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IN THE THIRD DISTRICT COURT

FOR SALT LAKE COUNTY, STATE OF UTAH

SALT LAKE COUNTY,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; ALLERGAN FINANCE, LLC (f/k/a ACTAVIS, INC.); WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; LYNN R. WEBSTER, MD; RUSSELL K. PORTENOY, MD; AND DOES 1 THROUGH 100, INCLUSIVE,

Defendants.

COMPLAINT AND JURY DEMAND

Civil No._____

The Honorable_____

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. JURISDICTION AND VENUE 7

III. PARTIES 7

A. Plaintiff 7

B. Defendants 7

IV. FACTUAL ALLEGATIONS 11

A. Manufacturing Defendants Used Every Available Avenue to Disseminate Their False and Deceptive Statements About Opioids. 11

1. Manufacturing Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded opioids. 12

2. Manufacturing Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids. 15

a. Key Opinion Leaders ("KOLs") 16

(1) Defendant Lynn Webster 18

(2) Defendant Russell Portenoy 25

b. Front Groups 28

(1) American Pain Foundation ("APF") 31

(2) American Academy of Pain Medicine 33

(3) Defendants coordinated and worked together through Front Groups. 36

B. Defendants' Marketing Scheme Misrepresented the Risks and Benefits Of Opioids. 37

1. Defendants falsely trivialized or failed to disclose the known risks of long-term opioid use. 37

2. Defendants grossly overstated the benefits of chronic opioid therapy. 51

3. Defendants also engaged in other unlawful, unfair, and fraudulent misconduct. 57

C. Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations. 58

D. Although Defendants Knew That Their Marketing of Opioids Was False and Deceptive, They Fraudulently Concealed Their Misconduct. 58

E. Defendants Have Created a Public Nuisance.....60

1. The Deceptive Marketing and Promotion of Opioids Foreseeably Led to Opioid Abuse that has Wrought Havoc on Salt Lake County Communities.60

2. Defendants Knew and Should Have Known That Their Conduct Would Lead to Overprescribing and Catastrophic Human and Economic Costs..71

3. Defendants' Conduct Is Not Excused by the Actions of Any Third Parties.71

F. Defendants' Fraudulent Marketing Has Led To Record Profits. 72

G. Defendants' Fraudulent Marketing Has Caused Salt Lake County Substantial Economic Injury.....72

V. CAUSES OF ACTION 75

FIRST CAUSE OF ACTION: PUBLIC NUISANCE UTAH CODE ANN. § 76-10-801 ET SEQ. (AGAINST ALL DEFENDANTS).....75

SECOND CAUSE OF ACTION: PUBLIC NUISANCE UTAH COMMON LAW (AGAINST ALL DEFENDANTS) 76

THIRD CAUSE OF ACTION: UTAH CONSUMER SALES PRACTICES ACT ("UCSPA") UTAH CODE ANN. § 13-11-1 ET SEQ. (AGAINST MANUFACTURING DEFENDANTS).....77

FOURTH CAUSE OF ACTION: COMMON LAW FRAUD (AGAINST ALL DEFENDANTS)84

FIFTH CAUSE OF ACTION: CIVIL CONSPIRACY (AGAINST DEFENDNTS PURDUE, JANSSEN, ENDO, LYNN WEBSTER, AND RUSSELL PORTENOY).....92

SIXTH CAUSE OF ACTION: UNJUST ENRICHMENT (AGAINST MANUFACTURING DEFENDANTS).....93

PRAYER FOR RELIEF 94

JURY DEMAND.....95

Plaintiff Salt Lake County, by Salt Lake County District Attorney Sim Gill and as authorized by Salt Lake County Mayor Ben McAdams, files this Complaint and alleges as follows:

I. INTRODUCTION

1. The opioid epidemic gripping Utah has grown into a public health crisis of historic proportions. At least one Utahn fatally overdoses on opioids every day, and widespread opioid abuse is devastating families and tearing at the fabric of Utah communities.

2. Although no region of the State has been untouched by this crisis, Salt Lake County has been disproportionately affected. The numbers are striking. Nearly half of all fatal opioid overdoses in Utah annually occur in Salt Lake County; here, 531 opioid overdoses occurred in 2014-2015 alone—roughly one every 33 hours. More than one third of all Utah emergency department encounters linked to opioids are reported by facilities operating in Salt Lake County. And while opioid-related crime is on the rise across the State, much of it has occurred in Salt Lake County urban encampments, like the Rio Grande area of downtown Salt Lake City, where opioid abusers congregate to become both the victimizers of others and the victims of drug dealers who prey on their addictions.

3. As this crisis has evolved, Salt Lake County has pursued a range of remedial initiatives, including innovative drug diversion programs (like Operation Diversion in 2016) and law enforcement crackdowns (like Operation Rio Grande in 2017 to today), in which opioid abusers are offered treatment, supervision and case management at public expense. Salt Lake County also has implemented intensive treatment programs in its jail facilities, both to care for detainees in the thralls of opioid withdrawal and to provide ongoing medically assisted treatments to support their recovery. Outside the jail, Salt Lake County has funded a range of public health programs addressing opioid abuse, including community treatment facilities and

needle disposal sites, while also expending substantial sums outfitting local law enforcement officers with Naloxone, a drug specifically designed to arrest and reverse opioid overdoses.

4. These efforts, and others, have saved countless Salt Lake County lives and given a second chance to numerous individuals swept into the criminal justice system as a result of their opioid addiction. But there is more work to be done.

5. The Utah Department of Human Services in 2017 developed an index that draws on opioid mortality and morbidity data to rank Utah counties based on the severity of the opioid-related issues they confront.[1] The purpose of this study was to identify those Utah counties most in need of resources to combat opioid abuse. On this index, Salt Lake County ranks second among all Utah counties, topped only by Carbon County.

Utah Counties Ranked Highest to Lowest Based on Opioid Mortality and Morbidity Index	
County	**Index Score**
Carbon	1.9971875
Salt Lake	**1.1817145**
Weber	0.69898
Tooele	0.6622465
Emery	0.6403785
Duchesne	0.438872
Utah	0.2257305
Washington	0.0223215
Morgan	-0.016289
Box Elder	-0.056396
Kane	-0.073293
Juab	-0.1185665
Davis	-0.1471655
Iron	-0.27035
Uintah	-0.309091
Sanpete	-0.438246
Cache	-0.6334995
Summit	-0.6958145
Sevier	-0.8067115
Wasatch	-0.8141125
Piute	-1.487913

[1] Utah Department of Human Services, Division of Substance Abuse and Mental Health, *Utah's Opioid Crisis Consequence and Resource Assessment* (July 2017) at 7.

6. Salt Lake County thus has not only already devoted a substantial segment of its taxpayer-funded financial resources toward combatting opioid abuse, but additional resources and even more comprehensive efforts plainly are needed to stem the tide.

7. While this burden has fallen on Salt Lake County, it was born from the misconduct of others who must be held accountable for their role. As more fully detailed below, and as Salt Lake County's investigation amply demonstrates, Utah's opioid crisis stems directly from a callously deceptive marketing scheme that was spearheaded by certain opioid manufacturers ("Manufacturing Defendants"[2]) and perpetuated by prominent doctors they bankrolled, including Defendants Lynn Webster, MD and Russell Portenoy, MD.

8. Prior to this marketing scheme, the prevailing view in the medical community was that opioids, while appropriate for treating short-term acute pain and providing palliative (end-of-life) care, were too addictive and debilitating to be prescribed for chronic pain (like back pain, migraines and arthritis).[3] This reasoned consensus effectively locked Manufacturing Defendants out of a particularly lucrative segment of patients who, by virtue of their chronic ailments, required prolonged treatment. To tap into this market, Manufacturing Defendants had to convince doctors nationwide, including in Utah, that the prevailing understanding of opioids was unfounded and that chronic pain patients not only could, but should, be prescribed opioids long-term.

9. To accomplish this, each Manufacturing Defendant spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain. As to the risks,

[2] Namely Defendants Purdue Pharma L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc., Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Allergan PLC f/k/a Actavis PLC, Allergan Finance, LLC f/k/a Actavis Inc., Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

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

Manufacturing Defendants falsely and misleadingly, and sometimes contrary to the language of their drugs' labels: (a) downplayed the serious risk of addiction; (b) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (c) exaggerated the effectiveness of screening tools in preventing addiction; (d) claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher opioid dosages; and (f) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Simultaneously, Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support these claims.

10. Manufacturing Defendants disseminated these messages in Utah directly, both through their sales representatives and in speaker groups led by physicians recruited by Manufacturing Defendants. Borrowing a page from Big Tobacco's playbook, Manufacturing Defendants also worked through third parties they controlled, including (a) "key opinion leaders" ("KOLs") in the medical community like Defendants Dr. Webster and Dr. Portenoy, and (b) seemingly neutral and credible professional societies and patient advocacy groups ("Front Groups"). Manufacturing Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Manufacturing Defendants persuaded doctors and patients that what they had long known—*i.e.*, that opioids are addictive and unsafe in most circumstances for long-term use—was untrue and, quite the opposite, that the compassionate treatment of pain required opioids.

11. Salt Lake County was particularly influenced by this marketing scheme through the efforts of Defendant Dr. Webster, a KOL based out of Salt Lake County. After founding the

Salt Lake County-based Lifetree Pain Clinic in 1990, Dr. Webster received millions of dollars in consulting fees and other funds from opioid manufacturers. Taking cues from Defendant Dr. Portenoy—a KOL of unparalleled national prominence—Dr. Webster has pursued a career in Salt Lake County, continuing to this day, of overstating the benefits and minimizing the risk of chronic opioid therapy.

12. Working as a paid consultant for the opioid industry, Dr. Webster has perpetuated a host of misconceptions, including the debunked concept of "pseudoaddiction." Dr. Webster also created what he styled the "Opioid Risk Tool," a one-minute screening that purportedly enables doctors to expediently identify patients likely to become addicted to opioids. Whatever its intended objective, the Opioid Risk Tool has promoted more liberal prescribing practices by giving doctors the false impression that, with just a few questions asked, opioids can be freely prescribed without endangering patients. This is precisely why the Opioid Risk Tool has been found on websites operated by Manufacturing Defendants.

13. In 2010, the DEA raided Dr. Webster's Salt Lake County clinic and, although the U.S. Attorney ultimately elected not to bring charges, the investigation revealed that more than 20 of Dr. Webster's patients died of opioid overdoses under his "care." Undeterred, Dr. Webster continues to receive substantial funding from opioid manufacturers and, as a paid consultant, mislead the medical community as to the efficacy of opioids while criticizing efforts to curtail opioid prescribing in Salt Lake County and nationwide.

14. Tragically, Defendants' collective efforts to promote chronic opioid treatment have been wildly successful, particularly in Utah. The data are astounding. In recent years, Utah's opioid prescribing rate—that is, the number of opioid prescriptions dispensed per capita—has hovered around 90%. This means that, every year, there are enough opioids prescribed in the State to supply nine out of every ten Utahns with one prescription each. Here

again, Salt Lake County has been disproportionately affected, with Salt Lake County opioid prescribing rates exceeding the State average in nine out of the last ten years.

15. Alarming as they are, these statistics do not illustrate fully the harm prescription opioid abuse has caused Salt Lake County communities. The dramatic increase in opioid prescriptions to treat chronic pain has resulted in a population of addicts who seek opioids wherever they can be obtained. Efforts by Salt Lake County physicians to reverse course for these patients are thwarted by illicit distribution channels in which diverted prescription opioids can be readily obtained. These addicts also are turning increasingly to heroin, which provides a similar euphoria at a fraction of the cost. Studies show that nearly 80% of heroin addicts nationwide started with prescription drugs. In Utah, there were 166 heroin overdoses in 2016, a more than 300% increase from 2007.

16. Salt Lake County recognizes that a significant number of patients suffer from chronic pain, a condition that may take an enormous toll on their health, lives and families. These patients deserve both appropriate care and the ability to make decisions, including when appropriate the decision to treat their pain with opioids, based on accurate and complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign has deprived, and continues to deprive, these patients and their doctors of the ability to make fully-informed medical decisions and, instead, has caused important and sometimes life-or-death decisions to be made based on hype rather than science.

17. Defendants' conduct also has exacted a foreseeable financial burden on Salt Lake County, which itself has spent substantial sums on opioid prescriptions for its insured employees and their dependents, along with millions of additional dollars on addiction treatment and other programs aimed at curbing the crisis for the Salt Lake County citizenry. And this is only the beginning. Eradicating opioid abuse and its devastating consequences will require an enormous further outlay of public health and law enforcement resources at the county level. These

abatement costs are directly attributable to Defendants' marketing scheme and the flood of opioids it unleashed on the region.

18. With this action Salt Lake County seeks to hold Defendants accountable, individually and collectively, for creating a public nuisance in violation of Utah Code Ann. § 76-10-806 and the common law, engaging in deceptive acts and practices in violation of the Utah Consumer Sales Practices Act, committing common law fraud, participating in a civil conspiracy, and unjustly enriching themselves at Salt Lake County's expense. Salt Lake County seeks all remedies available, including injunctive relief, damages, restitution, and abatement.

II. JURISDICTION AND VENUE

19. This Court has jurisdiction over this case under Utah Code Ann. § 78A-5-102(1).

20. This Court has personal jurisdiction over Defendants under Utah Code Ann. § 78B-3-205 because they transact business, supply services and goods, and have caused injury within the State of Utah.

21. Venue is proper in Salt Lake County pursuant to Utah Code Ann. § 78B-3-307.

III. PARTIES

A. Plaintiff

22. Plaintiff Salt Lake County is a political subdivision of the State of Utah.

B. Defendants

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

24. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States

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

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

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

27. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal

place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.")

28. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States and Salt Lake County. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States and Salt Lake County, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

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

Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.")

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

31. LYNN R. WEBSTER is a Utah resident and physician licensed to practice medicine in the state of Utah. Dr. Webster has received substantial funding from opioid manufacturers and has actively promoted the use of opioids to treat chronic pain in Salt Lake County and across the country. Dr. Webster currently serves as the vice president of scientific affairs at PRA Health Sciences, a research center located in Salt Lake County that conducts clinical trials for pharmaceutical products.

32. RUSSELL K. PORTENOY is a New York resident and physician licensed to practice medicine in the state of New York. Dr. Portenoy has received substantial funding from opioid manufacturers and has actively promoted the use of opioids to treat chronic pain in Salt Lake County and across the country. Dr. Portenoy currently serves as the executive director of the MJHS Institute for Innovation in Palliative Care and as chief medical officer at MJHS Hospice and Palliative Care.

33. Salt Lake County lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive, and they are therefore sued herein pursuant to Rule 9(a)(2) of the Utah Rules of Civil Procedure. Salt Lake County will amend this Complaint to show their true names and capacities if and when they are ascertained. Salt Lake County is informed and believes, and on such information and belief alleges, that each of the

Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

IV. FACTUAL ALLEGATIONS

34. Before the 1990s, generally accepted standards of medical practice dictated that opioids should be used only for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

35. Tens of millions of Americans suffer from and seek treatment for chronic pain. To take advantage of the lucrative market for chronic pain patients, each Manufacturing Defendant developed a well-funded marketing scheme based on deception. Each Manufacturing Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use. These statements were unsupported by or contrary to the scientific evidence, and they are also contrary to pronouncements by and guidance from the United States Food and Drug Administration ("FDA") and Centers for Disease Control and Prevention ("CDC") based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

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

36. Manufacturing Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Salt Lake County. Manufacturing Defendants also bankrolled and controlled professional societies and other

ostensibly neutral third parties in order to lend these deceptive statements an artificial veneer of independence and scientific legitimacy.

1. Manufacturing Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded opioids.

37. Manufacturing Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturing Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Manufacturing Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

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

39. Second, each Manufacturing Defendant promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual doctors and medical staff in their offices—and small-group speaker programs. Manufacturing Defendants have not corrected this misinformation. In 2014 alone, Manufacturing Defendants spent $154 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $10 million by Endo, and $2 million by Actavis.

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

41. Manufacturing Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Manufacturing Defendants. These speaker programs provided: (a) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (b) recognition and compensation for the doctors selected as speakers; and (c) an opportunity to promote the drug through the speaker to his or her peers. They were also one of the key ways Manufacturing Defendants' messages were disseminated as medical knowledge: these speakers give the false impression that they are providing unbiased and medically accurate presentations when they

were, in fact, presenting a script prepared by Manufacturing Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Manufacturing Defendants' prior misrepresentations about the risks and benefits of opioids.

42. Even without such studies, Manufacturing Defendants purchase, manipulate and analyze some of the most sophisticated data available in *any* industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Manufacturing Defendants *know* their detailing to doctors is effective.

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

44. Manufacturing Defendants ensured and continue to ensure marketing consistency nationwide through: (a) national and regional sales representative training; (b) national training of local medical liaisons, the company employees who respond to physician inquiries; (c) centralized speaker training; (d) single sets of visual aids, speaker slide decks, and sales training materials; and (e) nationally coordinated advertising. Manufacturing Defendants' sales

representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

45. In February 2018, with legal challenges mounting, Purdue announced that it would cease detailing physicians in respect to Purdue's branded opioids. Purdue did not, however, make any commitment to correct the misrepresentations its multi-decade detailing campaign has engendered in the medical community. Nor did Purdue commit to cease other deceptive marketing tactics, including the practice addressed below of laundering promotional messages through front groups and other ostensibly unbiased third parties. Far from reversing course, Purdue has indicated it will aggressively promote its drugs that treat opioid-induced constipation—drugs that can be profitable only if opioids are widely prescribed.

2. Manufacturing Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids.

46. Manufacturing Defendants also deceptively marketed opioids in Salt Lake County through unbranded advertising—*i.e.*, advertising promoting opioid use generally but not naming a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Manufacturing Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Manufacturing Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Manufacturing Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, and

CMEs, and at medical conferences and seminars. To this end, Manufacturing Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

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

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

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

a. Key Opinion Leaders ("KOLs")

49. Manufacturing Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Manufacturing Defendants because they had expressed support for using opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

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

51. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Manufacturing Defendants created opportunities for KOLs to participate in research studies that Manufacturing Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Manufacturing Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

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

53. Doctors are one of the most important avenues that Manufacturing Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Manufacturing Defendants know that doctors generally rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with

Purdue that through March 2015, the Purdue website *In the Face of Pain* (www.inthefaceofpain.com (discontinued Oct. 1, 2015)) failed to disclose that doctors who provided testimonials on the site were paid by Purdue. The settlement further concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

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

(1) Defendant Lynn Webster

55. Of the KOLs Manufacturing Defendants utilized, Defendant Lynn Webster has been one of the most influential, particularly in Salt Lake County where he is based. Dr. Webster founded the Lifetree Pain Clinic in Salt Lake City in 1990, serving as its CEO and medical director. In 2003, Dr. Webster expanded his operation by co-founding Lifetree Clinical Research, which provided drug development services to pharmaceutical clients. In 2013, Dr. Webster became the president of the American Academy of Pain Management (AAPM), a front group for the opioid industry (discussed further below), and he remained on AAPM's board of directors for a period thereafter. Dr. Webster also has served, and continues to serve, as a senior editor for *Pain Medicine*, a journal that sells advertising space to Manufacturing Defendants and has published an assortment pieces overstating the therapeutic benefits of treating chronic pain with opioids.

56. In these various capacities, Dr. Webster authored numerous studies and CMEs supporting chronic opioid treatment, and many of these were directly funded by opioid

manufacturers. As Dr. Webster's stature grew, Salt Lake County became a sort of "mecca" for opioid advocates and their backers in the pharmaceutical industry.[4] Dr. Webster was handsomely rewarded for his efforts. Between 2009 and 2013, he received nearly $2 million from opioid manufacturers.[5] In 2013, the Salt Lake Tribune reported that Dr. Webster was ranked "among the top 50 for single largest payments received" from pharmaceutical companies, "behind marquee hospitals, such as the Mayo Clinic, Cleveland Clinic and Duke and Harvard Universities."[6] LifeTree Research, co-founded by Dr. Webster, received an additional $3.4 million in drug company payments between 2009 and 2013.[7]

57. Dr. Webster's advocacy of opioids was designed to create a veneer of impartiality. But Dr. Webster was a forceful proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indicators of undertreated pain. The only way to differentiate the two, Dr. Webster claimed, was to *increase* a patient's dose of opioids. As he wrote in his book *Avoiding Opioid Abuse While Managing Pain* (2007), which is still available, when facing signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors and all Manufacturing Defendants latched onto the pseudoaddiction concept it articulated. Although Dr. Webster has since moderated his support for pseudoaddiction, the concept lingers in the pain management community and continues to be used to justify aggressive opioid treatment for the most vulnerable patients.

[4] Sam Quinones, Dreamland: The True Tale of America's Opiate Epidemic (Bloomsbury Press 2015), at 94.

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

[6] Kristen Steward and Jennifer Dobner, *Utah doctors paid $ 25.8 million by drug companies*, Salt Lake Tribune (March 12, 2013), available at: http://archive.sltrib.com/article.php?id=55962410&itype=CMSID.

[7] *Id.*

58. Another devastating contribution of Dr. Webster's is the so-called "Opioid Risk Tool," a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to assess and manage the risk that their patients will become addicted to opioids. In developing the Opioid Risk Tool, Dr. Webster claimed it "exhibited a high degree of sensitivity and specificity for determining which individuals are at risk for opioid-related, aberrant behaviors."[8] Regardless of Dr. Webster's understanding in developing the tool, this asserted ability to pre-sort at-risk patients gave doctors—particularly busy primary care doctors who are most often consulted for pain—confidence to prescribe opioids long-term. It is thus little surprise that the tool has been aggressively promoted by Manufacturing Defendants, with versions of it appearing on websites run by Endo, Janssen, and Purdue. Advising the Utah Department of Health, Dr. Webster also was successful in incorporating the Opioid Risk Tool into Utah's Clinical Guidelines on Prescribing Opioids for Treatment of Pain, first published in 2009.[9] Tellingly, opioid prescribing rates in Utah have increased since those guidelines were published.[10]

59. Although widely popular, the Opioid Risk Tool has been proven ineffective. The CDC has advised, in particular, that all known opioid addiction screening tools—including Dr. Webster's Opioid Risk Tool—show "insufficient accuracy for classification for patients as at low or high risk for abuse or misuse."[11] And among risk-assessment tools, the CDC singled out Dr. Webster's as being "extremely inconsistent."[12] By giving doctors the false impression that opioids can be safely prescribed to a "screened" population, the Opioid Risk Tool gave opioid

[8] Lynn Webster, *Predicting aberrant behaviors in opioid-treated patients: Preliminary validation of the Opioid Risk Tool, Pain Medicine* (2005), abstract available at: https://www.ncbi.nlm.nih.gov/pubmed/16336480.

[9] *Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain*, Utah Department of Health (2009), available at: http://health.utah.gov/prescription/pdf/guidelines/final.04.09opioidGuidlines.pdf.

[10] Utah Department of Health, Violence & Injury Prevention Program, *Opioid Prescribing Practices in Utah, 2002-2015* (April 2016), at 11.

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

[12] *Id.*

manufacturers their Trojan horse—a catalyst for risky prescribing that could be billed as a risk-management tool for conscientious practitioners.

60. While Dr. Webster was deceptively promoting chronic opioid treatment, he also maintained an active pain practice at his Lifetree Pain Clinic in Salt Lake City. At least 20 patients under Dr. Webster's care died of opioid overdoses, and subsequent lawsuits have revealed the staggering quantity of opioids these patients received.[13]

61. As but one example, one of Lifetree's patients, Tina Webb, was prescribed 32 pain pills a day, and as many as 296 over an eight-day stretch.[14] Within months of beginning this "treatment" regime at Lifetree, Ms. Webb began behaving erratically, falling asleep in the middle of meals and gasping for air in the night. After Ms. Webb crashed her car into her family's home, her husband confronted Lifetree to complain about the prescriptions she was receiving, but little changed. Ms. Webb then took the initiative and attempted to wean herself off opioids, but agonizing withdrawal symptoms led her back to Lifetree where she received a new prescription and fatally overdosed shortly thereafter.

62. Ms. Webb's story is not unique. Another deceased patient of Dr. Webster's, Carol Ann Bosley, was prescribed a six-fold increase in medication in the year before she overdosed, at which point she was receiving approximately 600 pain and anti-anxiety pills per month.[15] Ms. Bosley's husband complained to Lifetree that she was exhibiting signs of addiction and abuse, including passing out mid-meal and having difficulty conducting ordinary

[13] Although Dr. Webster's management of the Lifetree clinic illustrates the effect of his messaging on actual prescribing practices, Salt Lake County asserts no claim against Dr. Webster arising from his medical practice. The claims against Dr. Webster relate solely to his participation, as a KOL and otherwise, in Manufacturing Defendants' deceptive marketing campaign.

[14] Jesse Hyde and Daphne Chen, *The untold story of how Utah doctors and Big Pharma helped drive the national opioid epidemic*, Deseret News (Oct. 26, 2017), available at: https://www.deseretnews.com/article/900002328/theuntold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html.

[15] Stephanie Smith, *Prominent pain doctor investigated by DEA after patient deaths*, CNN (Dec. 20, 2013), available at: http://www.cnn.com/2013/12/20/health/pain-pillar/index.html.

conversations.[16] Nothing changed. When Ms. Bosley was unable to produce pills that should have been left over from a prior prescription, a nurse operating under Dr. Webster's pseudoaddiction theory concluded Ms. Bosley was not addicted but was instead overusing her medication because of untreated pain.[17] Ms. Bosley overdosed on opioids and died in November 2009.

63. Lifetree shut down in 2010 after it was raided by DEA agents who discovered an entire file cabinet labeled "deceased patients."[18] Within an hour, Dr. Webster had received calls from doctors in other parts of the country who were aware of the raid. How did they know? They knew because there were pharmaceutical representatives present in Dr. Webster's clinic when the DEA entered, and these representatives called their colleagues across the country who, likewise, were visiting pain clinics and other facilities to push their drugs.[19]

64. Although Dr. Webster ultimately was not charged with any crime, the Deseret News has reported that DEA agents believed there was sufficient evidence to prosecute Dr. Webster, and one agent described the case's termination as the most frustrating event of his career.[20] Dr. Webster has taken no responsibility, claiming that the overdose deaths at his clinic were "not as a result of treatment, but in spite of it."[21]

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[16] Jesse Hyde and Daphne Chen, *The untold story of how Utah doctors and Big Pharma helped drive the national opioid epidemic*, Deseret News (Oct. 26, 2017), available at: https://www.deseretnews.com/article/900002328/theuntold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html.

[17] *Id*.

[18] *Id*.

[19] Lynn Webster, *The Painful Truth: What Chronic Pain is Really Like and Why it Matters to Each of Us* (2015) at 145.

[20] Jesse Hyde and Daphne Chen, *The untold story of how Utah doctors and Big Pharma helped drive the national opioid epidemic*, Deseret News (Oct. 26, 2017), available at: https://www.deseretnews.com/article/900002328/theuntold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html.

[21] Lynn Webster, *Intimidating doctors won't solve the chronic pain epidemic*, (Aug. 11, 2014), available at: https://www.kevinmd.com/blog/2014/08/intimidating-doctors-wont-solve-chronic-pain-epidemic.html.

65. Today, Dr. Webster no longer treats patients. He does, however, still function as a mouthpiece for opioid manufacturers' agenda, who continue to pay him significant sums in consulting and other fees. Between 2013 and 2015, Dr. Webster received more than $150,000 from drug companies, much of it from manufacturers of opioids.[22]

66. Among the misconceptions Dr. Webster continues to promote is the notion that at-risk patients can be expediently prescreened before commencing opioids treatment. In his 2015 book *The Painful Truth: What Chronic Pain is Really Like and Why it Matters to Each of Us* ("Painful Truth"), Dr. Webster claimed there are just "four simple guidelines to follow if you want to avoid the risk of becoming addicted to opioids," one of them being the Opioid Risk Tool he developed.[23] The book invites readers to calculate their own "addiction risk level" by visiting Dr. Webster's website and clicking on the Opioid Risk Tool link. In addition, although Dr. Webster has attempted to walk back his support of "pseudoaddiction," he continues to invoke its faulty logic, claiming, for example, that many opioid overdose deaths are not the result of overprescribing but in fact suicides caused by "inadequately treated emotional and physical pain."[24]

67. Dr. Webster also has emerged as a vocal critic of recent efforts to limit opioid prescribing. In September 2017, for example, Dr. Webster criticized as "wrong" CVS Caremark's decision to reduce opioid prescribing by aligning reimbursement policies with CDC guidelines.[25] In December 2017, Dr. Webster published an article on his website claiming that the term "opioid crisis" is a misnomer arising from an "anti-opioid movement" and that the CDC has inappropriately linked heroin deaths to prescription opioids, notwithstanding overwhelming

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

[23] *Painful Truth*, at 77-78; *see also* Lynn Webster, *Emotional Trauma Affects Boys and Girls Differently: What You Need to Know*, available at: http://thepainfultruthbook.com/2016/11/emotional-trauma-affects-boys-and-girls-differently-what-you-need-to-know/.

[24] @DrLynnWebster, Facebook (Jan. 24, 2018 at 9:55am), available at: https://www.facebook.com/DrLynnWebster.

[25] @LynnRWebsterMD, Twitter (Dec. 7, 2017, 1:45pm), available at: https://twitter.com/LynnRWebsterMD/status/938887130545360898.

evidence showing that most heroin users start with prescription drugs.[26] More recently, when the Centers for Medicare & Medicaid Services (CMS) announced plans to monitor doctors who may be inappropriately or fraudulently overprescribing opioids, Dr. Webster blasted the proposal as "deeply flawed."[27]

68. Similarly, Dr. Webster has criticized DEA efforts to curb the flow of opioids and monitor suspicious prescribing patterns. He claims that doctors who have been arrested or prosecuted for overprescribing opioids were simply "trying to help patients the best way they know how" and that the authorities are engaging in "intimidation tactics" as a means of altering doctors' practices.[28]

69. Dr. Webster also continues to serve as an apologist for his pharmaceutical sponsors. As recently as March 2018, Dr. Webster criticized an article that attributed the opioid crisis in part to advertising by pharmaceutical companies. The article was "misleading," Dr. Webster claimed, because pharmaceutical companies "do[] not target the public" and do not "spend a lot of money" promoting opioids.[29] Both assertions are false. In fact, pharmaceutical companies routinely promote their drugs in brochures and other materials intended for public consumption, and they have spent enormous sums on these and other promotional efforts.

70. In an effort to counteract legislative initiatives to curb opioid prescribing, Dr. Webster's website even invites people to write congress using a provided form letter. The letter contains a prompt to describe "your story and how opioid treatments benefit you or your loved

[26] Lynn Webster, Gaslighting the Public (Dec. 30, 2017), available at: http://thepainfultruthbook.com/2017/12/gaslighting-the-public/.

[27] @LynnRWebsterMD, Twitter (Jan. 28, 2018 at 9:01 am), available at: https://twitter.com/LynnRWebsterMD/status/957659807137267713.

[28] *Painful Truth*, at 146, 154.

[29] DrLynnWebster, Facebook (March 27, 2018 at 12:20 pm), available at: https://www.facebook.com/DrLynnWebster.

one," but does not invite any description of the harms opioids have caused patients, their loved ones, or the community at large.[30]

(2) Defendant Russell Portenoy

71. Dr. Webster did not operate in a vacuum. He built upon the work of other KOLs supported by Manufacturing Defendants, most notably Dr. Russell Portenoy, the former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York. A preferred KOL of the opioid industry, Dr. Portenoy received research support, consulting fees, and honoraria from Endo, Janssen, and Purdue (among others), and was a paid consultant to Purdue.

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

73. Before Dr. Portenoy began advocating for chronic opioid treatment, the conventional wisdom in the medical community was that opioids should almost never be prescribed for the treatment of chronic pain. As one leading pain specialist at the University of Washington put it, "[i]t did not enter our minds that there could be significant numbers of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them."[31]

74. Dr. Portenoy gained national prominence, and sponsorship from opioid manufacturers, by attempting to poke holes in this conventional view. In an influential 1986 paper on chronic opioid treatment, Portenoy surmised that "opioid maintenance therapy can be a

[30] Letter to Congress, available at: http://www.lynnwebstermd.com/send-a-letter-to-congress/.

[31] John D. Loeser, *Five Crises in Pain Management*, 20 Pain Clinical Updates 1 (2012).

safe, salutary and more humane alternative" to other treatments.[32] This sweeping conclusion was not, however, predicated on any long-term study of non-malignant pain patients. It was generalized from observations of just 38 cancer patients who had received an opioid prescription.

75. Dr. Portenoy has published other articles claiming, falsely, that: (a) "the risk of addiction during opioid administration for chronic nonmalignant pain is probably very low"; (b) "opioid therapy can be discontinued without difficulty in virtually all patients"; and (c) "opioid-induced euphoria experienced by addicts occurs rarely among patients who receive an opioid for pain."[33] Dr. Portenoy arrived at these erroneous conclusions by again extrapolating largely from a limited number of studies involving a small number of cancer patients. Although no long-term studies supported the safety and efficacy of chronic opioid treatment, Dr. Portenoy opined that this should not discourage doctors from this treatment course because "documentation" of the efficacy of this approach "must be ongoing"—in other words, doctors should experiment on their patients.[34]

76. Predictably, if not by design, opioid manufacturers seized on this message. In the words of Dr. Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, Portenoy ascended the lecture circuit with Purdue "fl[yng] in people to resorts to hear him speak."[35] The message was simple and false: "Docs have been letting patients suffer; nobody really gets addicted; it's been studied."[36] In these lectures, given mostly to primary care doctors, Dr.

[32] Russel K. Portenoy and Kathleen M. Foley, C*hronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 Pain 171-86 (1986).

[33] Russell K. Portenoy, *Opioid therapy for chronic nonmalignant pain*, Pain Res Manage Vol 1, No. 1 Spring (1996) at 23-25.

[34] *Id.*

[35] Sam Quinones, Dreamland: The True Tale of America's Opiate Epidemic (Bloomsbury Press 2015), at 314.

[36] *Id.*

Portenoy routinely asserted that opioid addiction occurs in less than 1% of patients who receive opioids for chronic pain.[37] There was no sound, scientific support for this claim.

77. Dr. Portenoy also conveyed similar messages in promotional materials distributed directly by Manufacturing Defendants. By way of example, he edited Endo's promotional brochure *Understanding Your Pain*, a publication that is still available. *Understanding Your Pain* is directed toward patients, and seeks to alleviate their concerns with chronic opioid treatment by claiming (a) that a patient is not addicted to opioids so long as he can assure *himself* that he would not want the drugs if his pain subsided, and (b) that opioid tolerance is "not a problem" because the dose can always be increased.

78. 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 Salt Lake County and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[38] In a 1993 interview with the New York Times, Dr. Portenoy similarly claimed that opioids "can be used for a long time, with few side effects and that addiction and abuse are not a problem."[39]

79. Dr. Portenoy has since admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated

[37] Sonia Moghe, CNN, *Opioid history: From 'wonder drug' to abuse epidemic*, available at: https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html.

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

[39] Elisabeth Rosenthal, *Patients in Pain Find Relief, Not Addiction, in Narcotics*, N.Y. Times (Mar. 28, 1993), available at: https://www.nytimes.com/1993/03/28/us/patients-in-pain-find-relief-not-addiction-in-narcotics.html.

their benefits and glossed over their risks. He has stated, specifically: "because the primary goal was to destigmatize, we often left evidence behind."[40] Dr. Portenoy also has conceded that "[d]ata about the effectiveness of opioids does not exist."[41] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[42] The damage, however, had been done.

b. Front Groups

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

81. These Front Groups depended on Manufacturing Defendants for funding and, in some cases, for survival. Manufacturing Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. For example, Purdue's consulting agreement with APF (discussed further below) gave it direct, contractual control over APF's work. These efforts assured that Front Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups concealed the extent to which they were bankrolled by Defendants, holding themselves out as independent professional societies faithfully serving the

[40] Sonia Moghe, CNN, *Opioid history: From 'wonder drug' to abuse epidemic*, available at: https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html.

[41] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J. (Dec. 17, 2012), available at: https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[42] *Id.*

needs of their constituencies—whether patients suffering from pain or doctors treating those patients.

82. The U.S. Senate Homeland Security & Government Affairs Committee recently completed an investigation into the financial connections between opioid manufacturers and fourteen different Front Groups advocating opioid-related policies and practices. The investigation revealed that Manufacturing Defendants Purdue and Janssen, along with opioid manufacturers Mylan, Depomed and Insys, contributed more than $10 million to opioid Front Groups and their affiliates between 2012 and 2017.[43] Of these manufacturers, Purdue contributed the most, with payments exceeding $4 million between 2012 and 2017. Janssen was the second largest contributor until 2015, when it sold the licensing rights to its opioid Nucynta.[44]

83. These disturbing contributions are only the tip of the iceberg. The Senate did not investigate contributions of other opioid manufacturers, including Manufacturing Defendant Endo, and thus, admittedly, did not "capture the full extent of the financial ties between opioid manufacturers and patient advocacy groups and professional societies."[45]

84. The results of the Senate's investigation are set forth in a February 2018 report authored by Missouri Senator McCaskill's office. The report identifies a "direct link between

[43] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member McCaskill's Office, *Fueling the Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 2018), at 1, available at: https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf.

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

[45] *Id.* at 15.

corporate donations" made by opioid manufactures and the Front Groups' "advancement of opioids-friendly messaging."[46] Elaborating, the report observes:

> Initiatives from the groups in this report often echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of opioid manufacturers. These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain—the first national standards for prescription opioids and a key federal response to the ongoing epidemic.[47]

85. Senator McCaskill's report concluded that "[t]hrough criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies."[48]

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

[46] *Id*. at 1.
[47] *Id*.
[48] *Id*. at 3.

(1) American Pain Foundation ("APF")

87. The most prominent of Manufacturing 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. [49] Endo alone provided more than half that funding; Purdue was next, at $1.7 million.

88. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Salt Lake County.

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

90. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from

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

Manufacturing Defendants Purdue, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

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

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

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

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

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

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

(2) American Academy of Pain Medicine

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

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

Manufacturing Defendants Endo, Purdue, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

99. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs including Defendants Dr. Webster and Dr. Portenoy. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[50]

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

101. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

102. Recognizing the importance of opioid treatment guidelines in securing the acceptance of chronic opioid therapy, AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.

[50] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis, Medscape Neurology, Expert Interview (2005).

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, Endo, and Purdue.

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

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

105. When the CDC issued guidelines in 2016 recommending the use of non-opioid therapies in the treatment of chronic pain, AAPM's immediate past president Daniel Carr was highly critical, stating "that the CDC guideline makes disproportionally strong recommendations based upon a narrowly selected portion of the available clinical evidence.[51]

106. In an effort to retain credibility, AAPM has obscured its financial ties to opioid manufacturers. Nowhere on AAPM's website is it disclosed that AAPM has received millions of dollars in funding from the industry it has supported. Far from it, AAPM has a page on its

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

website purporting to list the "patrons" who have donated to the organization between January 1, 2017 and October 31, 2017—not a single opioid manufacturer (or other pharmaceutical company) is identified.[52]

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

(3) Defendants coordinated and worked together through Front Groups.

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

[52] *See* AAPM Foundation Donors, available at: aapmfoundation.org/donors.

B. Defendants' Marketing Scheme Misrepresented the Risks and Benefits Of Opioids.

109. To convince doctors and patients in Salt Lake County and across the nation that opioids can and should be used to treat chronic pain, Manufacturing Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Manufacturing Defendants made claims that were not supported by or were contrary to the scientific evidence. These claims were made in promotional materials distributed directly to doctors and patients; they also were advanced covertly through third parties Manufacturing Defendants controlled, including Dr. Webster and Dr. Portenoy. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Manufacturing Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

1. Defendants falsely trivialized or failed to disclose the known risks of long-term opioid use.

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

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

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

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

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

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

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

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

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that

less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

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

i. Dr. Portenoy gave numerous lectures to primary care physicians claiming, falsely, that less than 1% of patients prescribed opioids for chronic pain become addicted. Dr. Webster similarly has asserted, again falsely, that addiction occurs in as few as 2% of these patients.

112. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

113. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA (Extended Release/Long Acting) opioids in 2013 and for IR (immediate release) opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.

The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

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

115. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in Salt Lake County, nor has Endo engaged in a campaign to reverse the impact of previous statements that were to the contrary.

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

a. Purdue sponsored Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing

more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real.

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

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

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

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

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

g. Dr. Webster and Dr. Portenoy have both supported the "pseudoaddiction" construct. In his book *Avoiding Opioid Abuse While Managing Pain* (2007), Webster claimed that when facing signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."

117. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

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

119. ***Third,*** Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Defendants' misrepresentations made these doctors feel more comfortable

prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

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

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

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

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

e. Not only did Dr. Webster create the Opioid Risk Tool, he has continued to promote it, including in his 2015 book *The Painful* Truth, which asserts that the tool is one of "four simple guidelines to follow if you want to avoid the risk of becoming addicted to opioids."

e. Dr. Portenoy has repeatedly claimed that addiction risk can be managed by prescreening patients, claiming on *Good Morning America* in 2010 that "[i]f 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."

120. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by Defendants. The Guideline notes

that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

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

122. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur. Dr. Portenoy likewise claimed in a 1996 article that "opioid therapy can be discontinued without difficulty in virtually all patients."[53]

123. Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of

[53] Russell K. Portenoy, *Opioid therapy for chronic nonmalignant pain*, Pain Res Manage Vol 1, No. 1 Spring (1996) at 25.

opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

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

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

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

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

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

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

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

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

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

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,"[54] challenging the correlation between opioid dosage and overdose.

125. These claims conflict with the scientific evidence, as recently confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid

[54] *See* https://cpdd.org/.

dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

126. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged in response to a citizen petition by a physician group "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain.

127. ***Finally***, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids, described below, has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.[55]

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

[55] Catherine S. Hwang, *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175(2) JAMA INTERN. MED. 302-4 (Dec. 8, 2014), available at: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1984247.

129. Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has cautioned that "[a]ny communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health."[56]

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

131. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

[56] *Id.*

132. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market.[57] Approximately one month later, Endo did so.[58]

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

134. These statements and omissions by Purdue are false and misleading and conflict with or are inconsistent with the FDA-approved label for Purdue's AD opioids – which indicates that abusers do seek them because of their high likability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent properties and which does not indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

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

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

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

136. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.[59] Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

137. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."[60]

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

[60] Perrone et al., *Drugmakers push profitable, but unproven, opioid solution,* AP News (Dec. 15, 2016), available at: https://apnews.com/2179dcb0023847879d291804d7c9270b.

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

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

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

2. Defendants grossly overstated the benefits of chronic opioid therapy.

141. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guidelines now make clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized

trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

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

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

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

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

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

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

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

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

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

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

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

k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' quality of life, and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.

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

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

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
- "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

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

145. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described in paragraph 40, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[61] And in 2008, the FDA

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

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

146. Defendants also have promoted opioids as providing far more effective pain relief than non-opioid alternatives even through there is no scientific evidence supporting that conclusion. Researchers recently analyzed the comparative effectiveness of opioids in the treatment of 240 chronic pain patients. Half of the patients received a regimen of opioids, the other half was prescribed non-opioid alternatives, such as NSAIDs (like ibuprofen) and acetaminophen (*e.g.*, Tylenol). The study found that "[t]here was no significant difference in pain-related function between the 2 groups over 12 months" and that "[p]ain intensity was significantly better in the nonopioid group" over the same period.[62] In other words, ibuprofen and Tylenol can be more effective than opioids in treating chronic pain.

147. Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, Defendants have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Dr. Webster has even claimed that "[i]t's not hard to overdose on NSAIDs or acetaminophen."[63] Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative

[62] Erin E. Krebs, MD et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain*, JAMA (March 6, 2018) at 876.

[63] *APF releases opioid medication safety module*, Drug Topics (May 10, 2011), available at: drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-news/apf-releasesopioid-medication-safety-module.

treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

148. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

149. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours. And if a doctor suggests that OxyContin does not last 12 hours, these sales representatives, at Purdue's instruction, recommend increasing the dose, rather than the frequency of use. Purdue gave its sales representatives these instructions to prevent doctors from switching to a different drug and to address the unwillingness of insurers to pay for more frequent use of OxyContin.

3. Defendants also engaged in other unlawful, unfair, and fraudulent misconduct.

150. For over a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as is required) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

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

152. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and

failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

C. Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

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

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

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

155. At all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Manufacturing Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front

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

156. Nor have Manufacturing Defendants revealed the extent to which they have funded KOLs and Front Groups. Many Front Groups selectively disclose donors or provide no information whatsoever concerning industry backers. After studying payments to opioid-advocacy Front Groups in the 2012-2017 period, the Senate concluded that neither pharmaceutical companies nor Front Groups "fully or routinely disclose the extent of their financial relationships" and both the companies and the groups "fail to adequately disclose manufacturer contributions" resulting in a "lack of transparency."[64]

157. Finally, Manufacturing Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Manufacturing Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not

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

support. The lack of support for Manufacturing Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Salt Lake County.

158. Manufacturing Defendants' KOLs, including Drs. Webster and Portenoy, similarly concealed the marketing scheme by dressing their promotional messages in a veneer of scientific legitimacy. And to this day, Drs. Webster and Portenoy falsely claim that their viewpoints on opioids are not, and have never been, influenced by Manufacturing Defendants or the substantial payments they have received from the opioid industry. But numerous studies show that doctors are influenced by payments they receive from pharmaceutical companies. Opioid manufacturers would not have bankrolled Dr. Webster and Dr. Portenoy if they did not believe it would inure to their benefit.

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

E. Defendants Have Created a Public Nuisance

1. The Deceptive Marketing and Promotion of Opioids Foreseeably Led to Opioid Abuse that has Wrought Havoc on Salt Lake County Communities.

160. Manufacturing Defendants' misrepresentations, made both directly and through funded third-parties like Drs. Webster and Portenoy, deceived doctors and patients about the risks and benefits of long-term opioid use in Salt Lake County and across the nation. Studies reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them.

161. Both Manufacturing Defendants and their KOL surrogates knew and should have known that their misrepresentations about the risk and benefits of long-term opioid use were false and misleading when they made them.

162. This deceptive marketing conduct caused and continues to cause doctors to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' misrepresentations, these doctors would have prescribed fewer opioids, their patients would have sought fewer opioids, and there would be fewer opioids available for misuse and abuse.

163. The efficacy of Defendants' marketing efforts can be seen by comparing opioid use in the United States against other countries, where restrictions on pharmaceutical advertising typically are more stringent. Although the United States contains only 4.6% of the world's population, Americans consume nearly 100% of the global supply of hydrocodone (*e.g.*, Actavis's Norco) and approximately 80% of all oxycodone (*e.g.*, Purdue's Oxycontin).[65] Moreover, escalating opioid prescribing rates in the United States neatly track the elevated sums Defendants have expended on marketing their drugs, sums that rose from $91million in 2000 to $288 million in 2011.

164. The role of Defendants' marketing scheme in contributing to the opioid epidemic has now been acknowledged by members of the medical community. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[66]

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

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

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

166. The incumbent U.S. Surgeon General Jerome Adams issued a rare Surgeon General's Advisory on April 5, 2018, encouraging widespread distribution of Naloxone, an opioid antagonist that can reverse the effects of an opioid overdose. The advisory observes that opioid overdoses are on the rise nationwide and that a contributing factor is "an increasing number of individuals receiving higher doses of prescription opioids for long-term management of chronic pain."[67]

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

168. Contrary to Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet.[68]

[67] Surgeon General Advisory on Naloxone and Opioid Overdose, April 5, 2018, available at: https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html.

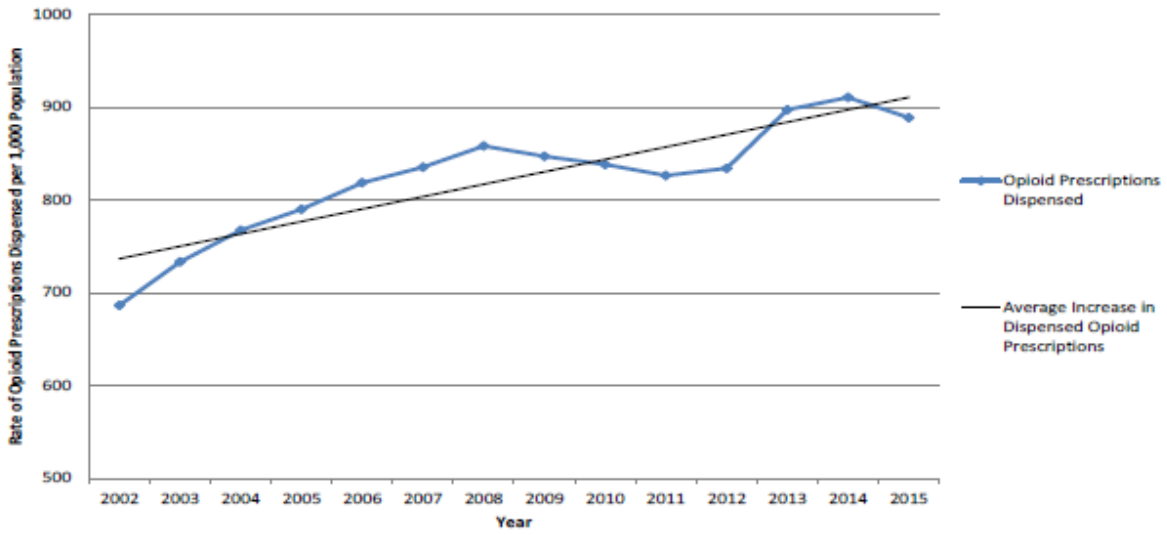
[68] *See* U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health*

Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

169. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing efforts is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the United States, including in Salt Lake County.

170. The data are staggering. Opioid prescribing rates in Utah have climbed steadily since Defendants began deceptively marketing these drugs. In 2014, 910 opioid prescriptions were issued in Utah for every 1000 residents, and prescribing rates have remained at historic levels since.[69]

Figure 3. Rate of Opioid Prescriptions Dispensed per 1,000 Population, Utah, 2002-2015



(Sept. 2012), available at: https://www.samhsa.gov/data/sites/default/files/Revised2k11NSDUHSummNatFindings/Revised2k11NSDUHSummNatFindings/NSDUHresults2011.htm.

[69] Utah Department of Health, Violence & Injury Prevention Program, *Opioid Prescribing Practices in Utah, 2002-2015* (April 2016), at 10, available at: https://www.health.utah.gov/vipp/pdf/RxDrugs/PrescribingPracticeInUtah.pdf.

171. Even more problematically, the number of doses included within an average opioid prescription has skyrocketed. In 2002, 96,025,233 morphine milligram equivalents (MME) of opioids were dispensed in Utah.[70] Fast forward to 2015 when 169,423,298 MME were dispensed in the state, a 76% increase.[71] To contextualize that number, the CDC has estimated that a daily opioid dose above 50 MME doubles the risk of overdose.[72] There were more than 3.3 million of these dangerous doses dispensed in Utah in 2015 alone, ***enough to supply every man, woman and child living in the state with a dose each and still have some 300,000 doses to spare***.

172. While the overprescription of opioids is a statewide (indeed, national) problem, it is particularly acute in Salt Lake County. Data maintained by the CDC shows that between 2006 and 2016, prescribing rates in Salt Lake County exceeded the Utah aggregate rate in every year but 2016, when the Salt Lake County rate dipped below the state rate by less than a percentage point. Prescribing rates in Salt Lake County also exceeded the national average in every year over the same period, including by as much as 25%.[73]

173. Misuse, abuse, and fatalities have followed. Since 2002, drug poisoning deaths have increased at alarming rates in Salt Lake County and across the state of Utah.[74]

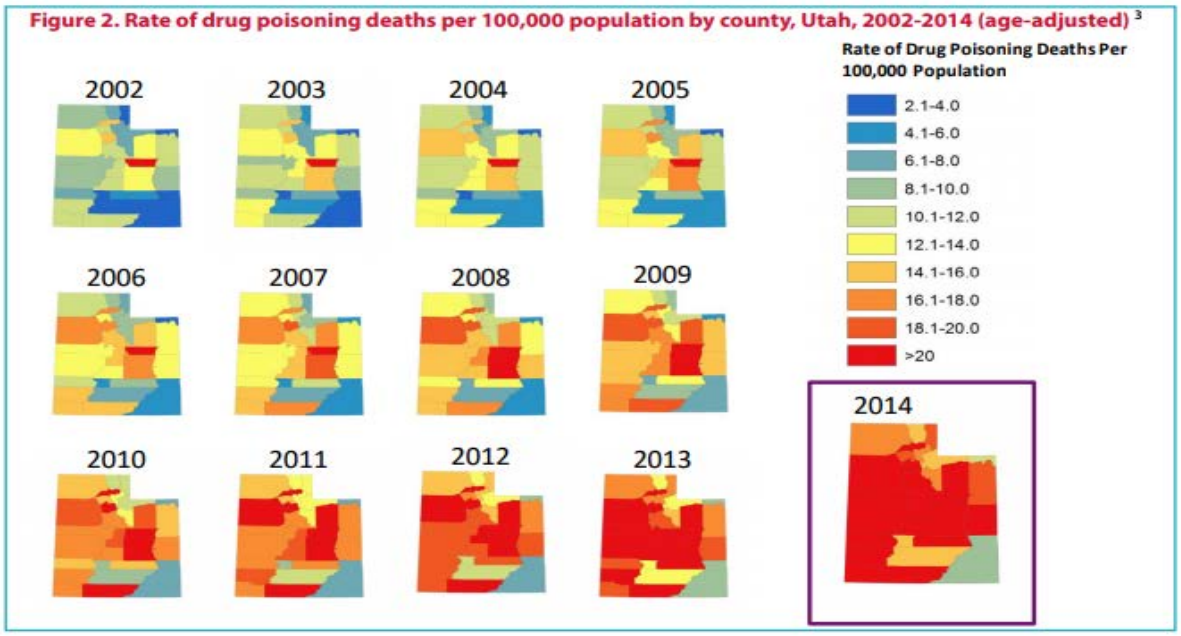
[70] *Id.* at 16.

[71] *Id.*

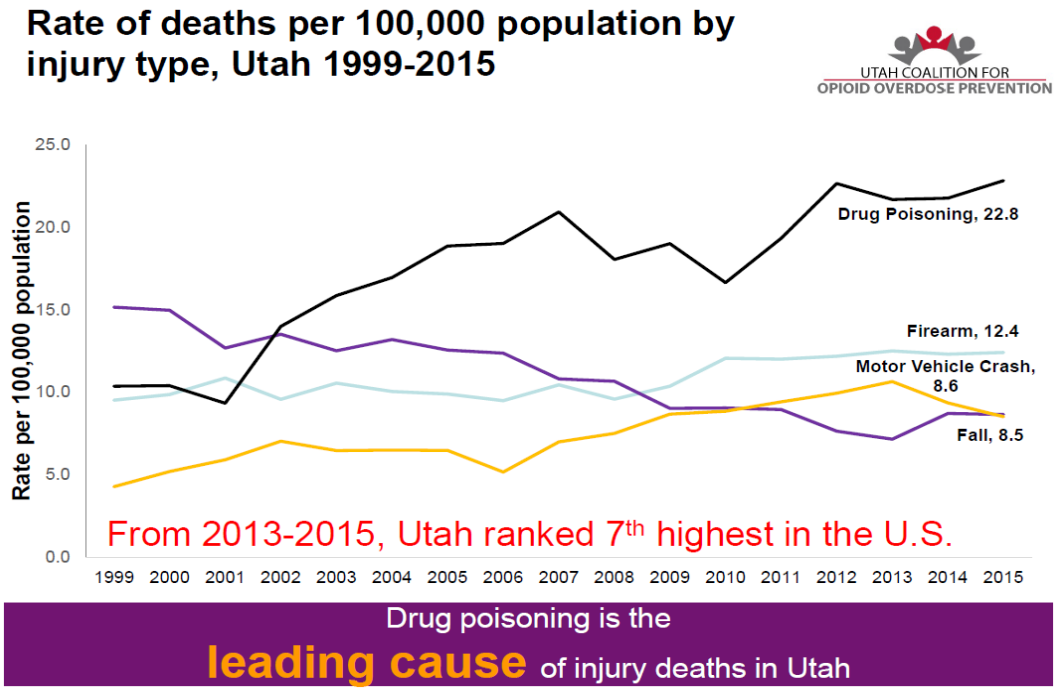
[72] CDC, Calculating Total Daily Dose of Opioids for Safer Dosage, available at: https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[73] CDC U.S. Prescribing Rate Maps, available at: https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

[74] Utah Department of Health, Prescription Opioid Deaths at 1, available at: https://health.utah.gov/vipp/pdf/RxDrugs/PDODeaths2015.pdf.



174. Statewide, drug poisoning deaths now significantly outpace deaths caused by firearms, falls, and motor vehicle crashes.[75]



[75] *Id.*

175. Prescription opioids are responsible for more of these drug poisoning deaths than any other drug category, and overwhelmingly so.[76] In 2014, the Utah Department of Health reported that approximately 82% of all drug poisoning deaths in Utah were accidental and, of these, 74.8 involved opioids.[77] In 2014 and 2015, a staggering 1,213 individuals in Utah overdosed on opioids and died—meaning that, on average, at least one person in Utah died from opioids every day for 730 consecutive days.[78]

176. No county has been hit harder than Salt Lake. Over the 2014 to 2015 period, approximately 44% of all opioid-related deaths in Utah occurred in Salt Lake County.[79] And this was not merely a function of Salt Lake County's disproportionate share of the state's population. The rate of opioid-related deaths in Salt Lake County was above the state average over the same period, and eighth highest in the state overall.[80]

OPIOID DEATHS		
COUNTY	2014-2015 TOTAL	2014-2015 RATE PER 100,000
Carbon	19	51.82
Duchesne	14	40.35
Tooele	39	33.96
Emery	6	28.97
Morgan	5	28.91
Weber	132	28.64
Juab	5	26.57
Salt Lake	531	24.68
Kane	4	24
State Total	1213	22.29

[76] *Id*. at 2.

[77] Utah Department of Health, *Prescription Drugs in Utah* (Sept. 24, 2014) at 12, available at: http://ufsac.org/wp-content/uploads/2014/09/Fall-Substance-Abuse-Conference.pdf.

[78] Utah Department of Human Services, *Substance Abuse and Mental Health, Utah's Opioid Crisis Consequence and Resource Assessment* (July 2015) at 5, available at: https://dsamh.utah.gov/pdf/Utah%20STR%20State%20Level%20Needs%20Assessment%20July%2031%202017.pdf.

[79] *Id*. at 6. These and other overdose statistics referenced in this Complaint are based on reported overdoses. They do not include opioid overdoses that go unreported.

[80] *Id*.

Sanpete	10	21.99
Box Elder	20	21.86
Washington	56	21.44
Iron	16	20.94
Utah	179	19.33
Uintah	12	18.69
Davis	108	17.4
San Juan	4	15.28
Summit	12	15.03
Wasatch	7	11.76
Cache	22	11.68
Sevier	4	9.58
Beaver	*	*
Daggett	*	*
Garfield	*	*
Grand	*	*
Millard	*	*
Rich	*	*
Piute	0	0
Wayne	0	0

177. Opioid abuse is also a leading cause of non-lethal drug poisonings and associated medical treatments, which, frequently, are provided at public expense. Between 2005 and 2014, the number of emergency department encounters in Utah linked to opioids increased by 51%.[81] Here again, Salt Lake County has been disproportionately affected. Of the 3,458 opioid-related emergency department encounters in 2013 and 2014, more than a third (or 1,443) occurred in Salt Lake County.[82]

178. In an effort to identify regional priorities, a working group of the Utah Department of Human Services analyzed opioid-related deaths and emergency department

[81] *Id*. at 3.

[82] *Id*. at 6.

encounter data to rank counties on an "opioid mortality and morbidity index."[83] Salt Lake County ranks second on that index, topped only by Carbon County.[84]

179. Tragically, the opioid epidemic in Utah has had a disproportionate impact on teenagers and young adults. In 2014, 4.18% of 12-17 year olds in Utah, and 7.02% of 18-25 year olds, reported using prescription painkillers for nonmedical use.[85] These figures eclipse the nonmedical use rate of Utah residents 26 years or older, which at approximately 3% already is troublingly high.[86] No less than 48 Utah residents aged 24 or younger died from prescription opioids in 2015 alone, and these deaths accounted for more than 7% of all prescription opioid deaths in the state.[87]

180. Newborns, too, have been harmed. Between 2005 and 2014, the number of Utah newborns diagnosed with a drug withdrawal symptoms—known as neonatal abstinence syndrome (NAS)— increased by 275%.[88] The Utah Department of Health has attributed elevated NAS rates to the increased use of opioids among pregnant women.[89] NAS is associated with increased incidence of seizures, respiratory problems, feeding difficulties and low birth weight, along with common symptoms of drug withdrawal, including diarrhea, excessive crying,

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[83] *Id.* at 7.

[84] *Id.*

[85] *Id*. at 2.

[86] Substance Abuse and Mental Health Services Administration, *2013-2014 National Survey of Drug Use and Health: Model-Based Prevalence Estimates (50 States and the District of Columbia)*, available at: https://www.samhsa.gov/data/sites/default/files/NSDUHsaePercents2014.pdf.

[87] Utah Dep't of Human Services, Substance Abuse and Mental Health, *Utah's Opioid Crisis, Consequence and Resource Assessment* (July 2017) at 4, available at: https://dsamh.utah.gov/pdf/Utah%20STR%20State%20Level%20Needs%20Assessment%20July%2031%202017.pdf.

[88] *Utah Women and Newborns Quality Collaborative: Strategies to Improve Care for Infants with Neonatal Drug Withdrawal* (November 2016) at 2, available at http://health.utah.gov/uwnqc/pages/documents/ChangePackageFinalDraft.pdf.

[89] Utah Dep't of Health, *Utah Health Status Update*: *Neonatal Abstinence Syndrome* (July 2013), at 2, available at: https://ibis.health.utah.gov/pdf/opha/publication/hsu/2013/1307_NAS.pdf.

fever, hyperactive reflexes, and sleeping difficulties.[90] For 2011 alone, the costs associated with treating Utah newborns exhibiting signs of NAS nearly reached $10 million.[91]

181. Prescription opioid abuse also has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on Salt Lake County agencies that address heroin use and addiction. Individuals who are addicted to prescription opioids often transition to heroin because it is a less expensive, readily available alternative that provides a similar high.[92] Nearly 80% of all people who began to abuse opioids in the 2000s, started with prescription drugs.[93]

182. The combined effects have contributed to an upsurge in chemical dependency that has overwhelmed Salt Lack County's public resources. The number of clients presenting in Salt Lake County treatment facilities with opioid-related diagnoses has spiked since 2008. A 2016 report by Utah's Department of Human Services indicates that 56,112 adults in Salt Lake County are in need of substance abuse treatment, but that space exists to treat only 6,575 of these individuals.[94] Another 4,077 Salt Lake residents aged 12-17 are in need of substance abuse treatment, but treatment space exists for only 636 of these endangered youths.[95] This means that, all told, nearly nine out of ten residents in Salt Lake County abusing opioids or other substances have nowhere to turn for treatment.

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[90] *Id.* at 1.

[91] *Utah Women and Newborns Quality Collaborative: Strategies to Improve Care for Infants with Neonatal Drug Withdrawal* (November 2016) at 2, available at http://health.utah.gov/uwnqc/pages/documents/ChangePackageFinalDraft.pdf.

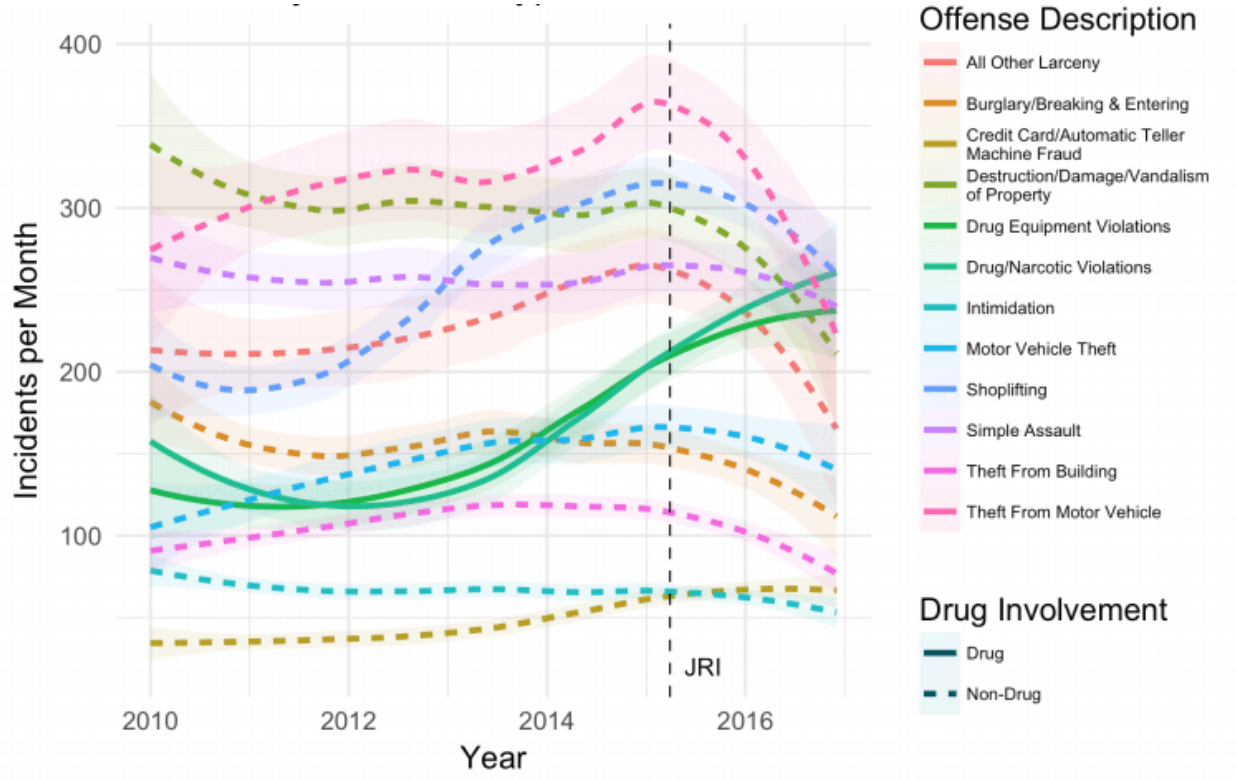
[92] JAMA Psychiatry, *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, May 28, 2014, available at: https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575.

[93] *Id.*

[94] Utah Department of Human Services, Division of Substance Abuse and Mental Health, Annual Report 2016, at 18, available at: https://dsamh.utah.gov/pdf/Annual%20Reports/2016%20Annual%20Report%20Web%20Final.pdf.

[95] *Id.*

183. Opioid abuse also has contributed to an increase in drug-related crime occurring in Salt Lake County. Many of these crimes occur in Salt Lake City, which since 2010 has seen a decrease in many criminal offense types, but a dramatic spike in drug-related offenses.[96]



184. As these data reflect, prescription opioid misuse, abuse and overdose have wide-ranging impacts. Beyond the tragic repercussions for addicted individuals—including overdoses, job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration—opioid misuse causes instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers and law enforcement. Salt Lake County, like many communities

[96] CityLab Report, What This Salt Lake City Heatmap Tells Us About Drug Crime (Aug. 11, 2017), available at: https://www.citylab.com/equity/2017/08/what-this-map-of-salt-lake-citys-drug-hotspot-really-show/536214/.

across the nation, is reeling from these effects and the enormous burden they impose on precious county resources.

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

185. Defendants knew and should have known about the harms that their deceptive marketing has caused. Manufacturing Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Manufacturing Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. In short, Manufacturing Defendants knew—and, indeed, intended—that their misrepresentations would persuade doctors to widely prescribe and patients to use their opioids for chronic pain.

186. Dr. Webster was similarly aware of the harms caused through the deceptive marketing of opioids. Not only did he participate in the marketing scheme, he executed the scheme's faulty recommendations at the Lifetree Clinic, including by distributing increasingly aggressive opioid dosages to patients exhibiting overt signs of abuse. And he saw the results—20 overdosed patients and untold numbers of additional patients battling addiction, misuse and abuse. Dr. Portenoy, too, saw the devastating consequences of his promotional activities, but continued to support chronic opioid therapy on Manufacturing Defendants' behalf.

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

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

188. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were

directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

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

F. Defendants' Fraudulent Marketing Has Led To Record Profits.

190. While the use of opioids has taken an enormous toll on Salt Lake County and its residents, Manufacturing Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Manufacturing Defendants. Indeed, financial information indicates that each Manufacturing Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above. Dr. Webster and Dr. Portenoy likewise profited from their participation in the scheme, receiving millions of dollars in consulting and other fees from the Manufacturing Defendants.

G. Defendants' Fraudulent Marketing Has Caused Salt Lake County Substantial Economic Injury.

191. Salt Lake County has, through health plans and workers compensation programs it administers, spent substantial sums on opioids that were produced by Manufacturing Defendants. Salt Lake County would not have paid for many of these prescriptions if Defendants had the truth about the risks and benefits of their drugs for treating chronic pain.

192. Salt Lake County also has expended millions of dollars combatting widespread opioid abuse, which is destroying Salt Lake County communities. These costs have been

incurred by an array of county agencies that play a role in law enforcement and public health. By way of example, in 2016, Salt Lake County launched Operation Diversion, a collaborative program involving Salt Lake City government and local law enforcement agencies. As part of this program, law enforcement ramped up arrests for opioid and other drug-related offenses occurring in downtown Salt Lake City. With District Attorney approval, the county then dropped or lowered charges against the arrested individuals subject to their participation in community treatment programs. Reflecting the scope of the opioid epidemic, more than 95% of the participants in Operation Diversion were diagnosed with an opioid-abuse disorder at their initial clinical assessment. To care for these patients, Salt Lake county brought online 63 additional treatments beds, access to medication-assisted treatment drugs, clinical assessments, criminogenic risk screens, social detoxification services and other outpatient care.

193. On the heels of Operation Diversion, Salt Lake County collaborated with the State to initiate Operation Rio Grande, which aimed to address the highly visible opioid and other drug abuse occurring in Salt Lake City's Rio Grande neighborhood. More than 1,000 arrests were made as part of this operation, forcing Salt Lake County to allocate additional resources to the county jail. After a period of incarceration, opioid addicts arrested as part of Operation Rio Grande were given a clinical assessment and certain high needs clients were permitted to participate in a special drug court program set up by Salt Lake County Criminal Justice Services. Through this program, clients received access to treatment, supervision, reduction of charges, and connection to employment training and housing referrals.

194. As a result of these efforts, and an overall spike in opioid-related crime, Salt Lake County jail facilities have been inundated with opioid addicts who, upon detention, undergo dangerous opioid withdrawal. Treating these individuals is labor and cost intensive, with Salt Lake County nurses spending substantial portions of their work days in the jail's quarantine unit providing the necessary care. Patients experiencing severe withdrawal must be transported to

and treated at area hospitals, all at the county's expense. To provide ongoing care to this endangered population, Salt Lake County established a pilot program in which incarcerated opioid addicts receive doses of Vivitrol, an injectable drug that can suppress opioid cravings and prevent relapse. Vivitrol is costly, must be administered monthly, and is most effective if treatment continues for at least a year.

195. Salt Lake County's role also does not end when opioid addicts are released from county jails. In 2015, Salt Lake County collaborated with State government to implement the Intensive Supervision Probation program, which monitors individuals who are released from jails with substance abuse disorders. More than 46% of the program's participants have identified opioids (including heroin) as their substance of abuse. Providing the intensive monitoring this at-risk population requires costs substantial sums – all told, the Intensive Supervision Program has received millions in State and county funds since inception.

196. Salt Lake County also supports treatment for county residents who have not been processed through the criminal justice system. By way of example, Salt Lake County provides funding to Project Reality, which runs the only public methadone clinic in the region. Services at Project Reality include daily methadone or suboxone medications, case management, and outpatient treatments. Since 2008, there has been consistent growth in the number of opioid addicts seeking treatment at Project Reality.

197. Salt Lake County also supports first-responders who provide services and medical interventions for opioid addicts. By way of example, since 2015, the Salt Lake County District Attorney's office has expended at least $50,000 on naloxone kits for local law enforcement agencies. Naloxone, when properly administered, can reverse an opioid overdose. Naloxone is costly however, and the drug has a shelf life, meaning naloxone supplies must be regularly replenished.

198. The foregoing costs exemplify, but do not exhaust, the financial burden Defendants' conduct has imposed on Salt Lake County. For Salt Lake County to recover from this crisis, additional resources will be needed to re-educate providers, support community health programs, sponsor preventative education, fund Naloxone distribution, monitor opioid prescribing, safely dispose of unused pills, police opioid-related crime, and to process and rehabilitate opioid offenders through the criminal justice system.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION:

PUBLIC NUISANCE
UTAH CODE ANN. § 76-10-801 ET SEQ.
(AGAINST ALL DEFENDANTS)

199. Utah realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

200. Under Utah law, a public nuisance "consists in unlawfully doing any act or omitting to perform any duty, which act or omission," *inter alia*, "annoys, injures, or endangers the comfort, repose, health or safety of three or more persons" or "renders three or more persons insecure in life or the use of property." Utah Code Ann. § 76-10-803(1).

201. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of Salt Lake County residents and interferes with the comfortable enjoyment of life in violation of Utah law.

202. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit.

203. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

204. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the least, a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

205. The health and safety of individuals in Salt Lake County, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to Salt Lake County.

206. Defendants' conduct has affected and continues to affect a considerable number of people within Salt Lake County and is likely to continue to cause significant harm to chronic pain patients who take opioids, their families, and the community at large.

207. Pursuant to Utah Code Ann. § 76-10-806, Salt Lake County seeks an order that provides for the abatement of the public nuisance Defendants have created, including by awarding damages equal to the cost of abatement, and enjoins Defendants from future violations of Utah Code Ann. § 76-10-801 *et seq*.

SECOND CAUSE OF ACTION:

PUBLIC NUISANCE
UTAH COMMON LAW
(AGAINST ALL DEFENDANTS)

208. Salt Lake County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

209. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of Salt Lake County residents and interferes with the comfortable enjoyment of life in violation of Utah law.

210. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit.

211. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

212. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the least, a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

213. The health and safety of individuals in Salt Lake County, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to Salt Lake County.

214. Defendants' conduct has affected and continues to affect a considerable number of people within Salt Lake County and is likely to continue to cause significant harm to chronic pain patients who take opioids, their families, and the community at large.

215. Salt Lake County seeks an order that provides for the abatement of the public nuisance Defendants have created, enjoins Defendants from creating future common-law nuisances, and awards Salt Lake County damages equal to the cost of abatement.

THIRD CAUSE OF ACTION:

UTAH CONSUMER SALES PRACTICES ACT ("UCSPA") UTAH CODE ANN. § 13-11-1 ET SEQ. (AGAINST MANUFACTURING DEFENDANTS)

216. Salt Lake County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

217. The UCSPA renders unlawful any "deceptive act or practice by a supplier in connection with a consumer transaction." Utah Code Ann. § 13-11-4(1).

218. A "supplier commits a deceptive act or practice if," *inter alia*, "the supplier knowingly or intentionally (a) indicates that the subject of a consumer transaction has sponsorship approval, performance characteristics, accessories, uses, or benefits, if it does not; [or] (b) indicates that the subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not." Utah Code Ann. § 13-11-4(2).

219. As alleged herein, each Manufacturing Defendant, at all times relevant to this Complaint, violated the UCSPA by making deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturing Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Manufacturing Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

220. Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to Salt Lake County consumers that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

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

- 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 NSAIDs;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

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

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- 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;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- 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;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

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

- Exclusively disseminating misleading statements in education materials to Salt Lake County hospital doctors and staff while purportedly educating them on new pain standards;

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Salt Lake County prescribers through in-person detailing; and

221. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

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

- 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;

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

- 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;

- 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 NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

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

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively 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;

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

- 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; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Salt Lake County prescribers through in-person detailing.

222. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive 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;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- 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;

- 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 NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

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

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

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive 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;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

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

- 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;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Salt Lake County prescribers through in-person detailing.

223. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Salt Lake County prescribers through in-person detailing;

- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

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

- Developing and disseminating scientific studies that deceptively 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.

224. These deceptive representations and concealments were reasonably and willfully calculated to deceive, were made with the intent to deceive, and did in fact deceive Salt Lake County, a direct consumer of prescription opioids.

225. But for these deceptive representations and concealments, Salt Lake County would not have incurred millions of dollars in overpayments, nor would Salt Lake County have expended millions of dollars to address and abate the public health crisis Defendants' conduct has foreseeably caused in the region.

226. As a direct and proximate cause of Manufacturing Defendants' false representations and concealments, Salt Lake County has been injured.

227. Salt Lake County seeks all remedies authorized under the UCSPA, including declaratory relief (Utah Code Ann. § 13-11-19(1)(a)), injunctive relief (Utah Code Ann. § 13-11-19(1)(b)), costs and damages, (Utah Code Ann. § 13-11-19(2)), and attorney's fees (Utah Code Ann. § 13-11-19(5)).

FOURTH CAUSE OF ACTION:

COMMON LAW FRAUD
(AGAINST ALL DEFENDANTS)

228. Salt Lake City realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

229. As alleged herein, Defendants engaged in false representations and concealments of presently existing material facts regarding the use of opioids to treat chronic pain.

230. Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to Salt Lake County consumers that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

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

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

- 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 NSAIDs;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

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

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- 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;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- 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;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

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

- Exclusively disseminating misleading statements in education materials to Salt Lake County hospital doctors and staff while purportedly educating them on new pain standards;

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Salt Lake County prescribers through in-person detailing; and

231. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

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

- 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;

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

- 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;

- 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 NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

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

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively 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;

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

- 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; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Salt Lake County prescribers through in-person detailing.

232. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive 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;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- 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;

- 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 NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

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

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

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive 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;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

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

- 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;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Salt Lake County prescribers through in-person detailing.

233. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Salt Lake County prescribers through in-person detailing;

- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

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

- Developing and disseminating scientific studies that deceptively 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.

234. Defendant Lynn Webster made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating and assisting in the distribution of CMEs and other physician education materials distributed in Salt Lake County that contained deceptive statements;

- Creating and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Creating and assisting in the distribution of publications that deceptively claimed that patients at risk of opioid addiction can be prescreened, including with the Opioid Risk Tool;

- Creating and assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Authoring scientific studies that misleadingly overstated the benefits of opioids in the treatment of chronic pain and minimized the risks;

- Authoring materials that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Falsely denying the influence of consulting fees and other payments received from Manufacturing Defendants and other opioid manufacturers.

235. Defendant Russell Portenoy made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating and assisting in the distribution of CMEs and other physician education materials distributed in Salt Lake County that contained deceptive statements;
- Creating and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- Creating and assisting in the distribution of publications that deceptively claimed that patients at risk of opioid addiction can be prescreened;
- Creating and assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- Authoring scientific studies that misleadingly overstated the benefits of opioids in the treatment of chronic pain and minimized the risks;
- Authoring materials that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Falsely denying the influence of consulting fees and other payments received from Manufacturing Defendants and other opioid manufacturers.

236. Defendants knew these representations and concealments were false, or were made recklessly without factual support, with the intention of deceiving Salt Lake County, physicians and patients.

237. Salt Lake County, physicians and patients reasonably relied on these false representations and concealments of material fact and with ignorance of their falsity.

238. But for these false representations and concealments of material fact, Salt Lake County and its agencies would not have incurred millions of dollars in overpayments for opioids or additional millions combatting the opioid epidemic afflicting the region.

239. As a direct and proximate cause of Defendants' fraudulent conduct, Salt Lake County has been injured.

FIFTH CAUSE OF ACTION:

CIVIL CONSPIRACY
(AGAINST DEFENDNTS PURDUE, JANSSEN, ENDO, LYNN WEBSTER, AND RUSSELL PORTENOY)

240. Salt Lake City realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

241. This claim is brought by Salt Lake City against Defendants Purdue, Janssen, Endo Lynn Webster, and Russell Portenoy. Throughout this Cause of Action only, "Defendants" refers to only these defendants.

242. Under Utah common law, the elements of a civil conspiracy are (a) a combination of two or more persons, (b) an object to be accomplished, (c) a meeting of the minds on the object or course of action, (e) one or more unlawful, overt acts, and (e) damages as a proximate result thereof.

243. As described more fully above, Defendants coordinated their efforts, as part of a shared plan and pursuant to a common agreement, to deceptively market opioids for chronic pain in Salt Lake County and across the nation.

244. To accomplish their unlawful objectives, Defendants, Front Groups, and KOLs, acting collectively, systematically misrepresented to the general public and Salt Lake County consumers – either affirmatively or through half-truths and omissions – the risks and benefits of using opioids for chronic pain. In particular, these conspirators concealed from the public and Salt Lake County consumers the serious risks and lack of corresponding benefits of using opioids for chronic pain. These misrepresentations ensured that a larger number of opioid prescriptions would be written and filled for chronic pain in Salt Lake County and elsewhere.

245. The conspiracy was the product of a meeting of the minds, with Manufacturing Defendants controlling the representations made about their respective drugs. Lynn Webster and Russell Portenoy, along with other KOLs and Front Groups, participated knowing, but without

disclosing, that others were involved in the same scheme. But for their agreement to participate in the conspiracy KOLs like Lynn Webster and Russell Portenoy, as well as Front Groups, would have been incentivized to disclose Defendants' deceit to their constituents and to protect patients. Instead, they joined the conspiracy with the expectation that the deceit would not be revealed by their co-conspirators.

246. As part of the conspiracy, Defendants engaged in a multitude of unlawful overt acts, including the herein alleged violations of Utah statutory and common law.

247. The conspiracy was reasonably calculated to deceive, and did in fact deceive, Salt Lake County, consumers and the physicians who prescribed opioids to patients for chronic pain and submitted the same for reimbursement from Salt Lake County.

248. But for the conspiracy, Salt Lake County would not have incurred millions of dollars in overpayments. Nor would Salt Lake County have expended millions of dollars to address and abate the public health crisis the conspiracy has foreseeably engendered in Salt Lake County.

249. As a direct and proximate cause of the conspiracy, Salt Lake County has been injured and seeks an order enjoining further operation of the civil conspiracy, damages in an amount to be determined at trial, and all other relief provided by law.

SIXTH CAUSE OF ACTION:

UNJUST ENRICHMENT
(AGAINST MANUFACTURING DEFENDANTS)

250. Salt Lake County realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

251. Under Utah law, unjust enrichment occurs when (a) a benefit is conferred on one person by another, (b) there is an appreciation or knowledge by the conferee of the benefit, and (c) it would be inequitable in the circumstances for the conferee to retain the benefit without payment of its value.

252. Through their deceptive and unlawful marketing of opioids for chronic pain, Manufacturing Defendants have been unjustly enriched at Salt Lake County's expense. Because of Manufacturing Defendants' scheme, Salt Lake County has overpaid for opioid prescriptions and permitting Manufacturing Defendants to retain overpayments it fraudulently procured would be inequitable.

253. In the event Salt Lake County lacks an adequate remedy at law, it seeks restitution of the sum, to be determined at trial, by which Manufacturing Defendants have been unjustly enriched.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays:

A. That the acts alleged herein be adjudged and decreed to be unlawful in violation of Utah statutory and common law and that the Court enter a judgment declaring them to be so;

B. That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Utah law;

C. That Plaintiff recover all measures of damages allowable under the statutes identified herein and the common law, and that judgment be entered against Defendants in favor of Plaintiff;

D. That Manufacturing Defendants make restitution in the amount they have been unjustly enriched at Plaintiff's expense;

E. That Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorney's fees as provided by law;

F. That Defendants be ordered to abate the public nuisance that they created in violation of Utah law, including by paying damages equaling the cost of abatement;

G. That Defendants be ordered to pay punitive and treble damages as provided by law; and

H. That the Court order such other and further relief as the Court deems just, necessary and appropriate.

JURY DEMAND

Salt Lake County demands a trial by jury for all claims herein.

DATED this 10th day of April, 2018.

Respectfully submitted,

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