force to make false, misleading and untrue statements to doctors concerning the risks of addiction and to promote the misleading concept of pseudoaddiction;

c. Instructing its sales force to present an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDS;

d. Making untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain to Chicago prescribers through in-person detailing;

e. Creating and disseminating advertisements that contained false, misleading and untrue statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

f. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

g. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

413. 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 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 of opioids.

414. Defendants repeatedly failed to disclose material facts about the risks of opioids, including significant risks of adverse effects, including the risk of addiction and the lack of evidence supporting the use of opioids long-term to treat chronic pain. 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 consumers and payors of opioid prescriptions to rely on those omissions and concealments.

415. All of this conduct, separately and collectively, was intended to deceive Chicago consumers who used or paid for opioids for chronic non-cancer pain, Chicago physicians who prescribed opioids for chronic non-cancer pain, and Chicago payers, including the City, who purchased, or covered the purchase of, opioids for chronic non-cancer pain.

416. Defendants' practices as described in the Complaint are also unfair practices that violated MCC § 2-25-090 because the practices offend public policy; are immoral, unethical, oppressive, or unscrupulous; or caused substantial injury to consumers.

417. Defendants' practices in deceptively exaggerating the benefits and minimizing the risks of these addictive drugs offend deep-seated public policies aimed at ensuring honest marketing and safe and appropriate use of pharmaceutical drugs, and preventing addiction and the sale and use of illegal drugs, among others, as described above. Defendants' conduct in sacrificing their duties to their customers and to public health in favor of blockbuster profits is immoral, unethical, oppressive, and unscrupulous. This conduct has caused grievous injury to

Chicago consumers. The staggering rates of opioid use, abuse, and addiction resulting from Defendants' marketing efforts have caused substantial injury, 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 non-cancer pain conditions. These high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths;

b. 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;

c. More broadly, opioid use and misuse have driven Chicagoans' health care costs higher;

d. 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;

e. This demand also has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process;

f. The diversion of opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids have increased the demands on emergency services and law enforcement in the City; and

g. 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 families and homes.

418. Defendants' practices have also violated MCC § 2-25-090 because the practices violate the Illinois Consumer Fraud and Deceptive Business Practices Act, which is incorporated into the MCC § 2-25-090 by reference. The Illinois Consumer Fraud and Deceptive Business

Practices Act makes unlawful, among other things, "the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act' . . ." 735 ILCS § 505/2.

419. Defendants employed several practices proscribed by the Uniform Deceptive Trade Practices Act:

a. By, among other things, using Front Groups, KOLs, and others to peddle their misrepresentations, by influencing the creation of misleadingly pro-opioid treatment guidelines and CMEs, and by distorting the scientific evidence for opioid use for chronic non-cancer pain, Defendants made it appear that opioids had sponsorship and qualities that opioids do not have. In so doing, Defendants:

i. "cause[d] likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services."
735 ILCS § 510/2(a)(2);

ii. "cause[d] likelihood of confusion or of misunderstanding as to affiliation, connection, or association with or certification by another."
735 ILCS § 510/2(a)(3);

iii. "represent[ed] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have." 735 ILCS § 510/2(a)(5).

b. By, among other things, deceptively characterizing the risks of NSAIDs in order to promote opioids, Defendants "disparage[d] the goods, services, or business of another by false or misleading representation of fact." 735 ILCS § 510/2(a)(8).

c. Altogether, Defendants "engage[d] in any other conduct which similarly creates a likelihood of confusion or misunderstanding." 735 ILCS § 510/2(a)(12).

420. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and/or 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.

421. By reason of the Defendants' unlawful acts, Chicago consumers and the City have been damaged and continue to be damaged, in substantial amount to be determined at trial.

422. 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.

423. 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, unfair competition, 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.

COUNT TWO

MISREPRESENTATIONS IN CONNECTION WITH SALE OR ADVERTISEMENT OF MERCHANDISE

VIOLATIONS OF MCC § 4-276-470 AGAINST ALL DEFENDANTS

424. 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.

425. 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.

426. 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 sale or advertisement of any merchandise.

427. At all times relevant to this Complaint, Defendants, directly or indirectly, 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.

428. 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 doctors, 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 of opioids.

429. 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 doctors, consumers, and other payors of opioid prescriptions to rely on those omissions and concealments.

430. 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 for chronic pain, and other payors, including the City, which purchased, or covered the purchase of, opioids for chronic pain.

431. As a direct and proximate 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.

432. By reason of the Defendants' unlawful acts, Chicago consumers and the City have been damaged and continue to be damaged, in 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) 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.

VII. COUNT THREE

FALSE STATEMENTS TO THE CITY

VIOLATIONS OF MCC § 1-21-010, *ET SEQ.* AGAINST ALL DEFENDANTS

433. 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.

434. 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.

435. 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.

436. 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.

437. 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, 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 the false and misleading statements disseminated by the Defendants about the

risks, benefits, and superiority of opioids for chronic pain. Opioids, however, are not "medically necessary" or "reasonably required" to treat chronic pain.

438. If the City had known of the false statements created and disseminated by Defendants in support of opioids and that doctors, pharmacists, and/or agents of the health plans and 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.

439. By virtue of the above-described acts, Defendants aided, abetted, incited, and caused others to make false statements of material fact to the City in connection with claims to pay for opioids to treat chronic pain, within the meaning of MCC § 1-21-010 and 1-21-020.

440. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has spent more than $9.5 million during this period to pay for over 400,000 prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

441. 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 Three 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 the 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.

VIII. COUNT FOUR

FALSE CLAIMS

VIOLATIONS OF MCC § 1-22-020 AGAINST ALL DEFENDANTS

442. 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.

443. 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."

444. 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."

445. 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.

446. Defendants knew, or by the exercise of reasonable care should have known, 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 or for other inappropriate uses. 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.

447. 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." Opioids, however, are not "medically necessary" or "reasonably required" to treat chronic pain. Yet doctors, pharmacists, and/or other agents of the health plans and workers' compensation program expressly or impliedly certified to the City that such prescriptions were "medically necessary" and "reasonably required" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic pain. Moreover, many of the prescriptions written by physicians 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.

448. 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.

449. Defendants' misrepresentations were material because if the City had known of the false statements disseminated by Defendants and that doctors, pharmacies, 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.

450. 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.

451. 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.

452. 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.

453. 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.

454. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has spent more than $9.5 million during this period to pay for over 400,000 prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

455. Each Defendant is responsible for the claims submitted and the amount the City spent on its opioids.

456. In addition, because Defendants acted concurrently and/or collaboratively in carrying out a common fraudulent scheme—causing others to submit false claims for opioids which were paid by the City—Defendants are jointly and severally liable for the City's total spend on opioids prescribed to treat chronic pain, which are neither "medically necessary" nor "reasonably required."

457. 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 § 1-21-020; (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 the 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.

IX. COUNT FIVE

CONSPIRACY TO DEFRAUD BY GETTING FALSE OR FRAUDULENT CLAIMS PAID OR APPROVED BY THE CITY

VIOLATIONS OF MCC § 1-22-020 AGAINST ALL DEFENDANTS

458. 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.

459. 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."

460. Defendants' practices, as described in the Complaint, violated Section 1-22-020 of the MCC. Defendants conspired to defraud the City by getting false or fraudulent claims allowed or paid, by acting in concert in a comprehensive scheme to defraud the City while illegally and deceptively promoting opioids in an effort to further opioids sales.

461. Defendants knowingly and voluntarily engaged in a concerted scheme to promote the widespread use of opioids for the treatment of chronic pain directly through their own publications and employees, and indirectly, through seemingly independent thought-leaders, advocacy groups, and professional societies, by making, funding, suggesting, editing, approving, and distributing untrue, false, and misleading statements and representations to doctors and patients. The concerted scheme was entered into for the purpose of getting insurers, including the City's health plans and workers' compensation program, to pay for opioids.

462. Defendants' common scheme was carried out through their own efforts and through their influence over Front Groups, KOLs, and CMEs. Defendants' nearly-identical marketing efforts demonstrate their level of coordination, as does their active and common

participation in the Pain Care Forum and other projects like it. Through funding and other means, Defendants were able to (and did) exert control over Front Groups and KOLs and cause them to issue false and misleading information favoring their products in ostensibly-neutral publications like CMEs. The result was an unrelenting stream of misleading information about the risks of using opioids to treat chronic pain from sources Defendants knew were trusted by doctors.

463. Because of the Defendants' scheme, doctors 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. Opioids, however, are not "medically necessary" or "reasonably required" to treat chronic pain. Yet doctors, pharmacists, and/or other agents of the health plans explicitly or implicitly certified to the City that such prescriptions were "medically necessary" and "reasonably required" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic pain. Moreover, many of the prescriptions written by physicians 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.

464. 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.

465. Defendants' misrepresentations were material because if the City had known of the false statements disseminated by Defendants in support of opioids and that doctors,

pharmacies, 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.

466. 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.

467. By virtue of the above-described acts, Defendants conspired to defraud the City by getting a false or fraudulent claim allowed or paid.

468. 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.

469. 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.

470. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has spent more than $9.5 million during this period to pay for over 400,000 prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

471. Each Defendant is responsible for the claims submitted and the amount the City spent on its opioids.

472. Because Defendants acted concurrently and/or collaboratively in carrying out a common fraudulent scheme—causing others to submit false claims for opioids which were paid

by the City—Defendants are jointly and severally liable for the City's total spend on opioids prescribed to treat chronic pain, which are neither "medically necessary" nor "reasonably required."

473. 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 instance Defendants 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 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 SIX

RECOVERY OF CITY COSTS OF PROVIDING SERVICES VIOLATIONS OF THE MCC § 1-20-020 AGAINST ALL DEFENDANTS

474. 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.

475. 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.

476. The defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

a. violating MCC § 2-25-090;

b. violating MCC § 4-276-470;

c. violating MCC § 1-21-010;

d. violating MCC § 1-22-020;

e. violating MCC § 1-20-020;

f. violating 720 ILCS § 5/17-10.5;

g. violating 21 U.S.C. § 331(a);

h. committing common law fraud; and

i. committing common law unjust enrichment.

477. The City has incurred costs reasonably related to Defendants' violations of federal, state, or local laws.

478. The City has incurred the costs of paying for opioids prescribed for chronic pain and related costs through its health plans, and these costs are reasonably related to Defendants' unlawful scheme.

479. The City's health plans have paid costs that include, but are not limited to, the costs immediately associated with prescribing opioids, such as doctors' visits and toxicology screens to monitor patients' drug-taking, as well as other 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, and more. In

addition, Defendants have imposed upon the City costs beyond its health plans, such as providing emergency services, funding addiction treatment, and paying other costs imposed by 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 Six of the Complaint; (b) compelling Defendants to pay the costs the City incurred that were reasonably related to the 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.

XI. COUNT SEVEN

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

480. 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.

481. 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.

482. 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.

483. Through their illegal and deceptive promotion of opioids, Defendants knowingly caused false claims to be made to the City's health plans and workers' compensation program, which are self-insured, and knowingly obtained or caused to be obtained through deception the property of the City in payments for those false claims.

484. The 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. Therefore, each claim for reimbursement to the City for chronic opioid therapy is the direct result of Defendants' marketing, which presented to doctors false information about the risks, benefits, evidence for, and superiority of opioids for the long-term treatment of pain.

485. 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. Opioids, however, are not "medically necessary" or "reasonably required" to treat chronic pain.

486. Doctors, pharmacists, or other agents of the health plans or workers' compensation program, explicitly or implicitly certified to the City that such prescriptions were "medically necessary" and "reasonably required" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic pain. Moreover, many of the prescriptions written by physicians 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.

487. The misrepresentations were material because if the City had known of the false statements disseminated by Defendants and that doctors, pharmacies, 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.

488. 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.

489. By reason of Defendants' insurance fraud, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has spent more than $9.5 million during this period to pay for over 400,000 prescriptions and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic pain.

490. 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 Seven 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.

XII. COUNT EIGHT

CIVIL CONSPIRACY
VIOLATIONS OF THE COMMON LAW PROHIBITION AGAINST CIVIL CONSPIRACY
AGAINST ALL DEFENDANTS

491. 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.

492. Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner.

493. Defendants' common scheme was carried out through their own efforts and through their influence over Front Groups, KOLs, and CMEs. Defendants' nearly-identical marketing efforts demonstrate their level of coordination, as does their active and common participation in the Pain Care Forum and other projects like it. Through funding and other means, Defendants were able to (and did) exert control over Front Groups and KOLs and cause them to issue false and misleading information favoring their products in ostensibly-neutral publications like CMEs. The result was an unrelenting stream of misleading information about the risks of using opioids to treat chronic pain from sources Defendants knew were trusted by doctors.

494. The defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

a. violating MCC § 2-25-090;

b. violating MCC § 4-276-470;

c. violating MCC § 1-21-010;

d. violating MCC § 1-22-020;

e. violating MCC § 1-20-020;

f. violating 720 ILCS § 5/17-10.5;

g. violating 21 U.S.C. § 331(a);

h. committing common law fraud; and

i. committing common law unjust enrichment.

495. By reason of the 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.

496. 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 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.

XIII. COUNT NINE

COMMON LAW FRAUD AGAINST ALL DEFENDANTS

497. 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.

498. Defendants made false statements of material fact that they knew were false to induce the City to act; the City relied on Defendants' false statements, relied on others who relied on Defendants' false statements, or both; and was damaged as a result.

499. 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 consumers and payors of opioid prescriptions to rely on those omissions and concealments.

500. Defendants engaged in this scheme because they intended prescription drug payors, including the City, to rely on its statements about the risks, benefits, and superiority of opioids to treat chronic pain and rely on its omissions about the risks of long-term opioid use.

501. The City relied on Defendants' statements or relied on others who relied on Defendants' statements about the risks, benefits, and superiority of opioids for the treatment of chronic pain when it paid for prescriptions for opioids to treat chronic pain. Had the City known about the false statements disseminated by Defendants in support of opioids for chronic pain, the City would have refused to authorize payment for such opioid prescriptions.

502. By reason of the Defendants' fraud, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has spent more than $9.5 million during this period to pay for over 400,000 prescriptions and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic pain.

503. 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 Nine of the Complaint; (b) compelling Defendants to pay restitution of any money acquired as a result of Defendants' fraud; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; (d) compelling Defendants to pay punitive damages because their false representations were

wantonly and designedly made; and (e) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XIV. COUNT TEN

UNJUST ENRICHMENT

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

504. 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.

505. 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.

506. By illegally and deceptively promoting opioids to treat chronic pain, Defendants have unjustly enriched themselves at the City's expense. The City has made payments for opioid prescriptions and treatments, 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.

507. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in 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.

XV. COUNT ELEVEN

SUBROGATION AGAINST ALL DEFENDANTS

508. 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.

509. The City has a self-funded medical benefits plan ("City Health Plan"), which provides payments for medical benefits such as prescription drugs, hospitalization, and physician treatment to its current and retired employees and their family members (called "Participants" under the Plan).

510. Under the Plan, the City has a right of reimbursement or subrogation for any payment of a medical benefit provided to a Participant arising out of any injury caused by a third party. Specifically, a Plan provision states:

> In the event the Plan provides benefits for injury, illness, medical care or other Loss ("the injury") to any person, the Plan is subrogated to all present and future rights of recovery that person, his parents, heirs, guardians, executors, or other representatives (individually and collectively called the "Participant") may have arising out of the injury.

511. Under the foregoing Plan provision, the City is subrogated to each Plan Participant's right of recovery against Defendants for injuries caused by the Defendants' conduct, as alleged in the foregoing paragraphs of the First Amended Complaint, with respect to the costs of prescription drugs, treatment, and hospitalization that were caused by Defendants' conduct and for which the Plan made payment.

512. The City also provides reimbursement for medical benefits under its workers' compensation program and is subrogated to each participant's right of recovery against Defendants for injuries caused by Defendants.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Eleven; (b) compelling Defendants to reimburse the City for all treatment costs caused by Defendants' conduct and for which the Health Plan and/or the City's workers' compensation program made payment; (c) compelling Defendants to pay court costs; and (d) awarding the City such other, further, and different relief as the Court may deem just.

DATED: October 20, 2014.

Respectfully submitted,

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