

STATE OF MINNESOTA

DISTRICT COURT

COUNTY OF HENNEPIN

FOURTH JUDICIAL DISTRICT

Case Type: Other Civil

State of Minnesota by its Attorney General,
Lori Swanson,

Court File No. _____

Plaintiff,

vs.

COMPLAINTPurdue Pharma L.P., Purdue Pharma, Inc., and
The Purdue Frederick Company, Inc.,

Defendants.

The State of Minnesota, by its Attorney General, Lori Swanson (“State or “AGO”), for its Complaint against Purdue Pharma, L.P., Purdue Pharma, Inc., and The Purdue Frederick Company, Inc. (collectively, “Purdue”), hereby states and alleges as follows:

INTRODUCTION

1. Minnesota, along with the rest of the country, is in the midst of a public health crisis caused by opioid drugs. An opioid marketing campaign originated and spearheaded by Purdue, maker of the blockbuster opioid painkiller OxyContin and leader of the prescription opioid industry, contributed to the opioid epidemic.

2. To ease health care providers’ traditional reluctance to prescribe opioids and to drive the market for OxyContin and other opioids, Purdue began and has sustained a marketing campaign to deceive Minnesota health care providers about the risks and benefits of opioids.

3. Combining in-person marketing with misleading and cherry-picked scientific support, Purdue has sought to confuse and deceive health care providers by, among other things:

- misrepresenting or failing to sufficiently disclose the risks of opioid addiction;

- misrepresenting the efficacy of opioids for the long-term treatment of chronic pain;
- misrepresenting the efficacy of OxyContin to provide 12 hours of pain relief;
- misleadingly exaggerating the qualities of “abuse-deterrent” opioid formulations to deter or prevent opioid addiction and abuse;
- misrepresenting the risks of non-opioid forms of pain treatment in order to misleadingly assert the superiority of opioids;
- falsely representing that opioids have no dose limit and misrepresenting the risks of increased doses of opioids; and
- falsely describing signs of patients’ drug-seeking or abusive behavior as “pseudoaddiction” that supported the patients’ need for larger doses of opioids.

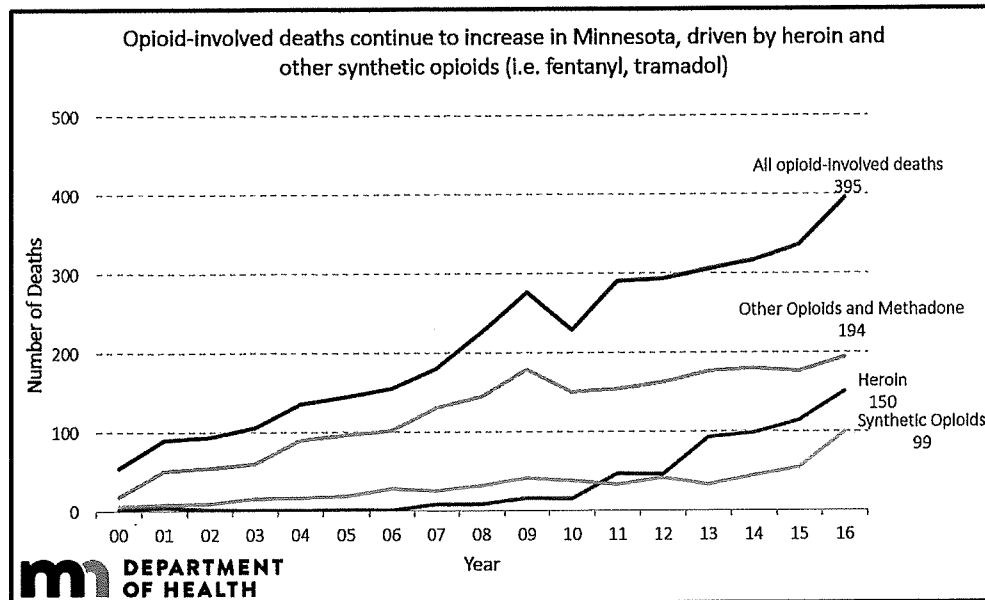
4. Purdue used numerous marketing channels to disseminate these messages to health care providers, including through a large force of sales representatives, opinion leaders, and sponsored medical education. Purdue also funded third party organizations that assisted in promoting a pro-opioid message to health care providers and patients under the guise of neutral, independent messaging.

5. Purdue’s efforts were successful. By marketing its own drugs and promoting opioids more generally for the long-term treatment of chronic pain, Purdue contributed to a rising tide of widespread opioid prescribing in Minnesota. Between 2005 and 2011, legal distribution of opioids in Minnesota increased by 72%.¹ Minnesotans filled 3.87 million opioid prescriptions in 2015, including prescriptions for nearly 50 million units of oxycodone, the active ingredient in OxyContin.²

¹ Jeanne Mettner, *The Opioid Crisis*, Minn. Medicine (Mar. 2013), <http://pubs.royale.com/article/The+Opioid+Crisis/1330890/0/article.html>.

² Minn. Board of Pharmacy, *Minnesota Prescription Monitoring Program 2015 Annual Report* (Apr. 2017), http://pmp.pharmacy.state.mn.us/assets/files/PDFs/Reports/FINAL_2015_Annual_ReportII.pdf.

6. From 2000 to 2016, the number of Minnesotans who died from opioid-related overdoses increased by more than 700 percent:³



7. Prescription opioids now kill more Minnesotans every year than homicides. When combined with other prescription drug-related deaths, the fatalities outnumber fatalities from car accidents.⁴ In Hennepin County alone, opioid-related deaths increased by nearly 60 percent between 2015 and 2016.⁵

³ Minn. Dep't of Health, *Drug Overdose Deaths Among Minnesota Residents, 2000–2016*, at 23, http://www.health.state.mn.us/divs/healthimprovement/content/documents-opioid/2016DrugOverdoseDeathReport_Final.pdf (last visited June 30, 2018); Minn. Dep't of Health, *Opioid Dashboard*, <http://www.health.state.mn.us/divs/healthimprovement/opioid-dashboard/#DeathTrends> (last visited June 30, 2018).

⁴ Jeremy Olson, *Opioid Overuse Kills More Minnesotans Than Homicide*, Star Trib. (November 28, 2015), <http://www.startribune.com/opioid-overuse-driving-minnesota-deaths/357244811/>.

⁵ Tim Nelson, Matt Sepic, *Opioid Deaths Leap in Hennepin Co.; Fentanyl Plays Deadly Role*, MPR NEWS (Apr. 10, 2017), <https://www.mprnews.org/story/2017/04/10/opioid-death-hennepin-county-jumped-2016>; see also Carol Falkowski, *Drug Abuse Trends in the Minneapolis/St. Paul Metropolitan Area* (April 2017), http://www.drugabusedialogues.com/drug_abuse_trends_reports/2017_April.pdf.

8. Purdue has made more than **\$35 billion** since it began marketing OxyContin more than 20 years ago.⁶

9. The State of Minnesota, by its Attorney General, Lori Swanson, brings this enforcement action to stop Purdue's unlawful practices, enforce Minnesota law, and hold Purdue responsible for remedying the harm its deceptive conduct has caused Minnesota.

PARTIES

10. Lori Swanson, Attorney General of the State of Minnesota, is authorized under Minnesota Statutes chapter 8, the Uniform Deceptive Trade Practices Act, Minn. Stat. §§ 325D.43–.48, the Consumer Fraud Act, Minn. Stat. §§ 325F.68–.70, Minnesota Statutes section 325F.71, and has common law authority, including *parens patriae* authority, to bring this action to enforce Minnesota's laws, to vindicate the State's sovereign and quasi-sovereign interests, and to remediate all harm arising out of—and provide full relief for—violations of Minnesota's laws.

11. Defendant Purdue Pharma L.P. is a Delaware limited partnership with its principal place of business in Stamford, Connecticut. The general partner of Purdue Pharma L.P. is Purdue Pharma, Inc.

12. Defendant Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

13. Defendant The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut.

⁶ Alex Morrell, *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/#489c4d8675e0>.

14. Collectively, the above-referenced Defendants are referred to herein as “Purdue.”

15. Purdue manufactures, promotes, markets, and distributes drugs in Minnesota and throughout the United States, including the following opioid brands:

- a. **OxyContin** (oxycodone hydrochloride extended release), which is a Schedule II⁷ opioid tablet indicated for the “management of pain severe enough to require daily, around-the clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, OxyContin was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.” OxyContin was initially approved only for adults. Purdue sought and received FDA approval for use of OxyContin in opioid-tolerant pediatric patients in August 2015.
- b. **Hysingla ER** (hydrocodone bitrate extended release), which is a Schedule II opioid tablet indicated “for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.”
- c. **Butrans** (buprenorphine), which is a Schedule III opioid transdermal patch indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative

⁷ The federal Controlled Substances Act and its implementing regulations identify drugs and other substances as “controlled substances,” and classifies them into one of five schedules based in part upon their potential for abuse, the degree of dependence they might cause, and their accepted medical use. *See generally* 21 U.S.C. §§ 801 *et seq.*; 21 C.F.R. §§ 1300–1399. Most prescription-opioid painkillers are Schedule II controlled substances, meaning they have a high potential for abuse, which may lead to severe psychological or physical dependence. *See* 21 U.S.C. § 812(b)(2).

treatment options are inadequate.” Prior to April 2014, Butrans was indicated for the “the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time.”

- d. **MS Contin** (morphine sulfate extended release), which is a Schedule II opioid tablet indicated for the “management of pain severe enough to require daily, around-the clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, MS Contin was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”
- e. **Dilaudid** (hydromorphone hydrochloride), which is a Schedule II opioid tablet and oral solution indicated for “the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.” Prior to 2016, Dilaudid was indicated for the “management of pain where an opioid analgesic is appropriate.”
- f. **Dilaudid-HP** (hydromorphone hydrochloride), which is a Schedule II opioid injection indicated for “use in opioid-tolerant patients who require higher doses of opioids for the management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate.” Prior to 2016, Dilaudid-HP was indicated for “the management of moderate-to-severe pain in opioid-tolerant patients who require higher doses of opioids.” Dilaudid-HP has also previously been indicated “for the relief of

moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief.”

- g. **Targiniq ER** (oxycodone hydrochloride and naloxone hydrochloride), which was a Schedule II combination product of oxycodone and naloxone, an opioid antagonist, indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.”
- h. **Ryzolt** (tramadol hydrochloride extended release), which was an opioid-like tablet indicated for “the management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time.”

JURISDICTION

16. This Court has subject matter jurisdiction over this action pursuant to Minnesota Statutes sections 8.01, 8.31, 8.32, 325D.15, 325D.45, 325F.70, 325F.71, and common law.

17. This Court has personal jurisdiction over Purdue because Purdue has purposefully and knowingly transacted business in Minnesota and with Minnesota residents, and has committed acts inside and outside Minnesota causing injury to the Minnesota public and in violation of Minnesota law.

VENUE

18. Venue in Hennepin County is proper under Minnesota Statutes section 542.09 because the cause of action arose, in part, in Hennepin County. Purdue has done business in Hennepin County, and Purdue’s unlawful acts have affected Hennepin County residents, among others.

FACTUAL BACKGROUND

19. Since the mid-1990s, Purdue has manufactured, promoted, and sold extended-release (also known as “long-acting”) opioids for the treatment of chronic,⁸ long-term pain.

20. Using face-to-face visits by its sales representatives, branded and unbranded marketing materials, and third party materials that it created, edited, funded, or otherwise sponsored, Purdue disseminated confusing, deceptive and misleading statements about the effectiveness of opioids, and the risks (or supposed lack of risks) of opioids, including the risks of addiction and abuse.

21. Purdue’s intent was to convince the members of the medical community to suspend their prior caution and restraint about prescribing opioids outside of cancer or end-of-life care, in order to expand the scope and amount of opioids prescribed and increase sales of these drugs. Following Purdue’s confusing and deceptive marketing, Minnesota health care providers prescribed opioid pain medications with greater frequency and in larger quantities.

22. OxyContin is Purdue’s best-selling opioid. Since 2009, Purdue’s annual sales of OxyContin have fluctuated between \$2 to \$3 billion. Purdue has reportedly sold more than \$35 billion worth of OxyContin since it began marketing the blockbuster painkiller in 1996.⁹ Since [REDACTED], more than [REDACTED] OxyContin prescriptions have been filled by Minnesota patients.

⁸ The Centers for Disease Control and Prevention (“CDC”) has defined chronic pain as pain lasting more than “3 months or past the time of normal tissue healing.” Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, at 1 (Mar. 18, 2016).

⁹ Alex Morrell, *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/#489c4d8675e0>.

23. The results of Purdue's confusing, deceptive, and misleading conduct adversely impacted Minnesota and has caused widespread public harm.

I. PURDUE CREATED A MARKET FOR OPIOIDS THROUGH FRAUDULENT MARKETING AND PROMOTING OF OXYCONTIN.

A. Background on Opioids.

24. Opioids are natural, semisynthetic, and/or synthetic derivatives of the opium poppy. There are several different types of opioid molecules used for illicit and medicinal purposes, including both illegal substances like heroin, and prescription painkillers like morphine (e.g., MS Contin), oxycodone (e.g., OxyContin and Percocet), hydrocodone (e.g., Hysingla), oxymorphone, hydromorphone, tapentadol, buprenorphine, and methadone.

25. Opioids act as central nervous system depressants which attach to receptors in the brain, spinal cord, and gastrointestinal tract, and suppress function. This results in the reduction of the intensity of pain signals that reach the brain, and is the reason why the primary clinical use of opioids is for pain relief, also known as analgesia. In addition to reducing pain, opioids trigger chemical processes that create intense feelings of euphoria, making them highly susceptible to addiction and abuse.

26. Opioid medications come in two basic formulations: immediate-release, or "short-acting," and extended-release, or "long-acting." Extended-release opioids contain greater doses of the same active ingredients as immediate-release opioids, but use a time-release matrix designed to release the drug over time. OxyContin, for example, is oxycodone in a time-release matrix that Purdue claims delivers the drug over a 12-hour period.

27. The immediate-release opioid market is heavily generic. The extended-release market has far more branded products. Purdue's drugs comprise a large portion of the extended-release market.

28. By design and marketing, Purdue's drugs are intended for long-term use. Purdue has marketed them heavily for treatment of chronic, non-cancer pain. As described below, long-term use of opioids, particularly in higher doses, greatly increases the risk of potentially deadly side effects.

29. While the federal Food and Drug Administration ("FDA") has approved the sale of opioids, Purdue deceptively marketed its opioid products beyond the indications approved by the FDA and in such a fraudulent and deceptive manner that the FDA's approval of its products cannot, and should not, shield Purdue from liability for its unlawful conduct.

30. Opioids place patients at significant risk of addiction, abuse, and overdose, all of which can lead to serious patient harm, including death. For instance, opioids depress respiration, meaning that they reduce the user's drive to breathe. Respiratory depression is the primary mechanism by which opioids have killed thousands of Minnesota residents and hundreds of thousands of Americans. "[V]ictims of a fatal overdose usually die from respiratory depression—literally choking to death because they cannot get enough oxygen to feed the demands of the brain and other organ systems."¹⁰ Opioids are undisputedly addictive and deadly.

B. Purdue Created and Expanded the Public Demand for Opioids with the Introduction and Marketing of OxyContin.

31. Before Purdue began aggressively marketing its opioids around the mid-1990s, generally accepted standards of medical practice were that opioids should only be used as a short-term treatment for short-term (acute) pain or for cancer or palliative care. In those instances, the risks of addiction are low or inconsequential.

¹⁰ See Dina Fine Maron, *How Opioids Kill*, Scientific American (Jan. 8, 2018), <https://www.scientificamerican.com/article/how-opioids-kill/>.

32. Dr. Russell Portenoy, a pain management specialist who received significant Purdue funding through research support and consulting work, described the prevailing attitude of the medical community toward opioids in 1994:

The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. . . . Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. **There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.**¹¹

According to Dr. Portenoy, these problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”¹²

33. Despite these warnings, in 1996 Purdue introduced OxyContin to the market and sought to change the perception of the medical community by marketing the new drug as the “solution” to the supposedly-unaddressed problem of chronic, non-cancer pain. Purdue lost no time in misrepresenting the addictive properties of OxyContin and opioids: in the press release announcing the release of OxyContin, Purdue claimed that “[t]he fear of [opioid] addiction is exaggerated” and “largely unfounded,” and quoted an executive of the American Pain Society, a pro-opioid, Purdue-funded organization described below, as saying that “there is very little risk of addiction from the proper uses of [opioids] for pain relief.”

¹¹ Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247, 247 (1994) (emphasis added).

¹² *Id.*

34. Through incessant and widespread marketing efforts, Purdue convinced health care providers that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. As detailed throughout, these representations were untrue, confusing, deceptive, and misleading.

35. Purdue knew from the beginning that it could not substantiate its claims about the benefits and lack of risks of long-term opioid use with scientific support. The FDA-approved labels of Purdue's extended-release opioids do not address use of those products for more than three months. From the first OxyContin label, dating back to 1995, to today, the only clinical study relied upon by Purdue to show OxyContin's efficacy in adults is a two-week study of 133 patients. No other clinical trials on the efficacy of opioids extend beyond 12 weeks. Nonetheless, Purdue marketed OxyContin and its other extended-release opioids with the understanding and expectation that health care providers—believing the drug to be appropriate for long-term use—would prescribe it to their chronic pain patients for months or years.

36. As a result of Purdue's marketing campaign, by the mid-2000s the medical community had abandoned its previous caution about prescribing these potent painkillers, and opioids had become entrenched as an appropriate—and often initial—treatment for chronic pain conditions. Purdue's marketing targeted generalists—primary care physicians, nurse practitioners, and physician assistants—who were both most likely to see patients with chronic pain conditions and the least likely to have the training and experience to evaluate Purdue's marketing and patients' pain conditions. Purdue's confusing and deceptive marketing resulted in certain doctors who treated chronic pain with opioids, and patients who expected and demanded opioid prescriptions from health care providers. This laid the groundwork for today's epidemic of opioid abuse and addiction.

37. Purdue skewed the medical and public understanding of prescription opioids to minimize their risks and exaggerate their benefits—a distortion that Purdue has failed to correct and from which it continues to benefit. It also provided the framework on which Purdue's equally confusing and deceptive marketing in the late-2000s through today was built.

38. To spread its false and misleading messages, Purdue marketed its opioids directly to health care providers and patients nationwide and in Minnesota. It did so principally through its sales force—sales representatives who made face-to-face sales calls to health care providers in which they misleadingly portrayed the risks and benefits of chronic opioid therapy.

39. This misinformation included, most prominently, deceptive statements about the risk of addiction. For example, the United States Department of Justice found in resolving criminal charges against Purdue in 2007 that sales representatives had “falsely told some health care providers that . . . OxyContin did not cause a ‘buzz’ or euphoria, caused less euphoria [and] had less addiction potential,” among other things.¹³ Similarly, the sales force was taught, and passed on to health care providers, that opioids were not addictive when legitimately prescribed.

40. Purdue also engaged in widespread advertising of OxyContin, including through print ads in medical journals and videos distributed directly to physicians. These ad campaigns deceptively portrayed both the risks and benefits of chronic opioid therapy. For example, Purdue distributed thousands of copies of a video to doctors that included the following statement: “Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. [Opioids] don’t wear out, they go on working, they do not have serious medical side effects.”

¹³ Criminal Information at 14–15, *United States v. The Purdue Frederick Company, Inc., et al.*, No. 1:07-CR-00029 (W.D. Va. May 10, 2007).

41. The FDA warned Purdue about ads that ran in the *Journal of the American Medical Association*, expressing concern that they would lead to ill-considered prescribing of OxyContin because the body of the ad text nowhere referred to the “potentially fatal risks associated with the use of OxyContin and the abuse liability of OxyContin,” and further made “unsubstantiated efficacy claims promoting the use of OxyContin for pain relief.” One of the advertisements featured a man and boy fishing under the tagline “There Can Be Life With Relief,” misleadingly implying long-term improvement in patients’ pain, function, and quality of life, and touting OxyContin as an “around-the-clock analgesic . . . for an extended period of time.”¹⁴

¹⁴ FDA Warning Letter to Michael Friedman, Purdue Executive Vice President and Chief Operating Officer, Nov. 2002 Ad Enclosed with Letter (January 17, 2003).

For moderate to severe pain when continuous, around-the-clock analgesic is needed for an extended period of time

THERE CAN BE LIFE WITH RELIEF

The most serious risk associated with opioids, including OxyContin[®], is respiratory depression. Common opioid side effects are constipation, nausea, sedation, dizziness, vomiting, pruritus, headache, dry mouth, sweating and weakness. OxyContin[®] is contraindicated in patients with known hypersensitivity to oxycodone, or in any situation where opioids are contraindicated. Please see **Contraindications** section in package insert.

Purdue is firmly committed to maintaining the highest standards of marketing practices in the industry while continuing to advance the proper treatment of pain in America. If Purdue's marketing and sales practices fail to meet this standard, we urge you to contact us at 1-888-690-9211.

0.12h
OXYCONTIN[®] II
(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS
IT WORKS

Please read brief summary of prescribing information including boxed warning on reverse side.

Copyright © 2007 Purdue Pharma L.L.C. All rights reserved. OX 0201 1420 4/07 45 P.S. 0000078

42. The FDA's warning letter called the ad "particularly disturbing" for promising that OxyContin would provide "Life With Relief," yet failing "to warn that patients can die from taking OxyContin."

43. Purdue also falsely promoted OxyContin as effective for a full 12 hours and providing "steady state" relief, claiming that it was less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse. In 2007, the federal government found that Purdue's sales representatives used misleading graphical depictions of OxyContin's 12-hour effect in order to "falsely state[] to some health care providers that OxyContin had less euphoric

effect and less abuse potential than short-acting opioids.”¹⁵ As further detailed below, Purdue’s promotion of OxyContin’s 12-hour effectiveness was critical to establish its market advantage over other competitors and justify its price.

44. Purdue’s sales strategies coalesced behind a message that opioids could be safely prescribed and used, even long-term, without causing patients to become addicted and potentially overdose and die. As addressed below, Purdue’s efforts to trivialize the risk of addiction and promote the supposed functional improvement offered by opioids were, and remain, at odds with scientific evidence.

45. Because Purdue’s claims regarding chronic opioid therapy lacked scientific support, Purdue sought to create the illusion of such support. Purdue reinforced its direct promotion of opioids with an array of marketing approaches that bolstered the same confusing and deceptive messages by filtering them through seemingly independent and objective sources.

46. For instance, Purdue funded biased research and sponsored continuing medical education (“CME”) programs that misleadingly portrayed the risks and benefits of chronic opioid therapy. It collaborated with professional associations and pain advocacy organizations to develop and disseminate pro-opioid educational materials and guidelines for prescribing opioids. And, Purdue created “unbranded” websites and materials, copyrighted by Purdue but implied to be the work of separate organizations, that echoed Purdue’s branded marketing.

47. Among these tactics, which originated in the late 1990s and early 2000s, three stand out for their lasting influence on opioid prescribing nationwide and in Minnesota: (1) Purdue’s use, for its own purposes, of an increased focus on pain treatment by the medical

¹⁵ Criminal Information at 9, *United States v. The Purdue Frederick Company, Inc., et al.*, No. 1:07-CR-00029 (W.D. Va. May 10, 2007).

community; (2) Purdue's efforts to create or sponsor flawed scientific literature on chronic opioid therapy; and (3) Purdue's corrupting influence on authoritative treatment guidelines issued by professional associations.

i. Purdue Used the Medical Community's Increased Focus on Pain as a Springboard for Its Confusing and Deceptive Marketing.

48. As Purdue developed OxyContin in the mid-1990s, it was able to both create and capitalize on a movement in the medical community to prioritize pain treatment a priority for all patients. Early boosters such as Dr. Portenoy, the pro-opioid researcher and beneficiary of significant Purdue funding, discounted the risk of opioid addiction and advocated that "opioid maintenance therapy [could] be a safe, salutary and more humane alternative" to not treating patients with chronic pain.¹⁶

49. In the late 1990s, the American Pain Society ("APS"), headed by Dr. Portenoy, pushed to make pain the "fifth vital sign"—an indicator doctors should monitor alongside blood pressure, temperature, heartbeat, and respiration. APS, like Dr. Portenoy, received substantial funding from Purdue.

50. In 2001, the Joint Commission on the Accreditation of Healthcare Organizations ("JCAHO"), which accredits hospitals and other health care programs across the United States, published pain treatment standards. The JCAHO standards called for assessment of pain in all patients and in each physician-patient interaction and made accreditation decisions contingent on institutions having policies to accomplish this goal.

51. JCAHO licensed Purdue to distribute educational videos about how to comply with the new pain management standards and a book about pain management, which were also

¹⁶ Russell Portenoy and Kathleen Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 Pain 171, 171 (May 1986).

available for purchase on the JCAHO website. Purdue also funded and disseminated the publication *How to Meet the JCAHO Standards*, which encourages discussing opioids in positive terms and identifies several pro-opioid pain advocacy groups as resources.

52. Both the “pain as the fifth vital sign” campaign and the JCAHO pain management standards have been widely integrated into medical practice, in Minnesota and nationwide. Minnesota prescribers were cognizant of this push to diagnose pain and treat it with opioids, and records of their visits with Purdue sales representatives show that they raised concerns about the effect these initiatives had in influencing patients to expect opioids and encouraging the over-prescription of opioids. For example, one Minnesota physician stated [REDACTED] [REDACTED] He stated his patients felt [REDACTED] [REDACTED], a sentiment echoed by other Minnesota physicians. Another physician said he wished that [REDACTED] while yet another said that he [REDACTED] [REDACTED] [REDACTED]

53. With these initiatives, Purdue was able to swing the pendulum away from fear of opioid prescribing, and toward overprescribing of opioids.

ii. Purdue Used Flawed and Biased Research to Misrepresent the Science Regarding the Efficacy and Risks of Opioids.

54. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific “support” for its marketing claims by sponsoring studies that were methodologically flawed, biased, and drew inappropriate conclusions from prior evidence. It then published studies with favorable outcomes and suppressed those that did not support its marketing goals. The result was literature cloaked in the imprimatur of legitimate scientific research, but whose actual primary purpose was to push the use of opioids for chronic pain.

Subsequent studies then cited—and continue to cite—this research, the upshot of which was that the body of evidence on which prescribers rely to prescribe opioids now fully incorporates Purdue’s fake science.

55. For example, Purdue-sponsored studies and marketing materials that cited them regularly made claims that “the risk of psychological dependence or addiction is low in the absence of a history of substance abuse.” One such study, published in the journal *Pain* in 2003¹⁷ and widely referenced since, ignored previous Purdue-commissioned research showing addiction rates between 8% and 13%.¹⁸

56. To support the claim that OxyContin was rarely addictive, the *Pain* article and others like it reached back, not to a peer-reviewed journal article, but rather to a decades-old letter to the editor. That letter—known as the “Porter-Jick Letter”¹⁹—is reproduced in full below:

¹⁷ C. Peter N. Watson et al., *Controlled-Release Oxycodone Relieves Neuropathic Pain: A Randomized Controlled Trial in Painful Diabetic Neuropathy*, 105 *Pain* 71, 72 (2003).

¹⁸ See Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10 *Headache Q.* 135, 137 (July 1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 *Headache Q.* 305, 306 (1999).

¹⁹ Jane Porter and Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 *New Eng. J. Med.* 123 (1980).

**ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS**

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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

57. The Porter-Jick Letter does not reflect any study, but simply describes a one-time review of the charts of hospitalized patients who received opioids. Although the letter notes that the review found almost no references to signs of addiction, there is no indication that caregivers were instructed to assess or document signs of addiction. And, because the opioids were administered in a hospital—unlike the outpatient opioids marketed by Purdue—there was no risk of patients increasing their use.

58. Purdue has referenced the Porter-Jick letter in its marketing brochures. Yet Purdue has failed to disclose both the nature of the citation (a letter, not a study) or any of its serious limitations. In fact, Dr. Jick publicly complained that the letter has been misused by drug companies “that were pushing out new pain drugs” and using his letter to conclude that their new

opioids were not addictive, stating that such representations were “not in any shape or form what we suggested in our letter.”²⁰

59. The New England Journal of Medicine published an analysis of the effect of the Porter-Jick Letter in June 2017, in which researchers noted that citation of the letter significantly increased after the introduction of OxyContin and that more than 72% of the articles referencing the letter cited it “as evidence that addiction was rare in patients treated with opioids.”²¹ Accordingly, the researchers concluded “that this citation pattern 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.”²² In response, the New England Journal of Medicine’s website has since taken the unusual step of appending the Porter-Jick letter with a note from the editor, stating that “[f]or 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.”²³

60. Purdue’s strategy to plant and promote supportive literature, while obscuring or failing to disclose less favorable scientific evidence, was confusing, deceptive, misleading, and in violation of its legal obligations to health care providers, patients, and the State. This strategy was intended to, and actually did, twist the truth regarding the risks and benefits of opioids for chronic pain relief, and harmfully increased opioid prescribing patterns as a result. Purdue’s

²⁰ Taylor Haney and Andrea Hsu, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed the Opioid Crisis*, Nat’l Pub. Radio (June 16, 2017), available at <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>.

²¹ Pamela Leung, et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 New Eng. J. Med. (June 1, 2017).

²² *Id.*

²³ Available at <https://www.nejm.org/doi/10.1056/NEJM198001103020221>.

marketing and “education” materials were not supported by substantial scientific evidence, excluded contrary evidence about opioids’ risks and benefits, and presented broad conclusions not supported by study results.

iii. Purdue Used Professional Associations to Create Treatment Guidelines that Overstated the Benefits and Understated the Risks of Opioids.

61. Treatment guidelines were important to Purdue in securing acceptance for chronic opioid therapy. They are relied upon by health care providers, especially general practitioners and family doctors who lack specific training in treating chronic pain. Treatment guidelines not only directly inform prescribing practices, but are cited throughout the scientific literature and referenced by third-party payers in determining whether they should cover treatments. Purdue financed and collaborated with multiple groups on guidelines that have been, and continue to be, influential in Minnesota and nationwide.

a. AAPM/APS Guidelines

62. In 1997, the APS and the American Academy of Pain Medicine (“AAPM”) released a “consensus statement” entitled *The Use of Opioids for the Treatment of Chronic Pain*, that was co-authored by Dr. J. David Haddox, who at the time was a paid speaker for Purdue and later become a senior executive for the company. Dr. Portenoy was the sole consultant on the statement. The consensus statement was distributed by Purdue sales representatives to Minnesota health care providers.

63. The statement contains a number of misrepresentations common to other Purdue and third-party materials that are further explained below, including that:

- opioids are an “essential part of a pain management plan”;
- “de novo development of addiction when opioids are used for the relief of pain is low”;

- even “known addicts can still benefit” from opioid use;
- respiratory depression associated with opioid use “tends to be a short-lived phenomenon” that generally only affected opioid-naïve patients; and
- “most opioids” did not have an “arbitrary upper dosage limit, as was previously thought.”

64. AAPM and APS then issued opioid prescribing guidelines in 2009 that continued to recommend the use of opioids to treat chronic pain. Six of the 21 panel members who drafted those guidelines, including Dr. Portenoy, received financial support from Purdue, and another eight received support from other opioid manufacturers. One panel member resigned because of his concerns that the guidelines were influenced by contributions from drug companies, including Purdue.²⁴

65. The 2009 AAPM/APS Guidelines champion opioids as “safe and effective” for treating chronic pain, and attribute the increase in opioid prescriptions to “a growing consensus that opioid therapy is appropriate” for chronic pain patients. The Guidelines propose a number of “strong recommendation[s]” despite “low-quality evidence,” including that opioids are appropriate for chronic pain treatment and that the risk of opioid addiction is manageable for patients, even patients with a prior history of drug abuse.

66. The 2009 AAPM/APS Guidelines are still available online, were reprinted in the influential *Journal of Pain*, and have been an especially effective conduit of deception influencing not only prescribers, but also the body of scientific evidence on opioids.

²⁴ John Fauber, *Chronic Pain Fuels Boom in Opioids*, Milwaukee J. Sentinel and MedPage Today (Feb. 19, 2012).

67. APS and AAPM each received substantial funding from Purdue. Since 2012, APS has received about \$542,000 from Purdue, and AAPM has received more than \$725,000.²⁵

b. American Geriatrics Society

68. The American Geriatrics Society (“AGS”), a nonprofit organization focused on health care providers who treat the elderly, published and disseminated guidelines regarding the use of opioids for chronic pain in 2002 and 2009.

69. The 2009 AGS Guidelines “strong[ly]” recommended that “[a]ll patients with moderate to severe pain, pain-related functional impairment, or diminished quality of life due to pain should be considered for opioid therapy,” despite noting the “low quality of evidence” supporting this recommendation. It also claimed that the risk of addiction was “exceedingly low in older patients with no current or past history of substance abuse,” and that “older age is significantly associated with lower risk for opioid misuse and abuse.” These recommendations are not supported by any study or other reliable scientific evidence.

70. AGS received a total of \$344,000 from opioid manufacturers, including Purdue, from 2009 to 2012.²⁶ Five out of the 10 participants on the panel for the 2009 guidelines disclosed financial ties to opioid makers, including two who had served as paid consultants for Purdue in the year before the guidelines were published.

²⁵ See U.S. Senate Homeland Security and Governmental Affairs Committee, Ranking Member’s Office, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 2018), <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf>.

²⁶ John Fauber and Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel and Medpage Today (May 30, 2012), <https://www.medpagetoday.com/geriatrics/painmanagement/32967>.

II. PURDUE HAS USED ITS SALES FORCE, THIRD-PARTY FRONT GROUPS, AND PAID MEDICAL PROFESSIONALS TO TARGET MINNESOTA HEALTH CARE PROVIDERS AND PATIENTS IN ORDER TO INCREASE OPIOID PRESCRIBING AND PURDUE'S OWN PROFITS.

71. Using the faulty science and publications mentioned above, among other things, Purdue has engaged in a marketing campaign to deceive health care providers and patients into believing that opioids, especially Purdue's own drugs, were effective and safe, and should therefore be widely prescribed. Purdue has continued to omit discussion of the serious risks of opioids and lack of evidence supporting long-term opioid use—thereby failing to correct its prior deceptions, to its benefit—and to affirmatively misrepresent the risks and benefits of opioids.

72. Even after pleading guilty to federal criminal charges in 2007 and agreeing to no longer misrepresent the risks of OxyContin and other opioids, Purdue continued to tell health care providers and patients that opioids in general, and Purdue's products in particular, are safe, effective, and suitable for widespread prescribing and use.

73. Purdue did so by continuing to use its sales force, third-party front groups, and Purdue-sponsored medical education to disseminate confusing, deceptive, and misleading information about pain treatment with opioids. Purdue's sustained efforts were successful in continuing to further two of the most important factors that led to, and continue to fuel, the ongoing opioid epidemic: (1) Purdue created a belief among health care providers that they should 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 to seek out health care providers who were willing to accommodate these expectations of opioids on request. Purdue centrally developed its marketing strategies and materials, which were deployed in Minnesota and throughout the country.

A. Purdue Used Sales Representatives to Engage in Deceptive Face-to-Face Marketing to Minnesota Health Care Providers.

74. Since the launch of OxyContin, Purdue has relied heavily on its sales representatives to market its opioids directly to prescribers, and that practice continues. Purdue has sent sales representatives to market its opioid products face-to-face in Minnesota doctors' offices, clinics, pharmacies, and hospitals. Since 2006, Purdue sales representatives have met with Minnesota health care providers **more than [REDACTED] times**. This frequency is consistent with Purdue's practice in other states; for instance, the Massachusetts Attorney General stated that Purdue sales representatives met with Massachusetts health care providers more than 150,000 times in a similar timeframe.

75. By establishing personal relationships with doctors, Purdue's sales representatives are able to disseminate their misrepresentations in targeted, one-on-one settings that allows them to differentiate Purdue's opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain.

76. Since 2006, Purdue's sales force of [REDACTED] Minnesota sales representatives has visited and distributed promotional materials to [REDACTED] of Minnesota health care providers. Most of these prescribers were visited repeatedly; in fact, more than [REDACTED] Minnesota health care providers were visited [REDACTED] times or more by Purdue in this time period, sometimes as often as every week.

77. Purdue developed sophisticated plans to select health care providers for sales visits based on their prescribing habits. Purdue purchased and closely analyzed prescription sales data from IMS Health Inc., a private vendor of health care information, that allowed Purdue to track the prescribing of both its own opioids and those of its competitors.

78. Purdue trained its sales representatives to minimize the risk of addiction, as well as exaggerate health care providers' abilities to manage patients' addiction to opioids. Sales representatives were 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 providers, Purdue directed its sales representatives through training activities and reviews of call notes from each visit.

79. In addition to addressing the concerns of health care providers who were disinclined to routinely prescribe opioids, Purdue also sought to become a source of information to which health care providers looked in making prescribing decisions. It did so by delivering and discussing the sort of confusing and deceptive unbranded materials described below directly to Minnesota health care providers.

80. The effects of in-person marketing on prescribing behavior are well-documented in studies and other literature, including a 2009 study partly attributing a nearly ten-fold increase in OxyContin prescriptions from 1997 to 2002 to Purdue's doubling of its sales force and tripling of its sales calls.²⁷ Studies have proven the inverse of this pattern true as well; for example, a 2017 American Medical Association study found that health care providers prescribed fewer brand-name drugs and more generic drugs if they worked at medical facilities that implemented policies restricting promotion of brand-name drugs by pharmaceutical sales representatives, with stricter policies resulting in greater differences in prescribing patterns.²⁸

²⁷ Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Public Health 221 (Feb. 2009).

²⁸ Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. Am. Med. Ass'n 1785, 1793 (May 2017).

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

B. Purdue Controlled and Funded Medical Education and Opinion Leaders In Order to Support Its Promotion of Opioids for Use in Treating Chronic Pain.

82. Purdue also paid certain health care providers to be "key opinion leaders," whom it designated as "experts" in the field, to deliver speeches about pain treatment and the risks and benefits of opioid prescribing. These opinion leaders are particularly influential on the prescribing habits of their peers due to their professional reputations and the appearance of independent objectivity. Opinion leaders received substantial funding and research grants from Purdue.

83. In addition, Purdue employees and opinion leaders identified, funded, published, and disseminated research that was designed to assist Purdue's marketing efforts and skewed or misrepresented the scientific evidence. Such misleading research and associated publications are described throughout this Complaint.

84. Most prominent among these opinion leaders was Dr. Russell Portenoy, mentioned above, who was the Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York. Dr. Portenoy, who received significant compensation from Purdue, served on the committees responsible for approving the APS and AAPM Guidelines, and was a board member of the American Pain Foundation ("APF"). Throughout Dr. Portenoy's involvement in shaping treatment guidelines like these, as well as his research and speaking events, he made numerous claims minimizing the risk of opioid addiction intended to ease the fear of opioids and expand their use.

85. Dr. Portenoy has since expressed regret about his role in destigmatizing opioid prescribing. He has called the increase in opioid prescribing “quite scary,” and said that “if [he] had an inkling of what [he knows] now then, [he] wouldn’t have spoken in the way that [he] spoke. It was clearly the wrong thing to do.”²⁹ He also admitted that his teachings on opioid therapy “reflect[ed] misinformation.”³⁰

86. In addition to national medical figures, Purdue has made significant payments to several Minnesota physicians for providing consulting services or making speeches on Purdue’s behalf. For example, from 2013 to 2016, Purdue paid four Minnesota doctors more than \$200,000 for such speaking and consulting services. One of these doctors [REDACTED], and was paid more than \$125,000 by Purdue from 2013–2016.

87. Purdue also often sponsored continuing medical education (“CME”) presentations focused on opioid prescribing or pain management, which contained numerous misrepresentations as described below. As a result of its role in funding these presentations, Purdue has had considerable influence over these medical education avenues, including the messenger, the message, and its distribution.

C. Purdue Supported Third-Party Front Groups and Distributed Their Unbranded Marketing Materials.

88. In addition to its support and influence regarding the treatment guidelines created by third parties described *supra*, Purdue has, through grants, supported other third party

²⁹ Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17, 2012).

³⁰ *Id.*

organizations. From 2006 through the end of 2016, Purdue provided more than \$ [REDACTED] million in direct grants to third parties.

89. Many of these grants went to organizations that assisted Purdue's marketing efforts. For instance, Purdue and other pharmaceutical manufacturers provided almost all of the funding for the APF, which offered publications targeted at health care providers, patients, policymakers, and journalists.³¹ APF's materials, and the materials of many of the other listed organizations, contained numerous misrepresentations about the efficacy and risks of opioids, as described throughout herein.

90. Purdue funded and acted through these third-party groups because health care providers were conditioned to trust their perceived objectivity—as opposed to Purdue's branded marketing materials—when making treatment and prescribing decisions.

91. In fact, a 2016 Purdue-commissioned marketing study of doctors recommended that [REDACTED]

III. PURDUE MADE MISLEADING STATEMENTS ABOUT THE RISKS OF PRESCRIBING OPIOIDS FOR CHRONIC PAIN AND FAILED TO SUFFICIENTLY DISCLOSE THE MAGNITUDE OF THOSE RISKS.

A. Purdue Misrepresented and Failed to Disclose the Risks of Addiction To Its Opioid Products.

92. Purdue, through its own marketing channels and those of third parties it funded and sponsored, falsely represented that opioids pose a low risk of addiction and that patients who had not previously experienced addiction would not become addicted to opioids.

³¹ Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011), <https://www.propublica.org/article/the-champion-of-painkillers>.

93. Extensive medical research shows that the opposite is true: opioids pose a considerable risk of addiction, abuse, and overdose. In particular, opioids pose a substantial risk of addiction when used long-term—such as for treatment of chronic pain—and when they are administered outside the close supervision of medical professionals. Some studies have found opioid dependence rates to be as high as 26% and opioid addiction rates to be as high as 14%.³²

94. Once a patient starts opioid treatment, especially with a longer initial prescription, it is enormously difficult to stop. A 2017 CDC study determined that the probability of continued long-term use escalates most sharply after five days of opioid use, and further increases when one month of opioids are prescribed—in the study, nearly 30% of those patients were still taking opioids one year later.³³ In another study, more than half of patients who used opioids for 90 days were still using opioids five years later.³⁴

95. This is also true for patients who use extended-release opioids like OxyContin. The CDC has found that patients who initiated treatment with an extended-release opioid have a 27.3% likelihood to be using opioids one year later, and a 20.5% probability to be using opioids three years later.³⁵

³² CDC Guideline, *supra* note 8, at 9–10.

³³ Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66 *Morbidity and Mortality Weekly Report* 265, 267 (2017).

³⁴ Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26 *J. Gen. Internal. Med.* 1450 (2011).

³⁵ Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66 *Morbidity and Mortality Weekly Report* 265, 266 (2017).

96. Many patients become addicted to opioids even when validly prescribed by a medical professional. One study found that 75% of those addicted to heroin first regularly used prescription opioids.³⁶

97. Opioid addiction can also affect even those patients with no prior history of addiction or substance abuse. The CDC's review of clinical research has "found insufficient evidence to determine how harms of opioids differ depending on past or current substance use disorder."³⁷

98. Extended-release opioids in particular, including Purdue's extended-release products like OxyContin, pose special risks for addiction due to their greater dosages of active opioid ingredients than immediate-release opioids. For instance, in response to a citizen request to review extended-release opioid labeling and its findings regarding the "disproportionate safety concerns" regarding extended-release opioids, in 2013 the FDA required a new black-box warning on opioid labels to "give greater emphasis and prominence to the risks of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death."³⁸

99. Purdue's marketing strategies and business model relies on the fact that its drugs are inherently addictive and can lead to long-term use by patients. Purdue's internal documents show that [REDACTED] of its OxyContin business and [REDACTED] of its Butrans business have been derived from continuing prescriptions. Purdue is financially incentivized to promote its drugs in a way that cultivates and sustains a patient base of chronic, long-term users.

³⁶ Theodore J. Cicero et al., *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71 J. Am. Med. Ass'n Psychiatry 821, 823 (July 2014).

³⁷ CDC Guideline, *supra* note 8 at 28.

³⁸ U.S. Food and Drug Administration, Letter to Dr. Andrew Kolodny, Docket No. FDA-2012-P-0818 (Sept. 10, 2013), at 6-7.

i. **Purdue Deceptively Claimed That Opioids Were Not Addictive and Hid the True, Substantial Risks of Opioid Addiction.**

100. Despite the wealth of evidence, both scientific and anecdotal, that opioids carry a significant risk of addiction, Purdue minimized or omitted any discussion with doctors of the risk of opioid addiction and trained its sales representatives to tell doctors that the risk of addiction is less than one percent. A number of Purdue-sponsored or Purdue-funded third-party publications also misrepresented the risk of opioid addiction and shifted the blame for addiction from the drug to the inherent addictive personalities of those to whom it was prescribed.

101. For example, shortly after its criminal guilty plea in 2007 Purdue began producing a pamphlet called *Providing Relief, Preventing Abuse*. Purdue targeted this publication toward “Healthcare Professional[s],” and purported to provide them information about “the safe and appropriate use of opioid analgesics.” Multiple versions of *Providing Relief, Preventing Abuse*—spanning from 2007 through 2014—deceptively claim that opioid addiction is not caused by opioids, but should instead be blamed on the user. The publication states:

Addiction is a disease. **It is not caused by drugs;** it is triggered in a susceptible individual by exposure to drugs, most commonly through abuse. The kind of drug, the person’s environment, their psychological makeup, and other social factors can contribute to the risk of addiction.

(emphasis added). Purdue sales representatives frequently provided copies of *Providing Relief, Preventing Abuse* to Minnesota health care providers.

102. Another Purdue publication from its unbranded *Partners Against Pain* project, entitled *Clinical Issues in Opioid Prescribing*, quoted the previously-described AAPM/APS consensus document, which it called “the most current thinking” on pain medicine terminology, to claim that the risk of opioid addiction “is not known and probably varies with genetic predisposition, among other factors” and “is not a predictable drug effect.” The publication—

widely disseminated to Minnesota health care providers— also cites a pain expert who claims that “scientific data show that almost all patients with painful medical conditions requiring opioids for treatment discontinue their use after the medical condition for which opioids were needed no longer exists.” Purdue’s internal documents show that the website on which it hosted this unbranded marketing material garnered nearly [REDACTED] visits by Minnesotans from 2012 through 2016.

103. Yet another Purdue publication provided to Minnesota health care providers, *Resource Guide for People with Pain*, instructed patients to not be concerned about the addiction risk of opioids:

Many people living with pain and even some health care providers believe that opioid medications are addictive. **The truth is that when properly prescribed by a health care professional and taken as directed, these medications give relief—not a ‘high.’**

104. Purdue funded and distributed many additional publications that were similarly misleading. For instance, APF’s *A Policymaker’s Guide to Understanding Pain and its Management* asserted that “misconceptions about opioid addiction” acted as a barrier to adequate pain relief, and that “[u]nless a person with pain has a past or current personal or family history of substance abuse, the likelihood of addiction is low when opioids are appropriately prescribed, taken as directed and monitored by a responsible and knowledgeable health care provider.”

105. This publication went further when discussing the use of opioids for children, stating that it was a “MYTH” that “[c]hildren can easily become addicted to pain medications,” and the “TRUTH” was that “[l]ess than 1 percent of children treated with opioids become addicted.”

106. Purdue's opioids were not indicated for treatment of children under the age of 18 at the time, and Purdue's internal documents show that it knew [REDACTED]

107. APF's *Treatment Options* taught that addiction is rare and shown through extreme usage of opioids, such as unauthorized dose escalations, obtaining opioids from multiple sources, and theft of opioids. The publication also states that "[d]espite the great benefits of opioids, they are often underused," that such "under-use has been responsible for much unnecessary suffering," and that "[r]estricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction."

108. APF's *Pain Resource Guide* conveyed a similar message, stating that "[m]any people living with pain—and even some healthcare providers—falsely believe opioids are universally addictive. Studies and clinical practice have shown that the risk of addiction is small when these medications are appropriately prescribed and taken as directed." The publication further claims that "[u]nless you have a past or current history of substance abuse, the chance of addiction is low when these medications are prescribed properly and taken as directed."

109. Another APF publication, a book targeted at veterans entitled *Exit Wounds*, described addiction as an "inborn vulnerability" for a portion of the population that has "complex roots in both genetics and upbringing," and claimed that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."

110. Purdue also sponsored a CME, entitled *Opioid Prescribing: Clinical Tools and Risk Management Strategies*, which told health care providers that "addiction is rare in patients

who become physiologically dependent on opioids while using them for pain control,” and that “behaviors that suggest abuse may only reflect a patient’s attempt to feel normal.”

111. Similarly, the Purdue-funded book *Responsible Opioid Prescribing* informed doctors that only a “small minority of people seeking treatment may not be reliable or trustworthy,” and therefore not suitable for chronic opioid therapy.

112. Guidelines published by AGS also minimized the risk of addiction for older opioid users, claiming that “[t]rue addiction . . . in older patients with persistent pain syndromes is probably rare in comparison with the known prevalence of undertreated debilitating pain,” and that “older age is significantly associated with lower risk for opioid misuse and abuse.”

113. Records of Purdue sales visits with Minnesota health care providers show this deliberate deflection of focus from the risk of addiction due to opioids to the risk of addiction inherent in patients.

114. Purdue’s message was confusing and deceptive in stating that opioids themselves are not addictive, and those who become addicted can only blame themselves for being inherently susceptible to addiction.

ii. Purdue Used the Confusing, Deceptive, and Misleading Term “Pseudoaddiction.”

115. Purdue, in its own marketing and educational materials and through third parties, falsely represented that many individuals who exhibit signs of opioid addiction are actually experiencing “pseudoaddiction,” and that doctors should treat this condition not by weaning patients off opioids, but by increasing the patient’s opioid dosage.

116. The concept of “pseudoaddiction” was originally put forth by J. David Haddox in a four-page case study from 1989, in which Haddox and his co-author coined the term based in

large part upon their review of the behavior of a single juvenile cancer patient.³⁹ As indicated above, Haddox later became a vice-president at Purdue throughout Purdue's introduction and marketing of OxyContin and other opioid medications.

117. Purdue explicitly referenced the term "pseudoaddiction" in its pamphlet *Providing Relief, Preventing Abuse*, oftentimes with a cover letter from Haddox himself. The 2007 version of the pamphlet described "pseudoaddiction" as such:

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. Patients with unrelieved pain may:

- Become focused on obtaining medications
- "Clock watch"
- Display behaviors ([e.g.,] doctor shopping, deception) to obtain relief

Pseudoaddiction can be distinguished from addiction in that the behaviors resolve when pain is effectively treated.

118. The pamphlet also provided "facts about addiction," including that "[m]isunderstanding of addiction and mislabeling of patients as addicts result in unnecessary withholding of opioid medications."

119. By 2011, Purdue had revised the brochure, but the second edition still promoted the same misleading message of appeasing drug-seeking behavior with additional opioids:

³⁹ David E. Weissman, J. David Haddox, *Opioid Pseudoaddiction—An Iatrogenic Syndrome*, 36 *Pain* 363, 364–65 (Apr. 1989).

Other Considerations: Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate.⁹ 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.^{9,10} 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.⁹ Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment.⁹

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

121. Records of Purdue sales visits with Minnesota prescribers show that Purdue sales representatives frequently distributed this publication directly to Minnesota prescribers and discussed pseudoaddiction with multiple Minnesota health care providers. For instance, Purdue convinced one health care provider that [REDACTED]

[REDACTED]

[REDACTED]

122. Purdue also propagated the concept of “pseudoaddiction” in a visual aid used as part of its *Partners Against Pain* unbranded marketing project. The visual aid reprints the *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, released by the Federation of State Medical Boards (“FSMB”), which state that “pseudoaddiction” is an “iatrogenic syndrome resulting from the misinterpretations of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.” The visual aid also cites to 2001 definitions created by various third parties, including AAPM and APS, which claim that behaviors indicative of addiction “sometimes are simply a reflection of unrelieved pain or other problems unrelated to addiction.”

123. In at least two versions of a Partners Against Pain publication entitled *Clinical Issues in Opioid Prescribing*, Purdue defined “pseudoaddiction” as “patient behaviors that may occur when pain is undertreated,” and that “[e]ven such behaviors as illicit drug use and deception can occur in the patient’s efforts to obtain relief.” Purdue further claimed that “[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.” The publication also generally urged health care providers to increase their prescribing and dosing of opioids, asserting that opioids are “frequently underdosed—or even withheld due to a widespread lack of information and appropriate education about their use among healthcare professionals.”

124. Purdue presentations, which it called “educational offering[s],” contained similar definitions of “pseudoaddiction.” For instance, one presentation prompted the instructor, after describing “pseudoaddiction,” to claim that “[i]t is the obligation of all clinicians to provide comfort and effective symptom control whenever possible.”

125. *Responsible Opioid Prescribing* also taught that behaviors such as requesting drugs by name, being demanding or manipulative, seeing more than one doctor, and hoarding were all signs of pseudoaddiction, not true addiction. The book claimed that such actions were signs that a patient was receiving an inadequate dose of opioid medication, and could be distinguished from truly addictive behavior because the behaviors would cease “when the patient obtains adequate analgesia”—in other words, by giving the patient a larger dose of opioids. Another APF publication, *A Policymaker’s Guide to Understanding Pain and its Management*, similarly defined “pseudoaddiction” and again stressed that “[p]seudo-addiction can be distinguished from true add[i]ction in that this behavior ceases when pain is effectively treated.”

126. The Purdue-sponsored CME *Opioid Prescribing: Clinical Tools and Risk Management Strategies* defined pseudoaddiction as “the need to seek additional medications due to the undertreatment of pain” and instructed medical professionals that “drug-seeking behavior that resembles addiction[] should, in theory, resolve when the pain is adequately controlled.”

127. Treatment guidelines further promoted the use of this confusing and deceptive term, including publications from the FSMB that defined “pseudoaddiction” as the “[p]attern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction,” and a model policy that similarly defined “pseudoaddiction” as the “misinterpretation of relief seeking behaviors.” One version of guidelines from the AGS contains the message that behaviors indicative of addiction simply mean the patient needs more opioids, stating that “[w]hen aberrant behaviors are observed, it is incumbent on clinicians to determine that these behaviors do not reflect poorly controlled pain.”

128. Purdue has not substantiated the concept of pseudoaddiction with valid scientific evidence. A 2015 article in *Current Addiction Reports* examining the supposed scientific

literature supporting the term found that pseudoaddiction “has not been empirically verified” and that “no evidence supports its existence as a diagnosable clinical entity with objective signs and specific treatments.”⁴⁰ The study found that, nonetheless, “the term is widely accepted and proliferated in the medical literature as an ‘influential educational concept commonly used in pain management lectures’ resulting from the ‘remarkable influence’ of one case report”⁴¹—namely, the 1989 article by now-Purdue executive J. David Haddock.

129. Further, the concept of pseudoaddiction has actually been abandoned by some of its proponents. For example, Dr. Lynn Webster, a Purdue opinion leader and AAPM officer, has said that the concept of pseudoaddiction “obviously became too much of an excuse to give patients more medication” and “led us down a path that caused harm.”⁴²

B. Purdue Deceptively Claimed that Opioid Dosages Could Be Increased Infinitely Without Added Risk and Failed to Disclose the Increased Risks of Higher Dosages.

130. Purdue, through its own representations and those of associated third parties, misrepresented that doctors and patients could indefinitely increase opioid dosages without added risks, and failed to disclose the greater risks that such increased dosages posed to patients.

131. Among other avenues, Purdue spread this message through its unbranded *Partners Against Pain* program. In a brochure distributed to Minnesota health care providers entitled *A Guide for Healthcare Professionals*, Purdue told prescribers:

Rather than ‘strong,’ think ‘effective.’ Opioids are among the most effective medications available for moderate to severe pain. Unlike most non-opioid pain medications, a single-entity opioid dose can usually be increased to an effective level, no matter how

⁴⁰ Marion S. Green and R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, 2 Current Addiction Reports 310, 313 (Oct. 2015).

⁴¹ *Id.*

⁴² Fauber, *supra* note 24.

severe the pain. The dosing limit is imposed only by side effects, the more serious of which may include somnolence and respiratory depression.

The brochure also instructed prescribers to “[k]eep in mind” that “usually the prescriber can increase the dose to achieve adequate analgesia for the patient, with minimal side effects,” and repeated that “**single-entity opioids are not limited to a ‘maximum’ dose as nonopioids are.**” (emphasis added).

132. Similarly, Purdue’s *In the Face of Pain* website promoted the notion that, if a patient’s doctor did not prescribe what the patient believed was a sufficient dosage of opioids, he or she should find another doctor who will, telling patients that “[f]inding good pain care can be a challenge, but persistence can pay off—don’t give up.” The website also promoted opioid treatment by urging patients to help health care providers “overcome” their “fear of producing addiction,” and also help other patients similarly “overcome” their “concerns about addiction.” Minnesotans visited this website more than [REDACTED] times between 2010 and 2015, when the website was shuttered following a governmental investigation.

133. Another Purdue publication, *Clinical Issues in Opioid Prescribing*, reiterated that “single entity” opioids, like OxyContin, have “no defined maximum dose,” and that the “ceiling” to pain relief “is imposed only by side effects.” Purdue’s *OxyContin Conversion and Titration Guide* stated that “pure opioid agonist analgesics” have “no defined maximum daily dose.”

134. Purdue-associated third party organizations also spread this message. APF’s *Treatment Options* attempted to justify dosage increases by claiming that “[m]any times when a person needs a larger dose of a drug, it’s because their pain is worse or the problem causing their pain has changed.” In what was a common refrain throughout the materials in this section, this publication also claimed that opioids have “no ceiling dose,” unlike other nonopioid medications,

and “continue to be useful unless side effects occur.” Purdue sales representatives repeated the this message to Minnesota health care providers, frequently comparing opioids to other analgesic products including NSAIDS, which the sales representatives warned had a maximum dose.

135. Another APF publication, *A Policymaker’s Guide to Understanding Pain and Its Management*, taught that dosage escalations are “sometimes necessary,” but did not disclose any of the risks of high-dosage opioids. In fact, the publication claimed that the development of tolerance to opioids meant “the need for higher doses of medications is not necessarily indicative of addiction.”

136. An American Medical Association (“AMA”) CME funded by Purdue and created by several Purdue-funded opinion leaders, *Overview of Management Options*, similarly claimed that “full mu agonists,” which include OxyContin, “do not exhibit a ceiling effect with increasing dose,” unlike non-opioid medications.

137. Further, as described below, Purdue and Purdue-sponsored publications also made claims about the lack of an opioid dose ceiling in misrepresenting the superiority of opioids over the dose limitations of non-opioid pain medications.

138. In actuality, Purdue has not substantiated the claim that larger doses of opioids are more effective for treating pain, but there is significant evidence that larger opioid doses increase risks of addiction, dependence, and overdose, as described herein.

C. Purdue Falsely Exaggerated the Efficacy of Opioids and Failed to Disclose the Lack of Evidence for Its Claims.

i. Purdue Has Not Substantiated the Effectiveness of Long-Term Opioid Use in Treating Chronic Pain.

139. Purdue has not substantiated its claim that opioids are an effective long-term treatment for chronic pain, much less that opioids are the best or a first-line treatment for chronic

pain. As stated by the CDC in a New England Journal of Medicine article, “[t]he science of opioids for chronic pain is clear: for the vast majority of the patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits.”⁴³

140. The CDC Guideline echoes this sentiment, providing 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,” as most scientific trials meant to assess the effectiveness of opioids lasted less than 6 weeks.⁴⁴ The Guideline further identifies the lack of evidence of the benefits of opioids, versus the strength of evidence showing their harms:

Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy **While 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.** Based on the clinical evidence review, long-term opioid use for chronic pain is associated with serious risks including increased risk for opioid use disorder [addiction], overdose, myocardial infarction, and motor vehicle injury⁴⁵

141. Accordingly, the Guideline states that “opioids should not be considered first-line or routine therapy for chronic pain,” given their unproven benefit and “potential for serious harms,” and “nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain” in opioids’ stead.⁴⁶ The National Safety Council has similarly stated that “[d]espite the widespread use of opioid medications to treat chronic pain, there is no significant

⁴³ Frieden & Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, New England J. Med. (April 21, 2016).

⁴⁴ CDC Guideline, *supra* note 8 at 15.

⁴⁵ CDC Guideline, *supra* note 8 at 18 (emphasis added).

⁴⁶ CDC Guideline, *supra* note 8 at 17, 19.

evidence to support this practice” and that “no evidence exists to support long term use—longer than four months—of opioids to treat chronic pain.”

142. The Minnesota Department of Health and the Department of Human Services released opioid prescribing guidelines in March 2018, which stated that “[o]pioid analgesics should not be used to manage chronic pain” as “[t]he evidence to support chronic opioid analgesic therapy for chronic pain is insufficient at this time, but the evidence of harm is clear.”⁴⁷ A recent, year-long study by a Minnesota physician regarding treatment outcomes for patients at Veterans Affairs health clinics found that opioid treatment “was not superior to treatment with nonopioid medications for improving pain-related function,” and that these results did not support the use of chronic opioid therapy for patients with “moderate to severe chronic back pain or hip or knee osteoarthritis pain.”⁴⁸

143. Purdue is aware of the lack of substantiation for its claims that opioids are effective as a long-term treatment for chronic pain. In an internal study of studies, Purdue stated that “ [REDACTED] ” The Purdue

study further acknowledged that [REDACTED]
[REDACTED]
[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

⁴⁷ State of Minnesota, *Minnesota Opioid Prescribing Guidelines*, at 7, 9 (1st ed. Mar. 2018).
⁴⁸ Erin Krebs et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain—The SPACE Randomized Clinical Trial*, 319 J. Am. Med. Ass’n 872, 881 (Mar. 2018).

ii. Purdue Deceptively Marketed Its Opioid Products, and Opioids Generally, As Effective for Long-Term Use to Treat Chronic Pain Patients.

144. In its own marketing materials and in sponsored third party publications, Purdue affirmatively misrepresented this lack of evidence as to the beneficial effects of long-term opioid use and claimed that opioids would improve patients' functionality and quality of life. By doing so, Purdue not only deceived health care providers about the efficacy of opioids in improving patient functionality, but also caused health care providers and patients not to give fulsome consideration to alternative methods of pain treatment, such as non-opioid medications, physical and occupational therapy, cognitive behavioral therapy, or massage therapy.

145. For example, the *OxyContin Conversion and Titration Guide* distributed by sales representatives to Minnesota prescribers likewise misleadingly promotes long-term use. One version of that guide recommended that the need for opioid therapy be reassessed every six to twelve months, but did not disclose the absence of evidence supporting the safety and efficacy of opioid use for six to twelve months. A later version of the guide omits the hypothetical timeframe for reassessment, but still claims that chronic opioid therapy is appropriate without disclosing the lack of evidence of use for more than 12 weeks or correcting the previous misinformation Purdue conveyed to prescribers.

146. Third-party publications sponsored by Purdue also claimed—without substantiation—that long-term opioid use would improve patients' daily functioning and quality of life.

147. For instance, APF's *A Policymaker's Guide to Understanding Pain and Its Management* claimed that “[m]ultiple clinical studies have shown that long-acting opioids, in particular, are effective in improving: [d]aily function[;] [p]sychological health[; and] [o]verall

health-related quality of life for people with chronic pain.” The same publication claimed that opioids were often a “necessary” part of pain management plans, because they “restore functioning and improve quality of life.” The sole meta-study referenced for these claims, however, noted the absence of long-term studies of opioid use, actually provided that “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids,” and warned that more than one-third of participants abandoned treatment in the opioid trials reviewed despite their relatively short lengths.

148. *Exit Wounds*, the publication designed for consumption by veterans, called opioids the “‘gold standard’ of pain medications,” whose “pain relieving properties . . . are unsurpassed” and “are often the main medications used in the treatment of chronic pain,” yet “despite their great benefits . . . are often underused.” The publication further claimed that, “[w]hen used correctly, opioid pain medications *increase* a person’s level of functioning” and “can go a long way toward improving . . . functioning in daily life.”

149. *Responsible Opioid Prescribing* not only touted the benefits of opioids, but further implied that patients had the right to demand opioids from prescribers in describing “widely accepted” “general principles” of opioid prescribing: “Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; [and] [p]atients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.”

150. The Purdue-sponsored CME *Overview of Management Options* similarly taught health care providers that, while tolerance to analgesia “can occur, . . . numerous surveys have demonstrated that most patients can be maintained on a stable dose of opioids for prolonged periods.”

151. The funding proposal for a Purdue-sponsored educational program, entitled *Managing Patient's Opioid Use: Balancing the Need and the Risk*, sought to teach physicians that "[REDACTED]

[REDACTED]

[REDACTED] It further claimed that "[REDACTED]

[REDACTED]

[REDACTED]"

152. Purdue even sponsored content in *The Atlantic* to advance unsubstantiated claims that "all physicians who treat chronic pain with opioids have a significant number of patients in our practices that are back at work as full-time employees or back at school as full-time students because their pain is tolerable and under control."⁴⁹

iii. Purdue Deceptively Claimed OxyContin Was Effective for 12 Hours.

153. Beyond misrepresenting the efficacy of opioids for long-term pain relief, Purdue also deceptively promoted OxyContin as delivering a full 12 hours of "steady state" pain relief. This message was intended to convey that OxyContin was not only more effective than immediate-release opioids, but also less likely to result in crashes and cravings that lead to addiction and abuse. In reality, in many patients OxyContin does not last for 12 hours, a fact known by Purdue since the product's launch.

154. OxyContin has been FDA-approved for twice-daily, 12-hour doses, known as "q12h" dosing, since its debut in 1996. Purdue chose to submit OxyContin for approval with 12-

⁴⁹ Gerald Aronoff, *Take My Pain Away: A Physician's Perspective of Prescription Opioids and Pain Management*, *The Atlantic* (January 9, 2015).

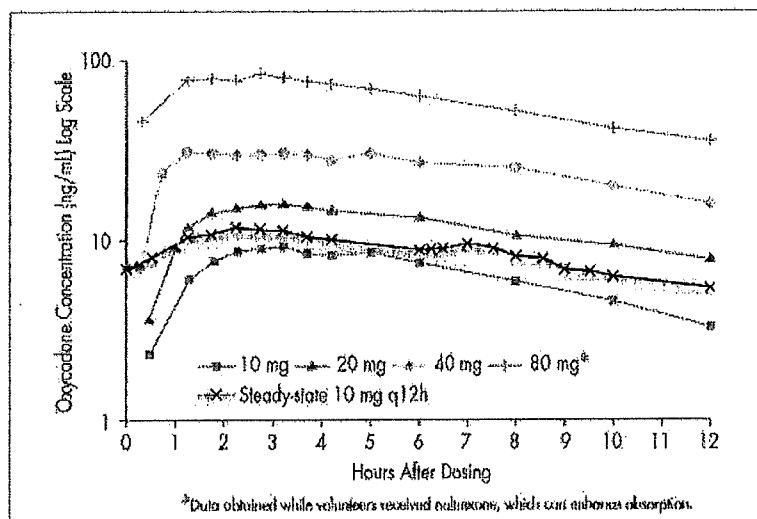
hour rather than 8-hour dosing, and made the 12-hour claim central to its marketing campaign.⁵⁰

As explained by a Purdue executive, [REDACTED]

155. Purdue promoted OxyContin as providing continuous, around-the-clock pain relief with the convenience of not having to wake up to take a third or fourth pill. The advertising claimed that OxyContin provides “Consistent Plasma Levels Over 12 Hours” and included a chart depicting plasma levels on a logarithmic scale. The chart deceptively concealed the steep decline in OxyContin’s effectiveness over 12 hours by condensing the scale of the chart’s Y-axis to make 10 mg appear to be half of 100 mg:

Consistent Plasma Levels Over 12 Hours

Plasma concentrations (ng/mL) over time of various dosage strengths



• OxyContin® 80 and 160 mg Tablets FOR USE ONLY IN OPIOID-TOLERANT PATIENTS requiring minimum daily oxycodone equivalent dosages of 160 mg and 320 mg, respectively. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids

Steady state achieved within 24 to 36 hours ...

⁵⁰ Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that “[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours,” Purdue has conducted no such studies.

This graph condensed the curve in order to make the absorption rate appear more steady or consistent than it really was.

156. In fact, Purdue's own research shows that the drug wears off in under 6 hours in one quarter of patients and in under 10 hours in more than half. The FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience "end-of-dose failure" with little or no pain relief at the end of the dosing period.

157. In a 2013 FDA public hearing, a doctor and medical professor testified.⁵¹

Now, why did we get to a Q12 hour dose? It wasn't because of the data on efficacy of the drug. It was because Purdue Pharma needed something to distinguish its drug from other short-acting narcotics, and this became the main marketing device to increase profits.

On the other hand, the data showed something else. As you can see, at 10 milligrams, the OxyContin product release was effective for less than six hours in at least 25 percent of patients. And the 20 and 30 milligram doses were effective for less than 10 hours in at least 50 percent of patients.

Other Purdue studies, all of them in fact, allowed rescue or short-acting oxy to cover patients who had pain breakthrough before 12 hours. However this does not—and this information is omitted from the label.

158. Regardless, Purdue still emphasized 12-hour dosing in detailing visits to Minnesota prescribers. Purdue was also aware of the common practice of prescribing OxyContin more frequently than 12 hours to address end-of-dose failure experienced by the patients, up to three or four doses per day. Notes from Purdue sales representatives' visits with Minnesota health care providers show that Purdue was repeatedly told that Minnesota patients were commonly prescribed OxyContin for use more frequently than twice per day.

⁵¹ Testimony of David Egilman, *Impact of Approved Drug Labeling on Chronic Opioid Therapy* at 90–91, FDA Center for Drug Evaluation and Research Public Hearing (Feb. 8, 2013), available at <http://www.tvworldwide.com/events/fda/130207/UCM342713.pdf>.

159. Purdue did promote a “solution”: increase dosage, rather than frequency, even though larger dosages carry greater risks of addiction, overdose, and death. This “solution” exposed patients to higher highs and lower lows, increasing their craving for the next pill. But Purdue trained its sales representatives to reassure prescribers that there is no ceiling on the amount of OxyContin a patient could be prescribed. And many prescribers followed the recommendation of the sales representatives to increase the dose rather than the frequency.

160. Records of Purdue sales representatives’ visits with Minnesota health care providers show sales representatives repeatedly conveying this message when discussing OxyContin dosing with prescribers.

161. For example, when one Minnesota health care provider told a Purdue sales representative that [REDACTED], the sales representative “[REDACTED]” The same sales representative claimed in a note from a visit with a different health care provider that he “[REDACTED]” when told about three-times-a-day dosing. In another call note, a Purdue sales representative “[REDACTED]” with a [REDACTED]. In yet another call note, a Purdue sales representative “[REDACTED]” told a Minnesota health care provider “[REDACTED]”

162. These 12-hour pain relief misrepresentations were particularly dangerous because when a patient is inadequately dosed, they begin to experience distressing psychological and physical withdrawal symptoms after taking a pill, followed by euphoria with the next dose—a

cycle that creates addiction. Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

163. According to an analysis conducted by the University of Arkansas, in 2014 more than 52% of patients taking OxyContin longer than three months were on doses greater than 60 milligrams per day⁵²—exceeding the 90 MME limit that the CDC Guideline urges prescribers to “avoid” or “carefully justify.”⁵³

164. Purdue has remained committed to 12-hour dosing because it is key to OxyContin’s market dominance and comparatively high price. 12-hour dosing set OxyContin apart from its competitors, and from less expensive, short-acting opioids. In a letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label and explained that, “Purdue has always trained its sale force to promote [12-hour] dosing only” because twice-daily “dosing confers additional benefits on patients” and “[t]he 12 hour dosing schedule represents a significant competitive advantage of OxyContin over other products.”

165. Purdue has not substantiated its misleading claims that OxyContin is effective for 12-hour dosing with significant evidence or clinical experience.

D. Purdue Deceptively Promoted Its Opioids as Superior to Other Methods of Pain Treatment.

166. In order to ensure that providers continued to prescribe its opioids instead of alternative, non-opioid pain treatments, Purdue continually touted the superiority of its opioid

⁵² Harriet Ryan, *‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem*, Los Angeles Times (May 5, 2016).

⁵³ CDC Guideline, *supra* note 8 at 16.

products, and opioids in general, while stressing the risks and downsides of safer methods of pain treatment.

167. Purdue was aware that its claims, comparative or implied, of opioid superiority were problematic. In internal documents, Purdue admitted that it could not "[REDACTED]" because Purdue "[REDACTED]"

i. Purdue Made False and Misleading Claims of Opioid Superiority by Misrepresenting the Relative Risks of Non-Opioid Pain Treatments

168. Purdue repeatedly sought to market its opioid-based product line as superior to alternative treatments for pain, largely focusing on the relative superiority of opioids to non-opioid drugs like nonsteroidal anti-inflammatory drugs ("NSAIDs"), which include aspirin and ibuprofen, and acetaminophen, more popularly known as Tylenol.

169. Purdue even commissioned a research firm to study [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] The study found, in part, that
[REDACTED]
[REDACTED]
[REDACTED]

170. Purdue's own marketing materials furthered this misleading assertion of superiority. One of its "educational" presentations asserted that "[p]ersistent use [of NSAIDs] may pose unacceptable risk" due to its effect on the gastrointestinal tract, heart, and kidney. Another version of this presentation dedicated a slide to "NSAID side effects" and warned that gastrointestinal events tied to NSAID use resulted in 100,000 hospitalizations per year and

16,500 deaths per year. In reality, statistics show that the number of NSAID-related deaths are much lower annually.⁵⁴ The corresponding slide on opioid adverse effects does not contain any similar statistics on hospitalizations or deaths tied to opioids.

171. Purdue sponsored third-party publications that primarily focused on the worst side effects and risks of non-opioid drugs, like NSAIDs and acetaminophen, when used to treat pain, in contrast with the same publications' relatively glowing description of the use of opioids for pain treatment.

172. For instance, APF's *Treatment Options* deceptively championed the superiority of opioids over NSAIDs. For example, as an initial framing device, the publication uses the heading, "**Should I take these pain medicines?**" in order to launch into a discussion of the dangers of NSAID side effects, but later takes a softer tact in describing opioids, calling them "under-used" despite their "great benefits." The publication further warned that NSAIDs have "life-threatening side effects" that result in "10,000 to 20,000 deaths each year." As mentioned above, this is a deceptive inflation of the true number of deaths attributable to NSAIDs.

173. An earlier APF publication, *Pain Action Guide*, made similar claims, asserting that acetaminophen and NSAIDs "are associated with liver damage," "can affect the kidneys and promote bleeding," and "also have a 'ceiling effect'—after the maximum dose is reached, there is no additional pain relief." As referenced above, this publication minimized opioid side effects, merely stating that "most side effects . . . can be managed" and "usually last only a few days."

174. Guidelines from the AGS detailed the risks of NSAIDs and ultimately concluded that for older patients, "[i]n the final analysis, the chronic use of opioids for persistent pain or

⁵⁴ 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. Ther. 17, 21 (2004).

some other analgesic strategies may have fewer life-threatening risks than does the long-term daily use of high-dose nonselective NSAIDs.”

175. Other Purdue-sponsored publications raise the same specter of dangerous side effects from non-opioid pain medications. The veteran-focused book *Exit Wounds* warned of “concern in the medical community about the growing rate of liver damage associated with large doses of acetaminophen.” Another publication goes to great lengths to describe the toxicity of acetaminophen and opined that “[c]hronic NSAID use should be avoided,” while stressing that opioid side effects “go away as you get used to the drug” and patients would gain “[t]olerance to respiratory depression”—the side effect primarily responsible for overdose deaths.

176. Another publication stressed that even short-term use of NSAIDs has serious side effects, like bleeding and bruising, and that long-term use of NSAIDs was “generally discouraged for older persons” due to “risks of serious medical complications.” The Purdue-sponsored CME *Overview of Management Options* further stressed the risk of “serious GI side effects,” renal toxicity, and elevated blood pressure associated with NSAIDs, and even included a large table of drugs that potentially interact negatively with NSAIDs.

177. Purdue-sponsored publications also emphasized the concept of a “dose ceiling” for non-opioid pain medications. For example, *Exit Wounds* stated that NSAIDs “alone are not effective treatments for chronic pain,” and that NSAIDs “have an important limitation, called a ‘dose ceiling,’” that if exceeded would cause “serious” and “life-threatening” side effects. The AMA CME stated that NSAIDs and acetaminophen “have a ceiling effect to analgesia” and included another table specifying maximum dosages for these drugs.

178. The corresponding, and misleading, comparison explicitly drawn by these publications was that opioids do **not** have a similar “dose ceiling.” The AMA CME referenced

above taught health care providers that opioids “do not exhibit a ceiling effect with increasing dose.” *Treatment Options* similarly claimed that opioids have “no ceiling dose as there is with the NSAIDs” and that “these medications continue to be useful unless side effects occur.”

179. Purdue also propagated this message directly. For example, Purdue created a document for health care providers entitled *Maximum Dose of OxyContin Tablets* that claimed that “when used appropriately, there is no established or fixed upper limit on the dosage of full, single entity, opioid agonists such as oxycodone.”

180. Even more troubling, records show that Purdue sales representatives told numerous Minnesota health care providers that OxyContin had no defined maximum or ceiling dose, including telling one provider [REDACTED]

[REDACTED]” On the other hand, Purdue sales representatives repeatedly warned Minnesota providers about the ceiling dose for drugs that contain non-opioid medications like acetaminophen.

ii. Purdue Made False and Misleading Claims of Opioid Superiority by Overstating and Misrepresenting the Benefits of Its Extended-Release Opioids Over Other Formulations.

181. Purdue also confusingly and deceptively promoted the superiority of its extended-release opioid products over the lower-dose, immediate-release opioids made by its competitors.

182. Purdue knew that it could not make such claims. In an internal compliance training for Purdue speakers, it cautioned speakers that [REDACTED] and instructed speakers to [REDACTED] [REDACTED] The training

further admitted that Purdue did “[REDACTED]”
[REDACTED]” The training told instructors that “[REDACTED]
[REDACTED]” and that speakers should [REDACTED]

183. Notwithstanding these materials, elsewhere Purdue instructed its sales representatives to persuade prescribers to switch patients from Vicodin or Percocet to OxyContin by stressing the “more convenient” and “less frequent” 12-hour dosing regimen of OxyContin (i.e., fewer pills) and the fact that OxyContin was a “single-entity” opioid as opposed to its competitors.

184. Sales representatives in Minnesota implemented these tactics when detailing Minnesota health care providers. Purdue sales representatives told Minnesota health care providers [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] This number of pills was not based on any medical authority.

iii. Purdue Misrepresented the Abuse-Deterrent Properties of Its Opioids.

185. After the risks of abuse and addiction to OxyContin gained publicity, Purdue’s solution was to claim that abuse and addiction were the result of diversion of its drug by those who snorted or injected the drugs and that Purdue could remediate this problem by developing a new drug that would make OxyContin more difficult to crush and unsuitable for injection.

186. Purdue introduced a reformulated version of OxyContin in 2010 that it claimed was an “abuse deterrent formulation” (“ADF”) of the prior version of OxyContin.

187. Purdue made numerous misleading claims about the benefits its ADF opioids had in preventing abuse, including that:

- Reformulated OxyContin was “[REDACTED]” per representations made by sales representatives;
- ADF technology “can make the opioids you prescribe harder to abuse—and make all clinicians part of the solution to prescription opioid abuse”;
- ADF opioids were “newer, safer alternatives” that make “certain forms of abuse much more difficult”; and
- ADF opioids were a [REDACTED]

188. Purdue sales representatives made similar representations to Minnesota health care providers, including that [REDACTED]

[REDACTED]

[REDACTED]

189. Purdue’s efforts to cast ADF opioids as safer and less addictive were effective. A 2014 nationwide study of 1,000 primary care physicians found that nearly half believed ADF opioids were inherently less addictive than their non-ADF opioid counterparts.⁵⁵

190. Purdue cannot substantiate its claims that its ADF opioids reduce the risks of abuse compared to other opioid medications. The 2016 CDC Guideline noted that ADF technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and [ADF opioids] can still be abused by nonoral routes,” and that “[n]o studies were

⁵⁵ Catherine S. Hwang, et al., *Primary Care Physicians’ Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32 *Clinical J. Pain* 279, 281 (Apr. 2016).

found in the [CDC's] clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse.”⁵⁶

191. Purdue knew this was the case, as it admitted internally that “[REDACTED]” and that “[REDACTED]” In fact, Purdue’s own research identified 32 publicly-known methods to circumvent the abuse-deterrent properties of ADF opioids.

192. Purdue’s representations about the effectiveness of its abuse-deterrent formulations, made to both prescribers and patients, were confusing, deceptive, and misleading.

E. Purdue’s Marketing Efforts Targeted Vulnerable Populations and Impressionable Prescribers.

193. As part of its overall effort to broaden the opioid patient pool and ease prescriber reluctance about prescribing opioids, Purdue identified vulnerable patient populations, including the elderly and veterans, in Minnesota and throughout the United States and targeted its marketing efforts at those patients and the health care providers who treat them.

194. Purdue created, funded, and distributed marketing materials targeted at the elderly and veterans that contained numerous misrepresentations. For instance, as detailed above, the Purdue-funded American Geriatrics Society issued pain treatment guidelines containing numerous misrepresentations about the efficacy of chronic opioid treatment, the risks of non-opioid medication use by older adults, and that signs of drug-seeking behavior may indicate a need to increase a patient’s opioid dose. These guidelines also misrepresented that the risk of

⁵⁶ CDC Guideline, supra note 8, at 21–22.

opioid addiction, misuse, and abuse was lower in elderly patients, going so far as to characterize addiction risk as “exceedingly low” and “probably rare” for older adults.

195. Another Purdue-sponsored publication echoed this same message, claiming that the risk of addiction “is small for older adults when the medication is taken specifically to fight pain, there is no prior history of substance abuse, and there is careful monitoring of the benefits and adverse effects.”

196. Purdue sales representatives repeatedly encouraged the prescription of Purdue opioids for older patients in visits with Minnesota health care providers, including by, among other representations, telling prescribers that [REDACTED]

[REDACTED] Visit records also show Purdue sales representatives making plans to follow-up with targeted questions to providers about older patients; for example, one note directs a sales representative to “[REDACTED]

[REDACTED]”

197. Purdue made misrepresentations regarding veterans as well. As discussed above, the book *Exit Wounds*, targeted at veterans and funded by Purdue, contains numerous misrepresentations about the risks and benefits of opioids. In particular, it discusses anxiety related to chronic pain and post-traumatic stress disorder (“PTSD”) at length, but entirely omits warnings about potentially fatal interactions that opioids have with benzodiazepines, which are commonly prescribed to veterans with post-traumatic stress disorder.

198. In reality, the vulnerable populations targeted by Purdue face more significant risks from chronic opioid treatment than the general population. For example, the 2016 CDC

Guideline found that the risk of harm from chronic opioid treatment is greater for older adults.⁵⁷ For older patients, “[a]ge-related changes” can “result in a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose,” and the elderly may also be “at increased risk for falls and fractures related to opioids.”⁵⁸ The Guideline accordingly recommends that doctors use “additional caution when initiating opioids for patients aged [more than] 65 years.”⁵⁹

199. Veterans, too, face greater risks from chronic opioid treatment. While the U.S. Department of Veterans Affairs (“VA”) recommends against use of benzodiazepines for treatment of PTSD,⁶⁰ studies have shown that VA clinicians prescribe benzodiazepines for as many as 30% of PTSD patients they treat.⁶¹ The 2016 CDC Guideline found that patients who use opioids and benzodiazepines concurrently are at a significantly greater risk for overdose than they would be using either drug alone, due to the fact that both drugs cause central nervous system depression and decrease users’ ability to breathe, and strongly recommended that prescribers avoid prescribing these medications concurrently.⁶²

200. Besides representations specific to classes of patients, Purdue more generally focused a significant portion of its in-person marketing on primary care providers, like family medicine and internal medicine doctors, who were more likely to have a patient population with

⁵⁷ CDC Guideline, *supra* note 8, at 13.

⁵⁸ *Id.*

⁵⁹ *Id.* at 23.

⁶⁰ U.S. Dep’t of Veterans Affairs and Dep’t of Defense, *VA/DOD Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Disorder*, at 56–57 (2017), <https://www.healthquality.va.gov/guidelines/MH/ptsd/VADoDPTSDCPGFinal012418.pdf>.

⁶¹ U.S. Dep’t of Veterans Affairs, *Use of Benzodiazepines for PTSD in Veterans Affairs*, <https://www.ptsd.va.gov/professional/treatment/overview/benzo-ptsd-va.asp> (last updated May 3, 2017).

⁶² CDC Guideline, *supra* note 8, at 13, 16, 32.

chronic pain problems that Purdue could argue needed treatment with opioids. Purdue also focused on non-physician prescribers, like physician assistants and nurse practitioners. These same health care providers, however, would likely have less familiarity with, and prior education about, the risks and benefits of opioids, and would be more likely to accept Purdue's confusing and deceptive representations about opioids at face value.

201. Records of Purdue sales representatives' visits with Minnesota health care providers illustrate the extent to which Purdue targeted this provider population. Of the visits in which Purdue sales representatives noted the health care provider's specialty, more than [REDACTED] [REDACTED]—nearly [REDACTED] visits since 2006—were with family medicine or internal medicine doctors. Purdue also made more than [REDACTED] visits to Minnesota physician assistants and nurse practitioners.

202. Purdue also funded publications targeted at these provider populations. For example, one publication targeted at physician assistants and their patients encouraged patients to seek out different providers if their physician assistant "cannot control the pain," and claimed that the risk of opioid abuse "is low in the general population" but "higher in young people, smokers, and people with a variety of risk factors."

IV. PURDUE HAD A DUTY TO DISCLOSE MATERIAL FACTS IN CONNECTION WITH ITS MARKETING AND SALE OF OPIOIDS.

203. At all times relevant to this Complaint, Purdue had a duty to disclose material facts about opioids and opioid prescribing in the course of its marketing and sale of opioids. Special circumstances exist that triggered a duty on the part of Purdue to disclose such material facts.

204. First, Purdue had special knowledge that Minnesota prescribers, third-party payors, and patients did not have at the time Purdue marketed and promoted opioids regarding

the lack of substantiation of the benefits and efficacy of opioids, and the lack of substantiation of the risks inherent with opioid use, such as the risk of addiction. Even among medical professionals, not all health care providers that Purdue targeted possessed this special knowledge, particularly given that Purdue promoted opioid products to primary care physicians, physician assistants, and nurse practitioners. Purdue knew or had reason to know that potential prescribers, third-party payors, and patients would place their trust in Purdue and rely on it to inform them of material facts relating to opioids and opioid prescribing. Purdue abused that trust by omitting such materials facts from its representations about opioids and opioid prescribing.

205. Second, the nature and quality of the representations that Purdue made to potential prescribers, third-party payors, and patients were so incomplete regarding the risks and benefits of opioids and opioid prescribing that Purdue did not say enough to prevent the representations it made to prescribers and others from being confusing, deceptive, and misleading. Purdue omitted telling prescribers, third-party payors, and patients that it could not substantiate many of its claims regarding the risks and benefits of opioids and opioid prescribing. Purdue has also failed to repudiate or correct its prior misrepresentations and confusing and deceptive conduct that caused confusion about opioids for Minnesota prescribers, third-party payors, and patients.

V. PURDUE FRAUDULENTLY CONCEALED ITS DECEPTIVE CONDUCT.

206. At all times relevant to this Complaint, Purdue took steps to fraudulently conceal its confusing and deceptive marketing behavior.

207. Purdue disguised its role in its confusing and deceptive marketing of opioids by funding and working through front organizations and opinion leaders. Purdue purposefully

cloaked itself behind the imprimatur of these organizations and individuals to avoid regulatory scrutiny, and to prevent doctors and the public from scrutinizing and discounting its messages.

208. While Purdue was listed as a sponsor of many of the publications described herein, it did not disclose its role in shaping, editing, and exercising approval over their content. Purdue did, in fact, wield influence over the content of these materials.

209. In addition to hiding its role in generating the misleading content, Purdue influenced promotional materials and scientific literature to make them appear accurate, truthful, and supported by substantial scientific evidence. Purdue mischaracterized the meaning or import of studies it cited, and offered such studies as evidence for propositions the studies did not support. The true lack of substantiation or support for Purdue's confusing and deceptive messages was not apparent to the medical professionals who relied on them in making treatment decisions, nor could such lack of support have been detected by the State.

210. Accordingly, Purdue intentionally concealed its role in causing the damage wrought by the opioid epidemic in order to further its marketing strategies. Purdue successfully concealed from the medical community, patients, and the State the facts sufficient to arouse suspicion of the existence of claims that the State now asserts. The State was not alerted to the existence and scope of Purdue's deception and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

211. Through its public statements, marketing, and advertising, Purdue's deceptions deprived the State of actual or presumptive knowledge of facts sufficient to put it on notice of potential claims.

VI. PURDUE'S DECEPTIVE AND MISLEADING CONDUCT HAS HARMED MINNESOTA'S PUBLIC INTEREST.

A. Purdue's Conduct Has Caused a Devastating Public Health Crisis in Minnesota.

212. Opioids have caused a devastating public health crisis in Minnesota, which has seen a more than 700 percent increase in opioid overdose deaths between 2000 and 2016.⁶³ Opioid-related overdoses are now the leading cause of drug-related deaths in the state, with prescription opioids contributing to 216 deaths in 2015, almost twice as many as heroin. In 2016, the number of deaths attributed to opioids increased to 395.⁶⁴

213. A recent study of drug abuse trends shows that opioid-related deaths increased by nearly 60 percent in Hennepin County alone from 2015 to 2016, resulting in 153 accidental opioid-related deaths.⁶⁵

214. Between 2005 and 2011, legal distribution of opioids increased 72% statewide.⁶⁶ According to Minnesota's Prescription Monitoring Program, Minnesotans filled 3.48 million opioid prescriptions in 2014, including nearly 45 million units of oxycodone, the active

⁶³ See Minn. Dep't of Health, *Drug Overdose Deaths Among Minnesota Residents, 2000-2016*, at 23, http://www.health.state.mn.us/divs/healthimprovement/content/documents-opioid/2016DrugOverdoseDeathReport_Final.pdf.

⁶⁴ *Id.* at 5.

⁶⁵ Carol Falkowski, *Drug Abuse Trends in the Minneapolis/St. Paul Metropolitan Area 2* (April 2017), http://www.drugabusedialogues.com/drug_abuse_trends_reports/2017_April.pdf.

⁶⁶ Jeanne Mettner, *The Opioid Crisis*, Minn. Med. (Mar. 2013), available at <http://pubs.royle.com/article/The+Opioid+Crisis/1330890/0/article.html>.

ingredient in Purdue's OxyContin.⁶⁷ Total opioid prescriptions increased to 3.87 million in 2015.⁶⁸

215. The proliferation of opioids in Minnesota has led to a significant amount of students and young adults misusing them and becoming addicted. Young people who obtain an opioid prescription are much more likely to misuse prescription opioids than those who have never obtained an opioid prescription.⁶⁹ According to a 2016 survey of Minnesota students, prescription painkillers are the fourth-most commonly abused drug among 11th grade students, behind only alcohol, marijuana, and attention-deficit disorder drugs.⁷⁰

216. The opioid addiction caused by Purdue's marketing and sales tactics has also resulted in the rapid resurgence of heroin use in Minnesota, as this illicit opioid is often cheaper and more easily available than the prescription painkillers that initially hook Minnesotans.

217. The abuse of prescription painkillers is a gateway to heroin use both nationwide and in Minnesota.⁷¹ One study found that people who previously used painkillers for nonmedical purposes were almost 20 times more likely to use heroin than those who did not.⁷²

⁶⁷ Minn. Board of Pharmacy, *Minnesota Prescription Monitoring Program 2014 Annual Report*, at 6, 9 (March 20, 2015), http://pmp.pharmacy.state.mn.us/assets/files/PDFs/Reports/2015/2014_Annual_Report_Updated.pdf.

⁶⁸ Minn. Board of Pharmacy, *Minnesota Prescription Monitoring Program 2015 Annual Report*, at 10 (Apr. 2017), http://pmp.pharmacy.state.mn.us/assets/files/PDFs/Reports/FINAL_2015_Annual_ReportII.pdf.

⁶⁹ Richard Miech et al., *Prescription Opioids in Adolescence and Future Opioid Misuse*, 136 *Pediatrics* 1169, 1173 (Nov. 2015).

⁷⁰ Minn. Dep't of Health, Ctr. for Health Statistics, *The Health of Adolescents—2016* (Oct. 2016), http://www.health.state.mn.us/divs/chs/mss/Health-related_fact_sheet_MSS_2016_10-31-16.pdf.

⁷¹ Rose Rudd et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, 64 *Morbidity & Mortality Wkly. Rep.* 1378, 1379 (Jan. 2016); Minn. Dep't of Health, *2017 Minnesota Statewide Health Assessment* 52 (2017), <http://www.health.state.mn.us/healthymnpartnership/docs/2017MNSStatewideHealthAssessment.pdf>; Minn. Dep't of Pub. (Footnote Continued on Next Page)

218. The number of heroin deaths in Minnesota has increased substantially. In 2016, there were 150 heroin overdose deaths in Minnesota, a more than fifteenfold increase from 2008.⁷³ This coincides with an increase in heroin overdose deaths nationwide, which more than tripled from 2010 to 2014.⁷⁴ The devastating and far-reaching impact of heroin on Minnesota was demonstrated by one 12-hour period in October 2016 when six separate heroin overdoses in Anoka County cost two Minnesotans their lives.⁷⁵

219. Even when users do not die from an opioid overdose, they often require major healthcare interventions. The increased availability and use of opioids has led to the admissions of many persons to hospitals and addiction treatment programs. In 2008, the rate of opioid-related inpatient stays in Minnesota was 172 per 100,000.⁷⁶ By the end of 2014, the rate increased to 247 per 100,000 persons, above the national rate of 224.6.⁷⁷ By the first quarter of

(Footnote Continued from Previous Page)

Safety, *Drug & Violent Crime Task Forces 2012 Annual Report* 4 (July 2012), <https://www.leg.state.mn.us/docs/2013/other/130488.pdf>.

⁷² Pradip Muhuri et al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Substance Abuse and Mental Health Servs. Admin. Ctr. for Behavioral Health Statistics and Quality (Aug. 2013).

⁷³ Minn. Dep't of Health, *Drug Overdose Deaths Among Minnesota Residents, 2000-2016*, *supra* note 63, at 5; Jon Collins, *Here's Why Minnesota Has a Big Problem with Opioid Overdoses*, Minn. Pub. Radio News (Apr. 18, 2016), www.mprnews.org/story/2016/04/18/opioid-overdose-epidemic-explained.

⁷⁴ Rose Rudd et al, *supra* note 71, at 1379.

⁷⁵ Pam Louwagie and Natalie Daher, *Two Dead in Six Separate Anoka County Heroin Overdose Cases Saturday*, Star Trib. (October 23, 2016), <http://www.startribune.com/two-dead-in-five-separate-anoka-county-heroin-overdose-cases-saturday/398046441/>.

⁷⁶ *HCUP Fast Stats—Opioid-Related Hospital Use*, Agency for Healthcare Research and Quality, www.hcup-us.ahrq.gov/faststats/opioid/opioiduse.jsp (last modified June 26, 2018).

⁷⁷ Audrey Weiss et al., *Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009-2014*, at 4, Agency for Healthcare Research and Quality (Jan. 2017), <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf>.

2017, the rate rose to 348 per 100,000.⁷⁸ The rate of opioid-related emergency department visits has also increased, rising to 134.1 per 100,000 persons in 2014, an 83% increase from 2009, accounting for the fourth-largest increase among the 27 states in which data is available.⁷⁹ In 2016, the figure jumped again to 196 visits per 100,000 persons.⁸⁰

220. In 2016, opioids accounted for 10,332 substance abuse treatment admissions in Minnesota, second only to alcohol.⁸¹ Almost one quarter of admissions that year in the Twin Cities metro area to addiction treatment programs were for opioid abuse, compared to just 4.7% in 2000.⁸² Treatment admissions for heroin use in the Twin Cities metro area increased from 3.3% of admissions in 2000 to 17.3% in 2016.⁸³

221. The number of individuals receiving medication-assisted treatment for opioid addiction has also increased. In 2009, 3,152 individuals enrolled in opioid treatment programs in Minnesota were receiving methadone for substance use treatment⁸⁴; by 2015, this figure had risen to 5,530 individuals.⁸⁵ Similarly, the number of Minnesotans receiving buprenorphine as part of their substance use treatment increased from 247 to 667 from 2009 to 2015.⁸⁶

⁷⁸ *HCUP Fast Stats—Opioid-Related Hospital Use*, *supra* note 76.

⁷⁹ Audrey Weiss et al., *supra* note 77, at 9.

⁸⁰ *HCUP Fast Stats—Opioid-Related Hospital Use*, *supra* note 76.

⁸¹ Minn. Dep't of Human Servs., *Drug and Alcohol Abuse in Minnesota a Biennial Report to the Legislature* 10, 14 (Jan. 2018), https://mn.gov/dhs/assets/2018-01-drug-and-alcohol-abuse-report_tcm1053-325460.pdf.

⁸² Carol Falkowski, *Drug Abuse Trends in the Minneapolis/St. Paul Metropolitan Area* 3 (Apr. 2017), http://www.drugabusedialogues.com/drug_abuse_trends_reports/2017_April.pdf.

⁸³ *Id.*

⁸⁴ Substance Abuse and Mental Health Servs. Admin., *Behavioral Health Barometer—Minnesota, 2014*, at 17 (2015), https://www.samhsa.gov/data/sites/default/files/State_BHBarometers_2014_1/BHBarometer-MN.pdf.

⁸⁵ Substance Abuse and Mental Health Servs. Admin., *Behavioral Health Barometer—Minnesota, Volume 4*, at 14 (2017), https://www.samhsa.gov/data/sites/default/files/Minnesota_BHBarometer_Volume_4.pdf.

⁸⁶ *Id.*; *Behavioral Health Barometer—Minnesota, 2014*, *supra* note 84.

222. Minnesota's opioid epidemic has had a disparate impact on minorities, with an especially large impact on Minnesota's Native American population. According to a Minnesota Department of Human Services report, Minnesota ranked first among all states in the ratio of deaths due to drug overdose among Native Americans and African Americans relative to white persons.⁸⁷ According to the CDC, between 1999 and 2014, Native Americans in Minnesota died of opioid overdoses at a rate nearly five times higher than that of white Minnesotans.⁸⁸ Although Native Americans make up only 1% of Minnesota's population, in 2015 they accounted for nearly 16% of those who entered opioid abuse treatment programs.⁸⁹

223. The increased use of opioids in Minnesota has affected even its most vulnerable residents, causing a dramatic increase in the number of infants born with neonatal abstinence syndrome ("NAS"), a postnatal withdrawal syndrome that results from exposure to opioids while in the mother's womb. More than half of pregnant Minnesotans who are known to be opioid dependent are nevertheless prescribed opioids during pregnancy.⁹⁰ According to the Minnesota Department of Human Services, the number of NAS infants born to participants in state health-care programs more than doubled from 2008 to 2012.⁹¹ The rate of infants born with NAS has nearly doubled again since 2012, increasing from 35.9 per 10,000 births in 2012 to 60 in

⁸⁷ Minn. Dep't of Human Servs., *Minnesota State Targeted Response to the Opioid Crisis* (Apr. 2017), https://mn.gov/dhs/assets/mn-opioid-str-project-narrative-april-2017_tcm1053-289624.pdf.

⁸⁸ Jon Collins, *supra* note 73.

⁸⁹ *Minnesota State Targeted Response to the Opioid Crisis*, *supra* note 87, at 6.

⁹⁰ Letter from Lucinda Jesson, Commissioner of Minnesota Department of Human Services, to Sylvia Burwell, Secretary of Health and Human Services (April 23, 2015), <https://www.documentcloud.org/documents/2073556-minnesota-dhs-response-to-secretary-burwells.html>.

⁹¹ Sarah Williams, *Pregnant and Addicted: An Awful Burden to Carry*, MinnPost (Feb. 5, 2014), <https://www.minnpost.com/mental-health-addiction/2014/02/pregnant-and-addicted-awful-burden-carry>.

2016.⁹² NAS rates are particularly troubling for Minnesota's Native Americans, whose infants are 7.4 times more likely to be born with NAS than white persons.⁹³

224. Infants born with NAS require lengthy hospital stays and thus dramatically increase health care costs. In 2013, state expenditures totaled \$10.5 million to treat infants born with NAS.⁹⁴

B. Purdue's Conduct Has Placed an Immense Financial Burden on Minnesota.

225. In addition to the human costs, the opioid epidemic has taken a massive economic toll on Minnesota and its residents. Purdue's deceptive tactics have caused the state to incur tens of millions of dollars in healthcare costs, including unnecessary and excessive opioid prescriptions and opioid abuse treatment services that it would not have incurred but for Purdue's role in misrepresenting the efficacy and risks of opioids. Purdue's conduct has also caused the state to incur significant societal costs, including increased criminal justice costs and lost workplace productivity costs.

226. This is true across the country. According to the United States Department of Health and Human Services, opioid poisonings cost the United States more than \$20 billion annually in "hospitalizations and emergency department care" alone.⁹⁵ After adding in societal costs of "increased health care expenditures, incarceration, premature death, and lost

⁹² Minn. Dep't of Health, *Neonatal Abstinence Syndrome (NAS) Data Brief: Statewide and County Trends, 2012-2016*, at 1 <http://www.health.state.mn.us/divs/healthimprovement/content/documents-opioid/NASmndatabrief.pdf>.

⁹³ *Minnesota State Targeted Response to the Opioid Crisis*, *supra* note 87, at 6.

⁹⁴ Chris Serres, *Minnesota Comes to the Aid of Opioid-Exposed Babies*, *Star Trib.* (March 5, 2015), <http://www.startribune.com/minnesota-comes-to-the-aid-of-opioid-exposed-babies/295105051/>.

⁹⁵ Dan Mangan, *Hospitalizations for Opioid Misuse Soared in United States as Painkiller and Heroin Epidemic Spread*, *CNBC* (Dec. 15, 2016), <http://www.cnn.com/2016/12/15/hospitalizations-soar-for-opioid-misuse-as-epidemic-spreads.html>.

productivity,” the nationwide estimated cost resulting from prescription opioid abuse was almost \$81 billion in 2013, a more than 590% increase from the \$11.7 billion estimated cost in 2001.⁹⁶

227. In Minnesota, healthcare costs of the opioid epidemic are partially borne by Minnesota’s Medical Assistance program (“Medicaid”), which provides health insurance for over 1 million low-income Minnesotans.⁹⁷ In 2016, Medicaid spending in Minnesota was \$11.2 billion, up from \$10.5 billion in 2015, and almost double the amount paid in 2008.⁹⁸ Costs are projected to rise to over \$14 billion in 2020.⁹⁹

228. By creating both the supply and the demand for chronic opioid users, Defendants have caused Minnesota to incur tens of millions of dollars in health care costs through its public health care programs, including through Medicaid. Minnesota Medicaid patients have made thousands of claims, and the State has paid millions of dollars, for Purdue opioid prescriptions. The State has also paid millions of dollars through Medicaid for health care services and drugs provided to patients in order to treat opioid addiction and abuse.

229. MinnesotaCare, a separate publicly-funded health care program for low-income Minnesotans, also accounts for significant state healthcare expenditures, including those borne as a direct result of the opioid epidemic. MinnesotaCare provides comprehensive low-cost health insurance to Minnesota residents who lack access to affordable coverage. In 2016, nearly \$500

⁹⁶ U.S. Congress Joint Economic Committee, *Medicaid Plays Key Role in Fight Against Opioid and Heroin Epidemic 2* (Mar. 2017), https://www.jec.senate.gov/public/_cache/files/2ebb740a-abd1-49e6-9d91-623368314bbc/medicaid-and-suds-20170324-formatted-final-002-.pdf.

⁹⁷ Minn. Dep’t of Human Servs., Reports and Forecasts Division, *Family Self-Sufficiency and Health Care Program Statistics 30* (May 2018), https://mn.gov/dhs/assets/family-self-sufficiency-health-care-0518_tcm1053-343724.pdf.

⁹⁸ *Id.*

⁹⁹ *Id.*

million was paid through MinnesotaCare for the more than 100,000 Minnesota residents enrolled.¹⁰⁰

230. According to a Department of Human Services analysis, there are approximately 19,000 chronic opioid users in Minnesota's public health care programs.¹⁰¹ About 5,000 Minnesota health care program enrollees transition from opioid-naïve to chronic opioid users per year, and over 80% of new chronic opioid users have recent diagnoses of mental illness, substance abuse disorder, or both.¹⁰² It is especially concerning that "among Medicaid enrollees who were previously opioid-naive, 80% of enrollees who received a 45 day supply of opioids over a 90 day period went on to receive a 90 day supply of opioids following the initial fill," placing those persons at significant risk for continued long-term opioid use.¹⁰³

231. In addition to opioid prescriptions, state expenditures include significant amounts to treat opioid addicts. In 2016, 70% of substance use treatment admissions were publicly-funded, paid for by either the State's Consolidated Chemical Dependency Treatment Fund or state-contracted Medicaid or MinnesotaCare managed care organizations.¹⁰⁴ Medicaid also covers 32% of medication-assisted treatment payments for opioid abusers in Minnesota, eight percent more than the national share.¹⁰⁵

¹⁰⁰ *Id.* at 31.

¹⁰¹ *Minnesota Opioid Prescribing Guidelines*, *supra* note 47, at 4.

¹⁰² *Id.* at 5.

¹⁰³ *Id.*

¹⁰⁴ Minn. Dep't of Human Servs., *State Treatment Court Conference: Substance Use Disorder Reform*, at 9 (June 2017), http://www.mncourts.gov/mncourtsgov/media/scao_library/ENE/SUD-Reform-Treatment-Courts-june-2017-final.pdf.

¹⁰⁵ U.S. Congress Joint Economic Committee, *supra* note 96, at 3.

232. Defendants' conduct has also forced Minnesota to devote tens of thousands of dollars toward the purchase, distribution, and use of naloxone, an opioid antagonist administered to persons suffering from an overdose.

233. The opioid epidemic has had a financial impact in Minnesota beyond just healthcare costs. It is also overwhelming Minnesota's criminal justice system. Almost 20% of Minnesota inmates are serving sentences for drug crimes, and 90% of inmates have been diagnosed as chemically abusive or dependent, resulting in the introduction of chemical dependency programs in Minnesota prisons.¹⁰⁶

234. Minnesota law enforcement personnel have been forced to devote substantial resources to fighting crime related to the proliferation of opioids. Prescription pill seizures, including opioids, increased by 231% from 2015 to 2016.¹⁰⁷ According to data reported to the DEA, instances of theft of controlled substances from pharmacies more than tripled from 2006 to 2010.¹⁰⁸ Heroin was present in almost 14% of drug reports from law enforcement seizures in

¹⁰⁶ EpiMachine, LLC, *Substance Abuse in Minnesota: A State Epidemiological Profile* 124 (2018), <http://sumn.org/~media/542/MNEpiProfile2018.pdf>.

¹⁰⁷ Press Release, Minn. Dep't of Pub. Safety, *Record Amounts of Drugs Seized in Minnesota* (March 6, 2017), <https://dps.mn.gov/divisions/ooc/news-releases/Pages/record-amounts-of-drugs-seized-in-minnesota.aspx>.

¹⁰⁸ Carol Falkowski and Barbara Carter, *Prescription Drug Abuse Trends and Minnesota's Prescription Monitoring Program* 18 (June 25, 2013), <https://minnesotaruralhealthconference.org/sites/default/files/presentations/2013/5C%20Rx%20Drug%20Abuse%20Trends%20and%20Minnesota%27s%20Prescription%20Monitoring%20Program.pdf>.

2014, compared to 10.2% in 2012,¹⁰⁹ and heroin arrests increased more than 400% from 2008 to 2011.¹¹⁰ Drug abuse also leads to other crimes, such as theft, burglary, and assaults.

235. One study reported that nationwide, the prescription opioid epidemic caused \$7.7 billion in criminal justice related costs in 2013, almost all of which were borne directly by state and local governments.¹¹¹

236. Minnesota forensic examiners have experienced an increased burden as well. The Hennepin County Medical Examiner estimated that because of the increase in overdose deaths, it would spend more than \$391,000 on lab work in 2017, a 43% increase from 2016.¹¹²

237. In addition to healthcare and criminal justice costs, societal costs from the opioid epidemic include those accounted for in the workplace. One study estimated that prescription opioid abuse costs \$25.6 billion in lost workplace productivity annually.¹¹³ A recent report found that over 40% of unemployed men between the ages of 25 and 54 reported taking painkillers daily, with the vast majority of those taking painkillers using prescription drugs.¹¹⁴

¹⁰⁹ Carol Falkowski, *Minneapolis/St. Paul Drug Abuse Trends* 3, 12 (Apr. 2016), http://www.drugabusedialogues.com/drug_abuse_trends_reports/2016_April.pdf; Carol Falkowski, *Drug Abuse Trends in Minneapolis/St. Paul, Minnesota: January 2014 Update* 2, 9 (Jan. 2014), http://www.drugabusedialogues.com/drug_abuse_trends_reports/2014_Jan.pdf.

¹¹⁰ Minn. Dep't of Pub. Safety, *supra* note 71, at 4.

¹¹¹ Curtis Florence et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54 *Med. Care* 901 (Oct. 2016).

¹¹² Kevin Doran, *Opioid Epidemic Taxing Death Investigators Like Never Before*, KSTP (July 2, 2017), <http://kstp.com/medical/nationwide-opioid-epidemic-taxing-minnesota-medical-examiners-carfentanil-/4531611/>.

¹¹³ Howard Birnbaum et al., *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, 12 *Pain Med.* 657, 657 (2011).

¹¹⁴ *Millions of Men Are Missing From the Job Market*, N.Y. Times (October 16, 2016), <https://www.nytimes.com/2016/10/17/opinion/millions-of-men-are-missing-from-the-job-market.html>.

**COUNT I
CONSUMER FRAUD**

238. The State re-alleges all prior paragraphs of this Complaint.

239. Minnesota Statutes section 325F.69, subdivision 1, provides:

The act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoined as provided in section 325F.70.

240. The term “merchandise” within the meaning of Minnesota Statutes section 325F.69 includes goods, such as prescription drugs. *See* Minn. Stat. § 325F.68, subd. 2.

241. The term “person” includes any partnership or corporation, foreign or domestic. Minn. Stat. § 325F.68, subd. 3. The Purdue entities are “person[s]” within the meaning of this statute.

242. Purdue repeatedly violated Minnesota Statutes section 325F.69, subdivision 1, by engaging in the deceptive and fraudulent practices described in this Complaint with the intent that others rely thereon in connection with its marketing and sale of opioids. These practices include, but are not limited to:

- a. minimizing the risks of long-term opioid use, specifically the risks of addiction;
- b. claiming that signs of drug-seeking, addictive behavior were “pseudoaddiction” reflecting undertreated pain that simply required treatment with more opioids;
- c. claiming that opioids had no ceiling dose and that dosages could be increased until achievement of pain relief;
- d. claiming that scientific evidence supports the long-term use of opioids for treatment of chronic pain;
- e. claiming that OxyContin provides a full 12 hours of pain relief;

- f. claiming that Purdue's abuse-deterrent formulations of opioid medications reduced and/or prevented abuse and addiction; and
- g. claiming that non-opioid pain treatments carried significant risks and limited efficacy, while exaggerating the efficacy and minimizing the risks of opioids.

243. Separately, Purdue repeatedly violated Minnesota Statutes section 325F.69, subdivision 1, by omitting material information in the course of marketing and selling opioids such that its failures to sufficiently disclose such material information constituted deceptive and fraudulent practices committed with the intent that others rely thereon in connection with the sale of opioids. Those failures to disclose and omissions include, but are not limited to:

- a. failing to sufficiently disclose the risks of long-term opioid use, including the risks of addiction and dangerous adverse side effects;
- b. failing to sufficiently disclose the fact that OxyContin does not provide a full 12 hours of pain relief;
- c. failing to sufficiently disclose the lack of evidence supporting the efficacy of opioids for long-term use in treating chronic pain;
- d. failing to sufficiently disclose the relative risks of opioid use when discussing the efficacy and risks of non-opioid pain treatments; and
- e. failing to sufficiently disclose that abuse-deterrent formulations of opioid medications are not proven to reduce the abuse and addiction liability of those medications.

244. Given the nature and quality of the representations Purdue made, the actual and special knowledge it had, and the other circumstances described in this Complaint, Purdue had a duty to sufficiently disclose all material facts in connection with its marketing of opioids.

245. Due to the fraudulent, deceptive, and misleading conduct, representations, and material omissions described in this Complaint, opioids were provided to many residents in

Minnesota, caused injury in Minnesota, and created a public health epidemic and a public nuisance, all while enriching Purdue.

246. Purdue's conduct, practices, actions, and material omissions described in this Complaint constitute multiple, separate violations of Minnesota Statutes section 325F.69.

**COUNT II
DECEPTIVE TRADE PRACTICES**

247. The State re-alleges all prior paragraphs of this Complaint.

248. Minnesota Statutes section 325D.44, subdivision 1, provides, in part:

A person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person:

(2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;

(5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;

(7) represents that goods or services are of a particular standard, quality, or grade . . . if they are of another;

(8) disparages the goods, services, or business of another by false or misleading representation of fact; [or]

(13) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

249. The Purdue entities are "person[s]" within the meaning of this statute.

250. Purdue, by engaging in the deceptive and fraudulent practices described in this Complaint, has engaged in a course of trade or commerce which had the capacity or tendency to deceive and/or mislead, and therefore constitutes multiple violations of Minnesota law by deceptive trade practices.

251. Purdue caused a likelihood of confusion or misunderstanding regarding the approval or certification of its opioid products, and opioids in general, by, among other things, making misrepresentations designed to mislead Minnesota health care providers regarding the safety and efficacy of opioids, including by misrepresenting the risks of opioid addiction, “pseudoaddiction” and how to treat patients with signs of addiction and abuse, the lack of an opioid dose ceiling and risks of increased opioid doses, the efficacy of opioids for long-term use in chronic pain patients, the effect of opioids on patient functionality and quality of life, the superiority of opioids over non-opioid pain treatments, the capability of OxyContin to provide a full 12 hours of pain relief, and the addiction- and abuse-prevention qualities of the “abuse-deterrent” formulations of its opioid products.

252. Purdue represented that its opioid products, and opioids in general, had approvals, characteristics, ingredients, uses, and benefits that they did not have by, among other things, misrepresenting the safety and efficacy of opioids, including by misrepresenting the risks of opioid addiction, “pseudoaddiction” and how to treat patients with signs of addiction and abuse, the lack of an opioid dose ceiling and risks of increased opioid doses, the efficacy of opioids for long-term use in chronic pain patients, the effect of opioids on patient functionality and quality of life, the superiority of opioids over non-opioid pain treatments, the capability of OxyContin to provide a full 12 hours of pain relief, and the addiction- and abuse-prevention qualities of the “abuse-deterrent” formulations of its opioid products.

253. Purdue misrepresented the standard, quality, or grade of its opioid products, and opioids in general, by, among other things, misrepresenting the safety and efficacy of opioids, including by misrepresenting the risks of opioid addiction, “pseudoaddiction” and how to treat patients with signs of addiction and abuse, the lack of an opioid dose ceiling and risks of increased opioid doses, the efficacy of opioids for long-term use in chronic pain patients, the effect of opioids on patient functionality and quality of life, the superiority of opioids over non-opioid pain treatments, the capability of OxyContin to provide a full 12 hours of pain relief, and the addiction- and abuse-prevention qualities of the “abuse-deterrent” formulations of its opioid products.

254. Purdue disparaged the goods, services, or business of another by making false or misleading representations of fact by deceptively claiming that opioids are superior to non-opioid pain treatments and misrepresenting the risks of non-opioid medications like acetaminophen and NSAIDs, by deceptively claiming that extended-release opioids are superior to immediate-release opioids, and by deceptively claiming that abuse-deterrent formulations of opioids are superior to non-abuse-deterrent formulations.

255. Purdue further engaged in conduct that created a likelihood of confusion or misunderstanding about its opioid products, and opioids in general, by, among other things, making false, deceptive, and/or misleading representations about the safety and efficacy of opioids, including by misrepresenting the risks of opioid addiction, “pseudoaddiction” and how to treat patients with signs of addiction and abuse, the lack of an opioid dose ceiling and risks of increased opioid doses, the efficacy of opioids for long-term use in chronic pain patients, the effect of opioids on patient functionality and quality of life, the superiority of opioids over non-opioid pain treatments, the capability of OxyContin to provide a full 12 hours of pain relief, and

the addiction- and abuse-prevention qualities of the “abuse-deterrent” formulations of its opioid products.

256. Separately, Purdue repeatedly violated Minnesota Statutes section 325D.44, subdivision 1, by omitting material information in the course of marketing and selling its opioid products, and in the course of promoting opioids in general, that subsequently caused a likelihood of confusion or misunderstanding, including by failing to sufficiently disclose the risks of opioids and the lack of evidence supporting the long-term use of opioids for chronic pain treatment.

257. Due to the fraudulent, deceptive, and misleading conduct, representations, and material omissions described in this Complaint, opioids were provided to many residents in Minnesota, caused injury in Minnesota, and created a public health epidemic and a public nuisance, all while enriching Purdue.

258. Purdue’s conduct, practices, actions, and material omissions described in this Complaint constitute multiple, separate violations of Minnesota Statutes section 325D.44.

**COUNT III
FALSE STATEMENTS IN ADVERTISING**

259. The State re-alleges all prior paragraphs of this Complaint.

260. Minnesota Statutes section 325F.67 provides, in part, that:

Any person, firm, corporation, or association who, with intent to sell or in anywise dispose of merchandise, securities, service, or anything offered by such person, firm, corporation, or association, directly or indirectly, to the public, for sale or distribution, or with intent to increase the consumption thereof, or to induce the public in any manner to enter into any obligation relating thereto, or to acquire title thereto, or any interest therein, makes, publishes, disseminates, circulates, or places before the public, or causes, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public, in this state, in a newspaper or other publication, or in the form of a book, notice, handbill,

poster, bill, label, price tag, circular, pamphlet, program, or letter, or over any radio or television station, or in any other way, an advertisement of any sort regarding merchandise, securities, service, or anything so offered to the public, for use, consumption, purchase, or sale, which advertisement contains any material assertion, representation, or statement of fact which is untrue, deceptive, or misleading, shall, whether or not pecuniary or other specific damage to any person occurs as a direct result thereof, be guilty of a misdemeanor, and any such act is declared to be a public nuisance and may be enjoined as such.

261. Purdue's opioid products and opioids generally are "merchandise, securities, service, or anything offered . . . directly or indirectly, to the public" within the meaning of this statute.

262. The Purdue entities are "person[s]" and "corporation[s]" within the meaning of this statute.

263. Purdue repeatedly violated Minnesota Statutes section 325F.67, by making, publishing, disseminating, circulating, and/or placing before the public, books, pamphlets, letters, and other forms of advertisements which contained material assertions, representations, or statements of fact that are untrue, deceptive, or misleading regarding the risks and efficacy of opioids, including by misrepresenting the risks of opioid addiction, "pseudoaddiction" and how to treat patients with signs of addiction and abuse, the lack of an opioid dose ceiling and risks of increased opioid doses, the efficacy of opioids for long-term use in chronic pain patients, the effect of opioids on patient functionality and quality of life, the superiority of opioids over non-opioid pain treatments, the capability of OxyContin to provide a full 12 hours of pain relief, and the addiction- and abuse-prevention qualities of the "abuse-deterrent" formulations of its opioid products.

264. Separately, Purdue repeatedly violated Minnesota Statutes section 325F.67, subdivision 1, by making, publishing, disseminating, circulating, and/or placing before the

public, books, pamphlets, letters, and other forms of advertisements which contained material assertions, representations, or statements of fact that are untrue, deceptive, or misleading by omitting material information regarding the risks and efficacy of opioids, including by failing to sufficiently disclose the risks of opioids and the lack of evidence supporting the long-term use of opioids for chronic pain treatment.

265. Due to the fraudulent, deceptive, and misleading conduct, representations, and material omissions described in this Complaint, opioids were provided to many residents in Minnesota, caused injury in Minnesota, and created a public health epidemic and a public nuisance, all while enriching Purdue.

266. Purdue's conduct, practices, actions, and material omissions described in this Complaint constitute multiple, separate violations of Minnesota Statutes section 325F.67.

**COUNT IV
DECEPTIVE ACTS PERPETRATED AGAINST SENIOR CITIZENS AND DISABLED
PERSONS**

267. The State re-alleges all prior paragraphs of this Complaint.

268. Minnesota Statutes section 325F.71, subdivision 2(a), provides:

In addition to any liability for a civil penalty pursuant to sections 325D.43 to 325D.48, regarding deceptive trade practices; 325F.67, regarding false advertising; and 325F.68 to 325F.70, regarding consumer fraud; a person who engages in any conduct prohibited by those statutes, and whose conduct is perpetrated against one or more senior citizens or disabled persons, is liable for an additional civil penalty not to exceed \$10,000 for each violation, if one or more of the factors in paragraph (b) are present.

269. Minnesota Statutes section 325F.71, subdivision 2(b), provides:

In determining whether to impose a civil penalty pursuant to paragraph (a), and the amount of the penalty, the court shall consider, in addition to other appropriate factors, the extent to which one or more of the following factors are present:

- (1) whether the defendant knew or should have known that the defendant's conduct was directed to one or more senior citizens or disabled persons;
- (2) whether the defendant's conduct caused senior citizens or disabled persons to suffer: loss or encumbrance of a primary residence, principal employment, or source of income; substantial loss of property set aside for retirement or for personal or family care and maintenance; substantial loss of payments received under a pension or retirement plan or a government benefits program; or assets essential to the health or welfare of the senior citizen or disabled person;
- (3) whether one or more senior citizens or disabled persons are more vulnerable to the defendant's conduct than other members of the public because of age, poor health or infirmity, impaired understanding, restricted mobility, or disability, and actually suffered physical, emotional, or economic damage resulting from the defendant's conduct; or
- (4) whether the defendant's conduct caused senior citizens or disabled persons to make an uncompensated asset transfer that resulted in the person being found ineligible for medical assistance.

270. Purdue engaged in conduct prohibited by Minnesota Statutes sections 325D.44, 325F.67, and 325F.69, as described above.

271. Purdue's conduct was perpetrated against one or more senior citizens (i.e., persons who are 62 years of age or older). *See* Minn. Stat. § 325F.71, subd. 1(a).

272. Purdue's conduct was perpetrated against one or more "disabled person[s]," meaning persons who have "an impairment of physical or mental function or emotional status that substantially limits one or more major life activities." Minn. Stat. § 325F.71, subd. 1(b). "Major life activities" include "caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working." *Id.*, subd. 1(c).

273. Purdue's conduct meets one or more of the nonexclusive factors listed in section 325F.71, subdivision 2(b), and satisfies other appropriate factors, including that Purdue knew that its conduct was directed to one or more senior citizens or disabled persons, that Purdue's conduct caused senior citizens or disabled persons to suffer loss or encumbrance of property, employment, income, and/or assets, and that one or more senior citizens or disabled persons were more vulnerable to the Purdue's conduct than other members of the public because of age, poor health or infirmity, impaired understanding, restricted mobility, or disability, and/or actually suffered physical, emotional, or economic damage resulting from the Purdue's conduct. These circumstances are established by the conduct described herein.

274. Purdue's conduct, practices, actions, and material omissions described in this Complaint constitute multiple, separate violations of Minnesota Statutes section 325F.71.

**COUNT V
UNLAWFUL TRADE PRACTICES**

275. The State re-alleges all prior paragraphs of this Complaint.

276. Minnesota Statutes section 325D.13 provides that:

No person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise.

277. The Purdue entities are "person[s]" within the meaning of this statute.

278. Purdue repeatedly violated Minnesota Statutes section 325D.13 in connection with the sale of its opioid products by knowingly misrepresenting, directly and/or indirectly, the true quality of its opioid products, including by misrepresenting the risks of opioid addiction, "pseudoaddiction" and how to treat patients with signs of addiction and abuse, the lack of an opioid dose ceiling and risks of increased opioid doses, the efficacy of opioids for long-term use in chronic pain patients, the effect of opioids on patient functionality and quality of life, the

superiority of opioids over non-opioid pain treatments, the capability of OxyContin to provide a full 12 hours of pain relief, and the addiction- and abuse-prevention qualities of the “abuse-deterrent” formulations of its opioid products.

279. Separately, Purdue repeatedly violated Minnesota Statutes section 325D.13 in connection with the sale of its opioid products by omitting material information such that it knowingly misrepresented, directly and/or indirectly, the true quality of its opioid products, including by failing to sufficiently disclose the risks of opioids and the lack of evidence supporting the long-term use of opioids for chronic pain treatment.

280. Due to the fraudulent, deceptive, and misleading conduct, representations, and material omissions described in this Complaint, opioids were provided to many residents in Minnesota, caused injury in Minnesota, and created a public health epidemic and a public nuisance, all while enriching Purdue.

281. Purdue’s conduct, practices, actions, and material omissions described in this Complaint constitute multiple, separate violations of Minnesota Statutes section 325D.13.

COUNT VI UNJUST ENRICHMENT

282. The State re-alleges all prior paragraphs of this Complaint.

283. Benefits have been conferred upon Purdue by Minnesota patients, third-party payors, and the State, who made payments to Purdue for the opioid products prescribed by health care providers to whom Purdue misleadingly and deceptively marketed its opioid products and opioids in general.

284. Purdue knowingly accepted and retained such benefits.

285. Purdue’s acceptance and retention of such benefits under the circumstances would be unjust and inequitable, given that Minnesota patients did not receive the promised benefits of

the opioid products marketed and sold by Purdue. Instead, Purdue's conduct has resulted in the harm described herein.

286. Further, Purdue has failed to pay for the consequences of its unlawful conduct.

287. As a result, the State has been required to pay for the medical costs stemming from Purdue's unlawful acts. The State has borne a duty that—in law, equity, and fairness—ought to have been borne by Purdue.

288. Purdue's conduct constitutes unjust enrichment under Minnesota common law, for which, as a matter of equity, Purdue should not derive any gain and those harmed should be made whole.

289. Purdue's conduct, practices, actions, and material omissions described in this Complaint constitute multiple instances of unjust enrichment under Minnesota law.

COUNT VII UNDERTAKING OF SPECIAL DUTY

290. The State re-alleges all prior paragraphs of this Complaint.

291. Under the law, and due to its responsibility as a manufacturer of an especially dangerous product and the role it assumed in purporting to inform health care providers of the risks and benefits of that product, Purdue owed a duty of care to patients, health care providers, third-party payors, and the State.

292. Purdue recognized that its undertaking of said duty was necessary for the protection of the public health, and that its conduct would affect the health and wellbeing of millions of Americans and many Minnesotans, the cost of medical care, and the operations of the health insurance market and government health care programs.

293. Through the conduct described herein, Purdue has breached and continues to breach its duty of care to patients, health care providers, third-party payors, and the State by its

failure to exercise such reasonable care in performance of its undertaking. Purdue's failure to exercise such reasonable care increased the risk of harm, including the risks of addiction, overdose, and death, and increased the cost of health care.

294. As a direct and proximate result of Purdue's conduct described herein, the State and its residents have suffered and will continue to suffer substantial injuries and damages.

295. Purdue's conduct, practices, actions, and material omissions described in this Complaint constitute multiple instances of breach of special duty under Minnesota law.

**COUNT VIII
PUBLIC NUISANCE**

296. The State re-alleges all prior paragraphs of this Complaint.

297. Minnesota Statutes section 609.74 provides, in part:

Whoever by an act or failure to perform a legal duty intentionally does any of the following is guilty of maintaining a public nuisance, which is a misdemeanor:

(1) maintains or permits a condition which unreasonably annoys, injures or endangers the safety, health, morals, comfort, or repose of any considerable number of members of the public; or

(3) is guilty of any other act or omission declared by law to be a public nuisance and for which no sentence is specifically provided.

298. The State and its residents have a public right to be free from interference with the public safety, health, comfort, or repose. The State is empowered by equity and law to allege a claim, and seek redress for, a public nuisance. The State, in its capacity as a public litigant and as *parens patriae*, as well as a payor of public monies for costs incurred through its provision of

governmental health care programs and services, has an important and unique interest in protecting health and safety.

299. Through the deceptive conduct described throughout this Complaint, Purdue has intentionally maintained or permitted, or was a substantial factor in maintaining or permitting, a public nuisance that has annoyed, injured, and endangered—and continues to unreasonably annoy, injure, and endanger—the common right of public health, comfort, or repose of considerable members of the public.

300. Purdue knew or should have known that its promotion of opioids was deceptive and misleading, and that its fraudulent and deceptive marketing tactics and other unlawful conduct would cause or contribute to the maintenance or permission of a public nuisance.

301. Purdue's conduct was, at the very least, a substantial factor in opioids becoming widely available and widely used in Minnesota. Purdue's conduct was also, at the very least, a substantial factor in deceiving health care providers, third-party payors, and patients about the risks and benefits of the use of opioids for the treatment of chronic pain. Without Purdue's conduct, opioid use, misuse, abuse, addiction, overdose, and death would not have been so widespread, and the existing Minnesota opioid epidemic would have been avoided.

302. Purdue's conduct is widespread and persistent, and has created, is creating, and will likely continue to create substantial ongoing harm to the State and its residents. The State has incurred and continues to incur substantial costs from investigating, monitoring, treating, policing, and remediating the opioid epidemic.

303. Purdue's conduct in maintaining or permitting a public nuisance has openly, publicly, repeatedly, continuously, persistently, and intentionally violated Minnesota law, as described throughout this Complaint. Purdue's conduct is sufficiently pervasive that it cannot be

adequately addressed or remedied by resort to criminal enforcement of Minnesota Statutes section 609.74 or other criminal statutes. Purdue's widespread interference with public rights and privileges, and its endangerment of public health, requires the State to seek injunctive and all other appropriate equitable relief against Purdue in order to abate this public nuisance and remedy the resultant harm, both retrospectively and prospectively.

304. Furthermore, pursuant to Minnesota Statutes section 325F.67, as pleaded above, Purdue's dissemination of books, pamphlets, letters, and other forms of advertisements which contained material assertions, representations, or statements of fact that are untrue, deceptive, or misleading, as described throughout this Complaint, constitutes a public nuisance for which the State is entitled to injunctive relief.

**COUNT IX
FALSE CLAIMS ACT**

305. The State re-alleges all prior paragraphs of this Complaint.

306. Minnesota Statutes section 15C.02(a) provides, in part, that a person may not:

(1) knowingly present[], or cause[] to be presented, a false or fraudulent claim for payment or approval; [or]

(2) knowingly make[] or use[], or cause[] to be made or used, a false record or statement material to a false or fraudulent claim[.]

307. The Attorney General is a "prosecuting attorney" authorized by chapter 15C to investigate and bring civil actions to enjoin violations of section 15C.02, and to recover statutory damages and penalties for false or fraudulent claims that involve money, property, or services provided by the State. *See* Minn. Stat. §§ 15C.01, subd. 7; 15C.04.

308. Purdue's conduct, as described herein, constituted multiple, separate violations of the Minnesota False Claims Act. Purdue, through its deceptive marketing of opioids for chronic pain, knowingly made, or caused to be made or used, false statements material to such claims.

309. Purdue knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading, and were made for the purpose of getting State health care programs to pay for opioids for long-term treatment of chronic pain. In addition, Purdue knew, deliberately ignored, or recklessly disregarded that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

310. Purdue knew that its fraudulent, false, and misleading statements and omissions were material to health care providers' decision to prescribe opioids to Minnesota government health care program patients. Indeed, Purdue intended such statements and omissions to be material to encourage additional opioid prescriptions.

311. Purdue's scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the State's government health care programs for payment. State health care programs only cover the cost of a covered service, including prescription drugs, that are "medically necessary," as "determined by prevailing community standards or customary practice and usage." Minn. R. 9505.0210. Specifically, Minnesota's rules governing its government health care programs define "medically necessary":

"Medically necessary" or "medical necessity" means a health service that is consistent with the recipient's diagnosis or condition and:

A. is recognized as the prevailing standard or current practice by the provider's peer group; and

B. is rendered in response to a life threatening condition or pain; or to treat an injury, illness, or infection; or to treat a condition that could result in physical or mental disability; or to care for the mother and child through the maternity period; or to achieve a level of physical or mental function

consistent with prevailing community standards for diagnosis or condition; or

C. is a preventive health service under part 9505.0355.

Minn. R. 9505.0175, subp. 25.

312. Health care providers, including doctors and pharmacists, and agents of State government health care programs expressly or impliedly certified to the State that opioids were medically necessary to treat chronic pain because they were influenced by the false and misleading statements disseminated by Purdue about the risks, benefits, and superiority of opioids for chronic pain. Moreover, many of the prescriptions written by health care providers or authorized by State government health care programs and submitted to the State were for uses that were misbranded.

313. To the extent that such prescribing is considered consistent with prevailing standards or customary or current practice and usage, it is only because such standards or practices have been tainted or influenced by Purdue's deceptive marketing.

314. Purdue knew, deliberately ignored, or recklessly disregarded that, as a natural consequence of their actions, governments such as the State would necessarily be paying for long-term prescriptions of opioids to treat chronic pain.

315. Because Purdue's marketing caused health care providers to prescribe, and the State to pay for, long-term opioid treatment using opioids manufactured or distributed by other drug makers, Purdue caused and is responsible for those costs and claims as well.

316. Purdue's misrepresentations and omissions were material because if the State had known of the false statements disseminated by Purdue and associated third parties that health care providers or agents of State government health care programs were relying on to certify and/or determine that opioids were medically necessary, the State would have undertaken efforts

to avoid its payment of false claims and to remediate and limit the harm from the inappropriate prescribing of opioids.

317. Alternatively, such misrepresentations and omissions were material because they would have a natural tendency to influence, or be capable of influencing, whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the State.

318. By engaging in the above-described conduct, Purdue knowingly presented, or caused to be presented, false or fraudulent claims, in violation of Minnesota Statutes section 15C.02(a)(1).

319. By engaging in the above-described conduct, Purdue knowingly made, used, or caused to be made or used, false records or statements, and omitted material facts, to induce the State to approve and pay false or fraudulent claims, in violation of Minnesota Statutes section 15C.02(a)(2).

320. By reason of Purdue's unlawful acts, the State has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. The State's damages from false claims submitted, or caused to be submitted, by Purdue are substantial.

RELIEF

WHEREFORE, the State of Minnesota, by its Attorney General, Lori Swanson, respectfully asks this Court to award judgment against Purdue as follows:

1. Declaring that Purdue's acts described in this Complaint constitute multiple, separate violations of Minnesota Statutes sections 15C.02, 325D.13, 325D.44, 325F.67, 325F.69, and 325F.71;

2. Enjoining Purdue and its employees, officers, directors, agents, successors, assignees, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries,

and all other persons acting in concert or participation with them from engaging in conduct in violation of Minnesota Statutes sections 15C.02, 325D.13, 325D.44, 325F.67, 325F.69, and 325F.71;

3. Requiring Purdue to undertake actions to address the unlawful acts and omissions described in this Complaint;

4. Awarding monetary relief to the State pursuant to Minnesota Statutes sections 8.31, Minnesota common law, the *parens patriae* doctrine, and the general equitable powers of this Court, as necessary to remedy the harm and injury to the State resulting from Purdue's acts and omissions described in this Complaint;

5. Ordering Purdue to disgorge all profits from sales of opioids in Minnesota;

6. Awarding civil penalties pursuant to Minnesota Statutes sections 8.31, subdivision 3, and 15C.02(a) for each separate violation of Minnesota law;

7. Awarding supplemental civil penalties pursuant to Minnesota Statutes section 325F.71 for each separate violation of Minnesota law;

8. Declaring that Purdue's acts described in this Complaint constitute a public nuisance under Minnesota law, and permanently enjoining Purdue and its employees, officers, directors, agents, successors, assignees, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with them from the acts, practices, and conduct that created the nuisance;

9. Ordering Purdue to abate the public nuisance it has created, including by ordering judgment against Purdue in an amount necessary to abate the public nuisance;

10. Awarding damages for injury sustained as a result of Purdue's repeated breaches of the special duty it undertook in Minnesota;

11. Awarding treble damages pursuant to Minnesota Statutes sections 15C.02(a);
12. Awarding the State its costs, including costs of investigation, attorney fees, and expert consultant and expert witness fees, as authorized by Minnesota Statutes sections 8.31, subdivision 3a, 15C.02(c), and 15C.12; and
13. Granting such further relief as provided by law or equity as the Court deems appropriate and just.

JURY DEMAND

The State demands a jury trial for all issues pled herein triable by a jury.

Dated: July 2, 2018.

Respectfully submitted,

LORI SWANSON
Attorney General
State of Minnesota

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ATTORNEYS FOR THE
STATE OF MINNESOTA

**MINN. STAT. § 549.211
ACKNOWLEDGMENT**

The party on whose behalf the attached document is served acknowledges through its undersigned counsel that sanctions may be imposed pursuant to Minn. Stat. § 549.211.

Dated: July 2, 2018.

/s/ Eric J. Maloney
ERIC J. MALONEY

