COMPB
ADAM PAUL LAXALT
Attorney General
ERNEST FIGUEROA
Consumer Advocate
MARK J. KRUEGER (Bar No. 7410)
Chief Deputy Attorney General
JOANN GIBBS (Bar No. 5324)
Chief Deputy Attorney General
LAURA TUCKER (Bar No. 13268)
Senior Deputy Attorney General
State of Nevada
Office of the Attorney General
100 North Carson Street
Carson City, Nevada 89701-4717
(775) 684-1100 (phone)
(775) 684-1108 (fax)
mkrueger@ag.nv.gov
jgibbs@ag.nv.gov
lmtucker@ag.nv.gov

Attorneys for Plaintiff

DISTRICT COURT
CLARK COUNTY, NEVADA

STATE OF NEVADA Plaintiff, vs. PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY; and ROE CORPORATIONS 1 through 100 Defendants.	Case No. : A-18-774437-B Dept. No.: Department 27 **JURY DEMAND** **REQUEST FOR BUSINESS COURT** **EXEMPT FROM ARBITRATION**

COMPLAINT

I. INTRODUCTION

1. Purdue's drugs are killing Nevadans.[1] These deaths are a direct result of Defendants' campaign to bolster their corporate profits by deceptively encouraging health care professionals to flood the state with enough opioid prescriptions for 87 out of every

[1] OFFICE OF PUB. HEALTH INFORMATICS AND EPIDEMIOLOGY, DEP'T OF HEALTH AND HUMAN SERVS., NEV. OPIOID SURVEILLANCE 2010-2017 7 (2018).

100 Nevadans by 2016.[2] Primary care health care professionals are responsible for prescribing nearly half of all opioid prescriptions.[3] Defendants, each of them, through a series of visits and promoting to health care professionals in Nevada, deceptively misrepresented the addictive concerns, health consequences, and impact to lives that opioids have on Nevadans. Moreover, Defendants used specialists in the medical industry, referred to as key opinion leaders, to misinform and deceptively educate health care professionals on opioid prescribing practices. The impact can be seen through examples of health care professionals overprescribing in Nevada communities, such as Dr. Robert Rand, Reno's notorious "Pill Mill" case, and Lam's Pharmacy, the Las Vegas top five seller of OxyContin in the nation. The opioid epidemic today, originated because of Defendants' conduct and deceptive acts.

2. Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., and the Purdue Frederick Company (collectively "Purdue") have been the leading force in the prescription opioid market, both nationwide and in Nevada, for over 20 years. Purdue was the leading manufacturer of opioids in its early form and now manufactures, markets, and sells extended-release opioids, profiting in the amount of an estimated $35 billion[4] since 1995 off a national crisis of epidemic proportions. Nevada's—and the entire nation's—opioid crisis is a direct result of a calculated business decision by Purdue designed to increase profits by getting Americans hooked on prescription drugs.

3. Plaintiff the State of Nevada, by and through Adam Paul Laxalt, Attorney General for the State of Nevada, and Ernest Figueroa, Consumer Advocate, files this Complaint on behalf of the State of Nevada to obtain permanent injunctive relief, fines, penalties, fees and costs and other equitable relief for Nevada, and its municipalities and

---

[2] Nev. Div. of Pub. and Behavioral Health, *The Scope of Opioid Use in Nevada, 2016*, NEV. DIV. OF PUB. AND BEHAVIORAL HEALTH (DPBH), 1 (Oct. 18, 2017), http://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Resources/opioids/Opioid%20Infographic.pdf.

[3] Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 MORBIDITY AND MORTALITY WEEKLY REPORT 1, 3 (2016) [hereinafter *2016 CDC Guidelines*].

[4] Alex Morrel, *The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, FORBES, July 1, 2015, https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#6255fcbf75e0.

counties, against Purdue for its acts or practices in violation of the Nevada Deceptive Trade Practice Act, NRS 598.0903 *et seq.*, ("Deceptive Trade Practices Act").

II. PARTIES

4. Plaintiff is a sovereign state of the United States of America. The State brings this action by and through its Attorney General, and its Bureau of Consumer Protection ("BCP") pursuant to NRS 228.310, 228.380, 228.390, and 598.0963(3). The Attorney General is the chief law enforcement officer in the State of Nevada with respect to violations of the Deceptive Trade Practices Act, and the Consumer Advocate within the BCP is vested with the authority to exercise the power of the Attorney General in areas of consumer protection, including enforcement of the Deceptive Trade Practices Act. The Consumer Advocate is vested, pursuant to NRS 228.390, with parens patriae authority to represent the public interest on behalf of the State, which includes its municipalities and counties.

5. Defendant Purdue Pharma, L.P., is a limited partnership organized under the laws of Delaware, with its principal place of business in Connecticut, and has been registered with the Nevada Secretary of State since October 14, 2008. At all times relevant to this Complaint, Purdue Pharma, L.P., has been in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and/or distributing, or causing to be distributed, opioids in the State of Nevada.

6. Defendant Purdue Pharma, Inc., is a New York corporation with its principal place of business in Connecticut, and is the General Partner of Defendant Purdue Pharma, L.P. At all times relevant to this Complaint, Purdue Pharma, Inc., has been in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and/or distributing, or causing to be distributed, opioids in the State of Nevada.

7. Defendant The Purdue Frederick Company is a Delaware corporation with its principal place of business in Connecticut. At all times relevant to this Complaint, The Purdue Frederick Company has been in the business of designing, testing,

manufacturing, labeling, advertising, promoting, marketing, selling, and/or distributing, or causing to be distributed, opioids in the State of Nevada.

8. The true names and the capacities, whether individual, agency, corporate or otherwise, of Defendant Roe Corporations 1 through 100, are unknown to Plaintiffs. Plaintiff will ask for leave of the Court to amend this Complaint to show the true names and capacities of these Defendants, when they become known to Plaintiffs, but are believed to be other manufacturer and distributors of prescription opioids. Plaintiffs believe each Defendant named as Roe Corporation was responsible for contributing to the misconduct alleged herein.

III. JURISDICTION AND VENUE

9. This Court has general subject matter jurisdiction over this action pursuant to state statute and Nev. Const. Art. 6, § 6.

10. Purdue's business includes the sale of opioids and other drugs in the State of Nevada, and the claims asserted herein arise from Purdue's business conducted in the State of Nevada.

11. Venue in the Eighth Judicial District in and for Clark County, Nevada, is proper pursuant to NRS 598.0989(3).

12. The exercise of personal jurisdiction over Purdue is consistent with due process.

IV. FACTUAL ALLEGATIONS

13. Purdue has been making and marketing opioids and extended-release opioids as the solution for chronic pain since the mid-1990s. From the early 2000s to the present, Purdue engaged in an extensive, well-crafted, and highly targeted marketing campaign of carefully curated third-party materials and branded and unbranded marketing to spread false and misleading messaging in Nevada. Purdue's intent was to convince the Nevada medical community to abandon prior caution and mislead healthcare providers into expanded and ongoing opioid-prescribing while playing down opioids' risks and exaggerating their benefits to increase Purdue's profits through the sale

of opioids, causing extensive public harm to Nevadans, the State, and its municipalities and counties.

14. Opioids are a class of highly addictive synthetic drugs derived from opium—pharmacologically similar to heroin. Their effects are far-reaching and deadly; the Director of the Center for Disease Control ("CDC") has noted, "We know of no other medication routinely used for a nonfatal medical condition that kills patients so frequently."[5]

15. Purdue developed OxyContin, its flagship branded opioid, in the 1990s. OxyContin was initially prescribed for acute and palliative care. Purdue then promoted opioids prescribing for broader uses including pain management, particularly for chronic conditions, such as back pain, migraines, and arthritis. Purdue both fostered and capitalized on the concepts that pain was undertreated and that treatment should be a higher priority of health care professionals, which paved the way for increased prescribing of opioids for chronic pain.

16. Purdue spent hundreds of millions of dollars on promotional activities and materials that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. These activities, conducted nationally and in Nevada, included directly marketing Purdue opioids to health care professionals through advertising, websites, and in-person sales calls. Purdue also relied on continuing medical education ("CME") treatment guidelines and other publications and programs disseminated by patient advocacy groups, professional associations, and health care professionals, all of whom were funded and/or directed by Purdue but presented as independent third parties. The result was a calculated and deliberate increase to Purdue's profitability.

///

///

///

[5] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374 NEW ENG. J. MED. 1501, 1053 (2016).

17. During the principal focus of this complaint, from 2007 to February 9, 2018, the date Purdue announced it would cease contacting health care professionals,[6] Purdue maintained and expanded the market for opioids in Nevada. Specifically, both before and since 2007, Purdue has: (1) minimized the risks and overstated the benefits of the long-term use of opioids; (2) downplayed the serious risk of addiction, claiming that signs of addiction are merely the result of undertreated pain; (3) advanced misleading statements on the efficacy of the use of opioids on a person's quality of life; (4) denied or failed to disclose the greater risks of opioids at higher doses; (5) exaggerated the effectiveness of abuse deterrent opioids to prevent abuse and addiction; (6) misleadingly promoted OxyContin as providing a full 12 hours of pain relief; and (7) overstated the effectiveness of health care professionals' ability to manage patients' addiction to opioids.

18. Purdue's deceptive conduct has dramatically affected Nevadans and caused extensive public harm to the State, and its municipalities and counties.

A. Purdue Manufactures and Sells Extended-Release Opioids, Narcotics Designed to Treat Severe Pain.

19. OxyContin is an opioid agonist tablet, a narcotic substance that is intended to relieve a person's pain without causing the loss of consciousness. OxyContin is a controlled-release form of oxycodone hydrochloride. Oxycodone is a very powerful prescription narcotic similar to morphine and is the active ingredient in OxyContin as well as oxycodone-combination drugs.

20. Purdue developed and manufactures OxyContin in all of its forms. OxyContin's controlled release of oxycodone purports to facilitate "12-hour dosing," which distinguishes it from other oxycodone tablets typically administered in four- to six-hour doses. Due in part to its controlled-release feature, OxyContin contains more oxycodone than other oxycodone-based narcotics.

---

[6] *We Manufacture Prescription Opioids. How Could We Not Help Fight the Prescription and Illicit Opioid Abuse Crisis?*, PURDUE, http://www.purduepharma.com/wp-content/pdfs/Purdue_Pharma_Strong_Track_Record_of_Addressing_Prescription_Drug_Abuse_and_Diversion.pdf (last visited May 14, 2018).

21. Purdue manufactures, sells, distributes, and promotes other opioid agonists, including MS Contin, Dilaudid, Dilaudid HP, and Hysingla ER, as well as Targiniq ER, a combination product of oxycodone, and Butrans, an opioid partial agonist transdermal patch.

22. The federal Drug Enforcement Administration has long expressly acknowledged that opioids have an abuse profile and addictive qualities similar to morphine. Users initially experience euphoria, making the narcotic prone to abuse. Opioids can also cause physical dependence after a short period of use, ensuring the user will experience withdrawal symptoms upon cessation. Tolerance is also common, meaning that over time, dosage must increase in order to provide the same level of pain relief.

23. Purdue acknowledged the true nature of its opioid products in its federal trademark registration for Dilaudid HP, where it is registered as a "***narcotic*** analgesic for ***severe pain***."[7] Elsewhere, however, (and consistent with its other efforts to downplay the risks of opioid use), Purdue has trademarked its opioid products as general "analgesics," without reference to their narcotic nature or appropriateness in treating severe—not chronic—pain.

24. In sum, opioids cause physical dependence and are prone to abuse and addiction.

B. Purdue Created and Sustained the Market for Chronic Use of its Opioids Through a Long-Running Campaign of Deception.

25. In the late 1990s, Purdue presented OxyContin—and later its other opioids—as the solution to the problem of chronic pain. Prior to Purdue's launch of OxyContin in 1996, the medical community widely recognized opioids as being highly addictive, risky, relatively ineffective in long-term use, and most appropriate for severe pain and short-term use, except in cases of terminal illness.[8]

---

[7] *See* DILAUDID – HP, Registration No. 1282055, https://www.uspto.gov.

[8] Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Conditions*, 16 EXPERIMENTAL & CLINICAL PSYCHOPHARMACOLOGY 405, 405-16 (2008), https://www.ncbi.nlm.nih.gov/pubmed/18837637.

26. Purdue realized that in order to increase its profits, it had to change the perception that opioids could only be used for the narrow purpose of end-of-life care. To that end, with the launch of OxyContin, Purdue also launched a deceptive and highly targeted marketing campaign designed to broaden the use of opioids to include the treatment of chronic pain. Through its deceptive marketing, Purdue convinced health care professionals that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved quality of life, were proven. Purdue's marketing campaign targeted not only pain specialists, but primary care specialists as well (along with nurse practitioners and physician assistants), who were most likely to see and treat patients with chronic pain conditions.

27. As a result, by the mid-2000s, the medical community abandoned prior caution, and opioids were entrenched as the first appropriate treatment for chronic pain conditions. Purdue's deceptive marketing created a collective mindset within the medical community to first look for pain and then use opioids to treat it, and fostered an even larger belief among patients that all pain was unbearable and to actively seek out only those health care professionals willing to treat that pain with prescription opioids. Purdue set out to—and did—convince health care professionals that, while opioids are generally addictive, patients with legitimate pain under a health care professional's care will not become addicted. This became the cornerstone for the current epidemic of opioid abuse, injury, and death. It also provided the foundation upon which Purdue's equally deceptive, post-2007 marketing was built.

28. In launching its campaign, Purdue relied heavily on the work of Dr. Russell Portenoy, whose theories it later adopted, in supporting its expansion of opioids use. Portenoy argued in favor of expanding the use of opioids for pain management, citing evidence from opioid use among cancer patients. He believed that there was a population of patients without cancer who could benefit from long-term opioid use, but Portenoy

///

///

admitted that his data was limited.[9] Nevertheless, Portenoy claimed that the lack of evidence should not stop health care professionals from prescribing opioids,[10] and proposed expanding the use of opioids for pain management and then monitoring patients to see what happened.[11]

29. Purdue latched on to Portenoy's theories and effectively launched a nationwide experiment on the American people by promoting opioids for uses other than cancer and end-of-life care. Purdue provided research support to Portenoy, who advocated that "opioid maintenance therapy [could] be a safe, salutatory and more humane alternative" to not treating patients with chronic pain.

30. Portenoy has since acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."[12] But by that time, Purdue's marketing strategy was in full effect, and chronic opioid use had already reached epidemic proportions.

31. In addition to branded promotion, Purdue also used general, unbranded materials, produced by Purdue or by alleged independent third parties, to build the market for chronic opioid use—a tactic Purdue used to market its opioids. These unbranded materials are generally more persuasive to health care professionals because they do not name a specific drug and therefore do not appear to be advertising. To that end, Purdue substantially funded the American Pain Society, headed by Portenoy, which pushed to make ***pain*** the "fifth vital sign"—an indicator that health care professionals should monitor alongside blood pressure, temperature, heartbeat, and breathing.

32. Purdue's campaign was further strengthened in 2001, when the Joint Commission on the Accreditation of Healthcare Organizations, which accredits hospitals and other health care programs across the United States, issued pain treatment

---

[9] "The generalizability of these data are questionable due to the brief periods of treatment and follow-up." Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A Review of the Critical Issues*, 11 J. PAIN & SYMPTOM MGMT. 203, 204 (1996).

[10] *Id.* at 206.

[11] *Id.* at 212.

[12] Thomas Catan & Even Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

standards that called for assessment of pain in all patients and in each health care professional-patient interaction, and made accreditation decisions contingent on institutions having policies in place to accomplish this. This meant that once health care professionals asked about pain, they were obligated to treat it, and Purdue sales representatives were on hand to inform and reaffirm to health care professionals that opioids were the analgesic they should be using to treat patients' pain.

33. The Joint Commission on the Accreditation of Healthcare Organization licensed Purdue, alone, to distribute certain educational videos about how to comply with the new pain management standards and a book about pain management. These videos and book were also available for purchase from the Joint Commission on the Accreditation of Healthcare Organization's website. Purdue also funded and disseminated the publication *How to Meet JCAHO Pain Standards*, which encourages discussing opioids in positive terms and identifies several pro-opioid pain advocacy groups as resources.

34. Both campaigns have been widely integrated into medical practice, and are responsible for the use of opioids to treat chronic pain. Purdue's marketing deliberately set out to change health care professionals' attitudes and positions about opioids, and it was successful.

35. In 2007, Purdue entered into a plea agreement with the federal government to resolve criminal enforcement actions concerning opioids. Purdue pleaded guilty to the federal felony of misbranding of a drug with intent to defraud or mislead, admitting that it had lied to health care professionals about OxyContin's abuse potential, and paid $600 million in fines.

36. In 2007, Purdue also entered into a Consent Judgment (the "2007 Consent Judgment") with the State of Nevada and other states, agreeing to cease its fraudulent marketing, to no longer misrepresent the risk of addiction to OxyContin, to provide "fair balance" in conveying the risks and benefits of OxyContin, and to implement an abuse and diversion detection system to identify and address suspicious prescribing.

///

37. In that 2007 Consent Judgment Purdue agreed, inter alia:

a. Not to market OxyContin with any claim that is false, misleading or deceptive;

b. Not to misrepresent the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence, relating to the Off-Label uses of OxyContin;

c. To establish, implement, and follow an OxyContin Abuse and Diversion Detection Program to internally report apparent pattern of excessive numbers of patients, atypical patterns of prescribing techniques or locations, information that a Health Care Professional or their patients are abusing or diverting medications, sudden unexplained changes in prescribing, disproportionate number of patients paying in cash, multiple allegations of overdose and "take such further steps as may be appropriate based on the facts and circumstances";

d. To provide written, non-branded education information to all health care professionals related to detecting and preventing abuse and diversion of opioid analgesics.

38. However, with a blind eye toward the intent and obligations of the Consent Judgment, Purdue's deceptive conduct did not end with those settlements.

C. Post-2007, Purdue Used Sophisticated Branded and Unbranded Marketing Targeted at Nevada Health Care Professionals and Patients to Boost Opioid Prescribing and its Own Profits.

39. From 2007 to the present, Purdue has built upon its deceptive marketing, which has established chronic opioid therapy as commonplace and reaped Purdue massive revenue from OxyContin and other opioids. Purdue continues to steer the discussion away from the serious risks associated with opioids and the lack of evidence supporting their long-term use, while affirmatively misrepresenting the risks and benefits of opioids—thereby failing to correct its prior deceptions, to its benefit.

40. Even after agreeing in 2007 to no longer misrepresent the risk of OxyContin and other opioids, Purdue engaged in a marketing campaign to deceive health care

professionals and patients into believing that opioids in general, and Purdue's in particular, were effective and safe, and therefore should be widely prescribed. Purdue did so through a two-pronged approach: 1) it created a force of health care professionals who faced blame for patients' addiction if they did not prescribe high-dose opioids for the treatment of pain; and 2) it encouraged a culture among patients to expect opioids for the treatment of pain and seek out health care professionals who were willing to dispense them. Purdue accomplished this goal with a combination of direct branded and unbranded marketing. Upon information and belief, Purdue centrally developed its marketing strategies and materials, which were deployed at the local level in Nevada and nationwide.

1. Purdue Used Sales Representatives to Engage in Deceptive In-person Marketing to Nevada Health Care Professionals.

41. To market its brand-name opioids, such as OxyContin, MS Contin, Butrans, and Hysingla, Purdue sent sales representatives directly to health care professionals, including into Nevada, who established personal relationships with those health care professionals they met. By establishing these relationships, Purdue's sales representatives were able to disseminate Purdue's misrepresentations in targeted one-on-one settings that allowed them to differentiate Purdue's opioids and to address any individual health care professional's concerns about prescribing opioids for chronic pain, 12-hour dosing, no-ceiling dosing, superiority, effectiveness, risk of addiction, management of addiction, the efficacy of abuse-deterrent properties, and to encourage the spread of the idea of pseudoaddiction—the idea that signs of addiction actually reflect undertreated pain that should be addressed with more opioids—rather than addiction, as discussed in more detail below.

42. Since the launch of its chronic opioids campaign, Purdue sales representatives have contacted, visited, and distributed promotional material to hundreds of health care professionals in the State of Nevada. Most health care professionals were visited frequently, often weekly, and some, almost daily.

43. Purdue knew that its in-person marketing worked. The effects of sales calls on prescribing behavior are well-documented in studies and other literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling of sales calls.[13] 2017 study found that health care professionals ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to visit and promote sales to (also known as "detailing") health care professionals.[14] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures.[15]

44. Purdue trained its sales representatives to minimize the risk of addiction, as well as exaggerate the health care professionals' abilities to manage patients' addiction to opioids. Sales representatives were carefully monitored to ensure that they did not stray from the message that opioids were safe and effective for treating long-term pain. To ensure that sales representatives delivered the desired messages to health care professionals, Purdue directed its sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' notes (also known as "notes" or "call notes") from each visit. Additionally, Purdue required sales representatives to use sales aids that were reviewed, approved, and supplied by the company and forbade them from using promotional materials not approved by the company's marketing and compliance departments. Furthermore, Purdue ensured marketing consistency nationwide through national and regional sales representative training.

45. In addition to addressing the concerns of health care professionals who were disinclined to routinely prescribe opioids, Purdue also sought to become a source of

---

[13] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 221-27 (2009).

[14] Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. AM. MED. ASS'N 1785 (2017).

[15] *Id.*

information to which health care professionals looked to in making prescribing decisions. They did so by delivering and discussing the sort of deceptive unbranded materials described *infra* directly to Nevada health care professionals one-on-one.

46. Purdue's one-on-one marketing strategy not only encouraged the prescription of Purdue's branded opioids, but pushed the acceptance of prescribing opioids in general, thus creating and perpetuating their accepted use within the medical community.

2. Purdue Used Key Opinion Leaders, CMEs, and Medical Journals to Support its Campaign for Chronic Pain Use.

47. Sales visits were not Purdue's only marketing tactic. To enhance its message downplaying the risks and boosting the benefits of opioids for chronic pain treatment, Purdue also used "key opinion leaders" who were experts in the field to deliver paid talks and CMEs that provided information about treating pain and the risks, benefits, and uses of opioids to health care professionals. This strategy originally was pioneered by Arthur Sackler, one of the three Sackler brothers who founded Purdue, who is credited for first promoting pharmaceutical narcotics directly to health care professionals with clinical-looking ads in medical journals, visits to health care professionals' offices, and prominent medical thought-leaders. These key opinion leaders were particularly influential on the prescribing habits of their peers due to their professional reputations and the appearance of independent objectivity. Key opinion leaders received substantial funding and research grants from Purdue. Purdue often sponsored the CMEs. As a result, Purdue had considerable influence over the messenger, the message, and the distribution of the program.

48. In addition, Purdue employees and key opinion leaders identified, funded, published, and disseminated research that was designed to assist Purdue's marketing efforts and skewed or misreported the scientific evidence. For example, to substantiate its claims that opioids were rarely addictive, Purdue included in promotional and educational materials a citation to the prestigious *New England Journal of Medicine*, but

did not disclose its source was a letter to the editor.[16] This letter has since become a mainstay in scientific literature. Drug companies cited to this letter as evidence that opioid products posed little risk of addiction, "[b]ut that's not in any shape or form what we suggested in our letter," according to one of the authors, Dr. Hershel Jick.[17]

49. A recent analysis in the *New England Journal of Medicine* in June 2017 found that citation to the letter significantly increased after the introduction of OxyContin and "contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy."[18] In June 2017, the *Journal* took the rarely used step of adding this note to its electronic copy of the letter: "For reasons of public health, readers should be aware that this letter has been 'heavily and uncritically cited' as evidence that addiction is rare with opioid therapy." This letter continued to be widely cited in literature until the present day.

3. Purdue Used Third-party Groups to Influence Treatment Guidelines that Misrepresented the Risks and Benefits of Opioid Use for Chronic Pain Therapy.

50. In addition to giving talks and CMEs, Purdue's key opinion leaders also served on the boards of patient advocacy groups and professional associations that published guidelines for the use of opioids to treat chronic pain. Two such groups were American Pain Society and the American Academy of Pain Medicine, which both, upon information and belief, received substantial funding from Purdue.

51. Through a joint statement, *The Use of Opioids for the Use of Chronic Pain*, these societies endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The sole consultant for this statement was Portenoy. Dr. J. David Haddox, a key opinion leader at the time and a future senior

---

[16] Jane Porter & Hershel Jick, Correspondence, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123 (1980).

[17] Taylor Haney & Andrea Hsu, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed the Opioid Crisis*, NAT'L PUB. RADIO, June 16, 2017, https://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisi.

[18] Pamela T.M. Leung et al., Correspondence, *A 1980 Letter on the Risk of Opioid Addiction*, 376 NEW ENG. J. MED. 2194, 2194-95 (2017).

executive for Purdue, co-authored the statement. The statement remained on the internet from 1997 until 2011.

52. Treatment guidelines are used by health care professionals to guide decisions regarding the diagnosis, management, and treatment in specific areas of healthcare. As such, establishing favorable treatment guidelines for opioids was of particular importance to Purdue in bolstering their use of opioids in chronic pain therapy.

53. American Academy of Pain Medicine and American Pain Society issued treatment guidelines in 2009, which continued to recommend the use of opioids to treat chronic pain. These guidelines were particularly important to Purdue in securing acceptance for chronic opioid treatment. Of the 21 panel members who drafted the guidelines, six received support from Purdue, and eight others received support from other opioid manufacturers. Portenoy and Dr. Perry Fine (also a key opinion leader) were both on the panel.

54. The 2009 guidelines state that opioids are "safe and effective" for treating chronic pain and made "strong recommendations" despite "low quality of evidence" that the risk of addiction is manageable for patients, even those with a prior history of drug abuse.[19] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions that opioid manufacturing companies, including Purdue, made to the sponsoring organizations and committee members. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who also served on the panel, described the guidelines as "skewed" by Purdue and other opioid manufacturing companies and "biased in many respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of low risk addiction.

///

[19] Roger Chou et al., *Clinical Guidelines for Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 J. OF PAIN 113 (2009).

55. Purdue incorporated and disseminated these guidelines without disclosing its contributions to both the American Academy of Pain Medicine and the American Pain Society. For example, Purdue's *Partner's Against Pain* website incorporated sections of a 2001 American Pain Society consensus statement about addiction to bolster Purdue's position that drug-seeking behavior in chronic pain patients should be interpreted as pseudoaddiction rather than addiction.

56. These guidelines are still available online and were printed in the *Journal of Pain*. They have been a particularly effective channel of deception and have influenced not only treating health care professionals, but also the body of scientific evidence on opioids.

57. Purdue also influenced guidelines from another organization, which advanced the idea of pseudoaddiction, the Federation of State Medical Boards. The Federation of State Medical Boards is a trade organization representing the various state medical boards in the United States. The member state boards of the Federation of State Medical Boards have the power to license doctors, investigate complaints, and discipline physicians. The Federation of State Medical Boards finances opioid- and pain-specific programs through grants from Purdue and other pharmaceutical manufacturers.

58. In 1998, the Federation of State Medical Boards produced *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* in collaboration with pharmaceutical companies, including Purdue. The guidelines described opioids as "essential" for the treatment of chronic pain, including as a first-line option, but did not mention the risks of respiratory depression and overdose, and addressed addiction only to state that "inadequate understandings" of addiction can lead to "inadequate pain control." The guidelines also warn health care professionals that they could face discipline if they do not adequately treat pain.

59. The claims are repeated in the 2007 book *Responsible Opioid Prescribing*. The book also claimed that opioids would improve patients' function and advanced the idea of pseudoaddiction.

60. The Federation of State Medical Boards website describes the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed to state medical boards.

61. In 2016, the Centers for Disease Control and Prevention Guidelines for Prescribing Opioids for Chronic Pain ("CDC Guidelines") rejected the concept of pseudoaddiction. Despite this rejection, the effects of more than a decade of misinformation is still being felt today.

62. Purdue funded and acted through these third-party groups because health care professionals were conditioned to trust them—more so than branded marketing material—when making prescribing decisions.

63. The third-party, unbranded materials, marketing messages, and scripts relied on by the Purdue sales representatives were not reviewed or approved by any regulatory agency. All of the messages referenced in the instant Complaint were disseminated to Nevada health care professionals and patients through sales representative visits, medical education programs, websites, and other sources.

64. Deploying in Nevada the same marketing tactics and messages it had deployed nationwide, Purdue has used its sales force, key opinion leaders, and third-parties to continue to misrepresent the risks and benefits of its opioids. Specifically, Purdue continued to misrepresent the risk and benefits of opioids in numerous ways, as set forth below.

D. Purdue Used Established Marketing Channels in Nevada to Misrepresent the Risks and Benefits of Opioids.

65. Since 2007, Purdue has perpetuated the idea among health care professionals that opioids should be the standard for chronic pain treatment, to its great reward and to the public's detriment. Despite the obligations in the Consent Judgment, Purdue has done little to nothing to correct its previous deceptions.

///

66. s described above, Purdue pursued a two-pronged strategy for marketing opioids: first, Purdue targeted primary care physicians, physician assistants, and nurse practitioners. Purdue also promoted OxyContin, Butrans, and Hysingla for chronic non-cancer pain to the highest opioid prescribers, who often worked at "pain clinics" and who accounted for writing an outsized portion of opioid prescriptions. Additionally, as nurse practitioners and physicians assistants became more active in prescribing opioids, Purdue shifted its focus to market to them as well, including those in Nevada.

67. Second, Purdue marketed directly to patients using both third-party (unbranded) and Purdue-branded educational resources and promotional materials. These materials were designed to persuade patients through misleading statements that opioids were both effective and safe. Purdue created and disseminated promotional materials directly to patients, such as patient brochures and branded public-facing websites like *HysinglaEr.com*, encouraging patients to seek out Purdue opioids from their health care professionals. Upon information and belief, Purdue also disseminated branded promotional materials directed toward patient consumers, such as the website *In the Face of Pain, Partners Against Pain* "Pain Management Kits," patient comfort assessment guides, and other resources guiding and encouraging patients to use opioids. Similarly, as discussed below, various third-party groups produced patient guides and pamphlets that Purdue either distributed or sponsored.

68. The effectiveness of Purdue's deceptive marketing is apparent by the fact that Purdue has dominated the market for opioids promotion since the 1990s.

1. Purdue Advanced False and Misleading Statements on the Appropriateness of Long-term Opioid Use.

69. As set forth above, Purdue successfully convinced Nevada health care professionals and patients that opioids were appropriate for long-term use (generally understood to be "opioid therapy use on most days for > 3 months").[20] To do this, Purdue had to persuade health care professionals that there were significant benefits to using

[20] *2016 CDC Guidelines*, *supra* note 3, at 8.

opioids to treat chronic pain.

70. First, Purdue accomplished this by influencing professional organizations, as described above. Second, Purdue published misleading studies to enhance the perception that opioids are effective treatment for long-term chronic pain conditions. For example, one study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, related to a chronic condition, but only provided opioids for 30 days. The authors acknowledge that the "results . . . should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[21] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[22] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects; there was no reported data regarding addiction; and the study was not long term. Another Purdue study of a chronic pain condition only evaluated patients over seven days, but found oxycodone effective in its treatment.[23]

71. The OxyContin "Conversion and Titration Guide" distributed by sales representatives to Nevada health care professionals likewise misleadingly promotes long-term use. A 2007 version of that guide recommended that "the need for opioid therapy should be reassessed periodically (e.g., every 6 to 12 months) as appropriate for patients on chronic therapy," but did not disclose the absence of evidence supporting safety and efficacy for 6-12 months. The 2012 version of the guide distributed in Nevada omits the parenthetical "(e.g., every 6 to 12 months)," but it still conveys that chronic opioid therapy is appropriate without disclosing the lack of evidence for use beyond 12 weeks, and

---

[21] Jacques R. Caldwell et al., *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflamatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266 J. OF RHEUMATOLOGY 862, 867 (1999).

[22] *Id.*

[23] Martin E. Hale et al., *Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain*, 15 CLINICAL J. OF PAIN 179 (1999), https://www.ncbi.nlm.nih.gov/pubmed/10524470.

without correcting the previous misinformation Purdue conveyed to health care professionals.

72. However, the risk of addiction and negative consequences increases when opioids are administered long-term.[24] In 2013, the Food and Drug Administration ("FDA") noted that the data reflects that risk of misuse and abuse is greatest for extended release opioids and observed that these drugs are often used chronically.[25]

73. One study has shown that the duration of opioid treatment is a strong risk factor for opioid use disorder, even more important than daily dose (which is itself a strong predictor of continued opioid use).[26] In fact, a study published in 2015 found that 1 in 5 patients on long-term opioid treatment will develop opioid use disorder.[27]

74. The 2016 CDC Guidelines makes clear that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[28] 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)"[29] 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." As a result, the CDC recommends that opioids not be used in the first instance and only after health care professionals have exhausted alternative remedies.

---

[24] *See, e.g.*, Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies,* 81 DRUG AND ALCOHOL DEPENDENCE 103, 104 (2006) (noting increased risk for addiction for long-term administration of opioids).

[25] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013) (on file with author), http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

[26] Mark J. Edlund et al., *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals With Chronic Noncancer Pain*, 30 CLINICAL J. OF PAIN 557 (2014).

[27] Louisa Degenhardt et al., *Agreement Between Definitions of Pharmaceutical Opioid Use Disorders and Dependence in People Taking Opioids for Chronic Non-cancer Pain (POINT): A Cohort Study*, 2 LANCET PSYCHIATRY 314 (2015).

[28] *2016 CDC Guidelines*, *supra* note 3, at 19.

[29] *Id.* at 15.

75. The CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder"—a technical term for addiction.[30] The CDC emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[31]

76. Whether the patient meets the clinical definition of addiction or is simply dependent and unable to stop using opioids, once opioids are prescribed for even a short period of time, patients are addicted or dependent on opioids.

77. Nevertheless, building on its earlier marketing, Purdue has continued to tout the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

2. Purdue Misrepresented that Opioids are Effective to Improve Everyday Functioning and Quality of Life.

78. Purdue falsely claimed and marketed—through branded and non-branded advertisements, promotional materials, and sales representatives—that long-term opioid use will help patients suffering from chronic pain resume their normal daily lives and work.

79. Purdue disseminated promotional materials in Nevada falsely stating or implying that long-term opioid use could help patients regain physical functionality and make it easier to conduct everyday tasks like working, walking, and exercising.

80. In one example, in 2012, Purdue published in medical journals and disseminated to health care professionals a series of ads titled "pain vignettes." Each "vignette" consisted of case studies describing patients with chronic pain conditions and recommended OxyContin for each. One ad described a "54-year old writer with osteoarthritis of the hands," and implied that opioids would help him work more effectively.

///

---

[30] *Id.* at 2.
[31] *Id.* at 25.

81. Each of the ads deceptively and falsely implied that an OxyContin prescription would enable the chronic pain patients to return to work more effectively and that it would improve physical functioning and quality of life long term.

82. There is no competent medical evidence demonstrating that long-term opioid use can improve patients' ability to physically function, or cure long-term pain. To the contrary, generally accepted medical evidence indicates patients will likely complain of greater pain over the course of long-term opioid treatment, as they develop tolerance to opioids.

83. Purdue was aware of such medical evidence but deceptively failed to disclose it in its advertisements.

84. Purdue has additionally promoted deceptive messages through unbranded materials that it directly funded and authored.

85. In 2011, Purdue sponsored the development and distribution of the American Pain Foundation's[32] *A Policymaker's Guide to Understanding Pain and 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 *Guide* was originally published in 2011 and is still available to Nevada patients online today.[33]

86. Purdue's statements that long-term use of opioids improves patient function and quality of life is unsupported by clinical evidence. There are no controlled studies on the use of opioids beyond 16 weeks, and there is no competent evidence that opioids improve patients' pain and function long-term. The CDC came to this determination in its 2016 CDC Guidelines (finding there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain.")[34]

---

[32] At relevant times Purdue exerted considerable financial and contractual control over the American Pain Foundation, an ostensibly neutral patient advocacy group that disseminated false and misleading material regarding long term opioid therapy.

[33] *See* Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[34] *2016 CDC Guidelines*, *supra* note 3, at 19.

87. Referencing and assessing existing science, the 2016 CDC Guidelines found that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely."[35]

88. To the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and that it may be detrimental to patient health. Increasing the duration of opioid use is strongly associated with increasing incidence of mental health conditions (including addiction, dependence, depression, and anxiety) and greater health care utilization. As concluded in the 2016 CDC Guidelines, "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[36]

89. These generally accepted medical conclusions have been widely known for the duration of Purdue's deceptive marketing scheme. The FDA has been warning opioid manufacturers for nearly a decade that claims of improved function and quality of life are misleading. In 2008, the FDA stated in a warning letter to a narcotic manufacturer 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."[37]

90. Purdue was aware, or should have been aware, that it was making false claims and omitting material facts about the effectiveness of opioids in improving daily functioning and quality of life, but made such claims and omissions anyway.

///

///

---

[35] *Id.* at 20 (emphasis added).

[36] *Id.* at 18.

[37] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver. & Commc'ns, to Brian A. Markison, Chairman, President and Chief Exec. Officer, King Pharmaceuticals, Inc. (March 24, 2008) (on file with author); *see also* Warning Letter from Thomas Abrams, Dir. FDA Div. of Mktg., Adver., & Commc'ns, to Doug Booth, CEO Actavis Elizabeth LLC (Feb. 18, 2010) (on file with author) (rejecting claims that opioid had "an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."). On information and belief, the FDA's warning letters were available to Purdue through the FDA's website.

3. Purdue Misleadingly Promoted OxyContin as Supplying 12 Hours of Continuous Pain Relief When it Knew, or Should Have Known, that, for Many Patients, This Was False.

91. Purdue has long marketed OxyContin as being unique among opioids in providing 12 continuous hours of pain relief from a single dose.

92. However, OxyContin does not last for 12 hours in a significant number of patients, information Purdue has known since clinical trials.

93. OxyContin's FDA-approved label directs twice daily—"Q12"—12 hour dosing. On information and belief, Purdue sought the 12-hour frequency labelling as a means to maintain a competitive advantage on more frequently dosed opioids. It utilized 12-hour dosing to promote OxyContin as providing continuous, around the clock pain relief. The 1996 press release for OxyContin touted it as providing "smooth and sustained pain control all day and all night."

94. To establish 12-hour dosing under FDA guidelines, however, Purdue merely had to show that OxyContin lasted for 12 hours in at least 50 percent of patients.

95. Purdue's marketing has consistently touted OxyContin as providing continuous, round-the-clock pain relief without having to take a third or fourth pill. In one chart, Purdue claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours" and includes a chart depicting plasma levels on a logarithmic scale. However, the chart deceptively manipulates the scale of the chart's Y-axis to make 10 mg appear to be half of 100 mg, thus concealing the steep decline of OxyContin's effectiveness over 12 hours. Purdue's manipulation of the curve makes the absorption rate appear more steady or consistent than it really was.

96. According to its own research and development for OxyContin, Purdue knew that the opioid wore off in under six hours in one-quarter of patients, and in under 10 hours in more than half. In a 2008 letter, the FDA found that a "substantial number" of chronic pain patients taking OxyContin experience "end of dose failure" with little or no pain relief at the end of the dosing period. Dr. David Egilman, an expert on prescription drug warning labels, testified at a 2013 public hearing that Purdue wanted the 12-hour

dosing because it would "distinguish its drug from other short-acting narcotics," making it the "main marketing device to increase profits."[38] However, the data showed that at 10 milligrams, OxyContin release was effective "for less than six hours in at least 25 percent of patients."[39] The 20 and 30 milligram doses were effective for less than 10 hours in at least 50 percent of patients.[40] All of the Purdue studies permitted rescue or short-acting opioids to cover patients who had breakthrough pain before the end of the 12 hours.[41]

97. Because OxyContin suffers from end-of-dose failure, the drug is even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—leading to a cycle that fuels a craving for OxyContin. Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[42] To alleviate the withdrawal symptoms, patients will often take their next dose ahead of schedule or resort to a rescue dose of another opioid, increasing the overall amount of opioids they are taking and exacerbating this cycle.

98. Despite this, Purdue continued to market 12-hour dosing because it was the key to OxyContin's market dominance and comparatively high price. Without the 12-hour advantage, the drug has little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval for a recommendation of more frequent dosing in the label because 12-hour dosing gave it a "significant competitive advantage."[43]

---

[38] *Impact of Approved Drug Labeling on Chronic Opioid Therapy*, FDA CTR. FOR DRUG EVALUATION AND RESEARCH, PART 15 - PUBLIC HEARING, at 91:6-11 (Feb. 8, 2013) (testimony of David Egliman), https://wayback.archive-it.org/7993/20170113151848/http:/www.fda.gov/downloads/Drugs/NewsEvents/UCM342713.pdf.

[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] Harriet Ryan et al., *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, L.A. TIMES, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

[43] Letter from Richard S. Morey, Counsel to Purdue Pharma L.P., to Dockets Management Branch, FDA, 12-13 (Apr. 14, 2014) (on file with author) (containing comments on citizen petition docket #2004P-0043), http://documents.latimes.com/purdue-response-fda-2004/.

99. On information and belief, Purdue has continuously claimed in marketing and sales communications to health care professionals in Nevada that OxyContin lasts for 12 hours and that 12-hour dosing is a key advantage of OxyContin, without disclosing that OxyContin fails to provide 12 hours of pain relief to many, and up to half, of patients prescribed OxyContin.

100. Purdue's misrepresentations are dangerous and deceptive to Nevadans. Inadequate dosing for pain relief can lead to "end-of-dose failure" and withdrawal symptoms as described above. Such symptoms often prompt health care professionals to recommend more frequent doses. Purdue conveyed to health care professionals in Nevada that the solution to end-of-dose failure is not more frequent dosing, but higher doses. Both practices substantially increase the risk of abuse and addiction.

101. Purdue's promotion of 12-hour dosing as 12-hour relief constituted a dangerous misrepresentation in the case of many patients. This misrepresentation in failing to disclose to health care professionals known information about OxyContin's actual duration was further perpetuated by Purdue's promotion of risky higher dosing as a solution to end-of-dose failure.

102. Purdue was aware that it was a common practice for health care professionals to prescribe OxyContin more frequently than every 12 hours to address end-of-dose failure experienced by the patients, often up to three or four doses per day. Purdue's proposed solution, to recommend dosages be higher in concentration, but stay on the 12-hour schedule, simply exacerbated or did nothing to address risks of overdose, dependence, and death. Higher dosages cause patients to experience greater highs and lows, increasing craving for the next dose.

103. Purdue's deceptive and misleading promises of 12-hour relief have directly contributed to the elevated frequency of opioid dosing and elevated dosage levels in patients in Nevada and elsewhere, dramatically increasing the risk of dependence, addiction, overdose, and death.

///

4. Purdue Misrepresented the Risk of Addiction and Harms.

104. In an effort to convince Nevadans that opioids are safe, Purdue, through deceptive conduct, has continued to minimize and failed to disclose the risks of long-term opioid use, particularly the risk of addiction. The United States Department of Justice found in resolving criminal charges against Purdue in 2007, sales representatives had "falsely told some health care professionals that OxyContin has less euphoric effect and less abuse potential than short-acting opioids."[44] These misrepresentations reinforced one another and created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for pain would not become addicted; (2) even patients who seemed addicted were not; they had undertreated pain and just needed more opioids; (3) patients at greatest risk of addiction could be identified, that all other patients could safely be prescribed opioids, and that even high risk patients could be prescribed opioid if closely managed; (4) health care professionals could prescribe higher opioid doses indefinitely without added risk; and (5) the abuse-deterrent formulations of Purdue's opioids both prevent abuse and overdose and are inherently less addictive. Each of these misrepresentations has been debunked by the FDA and CDC.

105. As discussed previously, Purdue funded, influenced, and distributed third-party publications of health care professional and patient "educational" materials that misled their target audiences about the additional danger of prescription opioids. Many of these publications further sought to convince health care professionals who did not treat patients' pain complaints with opioids that they were failing their patients, while those who prescribed long-term opioid treatment were following the compassionate (and professionally less risky) approach. For example:

a. Upon information and belief, Purdue maintained a website, *In the Face of Pain*, from 2008 through 2015, which asserted that policies limiting access to opioids are

[44] *United States v. Purdue Frederick Co., Inc., et al.*, 1:07-cr-00029-jpj-1 (W.D. Va. 2007) (Criminal Information, ¶ 24).

"at odds with best medical practices" and encouraged patients to be "persistent" in finding health care professionals who will treat their pain. The website contained testimonials from several dozen health care professional "advocates" speaking positively about opioids. Eleven of those advocates received a total of $231,000 in payments from Purdue from 2008 to 2013.[45] However, Purdue omitted this information from the site.[46] Purdue deactivated *In the Face of Pain* during an investigation, and later settlement, with the New York Attorney General.[47]

b. Purdue sponsored American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. The *Treatment Options* guide also states "[d]espite the great benefits of opioids, they are often underused," and emphasized that "[r]estricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction." The brochure also explained that opioids' "under-use has been responsible for much unnecessary suffering."

c. Purdue sponsored American Pain Foundation's *Exit Wounds* (2009), which was targeted to teach veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the rate is "so low as to be immaterial."

d. Purdue sponsored American Pain Foundation's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids would become addicted.[48] It also misleadingly concluded that "[u]nfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include. . .

---

[45] *In re* Purdue Pharma L.P., Assurance No.: 15-151 (Aug. 19, 2015) (filed by the Attorney General of the State of New York), https://ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf.

[46] *Id.*

[47] *Id.*

[48] *See* Am. Pain Found., *supra* note 33.

misconceptions about opioid addiction."[49]

e. *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 for health care professionals and law enforcement, includes pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the headings "Indications of Possible Drug Abuse." However, it is uncommon for opioid addicts to resort to these extreme abuse examples; they more typically become dependent and addicted to swallowing pills, as Purdue designed and intended the drug to be ingested. Purdue sales representatives gave the pamphlet *Providing Relief, Preventing Abuse* to health care professionals in Nevada.

106. As many as 26% of opioid users and as many as 30% or even 40% of long-term opioid users experience problems with addiction. Purdue's representations that the risk of addiction was either low or acceptable were misleading and deceptive.

5. Purdue Overstated the Ability of Health Care Professionals to Manage Addiction and Failed to Disclose a Lack of Evidence that Suggested Management Strategies Work.

107. Purdue has falsely instructed Nevada health care professionals and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care professionals to safely prescribe opioids to patients, including patients predisposed to addiction, and has failed to disclose the lack of evidence that these strategies will mitigate addiction risk.

108. Such misrepresentations were designed to make health care professionals more comfortable prescribing opioids to their patients, and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Purdue aimed them at general practitioners and family physicians who did not primarily specialize in chronic pain management and were less likely to closely manage higher-risk patients on opioids. Moreover, these misrepresentations were critical to assure health care professionals, who were beginning to see or hear about the rising tide

[49] *Id.* This claim also appeared in a 2009 publication by Am. Pain Found., *A Reporter's Guide.*

of opioid addiction, that they could safely prescribe opioids in their own practices and that addiction was not unavoidable, but rather the result of other health care professionals failing to rigorously identify and manage problems.

109. In Nevada, Purdue conveyed these messages in its in-person sales visits.

110. Purdue also promoted screening tools as a reliable means to manage addiction risk in CME and scientific conferences attended by or available to Nevada health care professionals.

111. Purdue sponsored a 2011 CME taught by Dr. Lynn Webster, a prominent opioid advocate, titled *Managing Patient's Opioid Use: Balancing the Need and Risk.* This presentation deceptively instructed health care professionals that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

112. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes.* The presentation deceptively instructed health care professionals that, by using screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids. This CME program was available to Nevada health care professionals.

113. Purdue used its involvement in an organization known as the College on Problems of Drug Dependence[50] to promote the idea that addiction risk can be managed. A Purdue employee served on the College on Problems of Drug Dependence board of directors. Purdue has been able to present a disproportionately large number of talks—with vastly different messages from non-Purdue talks—at each College on Problems of Drug Dependence conference. One of Purdue's consistent themes in its messaging is that "bad apple" patients, not opioids, are the source of the addiction crisis, and that once those patients are identified, health care professionals can safely prescribe opioids without patients becoming addicted. These were national conferences attended by hundreds of

[50] The College on Problems of Drug Dependence promotes scientific research and professional development to support addiction prevention professionals.

addiction treatment specialists and healthcare professionals from across the country, from 2006 to the present.

114. The 2016 CDC Guidelines confirm the misrepresentation of Purdue's claims about the utility of patient screening and management strategies in managing addiction risk. The Guidelines note that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse."[51] The Guidelines further found 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 health care professionals "should not overestimate the ability of [those] tools to rule out risks from long-term opioid therapy."[52]

6. Purdue Deceptively Promoted the Concept of Pseudoaddiction to Minimize Signs of Addiction.

115. Purdue downplayed the problem of addiction by simply re-labeling it. According to Purdue, the signs of addiction are actually the product of untreated pain, which should be treated by prescribing even more opioids.

116. As stated previously, Dr. J. David Haddox coined the term "pseudoaddiction," and popularized it for opioid treatment for chronic pain by Purdue. Pseudoaddiction was meant to differentiate between "undertreated pain" and "true addiction"—as if the two were mutually exclusive.

117. Purdue promoted the concept of "pseudoaddiction" while failing to disclose that it was not substantiated by component scientific evidence. For example:

a. Purdue sponsored the Federation of State Medical Boards' *Responsible Opioid Prescribing* (2007), which claimed that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one prescriber to obtain opioids, and hoarding, are not signs of genuine addiction, but only signs of

---

[51] *2016 CDC Guidelines*, *supra* note 3, at 11.
[52] *Id.* at 28 (emphasis added).

"pseudoaddiction."

b. Purdue also posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on the *Partners Against Pain* website in 2005, and upon information and belief circulated this pamphlet after 2007. The pamphlet represented that conduct like "illicit drug use and deception" was not evidence of "true" addiction, but instead an indication of "pseudoaddiction" caused by untreated pain. It explained: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is untreated . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

c. Purdue sponsored *A Policymaker's Guide to Understanding Pain & Its Management*,[53] which deceptively promoted the concept of "pseudoaddiction," by explaining that "[p]atients with unrelieved pain may become focused on obtaining medications and may otherwise seem inappropriately 'drug seeking,' which may be misidentified as addiction by the patient's physician."

d. A 2010 Purdue "Training Guide for Healthcare Providers" on OxyContin taught that "[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior."

e. Purdue disseminated the *Definitions Related to the Use of Opioids for the Treatment of Pain* section of an American Pain Society consensus through the *Partners Against Pain* website. American Pain Society defined pseudoaddiction in the same terms endorsed by Purdue:

> Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused . . . . Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts

[53] *See* Am. Pain Found., *supra* note 33.

> to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated. Physical dependence on and tolerance to prescribed drugs do not constitute sufficient evidence of psychoactive substance use disorder or addiction. They are normal responses that often occur with the persistent use of certain medications . . . . A patient who is physically dependent on opioids may sometimes continue to use these despite resolution of pain only to avoid withdrawal. Such use does not necessarily reflect addiction.

f. Purdue sponsored *Exit Wounds*, which sought to reassure veterans about addiction concerns by explaining that although they may become physically dependent on opioids, they will not become addicted:

> Physical dependence means that a person will develop symptoms and signs of withdrawal (*e.g.*, swearing, rapid heart rate, nausea, diarrhea, goose bumps, or anxiety) if a drug medication is suddenly stopped or the dose is lowered too quickly . . . . Physical dependence is normal. This does not mean you are addicted.
>
> Opioid medications can, however, be abused or used as recreational drugs, and some people who use drugs in this way *will* become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing them harm.

(Emphasis in original)

g. Purdue directly disseminated material about "pseudoaddiction" to all Nevada health care professionals. Following the entry of the 2007 Consent Judgment, Purdue was obligated to provide information about abuse and diversion to prescribers. Under the guise of education, Purdue sent annual "Dear Healthcare Provider" letters to all Nevada health care professionals who prescribed opioids, and enclosed two copies of *Providing Relief, Preventing Abuse*. Purdue represented that "[t]he brochure contains important information" about topics like "definitions related to the use of opioids for the treatment of pain," as well as "[i]ndicators of possible abuse" and "[s]trategies for identifying opioid abusers." Various editions of *Providing Relief, Preventing Abuse* contained deceptive statements about pseudoaddiction.

///

h. The 2008 edition of *Providing Relief, Preventing Abuse* explained that the term pseudoaddiction:

> describes the misinterpretation by members of the health care team of relief-seeking behaviors in a person whose pain is inadequately treated as though they were drug-seeking behaviors as would be common in the setting of abuse. The lack of appropriate response to the behaviors can result in an escalation of them by the patient, in an attempt to get adequate analgesia.

i. The 2008 edition of *Providing Relief, Preventing Abuse* further explained that "[p]seudoaddiction can be distinguished from addiction in that the behaviors resolve when pain is effectively treated."

j. By 2011, Purdue had revised the brochure, and the second edition of *Providing Relief, Preventing Abuse* explained that:

> [s]ome patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. The term *pseudoaddiction* has emerged in the literature to describe the inaccurate interpretation of these behaviors in patients who have pain that has not been effectively treated. Pseudoaddiction behaviors can be distinguished from addiction by the fact that, when adequate analgesia is achieved, the patient who is seeking pain relief demonstrates improved function, uses the medications as prescribed, and does not use drugs in a manner that persistently causes sedation or euphoria.

k. By 2014, the term pseudoaddiction no longer appeared in *Providing Relief, Preventing Abuse*, but the brochure included an "Other Considerations" section that taught "[s]ome patients may exhibit behaviors aimed at obtaining pain medication because their treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment."

l. The 2007 Purdue-sponsored book *Responsible Opioid Prescribing* warns health care professionals to "[b]e aware of the distinction between *pseudoaddiction* and addiction."[54] It explains that "[p]atients who are receiving an inadequate dose of opioid

[54] SCOTT M. FISHMAN, RESPONSIBLE OPIOID PRESCRIBING 62 (2007) (emphasis in original).

medication often 'seek' more pain medications to obtain pain relief," and "[t]his is called pseudoaddiction because healthcare practitioners can mistake it for the drug-seeking behavior of addiction."[55]

i. Health care professionals were instructed to tell pseudo- from "true" addiction by "observing as closely as possible the function consequences of opioid use. Whereas pseudoaddiction resolves when the patient receives adequate analgesia, the addictive behavior does not.[56]

ii. In short, to tell whether a patient is addicted to opioids, health care professionals are to give the patient more opioids, and then see if he or she keeps engaging in "demanding or manipulative behavior" *after* his or her demands are met or the manipulation has achieved its desired result.[57]

iii. Other examples of addiction-seeking behavior listed in the book—such as "[b]ought medications from a street dealer" and "[t]ried to get opioids from more than one source"[58] are likely to cease if a single prescriber is willing to provide all the opioids the patient needs to satisfy his needs.

iv. Conversely, the more extreme examples of addiction-indicating behavior listed in the book—such as "[s]tole money to obtain drugs," "[p]erformed sex for drugs," and "[p]rostituted others for money to obtain drugs"—are more indicative of a patient's financial ability to buy prescription opioids than his or her underlying need for, and dependence on, opioids.

m. Thus, condensing Purdue's distinction, the difference between pseudoaddiction and true addiction is really whether the patient has (a) a prescriber willing to prescribe more opioids until "need" is met, and (b) the insurance or money to pay for those opioids without resorting to prostitution, theft, or other criminal conduct. Purdue's message was that as long as health care professionals follow Purdue's

---

[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] *Id.* at 63.

instructions and increase opioid doses, they will see very few patients who are "addicted" to opioids as Purdue trained them to understand the condition.

118. In 2012, Purdue key opinion leader Webster acknowledged: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. It led us down a path that caused harm. It is already something we are debunking as a concept."[59]

119. In 2016, the CDC Guidelines rejected the concept of pseudoaddiction. Contrary to the Federation of State Medical Boards guidelines, the 2016 CDC Guidelines explain that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[60] and that health care professionals 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."[61] However, the effects of more than a decade of pseudoaddiction's influence are still felt today during the current crisis.

7. Purdue Deceptively Overstated the Nature and Efficacy of Abuse-deterrent Properties.

120. The risks of abuse and addiction to OxyContin were abundantly clear by the mid-2000s, and were the inevitable result of Purdue's misleading objective to convince health care professionals to routinely prescribe OxyContin for chronic pain. Yet, rather than scale back its marketing and profits ensuring the safety of patients, Purdue's solution was to (i) craft a narrative that abuse and addiction were primarily caused by diversion, with abusers snorting or injecting the drugs, and (ii) develop new features to make the drug more difficult to crush and unsuitable for injection.

121. The narrative created to explain the reasons for abuse and addiction is apparent on Purdue's website, which explains that abuse deterrent formulations "are

---

[59] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WIS. J. SENTINEL, Feb. 19, 2012.

[60] *2016 CDC Guidelines*, *supra* note 3, at 13.

[61] *Id.* at 25.

designed to provide pain relief when taken as directed while also deterring abuse by snorting and injection," and are "intended to help deter the abuse, misuse, and diversion of these prescription pain medications—while ensuring that patients in pain continue to have appropriate access to these important therapies."[62]

122. Contrary to Purdue's emphasis on diversion, snorting and injection, the 2016 CDC Guidelines found no evidence or studies to support the notion that abuse deterrent formulations have any effectiveness as a risk mitigation strategy for deterring or preventing abuse.[63] And, to the extent abuse deterrent formulations curbed abuse by some patients, they simply switched to other opioids, including heroin.[64]

123. Purdue's narrative about abuse was also contradicted in a study published in the Clinical Journal of Pain in 2016, which suggests that only 10% to 20% of all opioid users snort or inject pills, and there is no evidence that orally administered opioids are less addictive.[65] Nevertheless, this same study found that Purdue's narrative was successful, as 46% of health care professionals surveyed erroneously stated that abuse deterrent formulations were less addictive than non-abuse deterrent formulations.[66] Essentially, Purdue's narrative gave health care professionals a false sense of security regarding the use of "abuse deterrent" formulations.[67]

124. In addition to serving as a disclaimer of liability, Purdue's narrative about abuse and addiction being caused by diversion provided another profit-making opportunity, indeed a brand new market, for Purdue. In 2010, Purdue introduced a reformulation of OxyContin—an abuse deterrent formulation—and discontinued marketing its original formulation.

///

---

[62] *Opioids with Abuse Deterrent Properties*, PURDUE, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last visited Apr. 20, 2018).

[63] *2016 CDC Guidelines, supra* note 3, at 22.

[64] *Id.* at 14.

[65] Catherine S. Hwang et al., *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32 CLINICAL J. PAIN 279, 282 (2016).

[66] *Id.* at 281.

[67] *Id.* at 282.

125. Reinforcing the narrative that abuse and addiction were caused by diversion, rather than the natural consequence of routinely prescribing opioids for chronic pain, the abuse deterrent formulations were designed to make opioid pills harder to crush, dissolve, or otherwise manipulated for easy non-oral abuse.

126. Despite its features, the abuse deterrent formulation of OxyContin is still easily tampered with, as evidenced by websites and message boards[68] that explain how to successfully tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or juice in which a tablet is dissolved. Thus, it is public knowledge that the abuse deterrent formulations of Purdue's opioids are easily altered for abuse by those determined to do so.

127. Even without tampering, the abuse deterrent formulations of Purdue's opioids are no less subject to abuse through oral intake. The 2016 CDC Guideline expressly found that abuse deterrent formulations "do not prevent opioid abuse through oral intake, ***the most common route of opioid abuse***, and can still be abused by nonoral routes."[69]

128. While there is no evidence that the abuse deterrent formulations of its products substantively mitigate abuse or addiction to these opioids, Purdue's sales representatives have routinely emphasized these features to distinguish Purdue products from competitors. These representations have taken many forms, including claims or assertions that (i) the abuse deterrent formulations prevent tampering, (ii) the abuse deterrent formulations prevent or reduce opioid abuse, diversion, and addiction, and (iii) Purdue's abuse deterrent opioids are safer than opioids products offered by competitors. Furthermore, the sales representatives routinely neglect to disclose that Purdue's abuse deterrent opioids do not prevent opioid abuse through oral intake, the most common route to opioid abuse.

///

---

[68] *E.g.*, bluelight.org and reddit.com.

[69] *2016 CDC Guidelines, supra* note 3, at 21-22 (emphasis added).

129. The routine statements and omissions made by Purdue's sales representatives are contradictory to (i) the CDC's findings about the effectiveness of abuse deterrent formulations, (ii) the FDA-approved labels for Purdue's abuse deterrent formulations, and (iii) knowledge in the public domain that abuse deterrent formulations are readily altered for abuse. Accordingly, these statements and omissions are deceptive and promote a false narrative that abuse and addiction were, and are, caused by diversion, snorting, and injection, rather than being the natural consequences of routinely prescribing opioids to treat chronic pain.

8. Purdue Knew or Should Have Known, but Failed to Disclose, the Risks of Using Opioids in Higher Doses.

130. Purdue knew or should have known that prescribing higher doses of opioids increased the risks of addiction and overdose. Yet, Purdue ignored or downplayed these risks and encouraged health care professionals to prescribe higher doses of opioids to patients.

131. A study published in The Clinical Journal of Pain in 2014[70] provides insight into Purdue's strategy regarding higher dosages. This study found that higher daily doses and possible opioid misuse were (a) strong predictors of continued use, and (b) associated with higher risk of overdoses, fractures, dependence, and death. Furthermore, high daily doses is a strong predictor of continued opioid use, and prolonged duration of opioid therapy is a strong risk factor for opioid use disorder.

132. Purdue sought to obtain the financial benefits that would result from higher daily doses—continued use of its products for long periods of time—but deflect the significant adverse effects associated with higher doses and continued use.

133. Purdue's practices for the prescription of OxyContin illustrate its disregard for the greater risk of higher doses. Purdue knew that OxyContin frequently did not provide 12 hours of relief. Rather than endorsing the prescription of OxyContin more than twice per day, Purdue encouraged health care professionals to simply prescribe

[70] Mark J. Edlund et al., *supra* note 26, at 557-64.

higher doses of OxyContin.

134. In addition to in-person encouragement to prescribe higher doses, Purdue and Purdue-sponsored publications and CMEs available in Nevada also deceptively suggested there were no additional risks associated with higher opioid doses.

135. In a 2011 publication, *A Policymaker's Guide*, dosage escalations were conveyed as "sometimes necessary," even unlimited ones, but the publication did not disclose the risks from high-dose opioids. This publication was widely disseminated and is still available online.[71]

136. In 2013, Purdue sponsored a CME titled *Overview of Management Options*, which was edited by Portenoy, who also received research, support, honoraria and consulting fees from Purdue. This CME misled health care professionals by focusing on adverse effects associated with using nonsteroidal anti-inflammatory drugs ("NSAIDs") at high doses, but failing to disclose the risks associated with high-dosage use of opioids. This CME was presented online and continued to be available online via the American Medical Association through 2014.

137. Purdue presented this message to health care professionals in multiple ways to ensure health care professionals felt comfortable prescribing higher doses of opioids, to help avoid the risk of health care professionals not prescribing opioids to their patients.

138. Purdue's representations concerning higher doses have been debunked by scientific evidence. As confirmed by the 2016 CDC Guidelines, 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 dose."[72] Furthermore, "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dos[es]."[73]

///

---

[71] Purdue and the American Pain Foundation, a non-profit that received significant funding from Purdue, collaborated on this publication.

[72] *2016 CDC Guidelines*, *supra* note 3, at 22-23.

[73] *Id.* at 24.

139. The 2016 CDC Guidelines also declared "an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[74] In addition, higher opioid dosages are associated with risks of motor vehicle injury, opioid use disorder, and overdose.[75]

140. The 2016 CDC Guidelines reinforces earlier findings announced by the FDA.[76] For these reasons, the Guidelines advise health care professionals to "carefully reassess evidence of individual benefits and risks when increasing dosage to, or in excess of, 50 morphine milligram equivalents ("MME") per day, and should avoid increasing doses to, or in excess of, 90 MMEs per day."[77]

141. If Purdue's campaign of misinformation was not sufficient to convince all health care professionals, Purdue took the additional step of suggesting to patients that higher doses of opioids were acceptable. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's health care professional did not prescribe what the patient considered a sufficient dose of opioids, the patient should find another health care professional who would.

142. Purdue's strategy and misrepresentation was clear: increase the volume of opioids taken per day, and on a continuing basis, by conveying the false and misleading message that higher dosage is medically sound; relay that same message to health care professionals in multiple ways; and at the same time, market that message directly to patients. If some health care professionals exercise independent judgment about the safety of higher doses, they lose patients to other health care professionals.

///

///

///

---

[74] *Id.* at 19.

[75] *Id.* at 23.

[76] In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events," including risk of overdose and/or overdose mortality.

[77] *2016 CDC Guidelines*, *supra* note 3, at 16.

9. Purdue's Comparisons of the Risks and Benefits of Opioids Versus the Risks and Benefits of Alternative Forms of Pain Treatment Were Deceptive.

143. Not content with merely (i) creating a false narrative to explain abuse and addiction of opioids, and (ii) encouraging higher doses of opioids as medically sound, Purdue's deceptive strategy for profits at the expense of public health motivated it to present misleading comparisons of the risks and benefits of opioids versus other pain treatment methods.

144. In these comparisons, Purdue issued or contributed to marketing materials that omitted known risks of chronic opioid treatment, and emphasized or exaggerated the risks of competing products. The goal of these deceptive comparisons was to influence health care professionals and patients, increasing the chance they would favor opioids over other available treatments such as over-the-counter acetaminophen or over-the-counter prescription NSAIDs.

145. For example, Purdue sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some opioids differ from NSAIDs in that they have "no ceiling dose as there is with the NSAIDs" and therefore opioids are the most appropriate treatment for severe pain. While *Treatment Options* attributed 10,000 to 20,000 deaths annually to NSAID overdose, the true figure was significantly lower at the time.[78] *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," but omitted any corresponding warning about the long-term use of opioids.

146. As mentioned *supra*, Purdue also sponsored the American Pain Foundation's *Exit Wounds* (2009), which omits warnings about potentially fatal interactions between opioids and anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder; the target audience for *Exit Wounds*.

///

[78] At least one article estimates the true number to be closer to 3,200. *See* Robert E. Tarone et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 AM. J. OF THERAPEUTICS 17 (2004).

147. As mentioned *supra*, Purdue also sponsored a CME titled *Overview of Management Options* in 2013, which was edited by Portenoy. This CME misled health care professionals by focusing on adverse effects associated with using NSAIDs at high doses, but failing to disclose the risks associated with high dosage use of opioids.

148. Purdue's comparisons between Purdue narcotics and other narcotics that represent or suggest that Purdue's narcotics are safer or more effective than its competitor are deceptive without evidence that the comparisons are supported by factually objective scientific, clinical or quantifiable evidence that substantiates the claims. Of note, Purdue's comparison misrepresentations made in *Treatment Options*, *Exit Wounds*, and other publications or presentations distributed or accessible in Nevada, were not supported by factually objective scientific, clinical, or quantifiable evidence.

149. Despite the lack of factually objective scientific, clinical, or quantifiable evidence to support these comparative claims, Purdue's marketing campaign was successful, and opioids replaced other options (often safer options) in health care professionals' pain treatment repertoires. For example, a 2013 study led by the Johns Hopkins Bloomberg School of Public Health found that between 2000 and 2010, opioid prescriptions nearly doubled, from 11% to 19%, while prescriptions for non-opioid treatments significantly decreased from 38% to 29%.[79] This swing in prescribing behavior occurred "despite a lack of evidence showing opioids are more effective or safer than non-opioid treatments for such pain."

E. Purdue Knew or Should Have Known About and Showed Willful Disregard to Suspicious Prescribing in the State of Nevada.

150. Purdue has a history of ignoring suspicious prescribing activity in Nevada. From at least 2007 until the present, Purdue has consistently continued to market and sell opioids to health care professionals who exhibited signs of contributing to diversion in Nevada, sometimes without alerting the proper authorities. This pattern of conduct

[79] *As Opioid Use Soars, No Evidence of Improved Treatment of Pain*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH (Sept. 16, 2013), https://www.jhsph.edu/news/news-releases/2013/alexander-opiod-pain-use.html.

illustrates its willful disregard toward situations that threaten the public health but financially reward Purdue.

151. Purdue possesses a list it refers to as "Region Zero," which is a "confidential roster of health care professionals suspected of recklessly prescribing to addicts or dealers."[80] While Purdue knew that Region Zero contained more than 1,800 physicians, it admitted in a 2013 interview that only approximately 8% of the physicians on Region Zero had been reported to authorities.[81]

152. Purdue's willful disregard is illustrated through a history or pattern of conduct and include, but are not limited to, the following:

1. Dr. Robert Rand, Reno's Notorious "Pill Mill" Case

153. Dr. Rand was a Nevada-licensed family practitioner who practiced, owned and operated Rand Family Care, located at 6880 S McCarran Blvd. Ste. 14, Reno, Nevada.

154. Rand's practice included pain management and involved the prescription of opioids.[82] For example, one of Rand's patients, a victim of a car accident, received both OxyContin and oxycodone from Rand from approximately 2013 to 2016 to cope with the severe pain he continually experienced from his accident and subsequent surgeries.[83]

155. Rand would prescribe "rapidly escalating doses of oxycontin [sic] and other narcotics" without legitimate medical purposes and not in the usual course of his professional practice.[84]

///

---

[80] Ryan et al., *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. TIMES, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/ [hereinafter *OxyContin Pills*].

[81] *Id.*

[82] Anjeanette Damon, *'Pill-Mill' Doctor Faces 74 Counts of Malpractice for Opioid Prescriptions*, RENO GAZETTE J., Feb. 2, 2017, http://www.rgj.com/story/news/2017/02/02/pill-mill-doctor-faces-74-counts-malpractice-opioid-prescriptions/97429086/ [hereinafter *Pill-Mill Doctor*].

[83] Ed Pearce, *Former Patients of Dr. Rand Finding Little Help from Medical Community*, KOLO 8 NEWS NOW, May 20, 2016, http://www.kolotv.com/content/news/Former-patients-of-Dr-Rand-finding-little-help-from-the-medical-community-380334441.html.

[84] Anjeanette Damon, *'Monster with a Stethoscope': Reno Pill Mill Doctor Robert Rand Gets 10 years in Prison*, RENO GAZETTE J., Nov. 20, 2017, http://www.rgj.com/story/news/2017/11/20/reno-pill-mill-lawyer-fighting-limit-dr-rands-prison-term/882992001/ [hereinafter *Monster with a Stethoscope*]; *see* Affidavit In Support of Complaint, p. 9, ¶ 20, filed as #176 in *USA v. Rand et al.*, Case 3:16-cr-00029-MMD-WGC.

156. Evidence showed that Rand was the highest prescriber of pain pills in Northern Nevada by approximately half a million pills in 2015.[85] However, Purdue had a financial incentive to ignore these red flags and did ignore these red flags.

157. Rand's abusive prescription practices prompted an investigation by the Drug Enforcement Agency and other state and federal agencies.[86]

158. On April 27, 2016, the United States Attorney filed a complaint against Rand and eight other defendants.[87] Rand, Richard Winston West II, aka Richie West, Omar Ahsan Ahmad, Joshua Ross Green, Clint Mitchell Bloodworth, Kathleen Griffin, Alan Russel Martinez, and Braden Kyle Riley, all of Reno, and Ryan Daniel Smith, of Carson City, were each charged in the complaint with conspiracy to distribute and possess with intent to distribute controlled substances, such as oxycodone.[88] Rand and West were also charged with engaging in a continuing criminal enterprise with at least five other persons in which Rand and West occupied positions of management.[89] Rand was also charged with distribution of a controlled substance resulting in death, and West was also charged with three separate counts of distribution of oxycodone.[90]

159. The Affidavit filed in support of the Complaint identified the Reno-based Drug Enforcement Agency's and Reno-based Federal Bureau of Investigation's investigatory efforts into a drug trafficking organization that included Rand and the other eight defendants in the areas of Reno, Nevada, and areas of Northern California that were close in proximity to Reno.[91]

---

[85] *Id.*

[86] *See Reno Doctor Robert Rand And Eight Others Indicted On Federal Prescription Drug Distribution Charges*, DOJ, May 11, 2016, https://www.justice.gov/usao-nv/pr/reno-doctor-robert-rand-and-eight-others-indicted-federal-prescription-drug-distribution [hereafter *Reno Doctor Robert Rand*]; *see* Affidavit In Support of Complaint, pp. 6-11, filed as #176 in *USA v. Rand et al.*, Case 3:16-cr-00029-MMD-WGC.

[87] *See* Complaint, filed as #2 in *USA v. Rand et al.*, Case 3:16-cr-00029-MMD-WGC.

[88] *Reno Doctor Robert Rand, supra* note 86.

[89] *Reno Doctor and Eight Others Charged in Illegal Prescription Drug Distribution Case*, DOJ, Apr. 29, 2016, https://www.justice.gov/usao-nv/pr/reno-doctor-and-eight-others-charged-illegal-prescription-drug-distribution-case [hereinafter *Reno Doctor Charged*].

[90] *Id.*

[91] *See* Affidavit In Support of Complaint, p. 6, ¶ 13, filed as #176 in *USA v. Rand et al.*, Case 3:16-cr-00029-MMD-WGC.

160. Through the investigation, Rand was identified as a source of supply of the drug trafficking organization.[92] Beginning on about September 30, 2015, and continuing to about April 28, 2016, Rand would prescribe "substantial amounts of narcotics" to West, Ahmad, Smith, Bloodworth, Green, and Martinez, who, in turn would illicitly distribute the prescribed narcotics after filling the same at local pharmacies, based on the volume of narcotics they obtain pursuant to prescriptions from Rand.[93]

161. The Nevada Prescription Monitoring Program records provided evidence that Rand was prescribing the same co-defendants with a substantial amount of narcotics to help supply their drug trafficking enterprise involved in the illicit distribution of the same.[94]

162. The investigation further revealed that Rand was meeting with patients outside of regular business hours at his office in Reno, Nevada, to provide prescription narcotics illicitly to patients for substantial income, usually a $150 cash-only fee.[95]

163. The investigation also revealed that Rand would issue co-defendants involved in the drug trafficking organization prescriptions for narcotics for their distribution to others, at a substantial profit to the distributors.[96] Substantial income was generated from the distribution of these narcotics as prescribed by Dr. Rand to West, Ahmad, Smith, Bloodworth, Green, and Martinez.[97]

164. Rand personally generated substantial income from the criminal enterprise by issuing prescriptions for narcotics to West and other defendants, and by issuing prescriptions for narcotics to some of his patients for a $150 cash-only fee.[98]

165. Pursuant to the investigation, Rand and West were identified as leaders in the drug trafficking organization with Rand's leadership role being evidenced, in part, by

---

[92] *Id.* at p. 7, ¶ 14.
[93] *Id.*; *see also Reno Doctor Charged, supra* note 89.
[94] Affidavit In Support of Complaint, p. 7, ¶ 15, filed as #176 in *USA v. Rand et al.*, Case 3:16-cr-00029-MMD-WGC.
[95] *Id.* at p. 9, ¶ 23.
[96] *Id.* at p. 10, ¶ 23.
[97] *Id.*
[98] *Id.* at p. 10, ¶ 24.

the (a) issuance of numerous prescriptions for narcotics to several of his patients that were overtly or grossly excessive, and (b) the issuance of prescriptions for narcotics to patients who paid Rand the $150 cash-only fee.[99]

166. The eight defendants were arrested in the Reno area on April 28, 2016, and Rand was arrested on April 29, 2016.[100]

167. In addition to the arrests, law enforcement agents executed federal search warrants at six locations, including two residences, two offices, and two vehicles connected to the defendants, and seized evidence related to the lawful distribution of controlled substances.[101]

168. On July 17, 2017, Rand pleaded guilty to involuntary manslaughter of a patient and unlawful distribution of oxycodone to another patient.[102]

169. According to admissions made in the plea agreement, Rand prescribed an excessive amount of oxycodone to a patient without a legitimate medical purpose and not in the usual course of professional practice that resulted in the patient's death from oxycodone intoxication. From the start of treatment, in June 2014, Rand prescribed the patient oxycodone. In September 2014, a physician spoke with Rand about the patient receiving 180 oxycodone pills per month from Rand and the patient's history. The patient was hospitalized twice. Despite phone calls, records, and encounters, Rand continued to prescribe oxycodone to the patient. In September 2015, Rand prescribed 45 dosages of oxycodone in 30 mg amounts, as well as Xanax, to the patient. One week later, Rand prescribed an additional 180 dosages of oxycodone in 30 mg amounts to the patient.[103]

170. Additionally, the plea agreement detailed that from March 2011 to April 2016, Rand prescribed another patient a total of 23,645 oxycodone 30 mg pills without a

---

[99] *Id.* at pp. 10-11, ¶ 25.

[100] *Reno Doctor Charged, supra* note 89.

[101] *Id.*

[102] *Reno Doctor Robert Rand Pleads Guilty to Involuntary Manslaughter of Patient and Unlawful Distribution of Nearly 24,000 Oxycodone Pills*, DOJ, July 17, 2017, https://www.justice.gov/usao-nv/pr/reno-doctor-robert-rand-pleads-guilty-involuntary-manslaughter-patient-and-unlawful [hereinafter *Reno Doctor Pleads Guilty*].

[103] *Id.*

legitimate medical purpose.[104] Rand prescribed a number of opioids to this patient at the same time, including oxycodone in 5 mg, 10 mg, 20 mg, and 30 mg dosages, Percocet, hydrocodone, fentanyl, as well as other substances, such as carisoprodol and alprazolam.[105] The patient did not undergo any toxicology tests and Rand allowed another person to pick-up the oxycodone prescriptions for the patient.

171. At the sentencing hearing on November 20, 2017, a pharmacist testified that Rand disregarded the risks of overprescribing, which included pill distribution and addiction.[106] Additionally, one physician testified that when he tried to talk to Rand about the hostile behavior of one of Rand's patients who was seeking to fill multiple prescriptions at once, Rand responded by saying, "What these patients do when they leave my office is not my problem." Defendant West, himself, testified that Rand would provide him with a new opioid mixture whenever he would attempt to "transition to a drug that treats both pain and opioid addiction."[107]

172. At Rand's sentencing hearing, Judge Miranda Du overruled the plea agreement and increased Rand's sentence to 10 years in federal prison, stating that "Doctors like Dr. Rand . . . are enablers and contribute to the opioid crises in this community."[108]

173. Despite these clear indications of diversion that led to the arrest and conviction of Rand, Purdue, upon information and belief, continued to market to Rand and send sales representatives to his office to sell opioids up until shortly before Rand's arrest. Purdue chose to reap the profits from what turned out to be exactly what it looked like: an organized criminal enterprise to procure OxyContin and other Purdue opioids and products and distribute them on the black market, thereby poisoning an entire community and causing the death of at least one individual.

---

[104] *Id.*; *see* Plea Agreement, filed as #598 in *USA v. Rand et al.*, Case 3:16-cr-00029-MMD-WGC.
[105] *Reno Doctor Pleads Guilty, supra* note 102.
[106] *See Monster with a Stethoscope, supra* note 84.
[107] *Id.*
[108] *Id.*

2. Lam's Pharmacy, Top Five Seller of OxyContin in the Nation

174. Lam's Pharmacy, Inc., was a Nevada Pharmacy located at 2202 W. Charleston Blvd., Las Vegas, Nevada, and managed by pharmacist Jason Smith.

175. Beginning at a date unknown, and continuing to approximately August 2010, Henri Wetselaar, David Litwin, and Jason Smith worked together to distribute large amounts of highly addictive prescription drugs in and around Las Vegas.[109] Dr. Wetselaar was a licensed physician in Nevada who represented himself to be a specialist in pain management.[110] David Litwin held himself out to be Wetselaar's medical assistant, but in fact had no verifiable credentials in the United States.[111]

176. Wetselaar and Litwin prescribed large quantities of highly addictive prescription drugs, including oxycodone, hydrocodone, Xanax and Soma without medical necessity.[112]

177. Wetselaar and Litwin directed their patients to Lam's Pharmacy where Smith, a licensed pharmacist in Nevada and the pharmacy manager, filled and directed his staff to fill the unnecessary prescriptions, knowing that the drugs would be illegally diverted. An overwhelming majority of Wetselaar and Litwin's "patients," including at least two known drug dealers, filled their prescriptions at Lam's Pharmacy by agreement with Smith.[113]

178. In 2009, Lam's Pharmacy prescribed so much OxyContin it was "one of the top five sellers of OxyContin in the nation." The number of opioid prescriptions was so excessive that a former employee of Purdue who visited Lam's Pharmacy in 2009

---

[109] *See* Criminal Indictment, p. 1, ¶ 1, filed as #1 in *USA v. Wetselaar et al.*, Case 2:11-cr-00347-KJD-CWH.

[110] *Las Vegas Physician and Pharmacist Charged with Unlawful Sales of Large Quantities of Prescription Painkillers*, FBI Las Vegas Division, Sept. 29, 2011, https://archives.fbi.gov/archives/lasvegas/press-releases/2011/las-vegas-physician-and-pharmacist-charged-with-unlawful-sales-of-large-quantities-of-prescription-painkillers [hereinafter *Las Vegas Physician and Pharmacist*].

[111] *Id.*

[112] Criminal Indictment, pp. 1-2, ¶ 1, filed as #1 in *USA v. Wetselaar et al.*, Case 2:11-cr-00347-KJD-CWH.

[113] *Las Vegas Physician and Pharmacist, supra* note 110.

described the pharmacy's environment as a "drug-distribution operation."[114] However, while a phone tip and letter was provided to the Drug Enforcement Agency regarding Lam's Pharmacy, the former employee explained that Purdue "did not share the telltale sales data with the DEA or others in law enforcement" regarding what was actually occurring at Lam's Pharmacy.[115] Additionally, the former employee said that Purdue declined to completely cut off the supply of opioids to Lam's Pharmacy despite "telltale sales data" showing that it was furnishing pills to drug addicts.[116] In a *Los Angeles Times* article, the former Purdue employee recounted that he and his colleague sat in a rental car watching crowds of young people leave with pills.[117] While Purdue did eventually limit the amount of OxyContin that Lam's Pharmacy's wholesaler was receiving, it never stopped selling OxyContin to the wholesaler, thereby contributing to the "drug-distribution" environment at Lam's Pharmacy.[118]

179. On September 21, 2011, Wetselaar, Litwin, and Smith were indicted by the federal grand jury.[119] Each defendant was charged with one count of conspiracy to distribute oxycodone. Wetselaar was also charged with eight counts of distribution of oxycodone, one count of money laundering, and ten counts of structuring money transactions.[120] Litwin was also charged with eight counts of distribution of oxycodone and three counts of making a false statement to the Drug Enforcement Agency.[121]

180. However, by the time the defendants were indicted, Purdue had reaped its profits from the illicit sale and distribution of OxyContin, and the damage to the community had been done.

181. At Smith's trial, two "self-admitted drug dealers" testified that Lam's Pharmacy was the "go-to pharmacy" for filling multiple prescriptions obtained from

---

[114] *OxyContin Pills*, *supra* note 80.
[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] *Id.*
[119] *Las Vegas Physician and Pharmacist*, *supra* note 110.
[120] *Id.*
[121] *Id.*

Wetselaar by individuals who would simply pretend to be patients in order to obtain prescription narcotics.[122]

182. On March 23, 2017, Wetselaar was found guilty of conspiracy to distribute controlled substances (oxycodone), distribution of controlled substances, money laundering, and structuring of money transactions.[123] Litwin was found guilty of conspiracy to distribute controlled substances and distribution of controlled substances.[124] Smith's first trial ended in a mistrial and was rescheduled for late 2017.[125]

183. Despite the clear indications of diversion, Purdue continued to send sales representatives and market opioids to Lam's Pharmacy. Rather, Purdue chose to continue to reap the profits from a pharmacy supplying opioids to drug addicts.

F. Purdue's deceptive misconduct continued despite its 2007 Consent Judgment with the State of Nevada.

184. Purdue's purposeful misrepresentation of the risks and benefits of opioid use to health care professionals and patients and failure to disclose material facts regarding the health risks associated with opioid use to health care professionals and patients has contributed to Nevada's "pill problem."[126]

185. The 2007 Consent Judgment did not mark a change in Purdue's culture or conduct. Purdue continued to engage in false, misleading, or deceptive marketing practices of its products. Rather than correct its misrepresentations and reform its conduct, Purdue instead built upon the deceptive messaging that had established chronic opioid therapy as commonplace and reaped Purdue massive revenues. Since that time,

---

[122] Jenny Wilson, *Las Vegas Pharmacist Testifies at His Federal Drug Trial*, LAS VEGAS REVIEW-J., March 13, 2017, https://www.reviewjournal.com/crime/courts/las-vegas-pharmacist-testifies-at-his-federal-drug-trial/.

[123] *Physician Sentenced to 10 Years in Prison for Distribution of Oxycodone*, DOJ, Aug. 1, 2017, https://www.justice.gov/usao-nv/pr/physician-sentenced-10-years-prison-distribution-oxycodone [hereinafter *Physician Sentenced to 10 Years*].

[124] *Id.*

[125] *Las Vegas Doctor Gets 10 Years in Opioid Pill Mill Conspiracy*, LAS VEGAS SUN, Aug. 1, 2017, https://lasvegassun.com/news/2017/aug/01/las-vegas-doctor-gets-10-years-in-opioid-pill-mill/.

[126] *See* Anjeanette Damon & Jason Hidalgo, *Over-prescribing Doctors Can Escape Scrutiny in Nevada*, RENO GAZETTE J., http://www.rgj.com/story/news/2016/05/14/over-prescribing-doctors-can-escape-scrutiny-nevada/84301800/ (last visited Dec. 8, 2017) [hereinafter *Over-prescribing Doctors*].

and up to the present day, Purdue has both continued its deceptive acts for which it was cited in 2007, as well as making other diverse misrepresentations. Purdue has continued to (i) omit discussion of the serious risks of opioids and lack of evidence supporting long-term opioid use, and (ii) affirmatively misrepresent the risks and benefits of opioids for the treatment of chronic pain. By these omissions and misrepresentations, Purdue has failed to correct its prior deceptions, at the expense of the public health and to its financial benefit.

186. Purdue has accomplished much of its deceptive acts through its Nevada sales force, the messages they verbally conveyed to health care professionals, and the materials they showed or distributed to health care professionals and patients of those health care professionals. Since the launch of OxyContin, Purdue has relied heavily on its sales representatives to market its opioids directly to health care professionals. By establishing personal relationships with health care professionals, Purdue's sales representatives were and are able to disseminate their misrepresentations in targeted, one-on-one settings.

187. Purdue's thirst for profit, misrepresentations, and failure to adequately alert authorities of signs of diversion allowed, and may have encouraged, health care professionals, including those mentioned above, to overprescribe opioids to Nevadans, which has impacted the health and safety of and led to the loss of numerous Nevadan lives.

188. Additionally, upon information and belief, Purdue's implementation of the OxyContin Abuse and Diversion Detection Program failed to meet minimal standards of diligence and effectiveness, and Purdue routinely failed to (a) detect or investigate potential abuse or diversion, and (b) take appropriate action to stop it.

189. Purdue failed to investigate and take action in instances that reasonably would raise an inference of abuse or diversion—in other words, where Purdue had information that its products were likely harming public health. Upon information and belief, Purdue continued to engage in deceptive conduct and make misrepresentations to

market opioids to health care professionals it had reason to believe were engaged in diversion, reaping the profits to the harm of Nevadans.

G. Opioids Have Severely Impacted Nevada.

190. In the past 10 years, prescription drug misuse, heroin use, and opioid-related overdoses have developed into the deadliest drug epidemic in United States history.[127] In 2014, the National Governor's Association proclaimed that "the abuse of prescription drugs is the fastest growing drug problem in the United States, and prescription drugs are now the second most abused drug after marijuana among teens."[128] Moreover, the "issue is even more severe in Nevada than other states."[129] The National Governor's Association found that the opioid epidemic is fueled by inappropriate opioid prescribing, but clarified that while "most opioid overdoses involve prescription opioids, an increasing number are linked to illicit opioids such as heroin and fentanyl."[130]

191. Last year, Nevada was ranked as the sixth highest state for the number of milligrams of opioids distributed per adult according to a study by the Drug Enforcement Agency.[131] As of August 10, 2017, a recent study estimates that opioid deaths "may be underreported nationally by as much as 24 percent."[132] Some of this underreporting is due to the lack of autopsies or toxicology reports, especially in rural areas.

192. The opioid epidemic exists in all counties in Nevada. Opioid-related hospitalizations have increased from 2010 to 2016 by 136% in emergency room encounters

---

[127] Kelly Murphy et al., *Finding Solutions to the Prescription Opioid and Heroin Crisis: A Road Map for States*, NAT'L GOVERNORS ASS'N (July 2016), https://www.nga.org/files/live/sites/NGA/files/pdf/2016/1607NGAOpioidRoadMap.pdf.

[128] Nat'l Governors Ass'n Policy Academy on Prescription Drug Abuse Prevention, *State of Nevada Plan to Reduce Prescription Drug Abuse*, NEV. DIV. OF PUB. AND BEHAVIORAL HEALTH (DPBH), http://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Programs/ClinicalSAPTA/State%20of%20Nevada%20Plan%20to%20Reduce%20Prescription%20Drug%20Abuse.pdf (last visited Apr. 17, 2018) [hereinafter *State of Nevada Plan*].

[129] *Id.*

[130] Kelly Murphy et al., *supra* note 127.

[131] *State of Nevada Plan*, *supra* note 128.

[132] Jeremiah Lindemann, *Why Data About the Opioid Epidemic Is So Unreliable*, SLATE, Aug. 10, 2017, http://www.slate.com/articles/technology/future_tense/2017/08/the_opioid_epidemic_might_be_even_worse_than_we_realize.html.

and 84% in inpatient admissions.[133] Of those, 26% of the emergency room encounters and 34% of inpatient admissions were people aged 55 and older.[134] Moreover, Naloxone/Narcan was administered by the hospital to 20.7% of patients with opioid overdoses who arrived in the emergency room.[135] While the total number of opioid-related deaths has decreased 12% from 2010 to 2016, 85% of all opioid-related deaths were deemed accidents.[136]

193. The incidents of opioid overdose and death in Clark County remains almost 70% higher than the national average.[137] The cost between 2013 and 2015 to Clark County for healthcare utilization and expenditure for opioid misuse and use in more than 1,700 emergency visits was $13 million, and the cost for 1,700 inpatient hospitalizations was $94 million.[138]

194. Reports from Nevada's Prescription Monitoring Program by the Nevada Division of Public and Behavioral Health on the number of opioids prescribed are staggering. In 2015, the total prescriptions written for Hydrocodone, Oxycodone, and Alprazolam was 2,371,134.[139] Compared to Nevada's population at that time of 2,890,845, that equates to a per capita prescription for these opioids of 82/100 residents.[140] In 2012, on a national level, providers wrote enough opioid prescriptions for every adult American to have a bottle of pills.[141] Moreover, in 2013, 35% of all Nevada high school students reported having taken prescription narcotics without a prescription.[142]

///

///

---

[133] Nev. Div. of Pub. and Behavioral Health, *supra* note 2.

[134] *Id.*

[135] *Id.*

[136] *Id.*

[137] S. Nev. Health Dist., *Opioid Epidemic in Southern Nevada*, HEALTHY S. NEV., 1-2 (Feb. 3, 2017), http://www.healthysouthernnevada.org/content/sites/snhd/2017NVLeg_OpioidFactSheet.pdf.

[138] *Id.*

[139] Nev. Div. of Pub. and Behavioral Health, *supra* note 2. (Roughly 85% of all benzodiazepine-related overdose deaths also involve opioids).

[140] *Id.*

[141] Kelly Murphy et al., *supra* note 127.

[142] *Governor Brian Sandoval's Prescription Drug Abuse Prevention Summit, Summary of Findings*, Assemb. Comm.: Health and Human Servs.- Exhibit: G, 79th Sess. (Nev. 2017), https://www.leg.state.nv.us/Session/79th2017/Exhibits/Assembly/HHS/AHHS670G.pdf.

H. Purdue Greatly Contributed to and May Have Caused Nevada's Opioids Crisis.

195. Purdue's business model depends on creating addicts to fuel its sales of branded extended release opioids and opioid products. When dependent users are unable to obtain prescription opioids, they turn to illicit sources of opiates such as heroin.

196. As detailed in this Complaint, the impacts of opioids in and on Nevada are inextricably linked with Purdue's marketing campaign designed to convince health care professionals, patients, and the public that opioids were and are an effective medical solution for pain management.

197. When evidence of the widespread impacts opioids were having on Nevada and across the nation began to build, Purdue carefully packaged and targeted its messages to convince health care professionals that the risks of addiction were overstated and that addiction could be managed.

198. As a result of Purdue's deceptive business practices, opioid use, addiction, and death has grown to epidemic proportions, while Purdue continues to market and sell drugs that it knows or should know could be a health risk, dangerous, and deadly.

V. Causes of Action

FIRST CAUSE OF ACTION

(Violations of Nevada's Deceptive Trade Practices Act)

199. The State re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs as though fully alleged herein.

200. Purdue violated Nevada's Deceptive Trade Practices Act, NRS 598.0903, *et seq.*, by engaging in deceptive practices, misrepresentation, and the knowing concealment and omission of material facts in connection with the marketing, promotion and sale of goods within the State.

201. Pursuant to NRS § 0.039 and NRS § 598.0915, Purdue is a person for purposes of Nevada's Deceptive Trade Practices Act.

///

202. NRS § 598.0915(5) renders it unlawful for a person to "[k]nowingly make [ ] a false representation as to the characteristics, ingredients, uses, benefits, alterations, or quantities of goods or services for sale or lease . . . ."

203. NRS § 598.0915(15) renders it unlawful for a person to "[k]nowingly make [ ] any [ ] false representation in a transaction."

204. NRS § 598.0923(2) renders it unlawful for a person to "[f]ail to disclose a material fact in connection with the sale or lease of goods or services."

205. Purdue engaged in misrepresentations and knowing omissions of material fact in violation of NRS § 598.0915(5) and (15) and NRS § 598.0923(2) in overstating the benefits of and evidence for the use of opioids for chronic pain and understated the very serious risks of opioids, including the use of opioids for pain management, the risk of addiction, overdose, abuse, and misuse, and in falsely promoting "abuse-deterrent" formulations, and in falsely claiming that OxyContin provides 12 hours of relief.

206. Purdue's specific misrepresentations include, but are not limited to:

a. Claims minimizing the risks of long-term opioid use, particularly the risk of addiction;

b. Claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be treated by prescribing *more* opioids;

c. Claims that opioids are effective in curing long-term pain and improving physical functioning;

d. Claims that addiction is caused primarily by diversion, rather than being the natural consequence of routine, and long-term, use of opioids;

e. Claims that opioid doses can be increased until pain relief is achieved;

f. Claims misleadingly comparing the risks and benefits of opioids to those of alternative forms of pain treatment;

g. Claims that medical evidence supports the long-term use of opioids for chronic pain;

h. Claims that OxyContin provides a full 12 hours of pain relief; and

i. Claims that Purdue cooperates with authorities and supports efforts to prevent opioid abuse and diversion.

207. Purdue omitted to state material facts, in its labeling, advertising, promoting, marketing, selling and/or distributing, or causing to be distributed, of opioids that it had a duty to disclose, with the intent that others rely on its omissions, and failed to correct prior misrepresentations and omissions about the risks and benefits of short- and long-term opioid use, which omissions have rendered other seemingly truthful statements deceptive.

208. Purdue's specific omissions of material fact include, but are not limited to:

a. Failing to disclose evidence that opioids are highly addictive and that chronic use can result in addiction, overdose, or death;

b. Failing to disclose that high dosages of opioids subject the user to greater risk of addiction, other injury, or death;

c. Making claims regarding the benefits of opioid treatment, particularly to manage chronic pain, which lacked scientific support or were contradicted by scientific evidence;

d. Failing to disclose that Purdue's branded 12-hour OxyContin formulation fails to last a full twelve hours in many patients;

e. Failing to disclose that "abuse-deterrent" formulations are not designed to address, and have no effect on, the most common route of abuse and misuse (oral abuse);

///

///

///

///

///

///

f. Failing to adequately report suspicious health care professionals, including those with high-volumes of opioid prescriptions, to law enforcement, Nevada medical regulators, Nevada pharmacy regulators, or other authorities;

g. Failing to disclose that the concept of "pseudoaddiction" and treatment for it is not supported by scientific evidence;

h. Failing to disclose evidence and facts regarding harmful side effects associated with the sudden cessation of use of opioids; and

i. In addition to the other acts and practices described herein, Purdue, through deception and misrepresentation, employed a sales incentive program which encouraged practices contributing to overprescription of opioids, resulting in increased incidence of opioid abuse, misuse, addiction, and overdose among Nevadans.

209. Purdue's deceptive conduct in the marketing, distribution, and sale of opioids to health care professionals and consumers in Nevada affects the public interest in that it caused injury to countless Nevadans, State, and its municipalities and counties, and contributed to a catastrophic public health crisis.

210. NRS § 598.0973 renders authority to impose heightened penalties for each instance of deceptive trade conduct directed toward an "elderly person or person with disability."

///

///

///

///

///

///

///

///

211. Purdue, in violation of NRS § 598.0973, directed a significant amount of its deceptive conduct toward elderly persons or persons with a disability in the State, and its municipalities and counties.

212. In all matters alleged herein, Purdue acted in the course of its business or occupation within the meaning of NRS §§ 598.0903 to 598.0999.

213. In all requisite matters alleged herein, Purdue acted knowingly within the meaning of NRS §§ 598.0903 to 598.0999.

214. In all matters alleged herein, Purdue acted willfully in violation of NRS §§ 598, *et seq.*, as required by NRS § 598.0999(2).

215. In all matters alleged herein, consistent with NRS § 598.0953(1), Purdue's conduct and acts are evidence that a person has engaged in a deceptive trade practice and is further prima facie evidence of intent to injure competition and to destroy or substantially lessen competition in the State, and its municipalities and counties.

VI. PRAYER FOR RELIEF

216. WHEREFORE, the State respectfully requests that the Court:

a. Order permanently enjoining Defendants from continuing the unlawful acts and practices described in the Complaint;

b. Order requiring Defendants to pay a civil penalty in an amount not exceed $5,000 per violation pursuant to NRS § 598.0999(2);

c. Order Defendants to pay a civil penalty in a sum not to exceed $12,500 per violation for engaging in any method, act or practice declared unlawful under the above-cited statutes, that is directed toward an elderly person pursuant to NRS § 598.0793;

d. Order requiring Defendants to pay restitution pursuant to NRS § 598.0993;

e. Order Defendants to pay the costs and expenses of this action incurred by the State, including but not limited to, attorney's fees and costs pursuant to NRS § 598.0999(2);

f. Order Defendants pay damages in excess of $15,000;

g. Awarding such other, further, and equitable relief, as the Court may deem just and appropriate.

DATED: May 15, 2018.

SUBMITTED BY:

ADAM PAUL LAXALT
Attorney General
ERNEST D. FIGUEROA
Consumer Advocate

By: /s/ Mark J. Krueger
MARK J. KRUEGER (Bar No. 7410)
Chief Deputy Attorney General
Consumer Counsel

By: /s/ JoAnn Gibbs
JOANN GIBBS (Bar No. Bar No. 5324)
Chief Deputy Attorney General

By: /s/ Laura Tucker
LAURA M. TUCKER (Bar No. 13268)
Senior Deputy Attorney General