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State of Minnesota
8/5/2019 9:05 AM

STATE OF MINNESOTA | DISTRICT COURT

COUNTY OF HENNEPIN | FOURTH JUDICIAL DISTRICT

Case Type: Other Civil

State of Minnesota by its Attorney General, Keith Ellison,

Plaintiff,

vs.

Purdue Pharma L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Richard Sackler, Kathe Sackler, Mortimer D.A. Sackler, Jonathan Sackler, David Sackler, Ilene Sackler Lefcourt, Beverly Sackler, and Theresa Sackler,

Defendants.

Court File No. 27-CV-18-10788
Hon. Kevin S. Burke

FIRST AMENDED COMPLAINT

The State of Minnesota, by its Attorney General, Keith Ellison ("State or "AGO"), for its Complaint against Purdue Pharma, L.P., Purdue Pharma, Inc., and The Purdue Frederick Company, Inc. (collectively, "Purdue"), and Richard Sackler, Kathe Sackler, Mortimer D.A. Sackler, Jonathan Sackler, David Sackler, Ilene Sackler Lefcourt, Beverly Sackler, and Theresa Sackler (collectively, "Sackler Defendants"), 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—under the direction and control of

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the Sackler Defendants—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

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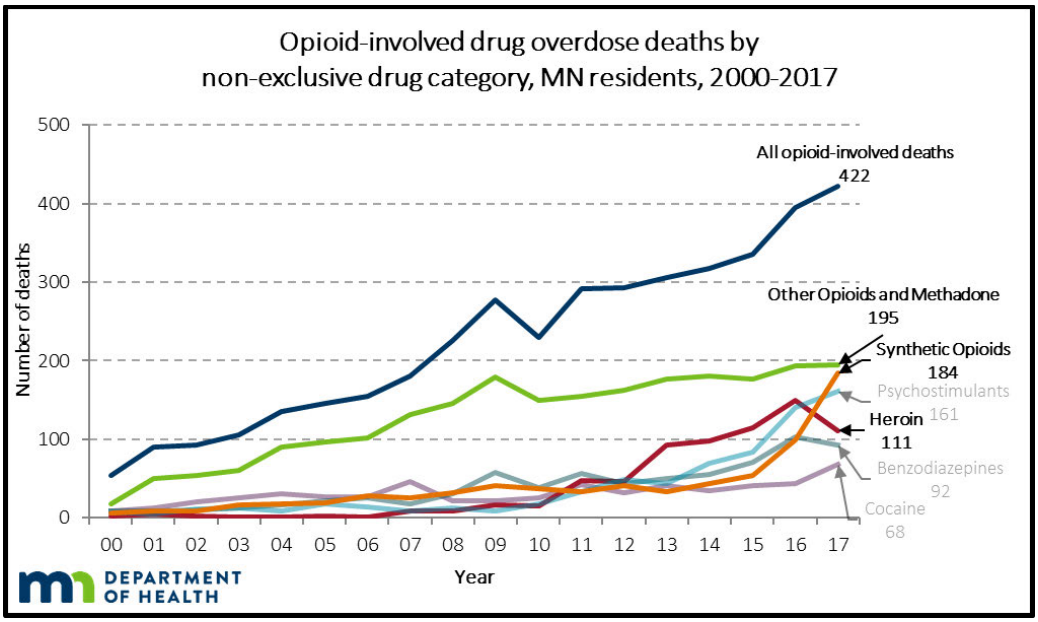
distribution of opioids in Minnesota increased by 72%.[1] Minnesotans filled 3.87 million opioid prescriptions in 2015, including prescriptions for nearly 50 million units of oxycodone, the active ingredient in OxyContin.[2]

6. From 2000 to 2017, the number of Minnesotans who died from opioid-related overdoses increased by nearly *800 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

[1] Jeanne Mettner, *The Opioid Crisis,* Minn. Medicine (Mar. 2013), http://pubs.royle.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.

[3] Minn. Dep't of Health, *Drug Overdose Deaths Among Minnesota Residents, 2000–2017*, at 4, 23, https://www.health.state.mn.us/communities/opioids/documents/2017opioiddeathreport.pdf (last visited April 30, 2019); Minn. Dep't of Health, *Opioid Dashboard*, https://www.health.state.mn.us/opioiddashboard#DeathTrends (last visited April 30, 2019).

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from car accidents.[4] In Hennepin County alone, opioid-related deaths increased by nearly 60 percent between 2015 and 2016.[5]

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, Keith Ellison, 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. Keith Ellison, 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.

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[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.

[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.

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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.

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 II[7] 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.

[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).

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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 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."

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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."

16. At all relevant times Purdue, which is a collection of private companies, has been controlled by members of the extended Sackler family, who are the ultimate intended beneficiaries of virtually all of Purdue's profit distributions. The individual Defendants named in this action are the remaining living Sackler family members who served on the board of directors of Purdue Pharma, Inc. (the "Purdue board"), which functioned as the nexus of

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decisionmaking for Purdue. The Sackler Defendants directed Purdue's deceptive sales and marketing practices, including in Minnesota, and paid themselves billions of dollars from the money that Purdue collected from selling its opioids.

17. Defendant Richard Sackler is a natural person currently residing in Florida who previously resided in Texas and Connecticut. He became a Purdue director in 1990, and served as Purdue board co-chair from 2003 until he left the Purdue board in 2018. Richard Sackler was also Purdue's head of research and development from at least 1990 through 1999, and was Purdue's president from 1999 through 2003.

18. Defendant Kathe Sackler is a natural person residing in Connecticut. She was a Purdue director from 1990 until she left the Purdue board in 2018.

19. Defendant Mortimer D.A. Sackler is a natural person residing in New York. He was a Purdue director from 1993 until he left the Purdue board in 2019.

20. Defendant Jonathan Sackler is a natural person residing in Connecticut. He was a Purdue director from 1990 until he left the Purdue board in 2018.

21. Defendant David Sackler is a natural person residing in New York. He was a Purdue director from July 19, 2012 until he left the Purdue board in 2018. The term "Sackler Defendants" includes Defendant David Sackler in relation to conduct that occurred on or after July 19, 2012.

22. Defendant Ilene Sackler Lefcourt is a natural person residing in New York. She was a Purdue director from 1990 until she left the Purdue board in 2018.

23. Defendant Beverly Sackler is a natural person residing in Connecticut. She was a Purdue director from 1993 until she left the Purdue board in 2017.

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24. Defendant Theresa Sackler is a natural person residing in New York and the United Kingdom. She was a Purdue director from 1993 until she left the Purdue board in 2018.

JURISDICTION

25. 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.

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

27. Furthermore, this Court has specific personal jurisdiction over the Sackler Defendants because the Sackler Defendants personally:

- Voted for, directed, managed, acquiesced to, and/or should have known about but failed to prevent, Purdue's deceptive and tortious marketing and sales of opioids in Minnesota;
- Controlled and voted on the hiring and retention of Purdue sales representatives, including sales representatives in Minnesota;
- Voted for and/or ordered Purdue sales representatives to make thousands of face-to-face visits to health care providers in Minnesota to implement Purdue's deceptive marketing scheme described in this Complaint;
- Controlled, directed, or acquiesced to the methods by which Purdue sales representatives, including Minnesota sales representatives, marketed Purdue opioids, including which health care providers were targeted, how often the health care providers were visited, and the messages and strategies used by Purdue sales representatives;
- Directed and/or managed the Purdue chain of command that caused the dissemination of tens of thousands of copies of deceptive marketing materials to health care providers throughout Minnesota;
- Directed, managed, and/or monitored efforts to influence regulatory activities in Minnesota that would impact Purdue's sales in Minnesota,

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showing that the Sackler Defendants knew and intended that Minnesota was an important market for Purdue's drugs; and

- According to Purdue board documents, enriched themselves by receiving billions of dollars from sales of Purdue opioid drugs by virtue of their ownership of Purdue and their roles as Purdue officers and directors, including tens of millions of dollars from Minnesota sales.

VENUE

28. Venue in Hennepin County is proper under Minnesota Statutes section 542.09 because the cause of action arose, in part, in Hennepin County. Defendants have done business in Hennepin County, and Defendants' unlawful acts have affected Hennepin County residents, among others.

FACTUAL BACKGROUND

29. 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.

30. In order to accomplish the fundamental erosion of health care providers' reticence to prescribing opioids that was key to successfully marketing their opioid products, the Sackler Defendants were personally involved in designing and implementing Purdue's deceptive marketing strategy. Lacking legitimate scientific research to support their claims, the Sackler Defendants, by and through Purdue, turned to the marketing techniques first pioneered by Sackler family patriarch Arthur Sackler to mislead the medical community and ultimately upend the long-settled understanding of the relative risks and benefits of opioids.

31. 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

[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).

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sponsored, Defendants, by and through 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.

32. Defendants' 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 Defendants' confusing and deceptive marketing, Minnesota health care providers prescribed opioid pain medications with greater frequency and in larger quantities.

33. 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 1998, more than 1.4 million OxyContin prescriptions have been filled by Minnesota patients.

34. The Sackler Defendants personally directed, authorized, promoted, acquiesced to, and profited from Purdue's misrepresentations about the risks and benefits of long-term use of opioids for treatment of chronic pain, even though they knew such marketing was false and misleading.

35. The results of Defendants' confusing, deceptive, and misleading conduct adversely impacted Minnesota and has caused widespread public harm.

[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.

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

A. Background on Opioids.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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-

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term use of opioids, particularly in higher doses, greatly increases the risk of potentially deadly side effects.

41. 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.

42. 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.

43. 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/.

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44. 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]

45. 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."

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

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46. 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.

47. 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.

48. 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.

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49. 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.

50. 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.

51. 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.

52. 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).

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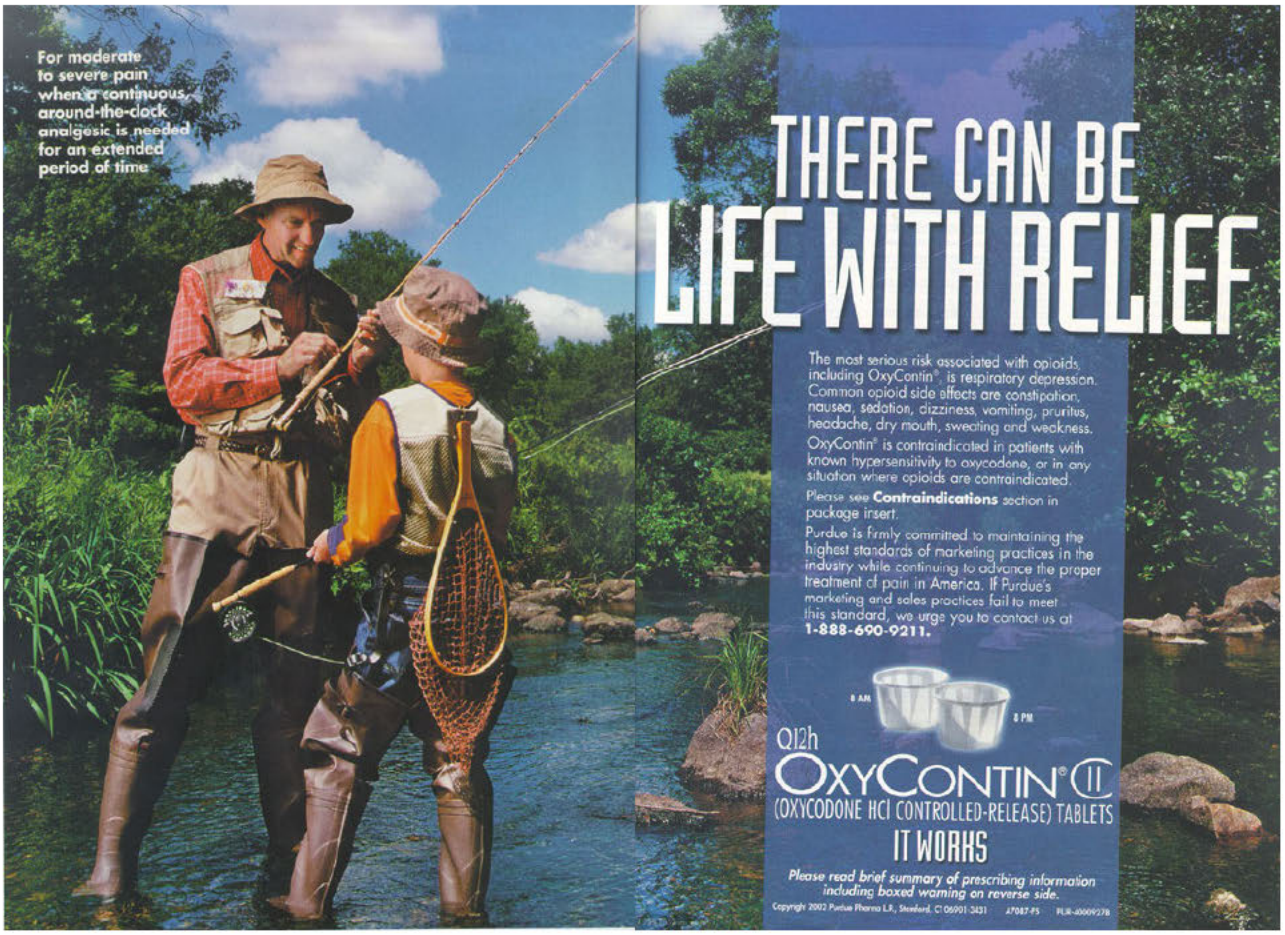
53. The FDA warned Purdue about ads that ran in the *Journal of the American Medical Association*, expressing concern that they would lead to ill-considered prescribing of OxyContin because the body of the ad text nowhere referred to the "potentially fatal risks associated with the use of OxyContin and 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).



54. 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."

55. 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

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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.

56. 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.

57. 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.

58. 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.

59. 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).

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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.

60. 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]

61. 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.

62. 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.

63. 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).

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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.

64. 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 that he felt opioids were overprescribed when pain became the "fifth vital sign." He stated his patients felt "entitled" to a pain-free life, a sentiment echoed by other Minnesota physicians. Another physician said he wished that pain as the fifth vital sign would "go away," while yet another said that he was "never comfortable" using a product like OxyContin, but that his patients "complain and complain and feel they have a right to be pain free so my hands are tied."

65. 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.

66. 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.

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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.

67. 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 2003[17] and widely referenced since, ignored previous Purdue-commissioned research showing addiction rates between 8% and 13%.[18]

68. 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 patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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

69. 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.

70. 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

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

71. 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]

72. 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

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[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.

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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.

73. 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

74. 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.

75. 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";

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- 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."

76. 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]

77. 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.

78. 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).

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79. 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

80. 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.

81. 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.

82. 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.

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[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.

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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.

83. 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.

84. 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.

85. 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.

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

86. 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 112,000 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.

87. 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.

88. Since 2006, Purdue's sales force of nearly 100 Minnesota sales representatives has visited and distributed promotional materials to thousands of Minnesota health care providers. Most of these prescribers were visited repeatedly; in fact, more than 150 Minnesota health care providers were visited 100 times or more by Purdue in this time period, sometimes as often as every week.

89. 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.

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90. 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.

91. 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.

92. 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).

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93. 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.

94. 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.

95. 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 misreported the scientific evidence. Such misleading research and associated publications are described throughout this Complaint.

96. 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.

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97. 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]

98. 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 is the third most frequent prescriber of OxyContin in Minnesota in the last 20 years, and was paid more than $125,000 by Purdue from 2013–2016.

99. 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.

100. 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 organizations. From 2006 through the end of 2016, Purdue provided more than $68 million in direct grants to third parties.

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

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101. 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.

102. 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.

103. In fact, a 2016 Purdue-commissioned marketing study of doctors recommended that for doctors reticent to switch patients from NSAIDs (non-opioid painkillers) to extended-release opioids, reading about conversion "in reputable journals (*American Academy of Pain Medicine* mentioned) and hearing from respected physicians will help overcome this barrier."

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.

104. 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.

105. 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

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

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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]

106. 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]

107. 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]

108. 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]

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[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).
[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).

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109. 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]

110. 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]

111. 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 87% of its OxyContin business and 82% 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.

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

112. 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

[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.

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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.

113. 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.

114. 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

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this unbranded marketing material garnered nearly 10,000 visits by Minnesotans from 2012 through 2016.

115. 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.'**

116. 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."

117. 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."

118. 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 there was a lack of evidence regarding the risks of treating of children with opioids.

119. 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

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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."

120. 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."

121. 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."

122. 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."

123. 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.

124. 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

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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."

125. 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.

126. 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."

127. 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.

128. 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.

129. 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:

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

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> **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.

130. 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."

131. 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:

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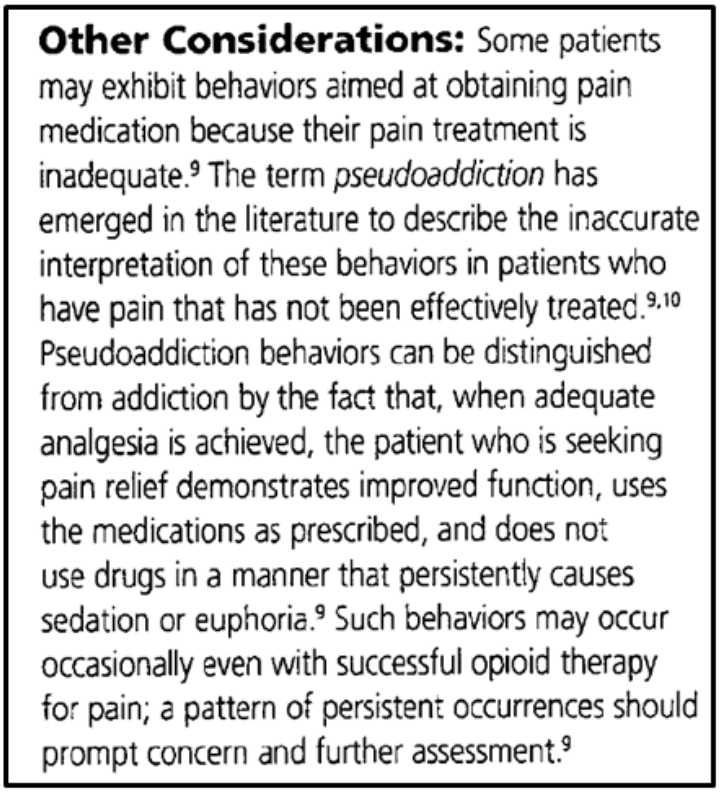

Other Considerations: Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate.[9] The term *pseudoaddiction* has emerged in the literature to describe the inaccurate interpretation of these behaviors in patients who have pain that has not been 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]

132. 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."

133. 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 her patients were suffering from pseudoaddiction, and sponsored a talk led by another prescriber, after which the sales representative noted "[a]ll agree underdose leads to pseudoaddiction."

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134. 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."

135. 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."

136. 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."

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137. *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."

138. 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."

139. 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."

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

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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 Haddox.

141. 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.

142. 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.

143. 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 severe the pain. The dosing limit is imposed only by side effects,

[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.

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> 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).

144. 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 6600 times between 2010 and 2015, when the website was shuttered following a governmental investigation.

145. 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."

146. 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

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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.

147. 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."

148. 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.

149. 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.

150. 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.

151. 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

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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]

152. 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 injury . . . .[45]

153. 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 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."

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[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.

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154. 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]

155. 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 "more evidence of [opioids'] long-term effectiveness and safety is needed." The Purdue study further acknowledged that even those chronic pain management guidelines that do recommend long-term use of opioid therapy indicate that their "recommendations are based on relatively weak or indirect evidence." One study noted by Purdue illustrated this point, as the studies' reassessment of patients after six months of treatment and throughout trial showed that extended-release opioid therapy "did not lead to either substantial deterioration or further improvement in function."

[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).

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

156. 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.

157. 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.

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

159. 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 qualify of life for people with chronic pain." The same publication claimed that

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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.

160. *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."

161. *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."

162. 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."

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163. 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 "[e]ffective pain control in individuals with acute or chronic pain can be associated with a number of benefits, including an increased ability to work, improved function, and performing activities of daily living and an improved quality of life." It further claimed that "[c]onsiderable evidence indicates that opioids have a major role in the treatment of chronic pain of a nonmalignant origin."

164. 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.

165. 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.

166. 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).

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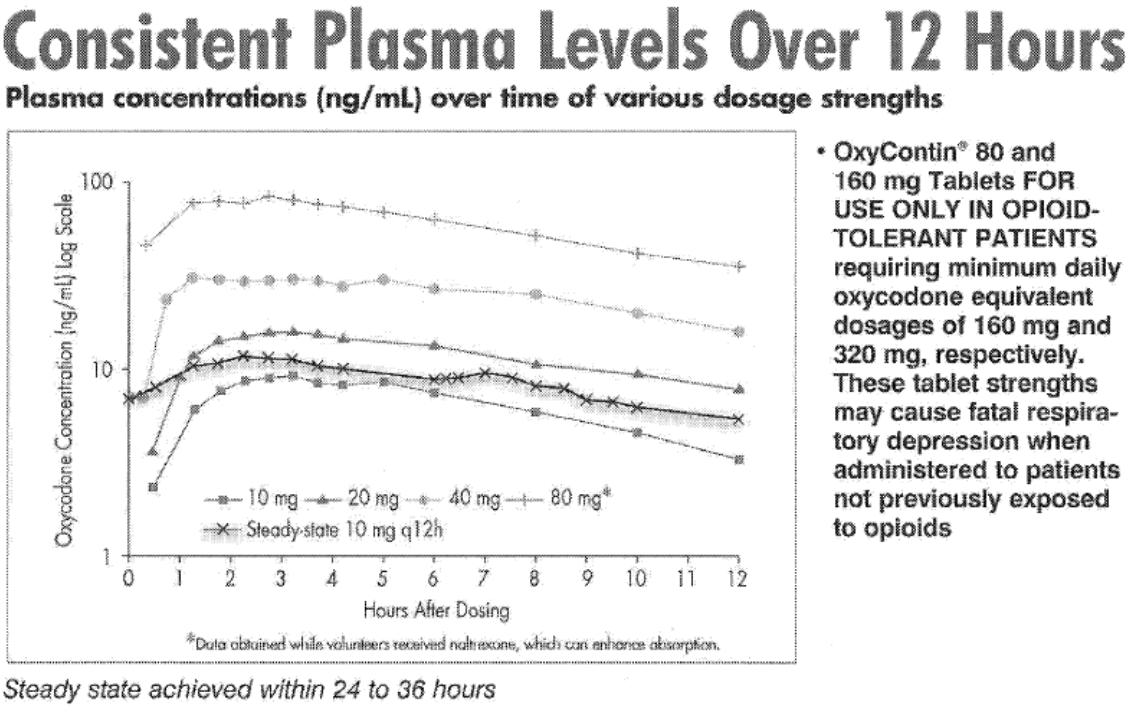
hour rather than 8-hour dosing, and made the 12-hour claim central to its marketing campaign.[50] As explained by a Purdue executive, the marketing focus for OxyContin was its "dosing schedule" and the drug's "ability to deliver that efficacy twice a day with an acceptable side [e]ffect profile."

167. 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:



[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.

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

168. 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.

169. 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.

170. 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.

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[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 .

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171. 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.

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

173. For example, when one Minnesota health care provider told a Purdue sales representative that she saw some OxyContin prescriptions written to have the patient take the drug every 8 hours, the sales representative "explained that [OxyContin] was studied as a q12h product and the strength of the dose should be increased rather than the frequency." The same sales representative claimed in a note from a visit with a different health care provider that he "ask[ed] that the providers increase the strength of [OxyContin and] not the frequency" when told about three-times-a-day dosing. In another call note, a Purdue sales representative "[d]iscussed titration versus changing dosing increment" with a Minnesota pharmacist who mentioned filling q8h OxyContin prescriptions at her pharmacy. In yet another call note, a Purdue sales representative "specifically" told a Minnesota health care provider "that she try the [additional] strengths [of OyxContin] instead of going to TID [three-times-a-day] dosing."

174. 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

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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.

175. 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 day[52]—exceeding the 90 MME limit that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[53]

176. 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."

177. 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.

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

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[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.

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179. Purdue was aware that its claims, comparative or implied, of opioid superiority were problematic. In internal documents, Purdue admitted that it could not "represent or suggest that a drug is safer/more effective (or make any other sort of comparative claim)" because Purdue "**ha[s] no drugs that satisfy this standard**."

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

180. 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.

181. Purdue even commissioned a research firm to study what factors motivate prescribers to switch pain patients from NSAIDs to extended-release opioids, which included "identify[ing] what obstacles need [to be] overcome to make [p]rescribers more comfortable switching patients from NSAIDs to [extended-release opioids]." The study found, in part, that prescribers who switch "focus on what can be accomplished for patients," with "improving patient function and QOL [quality of life]" as their reasons to prescribe extended-release opioids after NSAIDs.

182. 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

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much lower annually.[54] The corresponding slide on opioid adverse effects does not contain any similar statistics on hospitalizations or deaths tied to opioids.

183. 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.

184. 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.

185. 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."

186. 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 Gastroinstestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. Ther. 17, 21 (2004).

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

187. 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.

188. 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.

189. 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.

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

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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."

191. 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."

192. 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 who was prescribing one patient more than 400mg of OxyContin per day that "considering there is [n]o ceiling dose with OxyContin[,] he is not doing anything outside of normal prescribing for OxyContin." 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.

193. 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.

194. Purdue knew that it could not make such claims. In an internal compliance training for Purdue speakers, it cautioned speakers that claims touting the superiority of extended-release opioids were garnering "increased scrutiny," and instructed speakers to avoid "[i]mplying that a patient will benefit from an extended-release product [that] conveys a message that is not supported by the [full prescribing information] or any clinical studies." The training further admitted that Purdue did "not have evidence of convenience, safety, less pills are better,

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sleep through the night[,] etc." The training told instructors that "[t]his implication must be avoided," and that speakers should characterize extended-release products as "another option."

195. 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.

196. Sales representatives in Minnesota implemented these tactics when detailing Minnesota health care providers. Purdue sales representatives told Minnesota health care providers with patients taking large numbers of immediate-release opioid pills that they should transition those patients to Purdue's extended-release opioids like OxyContin, stressing the convenience of fewer pills for patients. Some sales representatives discussed arbitrary pill numbers at which providers should consider this switch (such as 90 or 120 pills per month). This number of pills was not based on any medical authority.

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

197. 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.

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

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

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- Reformulated OxyContin was "tamper-proof," "abuse-deterrent," "tamper-resistant," and "abuse-resistant," 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 "social[ly] responsib[le]" choice for prescribers.

200. Purdue sales representatives made similar representations to Minnesota health care providers, including that reformulated OxyContin was changed to "make [the] tablet more difficult to manipulate for intentional misuse and abuse" and "to make the product less abusable, divertable and lower the misuse of the product."

201. 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]

202. 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 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]

203. Purdue knew this was the case, as it admitted internally that "OxyContin is not tamper resistant" and that "there is no evidence that the reformulation of OxyContin is less

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

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subject to misuse, abuse, diversion, overdose or addiction[.]" In fact, Purdue's own research identified 32 publicly-known methods to circumvent the abuse-deterrent properties of ADF opioids.

204. 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.

205. 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.

206. 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 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.

207. 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."

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208. 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 older adults are a "low risk[,] high benefit patient population" and would benefit from the reduced pill count of extended-release opioids like OxyContin or the ease of using a transdermal patch like Butrans. 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 "focus [the doctor] on one patient type if [you] can, [and] talk about the unique delivery and how it is ide[al] for the older patie[nt] who fits our [label] indication."

209. 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.

210. 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

[57] CDC Guideline, *supra* note 8, at 13.
[58] *Id.*

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accordingly recommends that doctors use "additional caution when initiating opioids for patients aged [more than] 65 years."[59]

211. 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]

212. 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 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.

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[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.

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213. 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 half (53%)—nearly 40,000 visits since 2006—were with family medicine or internal medicine doctors. Purdue also made more than 15,000 visits to Minnesota physician assistants and nurse practitioners.

214. 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. THE SACKLER DEFENDANTS ARE INDIVIDUALLY LIABLE FOR PURDUE'S MISCONDUCT.

215. Purdue's deliberate actions to mislead prescribers and the public about the risks and benefits of long-term opioid treatment, as described throughout this First Amended Complaint, were personally orchestrated by the Sackler Defendants from the launch of OxyContin through the present. The Purdue entities are not publicly traded companies, but are family businesses owned, led, and controlled by the Sackler Defendants.

216. The Sackler Defendants personally control Purdue. Each of them took seats on the board of Purdue Pharma, Inc., and many served as officers of Purdue entities. Together, they maintained control over Purdue and its officers and other employees, and they frequently exercised that control in person at Purdue headquarters, some working there on a daily basis.

217. The Sackler Defendants were directly involved in developing and sanctioning Purdue's deceptive and illegal activities, and they each participated and/or acquiesced in decisions to mislead Minnesota health care providers, patients, government authorities, and

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insurers to normalize opioid prescribing and generate an enormous financial windfall for themselves.

218. Each of the Sackler Defendants knew and intended that Purdue's sales representatives and Purdue's other marketing employees would not disclose to Minnesota health care providers and patients the truth about Purdue's opioids and opioids in general. They each intended and personally directed Purdue staff to reinforce these misleading messages throughout Minnesota. And they each knew and intended that health care providers, patients, pharmacists, and insurers in Minnesota would rely on Purdue's deceptive sales campaign to request, prescribe, dispense, and reimburse claims for Purdue's opioids.

219. Through their positions as the owners, directors, and officers of Purdue, the Sackler Defendants had personal oversight and control over Purdue's unlawful sales and marketing described throughout this First Amended Complaint.

A. Purdue Launched OxyContin and Propagated OxyContin's Misleading Promotional Campaign Under the Direction and Control of the Sackler Defendants.

220. The Sackler Defendants each took seats on the board of directors of Purdue Pharma, Inc., from its inception in 1990, with the exception of Beverly and Theresa Sackler, who joined in 1993, and David Sackler, who joined the Purdue board in 2012.

221. Richard Sackler personally played an active and central role in the management of Purdue. He began working for Purdue as an assistant to the president in the 1970s. He later served as vice president of marketing and sales. In the early 1990s, he became senior vice president, which was the position he held at the time OxyContin was launched in 1996. In 1999, he became president and served in that position until 2003. Richard Sackler resigned as Purdue's president in 2003, but he continued to serve as co-chair of the Purdue board.

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222. Richard was directly involved in the invention, development, marketing, promotion, and sale of Purdue's opioids, including OxyContin. Under his personal control and direction, Purdue launched OxyContin with an unprecedented marketing campaign that caused OxyContin to generate a billion dollars in sales within five years of introduction.

223. Jonathan, Mortimer D.A., Kathe, and Ilene Sackler also served as vice presidents of Purdue during the period of development, launch, promotion, and marketing of OxyContin. They each resigned their officer positions in or after 2003, but each continued to serve on the Purdue board through at least 2018.

i. The Sackler Defendants Actively Participated In and Controlled the Marketing of OxyContin.

224. Richard Sackler was personally involved in maximizing Purdue's returns from OxyContin sales from the start. At the OxyContin launch party, Richard asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and most importantly, a blizzard. Richard then claimed to have spoken with the "Wise One" during a journey "high in the Himalayas," and boasted that the "Wise One" had told him that "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white that you will never see their [w]hite [f]lag."

225. From the beginning, the Sackler Defendants were personally behind Purdue's decision to deceive health care providers and patients about OxyContin's risk of abuse and addiction—as well as the risk of abuse and addiction of opioids generally.

226. For example, in 1997, Richard and Kathe Sackler, along with other Purdue executives, were personally involved in the decision to perpetuate health care providers' misconception that OxyContin was weaker than morphine, which led a wide variety of health

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care providers to prescribe OxyContin much more often. For instance, Purdue executive Michael Friedman (who later pleaded guilty to federal criminal charges of misbranding OxyContin due to his actions at Purdue[63]) told Richard Sackler in May 1997 that the company was "well aware of the view, held by many physicians, that oxycodone is weaker than morphine," but opined that "it would be extremely dangerous, at this early stage in the life of [OxyContin], to tamper with this 'personality,' to make physicians think the drug is stronger or equal to morphine." Richard agreed with this approach despite knowing that, in reality, OxyContin is about twice as potent as morphine.

227. The Sackler Defendants' conscious decision to allow physicians to be misled about the strength of OxyContin around the time of the drug's launch is emblematic of Purdue's continuing misrepresentations of the true qualities of OxyContin and its other opioid drugs ever since. As described throughout this First Amended Complaint (*see* ¶¶ 112–141), Purdue repeatedly misrepresented to Minnesota health care providers the qualities of OxyContin and opioids generally, including by misrepresenting the true addiction risk of opioids and claiming that patients' signs of opioid addiction and abuse were actually "pseudoaddiction" requiring treatment with larger doses of opioids.

228. Around the same time, Richard Sackler was personally involved in correcting what he believed was a "critical misconception": that experts believed that OxyContin "has a ceiling effect" which would limit health care providers from prescribing higher doses of the drug. Richard asked Michael Friedman to "put together some approaches and test whether they would be potent weapons" in "smash[ing] this critical misconception." When Friedman raised

[63] Plea Agreement, *United States v. Friedman*, Case No. 1:07-CR-29 (W.D. Va. May 10, 2007).

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concerns that such a marketing "barrage" would damage OxyContin's "personality" among doctors, Richard asked, "[W]hat about rifle shots?"

229. As detailed in this First Amended Complaint (¶¶ 142–150, 189–192), Purdue staff utilized and executed Richard's plan in Purdue's marketing to Minnesota health care providers, which included, for example, frequent misrepresentations to Minnesota health care providers that OxyContin and other opioids lack a "ceiling effect."

230. From the start, the Sackler Defendants were also the driving force behind Purdue's marketing strategy to push opioids with the false promise that they create an enhanced "lifestyle." In 1998, Richard Sackler personally instructed Purdue's executives that OxyContin tablets provide more than merely "therapeutic" value and instead "enhance personal performance," like Viagra. Again, as noted herein (¶¶ 156–164), Purdue has carried out the Sackler Defendants' marketing strategy by continuously misrepresenting to Minnesota health care providers that OxyContin and other opioids improve patients' functionality and quality of life.

231. Early on, the Sackler Defendants were also personally involved in Purdue's coordination of marketing efforts with, and provision of grants to, third-party front groups.

232. For instance, in 2001 Richard Sackler personally "pushed for" and became involved in planning a meeting between himself, Purdue staff, and leaders of the American Pain Society, American Pain Foundation, and the American Academy of Pain Medicine. Richard instructed a Purdue executive as to the purpose of this meeting:

> Our goal is to bind these organizations more closely to us than heretofore, but also to align them with our expanded mission and to see that the fate of our product(s) are inextricably bound up with the trajectory of the pain movement.

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The Purdue executive pleaded with Richard to not get involved in planning this meeting, saying: "You are the President, not the person who sets up meetings." Richard responded by asking the Purdue executive to call him and to not discuss this issue by email.

233. In another example, Richard Sackler discussed Purdue's grants to the American Pain Foundation, as well as the American Pain Society's campaign seeking to make pain the "fifth vital sign," in a 1999 email to Dr. Kathleen Foley, a board member of the American Pain Foundation. In a follow-up message, Richard told Purdue staff to let Dr. Foley "and others carry the ball" on this issue, and asked staff if Purdue would be able to secure a cover story on this issue in major news publications.

234. As noted herein (¶¶ 100–103), Defendants utilized third-party groups like the American Pain Society, the American Pain Foundation, and the American Academy of Pain Medicine to present Purdue marketing messages to Minnesota health care providers under the guise of perceived objectivity. The American Pain Society's "fifth vital sign" campaign significantly contributed to reversing the medical community's previous hesitation to prescribe opioids for pain, including in Minnesota (¶¶ 60–65), and the American Pain Foundation produced numerous publications containing multiple misrepresentations about the efficacy and risks of opioids that were provided to Minnesota health care providers. (¶¶ 101, 116–121, 146–147. 159, 184–185, 190)

235. The Sackler Defendants also monitored and directed Purdue's influence of Minnesota pain management standards and education. For example, in 2000, Michael Friedman sent Richard Sackler a report from a Purdue representative's visit with the Minnesota Board of Medical Practice. The Purdue representative reported that the Board was using a video to educate physicians about chronic pain patients that encouraged physicians to utilize "careful

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prescribing, vigilance, documentation," and "vigorous[]" management of chronic pain patients to avoid "manipulative behavior of addicted persons in their need to secure [opioid] drugs." In response, Richard called the representative's description of the video "illuminating and scary," and asked a series of questions:

> What sort of take away is it that if you treat patients with chronic severe pain and they get better they want you to continue the treatment. Is this a surprise? And why can't they give better advice than to say that they appear to disapprove the use of opioids in such treatments? That isn't very helpful, either.

236. In 2001, Michael Friedman then informed Richard and other Sackler Defendants that Purdue was setting up "educational pain management programs" throughout Minnesota, funded by a "significant unrestricted grant from Purdue." These programs asserted that Minnesota health care providers' reluctance to prescribe opioids was misplaced, that patient pain was being under-treated, and that Minnesota health care providers could treat "the pseudoaddict." The Sackler Defendants were told by Purdue staff that these Minnesota programs would serve as a model that was being replicated by Purdue in other states.

237. These actions reflect several varieties of Purdue's misconduct in Minnesota already described herein, including Purdue's concerted efforts to change Minnesota prescribers' traditional perception of the efficacy and safety of opioids (¶¶ 43–65), distributing materials on the under-treatment of pain to Minnesota health care providers (¶ 64), minimizing the addiction risk of opioid use in communications with Minnesota health care providers (¶¶ 112–125), and Purdue's propagation of the misleading concept of "pseudoaddiction" in Minnesota. (¶¶ 127–141)

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ii. The Sackler Defendants Had Knowledge of OxyContin's Risk of Abuse and Addiction as Early as 1999, But Intentionally Blamed Individuals Instead of Directing Purdue to Address the Risk Its Opioid Products Created.

238. The Sackler Defendants knew since at least 1999 that prescription opioids lead to addiction, and specifically that OxyContin could be, and was, abused. In November 1999, a Purdue sales representative wrote to a Purdue executive reporting widespread abuse and street sales of OxyContin. Purdue's general counsel told another company official in early 1999 that the company had "picked up references to abuse of our opioid products on the internet," and Michael Friedman forwarded some of these references to Richard Sackler.

239. In January 2001, Richard Sackler received an email from a Purdue sales representative describing a community meeting at a local high school organized by mothers whose children overdosed on OxyContin and died. The sales representative reported that "[s]tatements were made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor."

240. In February 2001, a federal prosecutor reported 59 deaths from OxyContin in a single state. Richard Sackler's reaction, in an email to Purdue executives, was that "[t]his is not too bad. It could have been far worse."

241. At the end of 2000, Time Magazine published an article about OxyContin deaths,[64] and Purdue employees told Richard Sackler they were concerned. Richard responded in early 2001 with a message to his staff. He wrote that *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," not

[64] Timothy Roche, *The Potent Perils of a Miracle Drug*, Time Magazine (Dec. 31, 2000), *available at* http://content.time.com/time/magazine/article/0,9171,93319,00.html.

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Purdue. He claimed that the increasing sales of OxyContin made Purdue a "target for sensational reports in the media," and implored Purdue staff to "continue to focus upon our noble mission."

242. Throughout 2001, Richard Sackler personally dictated Purdue's strategy for responding to the increasing evidence of abuse of prescription opioids and addiction to Purdue's opioids: blame and stigmatize victims of opioid addiction. He wrote in an email that "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are the reckless criminals."

243. That same year, in an email exchange discussing whether people dependent on opioids "want to be addicts," Richard wrote: "I'll tell you something that will totally revise your belief that addicts don't want to be addicted. It is factually untrue. They get themselves addicted over and over again." Richard emphasized: "[Opioid addicts] are criminals, and they engage in it with full, criminal intent. Why should they be entitled to our sympathies?" He further wrote: "This vilification is shit."

244. In another email exchange that year, Richard said that those who abused opioids "aren't victims; they are victimizers. And we decent people are the people they attack." In earlier correspondence with the same person, Richard had complained that he couldn't "call[] drug addicts 'scum of the earth'" because he would "become the poster child for liberals who . . . just want to distribute the blame to someone else."

245. Later on, the Sackler Defendants even explored the possibility of using PET scans to distinguish "patients" from "abusers," with Jonathan Sackler writing to Purdue staff in May 2008 that he "was thinking about the differences between pain patients and drug abusers in their reaction to opioids." Jonathan asked if "anybody [has] tried using PET to explore this?"

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Richard Sackler replied: "I think the idea of comparing PET scans of addicts and pain patients is very interesting."

246. The sentiment of these messages were later repeated in Purdue's deceptive and misleading statements to Minnesota health care providers that opioid addiction and abuse is the fault of the patient, not the drug, as detailed herein (¶¶ 112–125). As described below, the Sackler Defendants later acknowledged the false and misleading nature of these messages through their attempts to enter the opioid addiction treatment space with Purdue's *Project Tango* efforts.

247. Despite knowing that Purdue's drugs were creating a public health crisis throughout the country, the Sackler Defendants continued to personally participate, direct, and acquiesce to Purdue misconduct that contributed to the opioid epidemic currently plaguing Minnesota.

iii. The Sackler Defendants Admitted Purdue's Misconduct.

248. It is no coincidence that the Sackler Defendants resigned their Purdue officer positions in 2003. Starting in 2001, Purdue was investigated by the United States Department of Justice and a large group of states related to its promotion of OxyContin. Purdue board records show that in 2007, Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Kathe Sackler, Beverly Sackler, and Theresa Sackler unanimously decided that Purdue Pharma, Inc.'s predecessor, The Purdue Frederick Company, would pay nearly $700 million in criminal fines and plead guilty to a felony for misleading doctors and patients about opioids. These Sacklers also voted that three top Purdue executives—but no member of the Sackler family—should plead guilty as individuals.

249. These Sackler Defendants voted to admit in an Agreed Statement of Facts that, for more than six years, Purdue supervisors and employees intentionally deceived doctors about

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OxyContin by "market[ing] and promot[ing] OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."[65] To remove any doubt, the Sackler-approved plea agreement stated that "[Purdue] is pleading guilty as described above because [Purdue] is in fact guilty."[66] Those intentional violations of the law happened while Richard Sackler was president; Jonathan, Kathe, and Mortimer were vice presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler were all directors on the Purdue board.

250. These Sackler Defendants also voted for Purdue to enter a Corporate Integrity Agreement with the federal government. The agreement required the Sackler Defendants to ensure that Purdue did not deceive doctors and patients again.[67] These Sackler Defendants promised to comply with rules that prohibit deception about Purdue opioids, complete hours of training to ensure that they understood the rules, and report any deception.[68]

251. These guilty pleas, agreements, and other state settlements in 2007 should have ended Purdue's—and the Sackler Defendants'—misconduct. Instead, Purdue and the Sackler Defendants continued to deceive health care providers and patients in Minnesota (and the rest of the nation) about the risks and benefits of Purdue's opioids.

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[65] Agreed Statement of Facts at 5–6, *United States v. The Purdue Frederick Company, Inc.*, 1:07-CR-29 (W.D. Va. May 10, 2007).
[66] Plea Agreement at 2, *United States v. The Purdue Frederick Company, Inc.*, 1:07-CR-29 (W.D. Va. May 10, 2007).
[67] Corporate Integrity Agreement at 6–11, 13, *United States v. The Purdue Frederick Company, Inc.*, 1:07-CR-29 (W.D. Va. May 10, 2007).
[68] Corporate Integrity Agreement at 4–24, *United States v. The Purdue Frederick Company, Inc.*, 1:07-CR-29 (W.D. Va. May 10, 2007).

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B. The Sackler Defendants Had Knowledge of, and Actively Participated in, Purdue's Deceptive, Misleading, and Confusing Marketing of Opioids After the Company's 2007 Guilty Plea.

252. Even after Purdue's 2007 guilty plea and the Corporate Integrity Agreement binding Purdue's directors, the Sackler Defendants, as owners and directors of Purdue, maintained their control over Purdue's deceptive sales campaign and personally participated in each and every material decision relating to the development and sale of Purdue's opioids. Despite having full knowledge of opioids' risk of addiction, abuse, and diversion, the Sackler Defendants remained actively and personally involved in marketing Purdue's opioids in a way that deceptively minimized those risks and overstated the benefits.

253. Among other things, the Sackler Defendants personally:

- Made and/or approved the policies underlying Purdue's scheme to send sales representatives to visit Minnesota prescribers thousands of times every year to promote inappropriate prescribing of Purdue opioids; oversaw the policies that rewarded high prescribers to promote Purdue's opioids; oversaw and directed the policies and decision that caused Purdue to hire more sales representatives, to push sales harder, to compensate sales representatives in a manner that encouraged more opioids to be prescribed; and directed policy that disciplined the sales force if they fell short of ever-increasing sales goals;

- Oversaw, directed, and acquiesced to the deceptive tactics and misleading promotional claims that sales representatives used in Minnesota to push opioids;

- Oversaw, directed, and acquiesced to Purdue's production and dissemination of misleading and deceptive sales materials, and the exposure of Minnesota persons thereto;

- Requested, oversaw, directed, and received updates regarding Purdue's marketing and medical research, including market research showing that Purdue could increase opioid sales by having sales representatives visit more high-volume opioid prescribers and by having sales representatives promote higher doses and claim that opioids improve patients' quality of life;

- Oversaw, directed, and acquiesced to Purdue's strategy to push patients, including Minnesota patients, to higher doses of opioids which are more

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dangerous, more addictive, and more profitable. The Sackler Defendants routinely received reports of Purdue's efforts to push patients to higher doses and to use higher doses of opioids to keep patients on drugs for longer periods of time.

i. The Sackler Defendants Closely Monitored Purdue's Sales Force.

254. The Sackler Defendants focused their attention on the sales force, directing both the messaging and tactics, as well as closely monitoring compliance with their directives and the results.

255. Through at least 2014, the Sackler Defendants personally tracked and received reports regarding the exact number of Purdue sales representatives, the company's quarterly goals for sales visits, the exact number of visits representatives made to urge health care providers to prescribe Purdue opioids, how many visits sales representatives averaged per workday, and which Purdue opioids representatives were promoting. The Sackler Defendants required Purdue sales representatives to average as many as 7.5 prescriber visits per day, and tracked how much each visit cost Purdue.

256. The Sackler Defendants also personally made key decisions relating to Purdue's hiring, retention, and compensation provided to sales representatives. For example, they considered and approved specific plans to hire hundreds of new sales representatives and sales managers in 2008, 2010, and 2015. They personally approved sales representatives' receipt of increased bonus payments and even voted to provide new computers to sales representatives.

257. The Sackler Defendants' actions highlight their personal participation, direction, and acquiescence to the frequency of Purdue sales visits and marketing efforts in Minnesota described throughout this First Amended Complaint. Between 2006 and 2017, 63 Purdue sales representatives visited Minnesota prescribers more than 112,000 times under the Sackler Defendants' direction and control of the Purdue sales force.

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258. The Sackler Defendants were involved with Purdue sales force decisions on a granular level. For instance, in 2009, the Purdue board authorized Purdue's vice president of sales and marketing to hire a new staff member who would contact health care providers electronically and promote Purdue opioids through the deceptive website *Partners Against Pain*. As described throughout this First Amended Complaint, materials from this website misrepresented the addictiveness of opioids, furthered the concept of "pseudoaddiction," and claimed opioids had no dosing limit, among other things. (¶¶ 114, 134, 135, 143) *Partners Against Pain* materials were widely disseminated by Purdue sales representatives to Minnesota health care providers, and the *Partners Against Pain* website was visited by Minnesotans nearly 10,000 times between 2012 and 2016.

259. The Sackler Defendants personally oversaw the tactics that sales representatives used to promote opioids to health care providers. For example, a Purdue report sent to the Sackler Defendants analyzed a company initiative to use computer presentations during sales visits, which increased the average length of the sales meeting with the health care provider to "16.7 minutes in front of the customer."

260. In another example, after staff reported to the Sackler Defendants in 2011 that Purdue's opioid sales were hundreds of millions of dollars less than expected, with a prime reason being that doctors were not prescribing enough of the highest doses, Richard Sackler complained that Purdue's sales representatives were marketing to "non-high potential prescribers" and demanded to be sent into the field to shadow two Purdue sales representatives per day for a week.

261. A Purdue vice president raised Richard's plan with the company's chief compliance officer, warning that Richard going into the field with sales representatives was "a

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potential compliance risk." Compliance replied by laughing at the idea: "LOL." To make sure Richard's personal involvement in Purdue's marketing practices stayed secret, staff instructed: "Richard needs to be mum and be anonymous."

262. A group of Purdue executives, including the CEO, got involved in planning Richard's sales visits. All were worried. One wrote:

> About 5 last night, John [Stewart, Purdue CEO] was walking by my office—I yelled out to stop him—and said that you had mentioned to me that Richard wanted to go into the field, and that you had raised concerns with me. John seemed angry, and asked if I had concerns. I told him [there] could be issues and Richard could be out on a limb if he spoke about product at all or got into conversations with HCPs, or identified himself, especially with FDA Bad Ad possibilities. John agreed Richard would have to be mum throughout, and not identify himself other than as a home office person.

263. Richard Sackler nevertheless personally went into the field to promote opioids to doctors alongside a sales representative. When he returned, Richard argued to Purdue's vice president of sales that a legally-required warning on the FDA-approved label for one of Purdue's opioid products was not needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." Richard insisted there should be "less threatening" ways to describe Purdue opioids.

264. The Sackler Defendants' dissatisfaction with the Purdue sales staff did not end there. In 2012, following one of Purdue's large sales force expansions, Richard Sackler complained that Purdue management was "foundering" and that "all hands on deck" were needed to focus on "urgent current threats and our sales decline."

265. Another example demonstrates how personally involved the Sackler Defendants were in decisions concerning the sales force. In February 2012, during a lengthy exchange between Sackler Defendants and Purdue officers regarding a recent drop in prescriptions,

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Mortimer D.A. Sackler suggested that Purdue reschedule its annual January sales meeting to February so that there would not be an "extend[ed] period of time since the doctor last saw our rep" following the holiday season. While staff responded by arguing for "balance," Richard Sackler suggested that the annual sales meeting be cancelled altogether. This prompted Purdue's chief compliance officer, who was copied on Richard's message, to exclaim, "Oh dear."

ii. The Sackler Defendants Continuously Pushed for Increased Sales and Monitored Purdue's Sales Performance and Tactics.

266. The Sackler Defendants, as Purdue directors, were well aware of—and personally oversaw—Purdue's misleading and deceptive sales conduct.

267. The Sackler Defendants oversaw, directed, and acquiesced to Purdue's dissemination of misleading marketing materials, including in Minnesota. For instance, in 2007, staff reported to the Sacklers that they mailed out thousands of copies of deceptive marketing materials, including 12,528 publications in the first half of 2007. The single most-distributed material was the first volume of Purdue's "*Focused and Customized Education Topic Selections in Pain Management*" (FACETS). Staff told the Sacklers that another of the publications they had sent most often to doctors was *Complexities in Caring for People in Pain*.

268. Purdue, at the direction, control, and acquiescence of the Sackler Defendants, sent both of these misleading publications to health care providers in Minnesota. For instance, between January 2009 and August 2010, Purdue disseminated 1,151 items of so-called "medical education materials," including these publications, to Minnesota health care providers.

269. Like other Purdue and third-party publications described herein that were disseminated in Minnesota (¶¶ 127–141, 156–164), these materials falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients'

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quality of life, and falsely told health care providers and patients that signs of addiction are actually "pseudoaddiction" requiring treatment with more opioids.

270. The Sackler Defendants knew that Purdue's opioid marketing efforts were being targeted at health care providers in Minnesota and throughout the country. For example, in early 2012, staff told the Sackler Defendants that Purdue would be promoting OxyContin to targeted prescribers by expanding a special marketing program that gave health care providers a customized digital video recorder in exchange for the provider agreeing to watch one to two promotional programs a month. Purdue selected 15 Minnesota health care providers located throughout the state to watch this video, which featured a doctor paid by Purdue promoting OxyContin and encouraging health care providers to use Purdue's opioid savings cards.

271. The Sackler Defendants also oversaw and directed Purdue's improper response to signs of abuse and diversion by high-prescribing doctors in Minnesota. For instance, the Purdue board, including the Sackler Defendants, asked staff about opioid sales generated by health care providers suspected of diversion and abuse, which Purdue collected on a list code-named *Region Zero*. Staff reported back that Purdue had identified two *Region Zero* prescribers in Minnesota and provided a list of the specific problem prescribers by name, along with the number of prescriptions and amount of revenue each generated for Purdue. Staff also reported to the Sackler Defendants that if *Region Zero* prescribers stopped prescribing OxyContin, Purdue would lose nearly 10% of OxyContin sales.

272. The Sackler Defendants knew about the Minnesota *Region Zero* doctors, yet it does not appear that the company reported the doctors to Minnesota authorities. In fact, one of the Minnesota *Region Zero* doctors identified in Purdue documents voluntarily surrendered his medical license to the Minnesota Board of Medical Practice less than a year after Purdue staff

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provided the *Region Zero* list to the Purdue board, upon a finding that this doctor "routinely prescribed large quantities of narcotics" to patients without medical justification.

273. The Sackler Defendants also knew of Purdue's push to steer patients away from safer, non-opioid pain management treatment options. For instance, they tracked Purdue's effort to emphasize "the true risk and cost consequence of acetaminophen-related liver toxicity," and advocate for the "elimination of acetaminophen" for the elderly population. As noted above (¶¶ 178–192), Purdue's communications with Minnesota health care providers consistently overstated the risks of non-opioid pain management methods, while simultaneously minimizing the risks of opioids.

274. The Sackler Defendants were also personally involved in the introduction and research behind Purdue's reformulated OxyContin. In 2008, while Purdue was working on the reformulation, Mortimer D.A. Sackler suggested that Purdue conduct studies regarding its tamper-resistant technology. He wrote to Richard Sackler: "Purdue should be leading the charge on this type of research and should be generating the research to support our formulation. Why are we playing catch up . . . ? Shouldn't we have studies like this . . . ?" Richard disagreed and instructed Mortimer to call him. Later, before the drug was approved by the FDA, Richard Sackler provided lengthy, detailed feedback on a proposal from Purdue staff regarding how to respond to negative questions that could potentially be asked by the FDA at an upcoming meeting regarding the FDA's evaluation of ADF OxyContin.

275. As described herein (¶¶ 197–204), Purdue misleadingly exaggerated the ability of its reformulated OxyContin to prevent addiction and abuse in representations to Minnesota health care providers.

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276. The Purdue board, including the Sackler Defendants, was also deeply involved in decisions related to sales, including by reviewing sales forecasts and asking questions about them. For example, in 2008, Mortimer D.A. Sackler demanded answers to a series of questions about why Purdue sales would not grow, in response to a projection that OxyContin sales would plateau. The next month, Richard Sackler criticized a Purdue sales forecast as being too low and threatened to get the Purdue board to disapprove it. Two days later, he circulated his own sales analysis to the Purdue board, ordered Purdue staff to "put this high in the Board agenda" because this was a "vital issue," and proposed that he and Mortimer D.A Sackler personally redo the annual sales plan as well as the five-year sales plan for Purdue's opioids.

277. In 2009, Kathe and Richard Sackler personally met with the sales staff to review sales plans for 2010.

278. In 2011, Purdue staff worked to answer a number of questions from the Sackler Defendants. Mortimer D.A. Sackler asked about launching a generic version of OxyContin to "capture more cost sensitive patients." Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert. Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

279. In January 2012, Jonathan Sackler started the year pressing Purdue staff for weekly updates on sales.

280. In October 2013, Mortimer Sackler pressed for more information on dosing and "the breakdown of OxyContin market share by strength." Staff told Mortimer and the other Sackler Defendants that the "high dose prescriptions are declining," and "there are fewer patients titrating to the higher strengths from the lower ones." Staff promised to increase the budget for

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promoting OxyContin by $50,000,000, and get sales representatives to generate more prescriptions with a new initiative to be presented to the Sackler Defendants the following week.

281. The Sackler Defendants knew that Purdue's marketing had an immense effect in driving opioid prescriptions. For instance, staff reported to the Sackler Defendants in February 2014 that the company's sales and marketing tactics generated an additional 560,036 prescriptions of OxyContin in 2012 and 2013 alone.

282. In sum, the Sackler Defendants personally participated, approved, directed, acquiesced to, and/or should have known but failed to prevent Purdue's deceptive and misleading marketing conduct, including the company's deceptive and misleading marketing targeted at Minnesota. The Sackler Defendants further knew or willfully chose to avoid knowing that Purdue's sales efforts in Minnesota would greatly increase patients' risks of addiction and death, yet took no steps to stop Purdue's deception despite having the power to do so.

iii. *Project Tango*: The Sackler Defendants Directed Purdue to Develop, Market, and Sell Opioid Addiction Treatments.

283. The Sackler Defendants' full understanding of opioids' abuse and addiction risk is underscored by their willingness to research, quantify, and ultimately monetize opioid abuse and addiction by pursuing the development of medications to treat the addiction that Purdue's own opioids caused. Richard and Kathe Sackler, along with Purdue staff, determined that the millions of people who became addicted to opioids were the Sackler Defendants' next business opportunity. Staff reported to Kathe that opioid addiction treatment "is an attractive market" with a "[l]arge unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction."

284. In September 2014, Kathe Sackler participated in a call about *Project Tango*—a plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In internal

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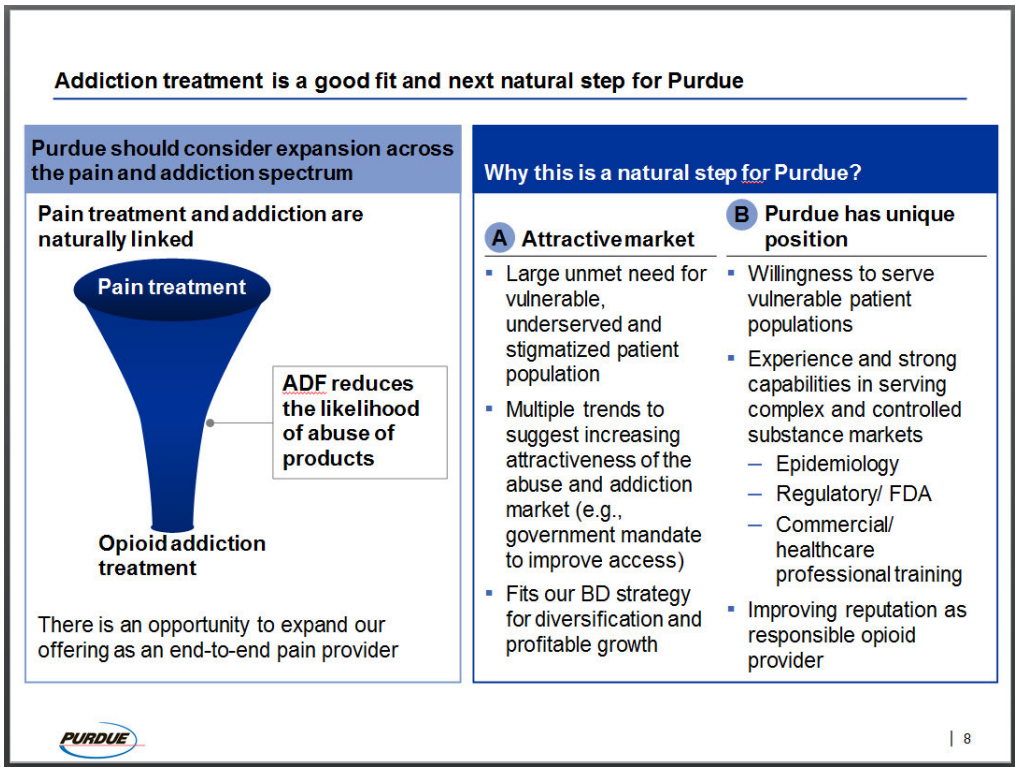
Purdue documents, Kathe Sackler and staff memorialized what Purdue publicly denied for decades: "Pain treatment and addiction are naturally linked."

285. Kathe Sackler and Purdue staff illustrated this point, and the business opportunity it presented, as a funnel that began with pain treatment leading into addiction treatment which emphasized Purdue's "opportunity to expand our offering as an end-to-end pain provider":



286. The same presentation also provided that opioid addiction can "happen to any-one—from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor." This internal statement directly contradicts Purdue's public-facing message that opioid addiction only affects patients that are already pre-disposed to addiction.

287. Kathe Sackler and Purdue's *Project Tango* team reviewed findings that sales of treatment medication to people addicted to opioids had more than doubled from 2009 to 2014. Kathe and the staff found that the national catastrophe Defendants caused provided an excellent

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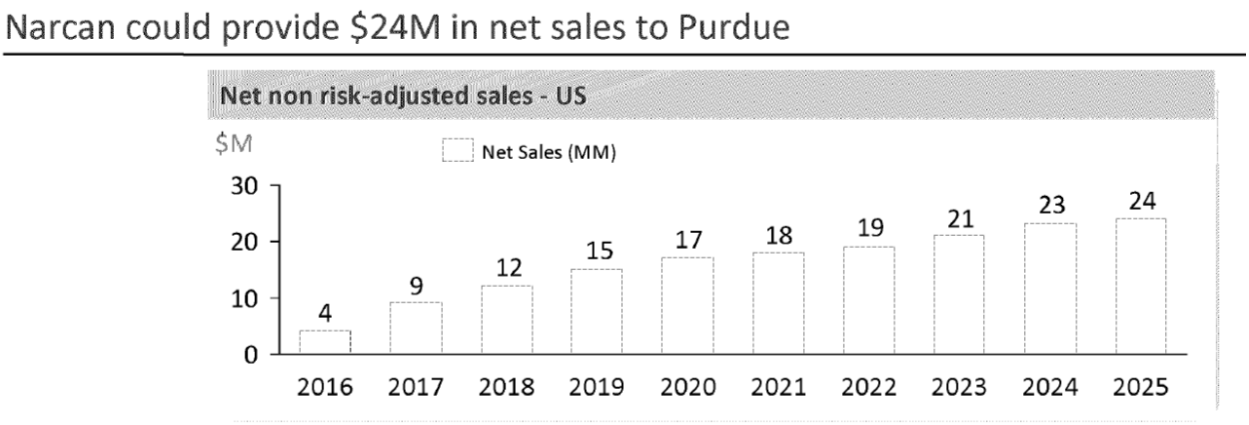
compound growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010."

288. Kathe Sackler ordered Purdue staff's "immediate attention, verification and assessment" of reports of children requiring hospitalization after accidentally swallowing buprenorphine. Staff reassured Kathe that children were overdosing on buprenorphine pills, not films, "which is positive for *Tango*." Of course, OxyContin and most of Purdue's other opioid products are dispensed as pills.

289. In February 2015, staff presented Kathe Sackler's work on *Project Tango* to the Purdue board. The plan was for a joint venture controlled by the Sackler Defendants to sell Suboxone film and acquire an addiction medicine pipeline. The presentation claimed that this would result in the Sackler Defendants' acquisition of the "market lead[] in the addiction medicine space."

290. During the presentation, the *Tango* team outlined how patients could get addicted to prescription opioid analgesics, like OxyContin, or heroin, and then become consumers of the joint venture's Suboxone film—and likely become repeat customers, as the presentation noted a "40–60% relapse rate in 1 year."

291. In June 2016, the Sackler Defendants met to discuss a revised version of *Project Tango* and considered a different scheme to sell the opioid overdose antidote Narcan. At this meeting, the Sackler Defendants and the Purdue board calculated that the need for Narcan to reverse overdoses could provide a growing source of revenue that would increase exponentially:



292. The Sackler Defendants viewed Narcan as a "complementary" product to their opioid portfolio, and identified patients on Purdue's prescription opioids as the target market for Narcan. Their plan called for studying "long-term script users" to "better understand target end-patients" for Narcan. The Sackler Defendants planned to "leverage the current Purdue sales force" to "drive direct promotion to targeted opioid prescribers" and determined that Purdue could profit from government efforts to use Narcan to save lives, including specifically in Minnesota, because Minnesota allows dispensing of naloxone without a prescription.

293. In December 2016, Richard, Jonathan, and Mortimer Sackler had a call with staff regarding yet another version of *Project Tango*: acquisition of a company that treated opioid addiction with implantable drug pumps. The business was a "strategic fit," because Purdue sold opioids and the new business treated the "strategically adjacent indication of opioid dependence."

294. In January 2018, Richard Sackler received a patent for a drug to treat opioid addiction — his own version of *Project Tango*. He assigned it to Rhodes Pharmaceuticals L.P., a different company controlled by the Sackler family, instead of Purdue. Richard's 2007 patent

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application says opioids *are* addictive, calls the people who become addicted to opioids "junkies," and asks for a monopoly on a method of treating addiction.[69]

295. Indeed, at least one Sackler Defendant had demonstrated interest in treatment of opioid addiction with buprenorphine years earlier. At the end of 2007, Jonathan Sackler emailed Purdue staff to inform them that he had spoken with a Minneapolis-based health care provider who treated opioid addicts, who had told him that Suboxone was achieving "great result[s]" in treating his patients suffering from opioid dependence and addiction.

296. The Sackler Defendants' efforts directing Purdue to develop, market, and sell addiction treatments demonstrates their full knowledge of the extent of opioids' addictive qualities, and their willingness to extract profit by selling the solution to an addiction epidemic of their own making. These efforts also stand as a stark and revealing contrast to Defendants' various misrepresentations that opioid addiction is not inherently caused by their prescription drugs, that the risk of addiction from opioids is low, and that patients with signs of abuse and addiction are actually exhibiting "pseudoaddiction" requiring larger doses of opioids, as alleged in this First Amended Complaint. (¶¶ 112–141)

C. The Sackler Defendants Enriched Themselves with Purdue's Profits.

297. The Sackler Defendants caused Purdue and other associated companies that they beneficially owned and controlled to ultimately distribute to the Sackler Defendants *billions* of dollars in connection with the sale of Purdue's opioids in Minnesota (and the rest of the nation). From the 2007 convictions of Purdue and its officers through 2018, the Sackler Defendants voted to pay their families hundreds of millions of dollars each year, reflecting both the Sackler

[69] 2018-01-09, U.S. Patent No. 9,861,628 ("a method of medication-assisted treatment for opioid addiction"); 2007-08-29, international patent publication no. WO 2008/025791 Al.

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Defendants' personal incentives to sell as many opioids as possible, as well as the extent of their control over the Purdue board and Purdue.

298. According to publicly available information, annual revenue at Purdue averaged about $3 billion, mainly due to OxyContin sales, and Purdue has made more than $35 billion since releasing OxyContin in 1995.[70] According to Purdue board documents, Purdue, at the direction of the Sackler-controlled board, paid the Sackler families **approximately $4 billion** in profits stemming from the sale of Purdue's opioids between 2007 and 2018.

299. Purdue also projected that the Sackler Defendants would be paid billions more. In June 2010, Purdue's staff gave the Sackler Defendants an updated 10-year plan for growing Purdue's opioid sales, in which the Sackler Defendants stood to receive at least $700 million each year from 2010 through 2020.

300. When the Sackler Defendants directed Purdue to pay their family, they knew and intended that they were paying themselves from opioid sales in Minnesota. Purdue and the Sackler Defendants tracked revenue from Minnesota. For example, after the 2016 CDC guideline was released, staff analyzed the potential negative effect of the guideline on Purdue's opioid sales and reported to the Sackler Defendants that the approximately 40,000 annual prescriptions of Purdue's high-dose opioids in Minnesota provided Purdue nearly $20 million per year, or about 2.3% of Purdue's annual high-dose opioid sales. If this percentage is applied to the overall distributions paid to the Sackler Defendants since May 15, 2007, the Sackler Defendants have paid their family approximately $92,000,000 from Minnesota.[71]

[70] Morrell, *supra* note 6.
[71] 2.3% of $4,000,000,000 is $92,000,000.

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V. DEFENDANTS HAD A DUTY TO DISCLOSE MATERIAL FACTS IN CONNECTION WITH PURDUE'S MARKETING AND SALE OF OPIOIDS.

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

302. First, Defendants 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 Defendants targeted possessed this special knowledge, particularly given that Purdue promoted opioid products to primary care physicians, physician assistants, and nurse practitioners. Defendants 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. Defendants abused that trust by omitting such materials facts from its representations about opioids and opioid prescribing.

303. Second, the nature and quality of the representations that Defendants made to potential prescribers, third-party payors, and patients were so incomplete regarding the risks and benefits of opioids and opioid prescribing that Defendants did not say enough to prevent the representations it made to prescribers and others from being confusing, deceptive, and misleading. Defendants 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. Defendants have also failed to repudiate or correct its prior misrepresentations and

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confusing and deceptive conduct that caused confusion about opioids for Minnesota prescribers, third-party payors, and patients.

VI. DEFENDANTS FRAUDULENTLY CONCEALED THEIR DECEPTIVE CONDUCT.

304. At all times relevant to this Complaint, Defendants took steps to fraudulently conceal their confusing and deceptive marketing behavior.

305. Defendants disguised Purdue's role in confusing and deceptive marketing of opioids by funding and working through front organizations and opinion leaders. Defendants purposefully cloaked Purdue 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.

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

307. In addition to hiding its role in generating the misleading content, Defendants influenced promotional materials and scientific literature to make them appear accurate, truthful, and supported by substantial scientific evidence. Defendants 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.

308. Accordingly, Defendants intentionally concealed its role in causing the damage wrought by the opioid epidemic in order to further Purdue's marketing strategies. Defendants 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

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to the existence and scope of Defendants' deception and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

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

VII. DEFENDANTS' DECEPTIVE AND MISLEADING CONDUCT HAS HARMED MINNESOTA'S PUBLIC INTEREST.

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

310. Opioids have caused a devastating public health crisis in Minnesota, which has seen a nearly 800 percent increase in opioid overdose deaths between 2000 and 2017.[72] 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 2017, the number of deaths attributed to opioids increased to 422.[73]

311. 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.[74]

312. Between 2005 and 2011, legal distribution of opioids increased 72% statewide.[75] 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

[72] *See* Minn. Dep't of Health, *Drug Overdose Deaths Among Minnesota Residents, 2000–2017*, at 4, 23, https://www.health.state.mn.us/communities/opioids/documents/2017opioiddeathreport.pdf
[73] *Id.* at 4.
[74] 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.
[75] Jeanne Mettner, *The Opioid Crisis,* Minn. Med. (Mar. 2013), *available at* http://pubs.royle.com/article/The+Opioid+Crisis/1330890/0/article.html.

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ingredient in Purdue's OxyContin.[76] Total opioid prescriptions increased to 3.87 million in 2015.[77]

313. 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.[78] 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.[79]

314. 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.

315. The abuse of prescription painkillers is a gateway to heroin use both nationwide and in Minnesota.[80] 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.[81]

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[76] 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.

[77] 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.

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

[79] 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.

[80] 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/2017MNStatewideHealthAssessment.pdf; Minn. Dep't of Pub.

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316. 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.[82] This coincides with an increase in heroin overdose deaths nationwide, which more than tripled from 2010 to 2014.[83] 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.[84]

317. 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.[85] By the end of 2014, the rate increased to 247 per 100,000 persons, above the national rate of 224.6.[86] By the first quarter of

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

[81] 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).

[82] Minn. Dep't of Health, *Drug Overdose Deaths Among Minnesota Residents, 2000-2016*, *supra* note 72, 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.

[83] Rose Rudd et al, *supra* note 80, at 1379.

[84] 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/.

[85] *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).

[86] 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.

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2017, the rate rose to 348 per 100,000.[87] 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.[88] In 2016, the figure jumped again to 196 visits per 100,000 persons.[89]

318. In 2016, opioids accounted for 10,332 substance abuse treatment admissions in Minnesota, second only to alcohol.[90] 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.[91] Treatment admissions for heroin use in the Twin Cities metro area increased from 3.3% of admissions in 2000 to 17.3% in 2016.[92]

319. 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 treatment[93]; by 2015, this figure had risen to 5,530 individuals.[94] Similarly, the number of Minnesotans receiving buprenorphine as part of their substance use treatment increased from 247 to 667 from 2009 to 2015.[95]

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[87] *HCUP Fast Stats—Opioid-Related Hospital Use*, *supra* note 85.
[88] Audrey Weiss et al., *supra* note 86, at 9.
[89] *HCUP Fast Stats—Opioid-Related Hospital Use*, *supra* note 85.
[90] 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.
[91] 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.
[92] *Id.*
[93] 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.
[94] 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.
[95] *Id.*; *Behavioral Health Barometer—Minnesota, 2014, supra* note 93.

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320. 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.[96] 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.[97] 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.[98]

321. 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.[99] 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.[100] 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

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[96] 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.
[97] Jon Collins, *supra* note 82.
[98] *Minnesota State Targeted Response to the Opioid Crisis*, *supra* note 96, at 6.
[99] 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.
[100] 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.

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2016.[101] 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.[102]

322. 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.[103]

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

323. 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.

324. 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.[104] After adding in societal costs of "increased health care expenditures, incarceration, premature death, and lost

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[101] 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.

[102] *Minnesota State Targeted Response to the Opioid Crisis*, *supra* note 96, at 6.

[103] 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/.

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

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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.[105]

325. 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.[106] 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.[107] Costs are projected to rise to over $14 billion in 2020.[108]

326. 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.

327. 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

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[105] 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.
[106] 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.
[107] *Id.*
[108] *Id.*

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million was paid through MinnesotaCare for the more than 100,000 Minnesota residents enrolled.[109]

328. According to a Department of Human Services analysis, there are approximately 19,000 chronic opioid users in Minnesota's public health care programs.[110] 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.[111] 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.[112]

329. 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.[113] Medicaid also covers 32% of medication-assisted treatment payments for opioid abusers in Minnesota, eight percent more than the national share.[114]

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[109] *Id.* at 31.
[110] *Minnesota Opioid Prescribing Guidelines*, *supra* note 47, at 4.
[111] *Id.* at 5.
[112] *Id.*
[113] 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.
[114] U.S. Congress Joint Economic Committee, *supra* note 105, at 3.

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330. 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.

331. 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.[115]

332. 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.[116] According to data reported to the DEA, instances of theft of controlled substances from pharmacies more than tripled from 2006 to 2010.[117] Heroin was present in almost 14% of drug reports from law enforcement seizures in

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

[116] 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.

[117] 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,[118] and heroin arrests increased more than 400% from 2008 to 2011.[119] Drug abuse also leads to other crimes, such as theft, burglary, and assaults.

333. 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.[120]

334. 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.[121]

335. 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.[122] 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.[123]

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[118] 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.

[119] Minn. Dep't of Pub. Safety, *supra* note 80, at 4.

[120] 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).

[121] 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/.

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

[123] *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.

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COUNT I
CONSUMER FRAUD
(ALL DEFENDANTS)

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

337. 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 enjoinable as provided in section 325F.70.

338. 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.

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

340. Defendants 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;

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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.

341. Separately, Defendants 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.

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

343. The Sackler Defendants are liable in their individual capacities because they personally participated in, directed, acquiesced to, should have known about and prevented,

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and/or derived financial benefit from the conduct by Purdue constituting the multiple, separate violations of Minnesota Statutes section 325F.69, subdivision 1, detailed above.

344. 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 Defendants.

345. Defendants' 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
(ALL DEFENDANTS)

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

347. 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:
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> ***
>
> (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
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> ***
>
> (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;

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> (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.

348. The Purdue entities and Sackler Defendants are "person[s]" within the meaning of this statute.

349. Defendants, by engaging in the deceptive and fraudulent practices described in this Complaint, have 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.

350. Defendants caused a likelihood of confusion or misunderstanding regarding the approval or certification of Purdue's 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.

351. Defendants represented that Purdue's 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

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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.

352. Defendants misrepresented the standard, quality, or grade of Purdue's 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.

353. Defendants 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.

354. Defendants further engaged in conduct that created a likelihood of confusion or misunderstanding about Purdue's opioid products, and opioids in general, by, among other

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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.

355. Separately, Defendants repeatedly violated Minnesota Statutes section 325D.44, subdivision 1, by omitting material information in the course of marketing and selling Purdue's 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.

356. The Sackler Defendants are liable in their individual capacities because they personally participated in, directed, acquiesced to, should have known about and prevented, and/or derived financial benefit from the conduct by Purdue constituting the multiple, separate violations of Minnesota Statutes section 325D.44, subdivision 1, detailed above.

357. 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 Defendants.

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358. Defendants' 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
(ALL DEFENDANTS)

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

360. 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.

361. 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.

362. The Sackler Defendants are "person[s]," and the Purdue entities are "person[s]" and "corporation[s]," within the meaning of this statute.

363. Defendants repeatedly violated Minnesota Statutes section 325F.67, by making, publishing, disseminating, circulating, and/or placing before the public, books, pamphlets,

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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.

364. Separately, Defendants 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.

365. The Sackler Defendants are liable in their individual capacities because they personally participated in, directed, acquiesced to, should have known about and prevented, and/or derived financial benefit from the conduct by Purdue constituting the multiple, separate violations of Minnesota Statutes section 325F.67 detailed above.

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

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

367. Defendants' 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
(ALL DEFENDANTS)

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

369. 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.

370. 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;

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(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.

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

372. Defendants' 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).

373. Defendants' 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).

374. Defendants' conduct meets one or more of the nonexclusive factors listed in section 325F.71, subdivision 2(b), and satisfies other appropriate factors, including that Defendants knew that their conduct was directed to one or more senior citizens or disabled persons, that Defendants' 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 Defendants' conduct than other members of the public because of age, poor health or infirmity, impaired understanding, restricted mobility,

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or disability, and/or actually suffered physical, emotional, or economic damage resulting from the Defendants' conduct. These circumstances are established by the conduct described herein.

375. The Sackler Defendants are liable in their individual capacities because they personally participated in, directed, acquiesced to, should have known about and prevented, and/or derived financial benefit from the conduct by Purdue constituting the multiple, separate violations of Minnesota Statutes section 325F.71, subdivision 2(b), detailed above.

376. Defendants' 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
(ALL DEFENDANTS)

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

378. 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.

379. The Purdue entities and Sackler Defendants are "person[s]" within the meaning of this statute.

380. Defendants repeatedly violated Minnesota Statutes section 325D.13 in connection with the sale of Purdue's 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

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provide a full 12 hours of pain relief, and the addiction- and abuse-prevention qualities of the "abuse-deterrent" formulations of Purdue's opioid products.

381. Separately, Defendants repeatedly violated Minnesota Statutes section 325D.13 in connection with the sale of Purdue's opioid products by omitting material information such that it knowingly misrepresented, directly and/or indirectly, the true quality of Purdue's 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.

382. The Sackler Defendants are liable in their individual capacities because they personally participated in, directed, acquiesced to, should have known about and prevented, and/or derived financial benefit from the conduct by Purdue constituting the multiple, separate violations of Minnesota Statutes section 325D.13 detailed above.

383. 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 Defendants.

384. Defendants' conduct, practices, actions, and material omissions described in this Complaint constitute multiple, separate violations of Minnesota Statutes section 325D.13.

COUNT VI
UNJUST ENRICHMENT
(ALL DEFENDANTS)

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

386. Benefits have been conferred upon Defendants 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 Defendants misleadingly and deceptively marketed its opioid products and opioids in general.

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387. Purdue knowingly accepted and retained such benefits, and the Sackler Defendants then knowingly caused Purdue to distribute such benefits to the Sackler Defendants.

388. Defendants' 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, Defendants' conduct has resulted in the harm described herein.

389. Further, Defendants have failed to pay for the consequences of their unlawful conduct.

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

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

392. The Sackler Defendants are liable in their individual capacities because they personally participated in, directed, acquiesced to, and/or should have known about and prevented the conduct by Purdue detailed above. The Sackler Defendants ultimately accepted and retained benefits from Defendants' misconduct under unjust and inequitable circumstances, and have failed to pay for the consequences of their unlawful conduct.

393. Defendants' 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
(ALL DEFENDANTS)

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

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395. 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.

396. Defendants recognized that Purdue's undertaking of said duty was necessary for the protection of the public health, and that Purdue's 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.

397. Through the conduct described herein, Defendants have breached and continue to breach Purdue's 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. Defendants' 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.

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

399. The Sackler Defendants are liable in their individual capacities because they personally participated in, directed, acquiesced to, should have known about and prevented, and/or derived financial benefit from the conduct by Purdue detailed above.

400. Defendants' 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
(ALL DEFENDANTS)

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

402. Minnesota Statutes section 609.74 provides, in part:

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> 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.

403. 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.

404. Through the deceptive conduct described throughout this Complaint, Defendants have intentionally maintained or permitted, or were 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.

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

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406. Defendants' conduct was, at the very least, a substantial factor in opioids becoming widely available and widely used in Minnesota. Defendants' 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 Defendants' 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.

407. Defendants' 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.

408. Defendants' conduct in maintaining or permitting a public nuisance has openly, publicly, repeatedly, continuously, persistently, and intentionally violated Minnesota law, as described throughout this Complaint. Defendants' 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. Defendants' 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.

409. Furthermore, pursuant to Minnesota Statutes section 325F.67, as pleaded above, Defendants' 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.

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COUNT IX
FALSE CLAIMS ACT
(ALL DEFENDANTS)

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

411. 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[.]

412. 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.

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

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

415. Defendants knew that Purdue's fraudulent, false, and misleading statements and omissions were material to health care providers' decision to prescribe opioids to Minnesota

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government health care program patients. Indeed, Defendants intended such statements and omissions to be material to encourage additional opioid prescriptions.

416. Defendants' 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.

417. 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

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or authorized by State government health care programs and submitted to the State were for uses that were misbranded.

418. 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.

419. Defendants 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.

420. 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, Defendants caused and are responsible for those costs and claims as well.

421. Defendants' 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.

422. 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.

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

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424. By engaging in the above-described conduct, Defendants 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).

425. The Sackler Defendants are liable in their individual capacities because they directly participated in, directed, acquiesced to, should have known about and prevented, and/or derived financial benefit from the conduct by Purdue detailed above.

426. By reason of Defendants' 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, Keith Ellison, respectfully asks this Court to award judgment against Defendants, jointly and severally, as follows:

1. Declaring that Defendants' 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. Enjoining the Sackler Defendants from engaging in conduct in violation of Minnesota Statutes sections 325D.13, 325D.44, 325F.67, 325F.69, and 325F.71;

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

5. Awarding judgment against Defendants, jointly and severally, for 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 Defendants' acts and omissions described in this Complaint;

6. Ordering Defendants, jointly and severally, to disgorge all profits from Purdue's sales of opioids in Minnesota;

7. Awarding judgment against Defendants, jointly and severally, for civil penalties pursuant to Minnesota Statutes sections 8.31, subdivision 3, and 15C.02(a) for each separate violation of Minnesota law;

8. Awarding judgment against Defendants, jointly and severally, for supplemental civil penalties pursuant to Minnesota Statutes section 325F.71 for each separate violation of Minnesota law;

9. Declaring that Defendants' acts described in this Complaint constitute a public nuisance under Minnesota law, and permanently enjoining the Sackler Defendants and 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;

10. Ordering Defendants to abate the public nuisance they have created, including by ordering judgment against Defendants, jointly and severally, in an amount necessary to abate the public nuisance;

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11. Awarding judgment against Defendants, jointly and severally, for damages for injury sustained as a result of Defendants' repeated breaches of the special duty they undertook in Minnesota;

12. Awarding judgment against Defendants, jointly and severally, for treble damages pursuant to Minnesota Statutes sections 15C.02(a);

13. 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

14. Granting such further relief as provided by law or equity as the Court deems appropriate and just.

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JURY DEMAND

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

Dated: July 8, 2019.

Respectfully submitted,

KEITH ELLISON
Attorney General
State of Minnesota

JAMES W. CANADAY (#030234X)
Deputy Attorney General

/s/ Eric J. Maloney
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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 8, 2019.

/s/ Eric J. Maloney
ERIC J. MALONEY