IN THE IOWA DISTRICT COURT FOR POLK COUNTY

STATE OF IOWA ex rel. THOMAS J. MILLER, ATTORNEY GENERAL OF IOWA Plaintiff, v. PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, INC., PURDUE PHARMA COMPANY, P.F. LABORATORIES INC., and RICHARD S. SACKLER, Defendants.	**EQUITY NO. EQCE 084514** **FIRST AMENDED PETITION**

I. INTRODUCTION

1. This proceeding is brought by the State of Iowa through its Attorney General, Thomas J. Miller, against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., P.F. Laboratories Inc., and Purdue Pharma Company (collectively, "Purdue") and Richard S. Sackler, pursuant to the Iowa Consumer Fraud Act, Iowa Code section 714.16 and the Older Iowans Law, Iowa Code section 714.16A. The lawsuit seeks redress for Defendants' false, deceptive, misleading, and omissive representations and unfair practices related to the advertisement, marketing, promotion and sale of OxyContin tablets in Iowa.
2. Since its debut in 1996, Purdue has aggressively marketed OxyContin, a powerful opioid painkiller that is twice as potent as morphine, to treat chronic pain that occurs as a result of common conditions such as low back pain and osteoarthritis.
3. Oxycodone, the active ingredient in OxyContin, has long been known to have addictive properties.

4. Despite the serious risks attendant with OxyContin use, Purdue repeatedly made false and deceptive claims in a myriad of forums and formats that OxyContin was safe and suitable for a wide range of pain patients because, *inter alia*, OxyContin posed a nearly nonexistent risk of addiction; its time-control release formula was "believed" to reduce the abuse liability of the drug; patient behaviors signaling addiction were in fact only "pseudoaddiction" indicating the need for more opioids; long-term opioid use improved patients' quality of life and function; and that opioids were suitable for vulnerable groups, such as elderly patients and veterans.
5. Purdue made deceptive comparisons between OxyContin and other pain relievers that implied that OxyContin was a safer alternative and failed to disclose or understated the risks attendant with its use.
6. Purdue misrepresented that OxyContin would provide 12 hours of pain relief, knowing that many patients experienced only 8-9 hours of pain relief, resulting in dangerous "end of dose failure" that can lead to misuse and addiction. When patients experienced less than twelve hours of pain relief, Purdue encouraged health care providers to prescriber higher, more dangerous doses of OxyContin.
7. Purdue omitted or understated important information about the risks of long-term opioid use, including the fact that higher doses or longer use of opioids pose greater risks of addiction and overdose.
8. Purdue perpetuated its unlawful practices through a broad, deep, and multifaceted marketing campaign that permeated all levels of the health care system in Iowa. It made individualized sales pitches to Iowa health care providers, developed and disseminated written materials and publications directed at prescribers and patients, sponsored pro-pain

patient advocacy groups, co-opted medical education programs, and used numerous other means in order to increase sales of their opioids.

9. As a Purdue executive and Board member, Defendant Richard S. Sackler was a primary participant in Purdue's false, deceptive, misleading, and omissive representations and unfair practices related to the advertisement, marketing, promotion and sale of OxyContin in Iowa. In his own words, Sackler has admitted that, "[i]t is almost as if I dedicated my life" to making OxyContin a huge success. Through his actions and decisions, Sackler played a central role in the unlawful conduct alleged in this Petition

I. PARTIES

10. **PLAINTIFF**, **STATE OF IOWA** brings this action through the office of the Iowa Attorney General, Thomas J. Miller. The Iowa Attorney General is expressly authorized to bring this action on behalf of the State of Iowa pursuant to the Iowa Consumer Fraud Act, Iowa Code sections 714.16 *et seq*. (2019) and 714.16A (2019) for remedies including but not limited to permanent injunctive and other equitable relief, restitution, disgorgement, civil penalties, and attorney's fees and costs.

11. **DEFENDANT THE PURDUE FREDERICK COMPANY, INC**., which did business as The Purdue Frederick Company, is a New York corporation with its principal place of business in Connecticut. The Purdue Frederick Company engaged in the initial design and development of OxyContin (patent filed December 1994), and engaged in the marketing and sale of OxyContin from December 1995 to December 2003. The Purdue Frederick Company received partnership income through the Purdue Pharma Company from December 1995 through September 20, 2007.[1]

[1] PPLP 4031375; PPLP 4031376.

12. **DEFENDANT PURDUE PHARMA COMPANY** was formerly a Delaware general partnership, with its principal place of business in Connecticut. Purdue Pharma Company was the owner of OxyContin from January 1994 to September 30, 2007. Defendants claim that The Purdue Pharma Company was terminated on or about September 30, 2007.[2]
13. **DEFENDANT PURDUE PHARMA L.P**. is a limited partnership established in Delaware with its principal place of business in Connecticut, whose general partner is Purdue Pharma Inc. Purdue Pharma L.P. was formed in 1991 to make, research and sell branded pharmaceutical products, including OxyContin.[3] Purdue Pharma L.P. is the successor in interest to The Purdue Pharma Company. Purdue Pharma L.P. engaged in the marketing and sale of OxyContin from December 1995 to August 2010. Purdue Pharma L.P. engaged in the marketing and sales of the reformulated version of OxyContin since August 2010, and also engaged in the research and development of OxyContin. Purdue Pharma L.P. received OxyContin partnership income through The Purdue Pharma Company from December 1995 to September 30, 2007.[4]
14. **DEFENDANT PURDUE PHARMA INC**. is a New York corporation with its principal place of business in Connecticut and is the general partner of Purdue Pharma L.P.[5]
15. **DEFENDANT P.F. LABORATORIES, INC.** is a New Jersey corporation with is principal place of business in New Jersey.
16. At all times material hereto, each of the above Defendants did develop, manufacture, promote, advertise, market, sell and/or distribute opioids, including OxyContin, in the

[2] PPLP 4031375.
[3] PWG 4812416.
[4] PPLP 4031375.
[5] PPLP 4031375.

United States and specifically in the State of Iowa. This Petition refers to these Defendants collectively as PURDUE**.**

17. **DEFENDANT RICHARD S. SACKLER** is a resident of Riviera Beach, Florida. Sackler began working for The Purdue Frederick Company in 1971. Beginning in the late 1970s Sackler held multiple executive positions at Purdue and related companies including the heads of research and development and the medical department. In 1996 he became Senior Vice President responsible for Marketing and Sales, the position he held at the time OxyContin was launched in 1996. In 1999, he became President of Purdue Pharma and he served in that position until 2003. Sackler has held a seat on Purdue Pharma's Board from 1995 through 2018 and served as its co-chair starting in 2003. Sackler was a primary participant in and directed false, deceptive, misleading and/or omissive conduct and unfair practices related to the advertisement, marketing, promotion, and sale of Purdue opioids in Iowa, as more particularly set forth below in Sections V and VI.
18. Richard S. Sackler is a trustee of a trust with a limited partnership interest in an entity within the chain of corporate ownership for Purdue Pharma L.P. He has received millions of dollars in payments from Purdue, and OxyContin in specific, over decades.

III. JURISDICTION AND VENUE

19. The Court has subject matter jurisdiction over this matter under Iowa Code section 714.16(7) (2019).
20. The Court has personal jurisdiction over Purdue because it regularly transacts business in the State of Iowa, and the claims asserted herein arise from Purdue's conduct in and intentionally directed toward the State of Iowa, including the advertisement, marketing, promotion, and sale of opioids. The Court has personal jurisdiction over Richard S. Sackler

as a primary participant in Purdue's conduct in and intentionally directed toward Iowa including the advertisement, marketing, promotion, and sale of opioids, for the reasons set forth in Section VI below.

21. Venue in Polk County is proper pursuant to Iowa Code section 714.16(10) (2019) because Defendants have done and are doing business in this county, and it is a county where some of the transactions giving rise to this action occurred.

IV. FACTUAL BACKGROUND

A. Oxycodone

22. For more than a century prior to Purdue's introduction of OxyContin in 1996, the medical community recognized the inherent dangers[6] of strong opioids.[7] In the latter half of the twentieth century, opioids were used principally for cancer care and end-of-life care.

23. Under the Comprehensive Drug Abuse Prevention and Control Act of 1970, every controlled substance is classified into a schedule between I-V based upon its potential for abuse, currently accepted medical use in treatment in the United States, and the degree of dependence the drug may cause. 21 U.S.C. § 812. Drugs that have a high potential for abuse which may lead to severe psychological or physical dependence are placed in Schedule II.[8]

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[6] *See, e.g.* J.F.A. Adams, *Substitutes for Opium in Chronic Disease*, 121 Boston Med. Surg. J. 351, Oct. 10, 1889 (late nineteenth century article advocating greater restrictions on the use of opiates due to dangers of addiction, overdose and other risks).

[7] *See, e.g. Narcotic Analgesics - I*, 2 Br. Med. J. 525, May 30, 1970 ("Intractable pain of non-malignant origin is nearly always best treated other than by narcotic analgesics since their continued use must lead to dependence" and "Tolerance develops relatively quickly- sometimes a dosage of 500mg of morphine a day is reached within 10 days"); L. Halpern, *Analgesic Drugs in the Management of Pain*, 112 *Arch Surg.* 861, July 1977 ("The use of potent narcotics to control severe pain should be of short duration and limited to patients with acute diseases or inoperable or metastatic cancer who require long-term relief. Continued and prolonged use of narcotics in patients with chronic benign pain is not recommended because of serious behavioral consequences, the development of tolerance, and addiction liability. Long-term use of analgesic drugs in chronic pain usually produces negative behavioral complications that are more difficult to manage than the pain it was desired to eliminate").

[8] Drugs of Abuse – A DEA Resource Guide (Drug Enforcement Administration, 2017 ed.) pp. 8-9. (Substances with progressively less potential for harm and abuse are placed in Schedules III through V.)

24. Oxycodone is a Schedule II drug, which means, by definition, it has a high potential for abuse, dependence, and addiction. Oxycodone is synthesized from the thebaine alkaloid of the opium poppy and possesses properties similar to its illicit cousin, heroin. As early as 1931, oxycodone was recognized as a narcotic drug whose manufacture and distribution should be limited.[9] The federal Drug Enforcement Administration has characterized the pharmacological effects of oxycodone as similar to those of heroin.[10]

25. Oxycodone works by attaching or binding to certain specialized receptors in the brain. The effect on the user is to dampen or block pain, slow breathing, and "reward" the taker with feelings of pleasure or euphoria.[11]

26. Oxycodone is used for its analgesic properties to treat pain and is a central nervous system depressant. Respiratory depression resulting in death can occur even when oxycodone is taken as directed.

27. When opioids such as oxycodone are taken by persons without significant pain and the drug activates these "reward" feelings in the brain, the user can be motivated to continue taking the drug for these pleasurable effects.[12]

28. Opioids, such as OxyContin, are highly addictive. Some studies have found diagnosed addiction rates in a primary care setting as high as 26%.[13]

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[9] *See e.g.* League of Nations Treaty Limiting Manufacture and Regulating Distribution of Narcotic Drugs, July 13, 1931, which followed earlier international agreements on the limitation of the manufacture of narcotics to the world's legitimate requirements for medical and scientific purposes, and by regulating the distribution of narcotic drugs.

[10] *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office, December 2003 at 2 ("GAO Report").

[11] Thomas R. Kosten & Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 Sci. Pract. Perspect. 13, July 2002.

[12] *Id.* at 14.

[13] Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain –United States, 2016*, 65 Morbidity & Mortality Weekly Report, 1, 9-10 (2016).

29. Opioid tolerance occurs when the brain's opioid receptors gradually become less responsive to the opioid stimulation.[14]

30. Patients who use opioids over a course of time grow tolerant to the drugs' analgesic effects, requiring higher doses to obtain the same levels of relief or pleasure. When patients who have developed tolerance stop taking opioids, they can experience withdrawal symptoms, such as jitters, anxiety, muscle cramps, diarrhea and other intense flu-like symptoms, such as vomiting, sweating, and shaking.[15]

31. The most serious risks of opioids, such as addiction and death by overdose, increase substantially with higher doses.[16] Such risks rise in a dose-dependent fashion, meaning the risk increases proportionately with the dose.[17]

32. The risk of developing addiction also increases when opioids are used on a long-term basis.[18]

33. There is no evidence that opioids are effective for long-term treatment of non-malignant chronic pain. In 2016 the Centers for Disease Control ("CDC") found no long-term (more than 12 months) studies comparing opioid therapy with placebo, with no opioid therapy, or with non-opioid therapy that evaluated long-term outcomes related to pain, function or quality of life.[19] The CDC concluded that while opioids can reduce pain short-term, there

[14] Kosten & George, *supra* note 11, at 15.
[15] *Id.*
[16] Dowell *supra* note 13, at 9-10; *see also* Thomas H. Frieden & Debra Houry, *Reducing the Risks of Relief- The CDC Opioid Prescribing Guidelines*, 374 New. Eng. J. Med. 1501 (2016) (while 1 in 550 patients on opioid treatment dies of opioid-related causes, that number increases to 1 in 32 people when patients are taking high doses of opioids (200 morphine milligram equivalents daily)).
[17] Dowell, *supra* note 13, at 9, 13.
[18] Mark J. Edlund, et. al. *The Role of Opioids Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-Cancer Pain*, 30 Clin. J. Pain 557-564 (2014).
[19] Dowell, *supra* note 14, at 9.

is "insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."[20]

34. Opioids pose particular concerns for older adults, for whom opioid use can result in an increased risk for falls and fractures.[21] Older adults are also at greater risk of respiratory depression from opioid use.[22]

35. Veterans are also susceptible to the risks of opioid use. In 2014 the U.S. Veterans Administration found that veterans were twice as likely to die of opioid overdoses than the rest of the population, and that veterans with posttraumatic stress disorder were likely to be prescribed the dangerous combination of opioids and benzodiazepines.[23]

36. Oxycodone can be abused like other legal and illicit opioids including fentanyl, morphine and heroin. Abuse of oxycodone may lead to severe psychological or physical dependence, that is, addiction and tolerance.

B. OxyContin

37. Purdue released OxyContin, a single agent version of oxycodone, in early 1996.[24] It was the first extended-release oxycodone product on the market. Prior to the introduction of OxyContin, oxycodone was usually prescribed by way of an opioid combination drug—a low dose of oxycodone combined with a non-opioid analgesic such as acetaminophen.

38. OxyContin contained large doses of pure oxycodone- from 10 mg to 160 mg. At the time of its release, other oxycodone-containing drugs had a maximum dose of 10 mg of oxycodone per pill.

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[20] *Id.* at 18, 20.
[21] *Id.* at 13.
[22] *Id.*
[23] *Pain Management Opioid Safety Educational Guide*, U.S. Department of Veterans Affairs (2014).
[24] Purdue created OxyContin following its success with MS Contin, a morphine-based extended-release product that Purdue promoted for the treatment of cancer pain.

39. OxyContin is an "extended-release" formulation, meaning the active ingredient – oxycodone – is released slowly, over time.[25] It is approved by the Food and Drug Administration ("FDA") for use every 12 hours. While extended-release formulations provide medication in a time-controlled manner and therefore may reduce the frequency of dosing, they can pose a greater danger than immediate-release preparations because they contain a larger dose of pure oxycodone.

40. OxyContin is twice as potent as morphine.[26]

41. OxyContin can cause fatal respiratory depression and death even when used as prescribed.

42. The consumption of OxyContin under appropriate medical supervision puts the patient at risk for addiction, abuse, misuse, overdose, and death, even at recommended doses.

43. The risk of addiction in any individual taking OxyContin is unknown.

44. At all times material hereto, clinical studies evaluating the addictive properties of OxyContin had not been performed.

C. Purdue's Marketing and Promotional Campaign for OxyContin

45. To achieve the sales it desired and position OxyContin as the leader in pain control, Purdue had to change fundamentally the way health care providers and patients perceived and used Schedule II controlled substances, particularly OxyContin. Purdue had to convince the health care industry that opioids were safe not just for cancer pain or end-of-life care, but for a host of chronic and more common aches, pains, and conditions over long periods of time.

[25] By contrast, immediate-release or short-acting opioids, such as Vicodin or Percocet, release the active ingredient more quickly and are typically effective for 4-6 hours.
[26] *GAO Report*, *supra* note 10, at 29.

46. To accomplish this fundamental change in the perception and the use of opioids, beginning in the mid-1990s Purdue unleashed a massive, and massively deceptive, marketing campaign that greatly exaggerated the benefits of OxyContin and substantially downplayed its risks.

47. When Purdue formally launched OxyContin in early 1996 and for years after, Purdue claimed that it believed the controlled-release nature of OxyContin reduced its abuse liability, that is, reduced its potential to be abused. In truth, however, *Purdue did not conduct any abuse liability studies on OxyContin before it rushed OxyContin to market*.

48. In fact, the Purdue executive in charge of clinical research and of OxyContin's development acknowledged in 1997, more than a year *after* the unleashing of OxyContin, that Purdue didn't "have a sufficiently strong case to argue that OxyContin has minimal or no abuse liability." Purdue and Sackler knew at that time that oxycodone products had once been less controlled by the government, but their use was restricted as oxycodone was among the most abused opioids in the United States.

49. Purdue's failure to clinically study the abuse liability of OxyContin before its release was unfortunately matched by Purdue's years-long failure to put in place any formal post-launch programs to monitor abuse or to develop a database from which it could collect and track reports of abuse or overdose.

50. Instead, Purdue focused on how it could further mislead health care providers about the supposed safety of OxyContin so that they would write more OxyContin prescriptions. Even prior to first releasing OxyContin, Purdue was banking on health care providers to fundamentally misunderstand OxyContin. Purdue hoped, and believed, prior to launching OxyContin, that physicians would perceive OxyContin as a controlled-release version of

Percocet, a much weaker and lower dose oxycodone/acetaminophen combination product, without the acetaminophen.

51. After the introduction of OxyContin, Sackler and Purdue knew that physicians did, in fact, have a misconception about the potency of OxyContin, which is two times as potent as morphine. Accordingly, and as discussed further below in Section VI Purdue decided, *at the highest levels of the company* and approved by Sackler, not to change this critical misperception, including in all of its promotional pieces, articles, studies, and other materials.

52. Sackler was proud of the role that Purdue's marketing team played in the development of OxyContin. He boasted that the package insert, the document containing medical information about the drug's use and risks for health care providers, was a powerful sales tool.

53. In 1996, Purdue embarked on a widespread and aggressive marketing campaign for OxyContin. Purdue's marketing of OxyContin was like a giant octopus: it reached into each different segment and level of the health care system and unfurled Purdue's false, deceptive, misleading, and omissive representations and unfair practices regarding the claimed safety and benefits of OxyContin. Purdue reached into Iowa health care providers' offices, hospitals and clinics through its sales representatives and millions of pieces of mail, literature, and promotional items; it reached into Iowa's legislative and health care regulatory bodies and boards; it reached into medical societies and associations; it reached into scientific and medical publishing; it reached into physicians' medical education; it reached into patients' lives directly through dissemination and distribution of patient

"education" and advocacy materials, including through the internet; and it reached into veterans' lives.

54. Beginning with its first press release introducing OxyContin in 1996, Purdue falsely and boldly claimed that "the fear of addiction is unfounded."

55. Part of Purdue's promotional strategy was to: (1) expand the permissible types of drugs on Step 2 of the widely-recognized World Health Organization ("WHO") analgesic ladder for *cancer pain* to include OxyContin, and (2) to apply the ladder steps to *non*-cancer pain. Purdue did this while knowing that the use of opioids in non-cancer pain was very controversial.

56. Purdue's OxyContin promotional theme became "The One to Start With and Stay With." Purdue promoted OxyContin, a strong Schedule II opioid, for non-cancer pain in place of weaker opioid combination products that historically had been used at Step 2 for cancer pain. Purdue did this despite its knowledge that OxyContin was twice as potent as morphine and contained much larger quantities of pure oxycodone than the weaker oxycodone combination products.

57. Purdue's sales representatives were essential in delivering Purdue's messages directly to Iowa health care providers.[27] Purdue amassed, trained and deployed huge numbers of sales representatives – including a dedicated Iowa sales force – who visited health care providers to deliver Purdue's misleading messages about the safety, benefits and efficacy of OxyContin for chronic pain and a host of medical conditions.

[27] Studies show that in-person sales visits by pharmaceutical company representatives to individual health care providers, a practice known as "detailing," are associated with increased sales of detailed products. *See Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 Journal of the American Medical Association 1785, May 2, 2017.

58. Purdue utilized sophisticated marketing data to track which health care providers prescribed opioids most liberally, and in some cases, most recklessly, and targeted those practitioners with overzealous teams of sales representatives whose lucrative compensation was based on their ability to get health care providers to prescribe OxyContin. Purdue instructed its sales staff in Iowa to target family medicine practitioners even when they knew those prescribers were unfamiliar with pain management and addiction.

59. Over the years, Purdue's sales staff made tens of thousands of calls on Iowa health care providers. According to Purdue's own data, its sales representatives conducted over 90,000 health care provider visits in Iowa between 2006-2017, including a peak of 11,173 calls in 2012 alone[28] sometimes visiting a single high prescriber multiple times in a month.

60. Sales representatives were trained to make individualized pitches to prescribers, to "challenge" their existing beliefs about how to treat patients, and to handle and "overcome" prescribers' medical objections to prescribing OxyContin.

61. Iowa's Purdue sales representatives hosted breakfasts, lunches and dinners for Iowa health care providers, at which Purdue-paid speakers promoted OxyContin and repeated many of the misrepresentations described below.

62. Purdue's sales force distributed tens of thousands of promotional videos to distribute to physicians' offices, including in Iowa, to be checked out and viewed by patients.[29]

63. Purdue flooded the offices of health care providers, including in Iowa, with millions of pieces of branded OxyContin sales and marketing materials, promotional gifts, office supplies and trinkets.

[28] PWG 4285192.
[29] *GAO Report*, *supra* note 10, at 24, 28.

64. Purdue sales representatives handed out OxyContin coupons and savings cards to Iowa health care providers for distribution to Iowa patients, giving Iowans up to 30 days' supply of a Schedule II controlled substance at free and substantially reduced cost. Purdue's early patient starter coupon program for OxyContin, utilized to provide patients with a free prescription, ran intermittently for four years between 1998 and 2001.[30] By its conclusion, at least 34,000 coupons for free OxyContin prescriptions had been used nationally.[31]

65. Another component of Purdue's marketing campaign was the development and dissemination of seemingly truthful scientific and educational booklets, guides, articles, studies, websites, and other materials that misrepresented the risks, benefits, and superiority of opioids to safely treat a wide variety of pain conditions, including chronic pain. Purdue wrote many of these materials itself, or paid others to write them for Purdue, without disclosing these facts. Purdue then distributed these materials as unbiased expert endorsements of OxyContin.

66. Purdue funded and directed or assisted numerous professional societies, pain advocacy groups, and associations ("Third Party Front Groups") to further develop and disseminate Purdue's false, deceptive, misleading, and omissive representations and unfair practices related to opioids, as fully described herein. Purdue's sales representatives distributed numerous Third Party Front Group publications that contained misleading and deceptive messages to Iowa prescribers.

67. The American Pain Foundation ("APF"), self-described as the nation's largest advocacy group for pain patients, was a crucial Third Party Front Group collaborator in Purdue's

[30] *Id.* at 23.
[31] *Id.*

marketing efforts. Purdue made substantial financial contributions to APF[32] and worked closely with the organization to develop and spread its pro-opioids message. Purdue sponsored numerous APF publications directed at consumers, including *Treatment Options: A Guide for People Living with Pain; Exit Wounds – A Survival Guide to Pain Management for Returning Veterans and Their Families;* and *Resource Guide for People with Pain.*

68. Another significant Third Party Front Group pro-opioid publication was *Responsible Opioid Prescribing* written by Dr. Scott Fishman, which advanced the notion of "pseudoaddiction." Purdue worked with Dr. Fishman in developing *Responsible Opioid Prescribing*'s content and Purdue donated at least $50,000 to the Federation of State Medical Boards ("FSMB"), an association of medicals boards, to publish the book and an additional $100,000 for its distribution.

69. Purdue played a key role in developing continuing medical education ("CME") programs. From 1996, when OxyContin was unleashed on the market, through the first half of 2002, Purdue funded over 20,000 pain-related "educational programs" for health care providers through direct sponsorship or financial grants, further erasing the line between unbiased medical education and pharmaceutical marketing.[33] Such funding often allowed Purdue to contribute to or control the content of health care practitioners' continuing education content.

70. Purdue recruited and/or aligned with physicians called "Key Opinion Leaders" ("KOLS"), and paid for their studies, research, writing, travel, and expenses, all designed to develop,

[32] For example, in 2010 APF reported contributions of between $100,000 - $499,000 from Purdue. *See* American Pain Foundation 2010 Annual Report, https://www.documentcloud.org/documents/277604-apf-2010-annual-report.html.
[33] *See GAO Report, supra* note 10, at 23.

disseminate and deliver inaccurate and misleading pro-opioid and pro-OxyContin studies, speeches, presentations, videos, CME programs, books, guides, promotional materials, peer meetings, and other efforts promoting the message that opioid therapy was safe to treat chronic, non-cancer pain.

71. The goal of these efforts by Purdue was to further disseminate its false, misleading, deceptive, and omissive representations and unfair practices related to opioids, particularly that OxyContin could be safely used to treat chronic pain and a host of medical conditions, and that the benefits of such use outweighed the risks. Purdue:

    a. trivialized, understated or failed to disclose OxyContin's serious risks and adverse outcomes, including the risks of tolerance, addiction, overdose, and death;

    b. overstated and/or misrepresented the claimed benefits of opioid therapy, including chronic opioid therapy, including but not limited to improvements in patient quality of life and functionality;

    c. failed to disclose the lack of scientific research supporting long-term use of OxyContin;

    d. overstated and/or misrepresented the risk of physical dependence on OxyContin and the difficulty of withdrawal from OxyContin;

    e. understated or misstated the likelihood of withdrawal symptoms when ending OxyContin usage;

    f. overstated or misstated the superiority of opioids and OxyContin over non-opioid treatments such as combination opioid products, NSAIDS, physical therapy or other non-opioid pain relief modalities;

g. marketed OxyContin as the opioid to start with on step 2 of the WHO analgesic ladder when other non-opioids or less strong opioid combination products were appropriate starting therapies on step 2 of the WHO ladder; and

h. failed to disclose the lack of scientific research supporting the claim that OxyContin had little or no risk of addiction.

72. In May 2007, The Purdue Frederick Company and three of its top executives pled guilty to felony and misdemeanor criminal charges of "misbranding"[34] OxyContin in violation of federal law in the United States District Court for the Western District of Virginia and paid a combined $634 million in fines, described further below.

73. At the same time, Purdue entered into a civil Consent Judgment with 26 States and the District of Columbia concerning its marketing and promotion of OxyContin and alleged violations of state consumer fraud laws. Under that Consent Judgment, Purdue paid $19.5 million and agreed to certain injunctive relief regarding its future marketing, promotion and sale of OxyContin. The State of Iowa was not a party to that multistate settlement agreement.

D. The Opioid Crisis in Iowa

74. Opioids are the single leading cause of accidental death in the United States. In 2017, 67.8% of the 70,237 drug overdose deaths in this country involved prescription opioids.[35]

[34] "Misbranding" of a drug generally means that a drug's labeling representations are false and misleading. The federal Food, Drug, and Cosmetic Act ("FDCA") defines "labeling" broadly to include all "labels and other written, printed, or graphic matter…." 21 U.S.C. § 321(m). Labeling includes such things as brochures, booklets, mailing pieces, letters, films, sales representatives' detailing pieces and similar printed, audio or visual matter disseminated by the manufacturer which is descriptive of a drug and designed for and used in the distribution and sale of the drug. 21 C.F.R. § 201 (l)(2). A drug is "misbranded" if its labeling is false or misleading in any particular, and federal law prohibits the delivery of misbranded drugs into interstate commerce. 21. U.S. C. § 331(a).

[35] Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G, *Drug and Opioid-Involved Overdose Deaths – United States, 2013-2017*, 67 Morbidity and Mortality Weekly Report 1419, January 4, 2019.

75. Like the rest of the nation, the State of Iowa has experienced an opioid epidemic stemming from the use and abuse of prescription opioids over the past two decades.

76. Rates of opioid prescribing have increased significantly in the State. In 2006, Iowa had 59.3 opioid prescriptions per 100 persons and by 2012, the rate had grown to 74.1 prescriptions per 100 people.[36] According to a report by the Injury Prevention Research Center at the University of Iowa based on claims from a large medical insurance database, between 2003-2014 an average of 77,653 Iowa residents per year were prescribed an opioid pain reliever.[37] One quarter of first opioid prescription fills in this group had a daily dose of more than 50 morphine milligram equivalents ("MME").[38] The CDC defines a "high" opioid dosage to be at least 50 MME and at this level, the risk for an opioid overdose doubles.[39]

77. The effect of this sea change in the saturation of Iowa in opioids has been dire. Prescription opioid deaths in Iowa have quadrupled in the past twenty years, making it one of only four states to see such a large increase.[40] Opioid pain relievers, such as oxycodone and hydrocodone, contributed to sixty percent of the drug overdose deaths in Iowa in 2017.[41] In 2017 there were 206 opioid-related deaths (including deaths attributed to heroin) in the State, compared with 67 such deaths in 2005.[42] During the period between 2002 and 2014, there were a total of 1,239 overdose deaths due to prescription opioids in Iowa. [43]

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[36] https://www.cdc.gov/drugoverdose/maps/rxstate2006.html (Last accessed March 13, 2019).
[37] *The Prescription Opioids Crisis: Policy and Program Recommendations to Reduce Opioid Overdose and Deaths in Iowa*, University of Iowa Injury Prevention Research Center, August 1, 2017, at 5.
[38] *Id.*
[39] *Id.*
[40] *Id.* at 4.
[41] *Iowa Substance Abuse Brief Issue 7*, Iowa Department of Public Health, December 2018 https://idph.iowa.gov/Portals/1/userfiles/133/IASubAbuseBriefNewsletterDec2018_Final.pdf (Last accessed May 13, 2019).
[42] *Iowa's Opioid Crisis- An Update*, Iowa Department of Public Health, January 2019, at 6.
[43] *The Prescription Opioids Crisis, supra* note 37, at 5.

78. People who abuse prescription opioids often turn to heroin, and Iowa has seen a rise in heroin use in recent years. The Iowa Department of Public Health reports that between 2014 to 2017 deaths due to heroin use in Iowa increased more than 700%, from 8 to 64 deaths annually.[44] Another source indicates that in between 2002 -2015, heroin overdose deaths increased in Iowa more than nine-fold, a rate two to three times the national average.[45]

79. In addition to deaths, the State has seen a substantial increase in both emergency and long-term care for people with opioid overdose and opioid use disorder. In the last several years, Iowa emergency medical services providers reported substantial increases in administration of naloxone, the opioid overdose antidote. Substance use treatment admissions for Iowans with opioid use disorder increased from 653 in 2005 to 2,506 in 2015.[46]

80. Neonatal abstinence syndrome, which is a group of symptoms that occur in infants exposed to opiates in the womb, has increased in Iowa from 0.3 cases per 1,000 births in 1999 to 2.2 cases per 1,000 births in 2013, a more than seven-fold increase.[47]

V. Purdue's False, Deceptive, Misleading, and Omissive Conduct and Unfair Practices in the Advertising and Sale of OxyContin in Iowa

A. Purdue's 2007 Criminal Agreement Statement of Facts

81. As part of the 2007 federal criminal plea agreements referenced above, The Purdue Frederick Company Inc., Michael Friedman, Purdue's President and Chief Operating Officer, Howard Udell, Purdue's General Counsel, Chief Legal Officer and Executive Vice

[44] *Iowa Substance Abuse Brief*, *supra* note 41.
[45] *The Prescription Opioids Crisis*, *supra* note 37, at 5.
[46] *Iowa's Opioid Crisis*, *supra* note 42, at 7.
[47] Https://www.drugabuse.gov/opioid-summaries-by-state/iowa-opioid-summary (Last accessed May 1, 2019).

President, and Dr. Goldenheim, Purdue's former Chief Scientific Officer and Executive Vice President of Worldwide Research and Development, admitted that Purdue, *with the intent to defraud or mislead*, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:

a. Told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers;

b. Told health care providers that OxyContin potentially created less chance for addiction than immediate-release opioids;

c. Sponsored training that taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in OxyContin having less euphoria and less potential for abuse than short-acting opioids;

d. Told health care providers that patients could stop OxyContin therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

e. Told health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse.

82. Purdue used graphical depictions which misrepresented clinical data regarding blood plasma levels, falsely claiming that OxyContin had significantly fewer "peak and trough"

blood level effects than immediate-release opioids, resulting in less euphoria and less potential for abuse than short-acting opioids.

83. Purdue's sales representatives were permitted to draw their own blood level graphs which falsely represented that OxyContin, unlike immediate-release or short-acting opioids, did not swing up and down between euphoria and pain, and resulted in less abuse potential.

84. Beginning in at least 1999, Purdue sales representatives used graphical depictions similar to the one described above and falsely stated to some health care providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids.

85. In or about May 1997, Purdue supervisors stated that while they were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything "to make physicians think that oxycodone was stronger or equal to morphine" or to "take any steps in the form of promotional materials, symposia, clinicals, publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians [*sic*] mind."

86. Additionally, on or about January 16, 1997, certain Purdue supervisors and employees sent to the FDA the results of a clinical study pertaining to the use of low doses of OxyContin by osteoarthritis patients ("Osteoarthritis Study"), and a final study report that stated that "[n]o investigator reported 'withdrawal syndrome' as an adverse experience during the respite periods." In a section titled "Adverse Experiences by Body System During Respite Periods," the report's summary of the major results listed the most frequently reported adverse experiences in respite periods to be nervousness, insomnia, nausea, pain, anxiety, depression, and diarrhea.

87. On or about February 12, 1999, Purdue was provided with an analysis of the Osteoarthritis Study together with another clinical study ("Study Analysis"). The Study Analysis disclosed that patients did, in fact, experience physical dependence and withdrawal symptoms during the Osteoarthritis Study, and recommended to Purdue that it report the incidents of withdrawal. The Study Analysis' conclusion included the statement: "*As expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided*."

88. Purdue supervisors and employees participated in the drafting of a medical journal article regarding the Osteoarthritis Study that was published in a medical journal on or about March 27, 2000 ("Osteoarthritis Study Medical Journal Article"). The "Results" section of the Osteoarthritis Study Medical Journal Article deceptively failed to disclose the true results of the Osteoarthritis Study and failed to accurately report the incidents of withdrawal symptoms.

89. The Osteoarthritis Study Medical Journal Article also included a "Comment" section. The statement regarding withdrawal in this section largely summarized the information in the three statements in the "Results" section and further suggested that patients taking low doses could have their OxyContin treatment abruptly discontinued without experiencing withdrawal "if their condition so warranted."

90. On or about May 18, 2000, after millions of OxyContin tablets had been taken by patients for several years, Purdue's Medical Services Department reported to certain Purdue supervisors and employees that it had recently received a report of a patient who said he or she was unable to stop taking OxyContin 10 mg every 12 hours without experiencing withdrawal symptoms, and the report indicated that "this type of question, patients not

being able to stop taking OxyContin without withdrawal symptoms has come up quite a bit here in Medical Services lately (at least 3 calls in the last 2 days)."[48]

91. On or about June 26, 2000, certain Purdue supervisors and employees sent the full text of the Osteoarthritis Study Medical Journal Article together with a "MARKETING TIP" to Purdue's entire sales force. The MARKETING TIP falsely stated that: "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking [controlled-release] oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that [controlled-release] oxycodone at doses below 60 mg/d can be discontinued without tapering the dose if the patient's condition so warrants."

92. On or about February 13, 2001, certain Purdue supervisors and employees received a review of the accuracy of the withdrawal data in the Osteoarthritis Study that stated: "Upon a review of all comments for all enrolled patients, it was noted that multiple [patients] had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms."

93. Purdue distributed copies of the reprint of the deceptive Osteoarthritis Study Medical Journal Article to all Purdue sales representatives for use in the promotion and marketing of OxyContin to health care providers, including the distribution of 10,615 copies to certain Purdue sales representatives. Purdue continued to use the reprint in Iowa through at least 2006.

[48] While the statement regarding Purdue's knowledge as of May 2000 about withdrawal symptoms after patients stopped taking OxyContin was set forth in the 2007 plea documents, Purdue knew much earlier that patients suffered withdrawal symptoms upon ceasing use of OxyContin.

B. Purdue's Unfair and Deceptive Acts and Practices

94. Purdue engaged in the fraudulent and deceptive conduct in Iowa to which it pled in guilty in the years preceding its 2007 plea agreement. Despite the judicial admissions in the 2007 agreement, Purdue continued to make false, misleading, deceptive, and omissive claims and engaged in unfair practices related to the advertising, marketing, promotion and sale of OxyContin in Iowa after the guilty plea.

1. Risk of Addiction

95. Purdue trained its sales representatives to make, and the representatives made false, unfair, misleading, and deceptive statements that understated the risk of addiction from OxyContin, including, as examples, the following:

a. Addiction to opioids, including OxyContin, was "very rare" or "rare" and had been exaggerated, and that OxyContin patients need not fear becoming addicted;

b. OxyContin specifically had a lower risk of abuse than other opioids, and that street drug users and criminals - rather than legitimate pain patients -were responsible for opioid abuse and diversion;

c. OxyContin was less likely to be habit-forming;

d. OxyContin was safe for everyday pain conditions such as headaches, back pain, arthritic pain and osteoarthritis, dentistry pain, and chronic pain; and

e. The biggest side effect of OxyContin was constipation, rather than respiratory depression or death.

96. In a 1996 sales representatives training magazine titled *TeamLink*, which Purdue encouraged all of its sales staff to utilize, Purdue featured a Connecticut sales

representative who described OxyContin as a "drug with reduced abuse liability in the non-cancer setting." She advised other Purdue sales representatives that:

> [W]hen it comes up I talk about the reduced abuse liability with OxyContin. If it's a physician that's leery of substance abuse I talk about OxyContin as their first opioid…the patient will not get what I call the extra analgesic benefits that are associated with drugs like Percocet -- the euphoria, the buzz, and the high.[49]

97. As one component of its selling strategy, Purdue provided its sales representatives with a series of promotional letters to send to OxyContin prescribers. A 1998 promotional letter on the subject of addiction stated that "[t]he risk of addiction to opioids in clinical care has been greatly exaggerated" and "very few patients taking opioids for pain fit" the definition of addiction. Further, the promotional letter stated that "a survey of more than 11,000 opioid-using patients, taken over several years, found that less than 1% (4 cases) of these patients had documented cases of addiction."[50] This survey statistic was based on a 1980 letter to the editor in the New England Journal of Medicine by Jane Porter and Hershel Jick, M.D. ("Porter-Jick letter"). Purdue cited, and had its KOLs and Third Party Front Groups cite, the Porter-Jick letter in a myriad of publications and materials for the proposition that OxyContin was not addictive. However, the Porter-Jick letter does not describe a clinical or peer-reviewed study, but instead describes a retrospective review of certain hospital charts of patients who received opioids. The Porter-Jick letter does not describe the process by which the charts were reviewed and pertains only to hospitalized patients. It does not identify the name, strength or dosage of opioids given to the hospital patients, whether they were given low dose or weaker combination opioid products (e.g. combined with non-opioids such as acetaminophen), the duration of time the opioids were

[49] PWG 3803272; PWG 3803284; PWG 3803287.
[50] PWG 1165064.

given or on what schedule the opioids were given. Additionally the Porter-Jick letter could not represent the possible rate of addiction to OxyContin, as it was written 15 years prior to the launch of OxyContin.[51]

98. Purdue perpetuated the idea that patients being treated for pain were not at risk of becoming addicted to opioids in a 1998 publication directed at health care providers titled *Dispelling the Myths About Opioids*. The *Dispelling the Myths* booklet said it was a "myth" that "[o]pioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids." To counter this "myth" it stated "[f]ears about psychological dependence are exaggerated when treating appropriate pain patients with opioids….Addiction risk also appears to be low when opioids are dosed properly for chronic, non-cancer pain," again citing the Porter-Jick letter.[52]

99. In 1998 Purdue developed a deceptive OxyContin marketing video titled *I Got My Life Back* and distributed it to thousands of prescribers, including in Iowa. *I Got My Life Back* featured physician Dr. Alan Spanos repeating the baseless claim that opioids cause addiction in less than one percent of patients, a claim that the FDA has determined has never been substantiated.[53]

[51] In 2017, the New England Journal of Medicine added an editor's note to the Porter-Jick letter: "For reasons of public health, readers should be aware that this letter has been 'heavily and uncritically cited' as evidence that addiction is rare with opioid therapy." *See* https://www.nejm.org/doi/10.1056/NEJM198001103020221 (last visited August 27, 2019). In a June 2017 Washington Post article, Dr. Jick stated "I'm essentially mortified that that letter to the editor was used as an excuse to do what these drug companies did." Derek Hawkins, *How a short letter in a prestigious journal contributed to the opioid crisis*, Washington Post, June 2, 2017.

[52] PKY 180120984.

[53] *GAO Report, supra* note 10 at 25.

100. *I Got My Life Back* also featured seven patients taking OxyContin. Two of them were active opioid abusers when they died, and a third became addicted and quit using opioids once she realized she was headed for an overdose.[54]

101. *I Got My Life Back* was used to train the large Purdue sales force. It was shown to sales representatives at the 1998 National Sales Meeting[55] and was part of the "Developmental Action Plan" in Purdue's Standard Operating Procedures Manual used for sales representatives as early as September 2000.[56]

102. Iowa sales representatives showed and provided copies of *I Got My Life Back* to Iowa prescribers during sales calls.

103. In 1999 Purdue distributed a pamphlet and marketing video titled *From One Patient to Another*, based upon excerpts from *I Got My Life Back* but directed to consumers rather than prescribers.[57] *From One Patient to Another* (available in English and Spanish) repeated the false claim that less than 1% of patients taking opioids become addicted to them.[58]

104. Purdue directed its sales representatives to leave copies of *From One Patient to Another* in office waiting rooms, to lend copies to patient advocacy groups, to make copies available at public education events, and to show the video at pain clinics.[59]

105. In a 1999 training, sales representatives were taught that the OxyContin "Selling Message" included that "Addiction occurs very rarely in patients treated with opioids."[60]

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[54] John Fauber & Ellen Gabler, *What Happened to the Poster Children of OxyContin?* Milwaukee Wisc. Journal Sentinel (May 17, 2019).
[55] PKY 183293382.
[56] PKY 181740377.
[57] PKY 183293597.
[58] PDD 9520505176; PKY 9520505181; PDD 1701118803; PDD 170118807.
[59] PKY 183293597.
[60] PDD 8801315802; PDD 8801315808.

106. Purdue required sales representatives to use the company's written sales materials when calling upon prescribers, including materials that were for use only by the representatives and other materials intended to be left behind with health care providers. Purdue's 1999 "Core Visual Aid" was titled *Don't Complicate Pain Relief*. It implored prescribers to "Keep It Simple" by prescribing OxyContin and included as one of five messages that OxyContin had a "low incidence of addiction and tolerance," which Purdue could not substantiate.[61]

107. In early sales activity particularly, Iowa sales representatives de-emphasized the addictive nature of OxyContin. For example:

    a. In an October 1997 sales call, the Purdue representative described a prescriber who was "concerned that [a patient] is addictive [*sic*] because she need he [*sic*] pain meds." In response, the representative "explained that we know risk is less that [*sic*] 1% and we are atan [*sic*] advantage because we know our patients here in Iowa."[62]

    b. In a March 1999 sales call, an Iowa sales representative reported telling a prescriber that OxyContin "will help get patient's pain under control without risk of addiction or dependence."[63]

    c. In an April 1999 sales note, the Iowa sales representative described a detailing call in which a health care provider had "fired" one patient and who described another patient who "everyone belives [*sic*]…has an addiction problem," and said the

[61] PKY 183076133; PKY 183076141; PKY 183293573; PKY 18329574.
[62] PIA 6518, line 6702 (10/31/1997). All typographical errors in this call note and other cited throughout this First Amended Petition appear in the original text of the call note.
[63] PIA 6518, line 13589 (3/17/1999).

prescriber would now "talk to her about changing to Oxy so she doesn't have to worry about RN schedules or having the med wear off."[64]

d. In a note from an August 2000 sales call, the sales representative wrote: "Have a chance to speak with the Dr. talk to him about pain. I basically just pleaded with him, and told him that pain management is so bad, and the JCAHO is coming down hard on managing pain, and that drug addiction is so rare."[65]

e. In a February 2001 call, an Iowa sales representative stated that a prescriber she called upon "[s]ometimes has to sell his pats that opioids are 'not addictive.'"[66]

f. One sales representative described a visit to prescriber's office where a nurse commented that OxyContin "must be very addictive." The salesperson noted, "I corrected her on that!!"[67]

g. In an August 2001 detailing visit, the representative reported an interaction with an Iowa physician and staff "Dr. and especially Jane wanted to know what the difference was between oxycodone and hydrocodone and their addiction. I commented that addiction first of all is very rare when treating patients in pain."[68]

h. In a 2007 call where an Iowa health care provider said he was concerned about the "higher rate of abuse with oxycontin and patients like to snort it." The sales representative countered that "Vicodin was the number one abused drug in the US."[69]

[64] PIA 6518, line 14052 (4/26/1999).
[65] PIA 6518, line 22613 (8/29/2000).
[66] PIA 6518, line 25539 (2/9/2001).
[67] PIA 6518, line 27736 (5/4/2001).
[68] PIA 6518, line 31174 (8/30/2001).
[69] PIA 2, line 5500 (4/27/2007).

108. Beginning in 2007, Purdue developed and distributed to Iowa prescribers a booklet for health care providers called *Providing Relief, Preventing Abuse – A reference guide to controlled substance prescribing practices ("Providing Relief")*, that made misleading claims that patients are responsible for opioid addiction. The First Edition of *Providing Relief* stated that addiction "is triggered in a susceptible individual by exposure to drugs, most commonly through abuse" and "is not caused by drugs."

109. *Providing Relief* showed photos of skin popping, track marks, constricted pupils, and a perforated nasal septum as "Indications of Possible Abuse." These images misleadingly implied that OxyContin abuse usually took these extreme forms, although it is common for people addicted to OxyContin simply to swallow more tablets.

110. Purdue's patient-focused website, *In the Face of Pain*, stated that policies limiting access to opioids are "at odds with best medical practices," and encouraged patients to be "persistent" in finding doctors to treat their pain. The *In the Face of Pain* site had over 3,900 visits from Iowa users from 2010 through October 2015.[70]

111. Purdue published and distributed the *Resource Guide for People with Pain* directly to consumers, including on the *In the Face of Pain* website. The *Resource Guide* misleadingly understated the risk of opioid addiction when used as directed by a prescriber, stating, "Many people living with pain and even some healthcare providers believe that opioid medications are addictive. The truth is that when properly prescribed by a healthcare professional and taken as directed, these medications give relief – not a 'high.'"

112. Purdue perpetuated the misleading and deceptive idea that patients would not become addicted to opioids if they used them as prescribed by a health care provider. A 2009

[70] PWG 4285191.

Purdue-sponsored CME program for physicians titled *Opioid Prescribing: Clinical Tools and Risk Management Strategies* stated:

a. "Addiction is rare in patients who become physiologically dependent on opioids while using them for pain control," and;

b. "Behaviors that suggest abuse may only reflect a patient's attempt to feel normal."

113. The Federation of State Medical Boards' (FSMB) *Responsible Opioid Prescribing*, funded by Purdue, made misleading and deceptive claims that addiction was unlikely to occur with opioid use, such as: "A small minority of people seeking treatment may not be reliable or trustworthy, i.e. not suitable candidates for Schedule II controlled substances." It further described "Behaviors LESS indicative of addiction" to include hoarding medications, taking some else's pain medications and using more opioids than recommended.

114. According to FSMB and the Iowa Board of Medicine, over 3,000 copies of *Responsible Opioid Prescribing* were distributed in Iowa between 2007 and 2015.

115. Purdue sponsored and disseminated APF's *Treatment Options: A Guide for People Living with Pain*, which understated the risk of addiction from opioid use and implied the risk of addiction was low or unfounded. It stated:

a. "Despite the great benefits of opioids, they are often under-used;"

b. Concerns about addiction "lead to confusion and hesitation on the part of some providers to prescribe these for pain control;" and

c. People with the "disease of addiction may abuse their medications," but deceptively failed to disclose that patients with prescriptions can become addicted when using opioid medication as medically directed.

2. "Pseudoaddiction"

116. Purdue and its sales representatives made deceptive and misleading statements that patients' symptoms appearing as addiction were really "pseudoaddiction" that required more opioid therapy, not less.[71]

117. Purdue's early prescriber-directed pamphlet, *Dispelling the Myths About Opioids*, described "pseudoaddiction" as:

> Drug-seeking behavior that seems similar to addiction, but is due to unrelieved pain. This behavior stops once that pain is relieved, often through an increase in opioid dose. "Misunderstanding of this phenomenon may lead the clinician to inappropriately stigmatize the patient with the label 'addict.' In the setting of unrelieved pain, the request for increases in drug dose requires careful assessment, renewed efforts to manage pain and avoidance of stigmatizing labels."[72]

118. Purdue's *Don't Complicate Pain Relief* visual aid, used by sales representatives in their detailing visits, contained a similar definition of "pseudoaddiction."[73]

119. Iowa sales representatives used the term "pseudoaddiction" in their sales visits to encourage health care providers to disregard addiction concerns and to encourage them to write more and higher dose opioid prescriptions. For example:

[71] The term "pseudoaddiction" was made up by Dr. J. David Haddox and Dr. David Weissman in 1989 based on their experience with a single cancer patient. *See* Pain, 3 Mar. 363. Haddox was a Purdue consultant in 1989 and later became Vice President of Health Policy at Purdue. The term "pseudoaddiction" was commonly used by Purdue, its paid speakers, and in its written materials, to promote opioid overuse and squelch health care providers' legitimate concerns about addiction.
[72] PKY 180120984.
[73] PKY 183076133; PKY 183076141.

a. In a September 2000 call, an Iowa sales representative wrote: "patient doing fine at low dose… how do you differentiate between psuedo and addicts? solution, use oxycon and dose adjust upward."[74]

b. In a December 2001 sales call, the Purdue sales representative described an Iowa prescriber concerned about a patient who "has a history of drug abuse and her family is concerned…she was stealing her husbands Lortab." The salesperson wrote that she responded by "Detail[ing] on the difference of pseudoaddiction and addiction."[75]

c. In a May 2002 call, an Iowa salesperson described a prescriber with "concerns about chronic opioid use – could lead to addictiohn [*sic*]." The Purdue representative responded with, "tried to separate addiction from phys depend…Disc[ussed] pseudoaddiction & told him not to confuse the two."[76]

120. In its 2005 booklet titled *Clinical Issues in Opioid Prescribing*, Purdue defines "pseudoaddiction" as a "Key Term in Pain Management." Although slightly altered, it contains much of the same information as in the *Dispelling the Myths About Opioids* definition. *Clinical Issues* states:

> [Pseudoaddiction is] a term used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.

[74] PIA 6518, line 22707 (9/6/2000).
[75] PIA 6518, line 34645 (12/12/201).
[76] PIA 6518, line 39392 (5/13/2002).

121. The First Edition of *Providing Relief* similarly states that 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 that would be common in the setting of abuse." It stated that persons with "unrelieved pain" may show behaviors such as being "focused on obtaining medications" or "clock-watch[ing]," but that pseudoaddiction "can be distinguished from addiction in that the behaviors resolve when pain is adequately treated."

122. The Second Edition of *Providing Relief* included the same misleading concept and definition of pseudoaddiction under the heading "Other Considerations."

123. *Clinical Issues* and both the First and Second Editions of *Providing Relief* encouraged prescribers to use the concept of pseudoaddiction to disregard signs of addiction in patients and to treat patients exhibiting indications of addiction as in need of more opioids. These publications failed to disclose the lack of clinical studies justifying the concept of pseudoaddiction or that it was made up by a Purdue Vice President.

124. The concept of "pseudoaddiction" appears in Third Party Front Groups' publications as well. *Responsible Opioid Prescribing* states:

> Patients who receive an inadequate dose of opioid medication often "seek" more pain medications to obtain pain relief. This is called pseudoaddiction because healthcare practitioners can mistake it for the drug-seeking behavior of addiction.

Responsible Opioid Prescribing also states that pseudoaddiction "resolves when the patient obtains adequate analgesia," and describes demanding or manipulative behavior, taking opioid drugs for an extended period, and obtaining opioid drugs from more than one physician as some of the signs of "pseudoaddiction."

125. In 2012, Purdue KOL Dr. Lynn Webster admitted that pseudoaddiction was a fundamentally flawed concept, stating that it "obviously became too much of an excuse to give patients too much medication....It is something we are debunking as a concept."[77] An 2015 independent review of medical literature mentioning pseudoaddiction concluded that "no empirical evidence yet exists to justify a clinical 'diagnosis' of pseudoaddiction."[78]

126. The concept of "pseudoaddiction" was pure Purdue propaganda. There is no empirical evidence or validation which supports it as a clinical diagnosis. It is not a recognized diagnosis in the International Statistical Classification of Diseases and Related Health Problems. It was deceptively used by Purdue to sell more OxyContin and advance the notion that the undertreatment of pain was a more authentic clinical problem than addiction to OxyContin.

3. Higher Doses of Opioids

127. Purdue deceptively told prescribers that giving patients higher doses of OxyContin is safe and necessary, without disclosing that the risks of addiction, overdose and other negative side effects substantially increases with higher opioid doses.

128. Purdue knew that OxyContin was "promotionally sensitive, specifically with higher doses," and that the company's research "reinforce[d] the value of sales calls."[79]

[77] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. Journal Sentinel (Feb. 19, 2012).
[78] M. Greene & R. A. Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, 2 Cur. Addict. Rep. 310, Oct. 1, 2015.
[79] PWG 432383.

129. Accordingly, Purdue trained its sales staff to encourage health care providers to increase doses of OxyContin by "titrating" to a higher dose of the drug. In a 2013 training, sales representatives were told to practice "verbalizing the titration message."[80]

130. Iowa sales representatives regularly touted the seven available strengths of OxyContin, pushed Iowa prescribers to "titrate up" and distributed marketing materials that encouraged increased dosages. For example:

    a. In a 2001 sales call, detailing notes show the Iowa Purdue salesperson told a prescriber "Keep them aware they may need to go higher."[81]

    b. In a June 2008 sales call, a sales representative's manager encouraged her to ask an Iowa prescriber "how he titrates and what triggers him to move to a large dose…."[82]

    c. Another manager encouraged the Iowa sales representative to "discuss when she will titrate – what does he need to see from pt to do so?" in a 2009 sales call.[83]

131. Purdue's *Clinical Issues in Opioid Prescribing* perpetuated the misleading and deceptive claim that opioids have no upper dose limit, without disclosing the risk of overdose and death that comes with higher doses. *Clinical Issues* stated that "with 'pure' opioids there is no defined maximum dose; the ceiling to analgesic effectiveness is imposed only by side effects, the most serious of which is respiratory depression." It suggested adverse effects of opioids could actually *decrease* with higher doses, stating, "even if opioid doses need to be gradually increased in a patient, common adverse effects may often decrease."

4. Deceptive Comparisons of OxyContin to Other Pain Treatments

[80] PWG 197629.
[81] PIA 6518, line 25539 (10/9/2001).
[82] PIA 002, line 510 (6/9/2008).
[83] PIA 002, line 736 (2/12/2009).

132. The FDA medical officer who reviewed Purdue's New Drug Application for OxyContin (and who then left the FDA and worked for Purdue) concluded that OxyContin's efficacy was equivalent to immediate-release oxycodone, with a similar adverse event profile. Accordingly, the FDA would not allow Purdue to make any claim that OxyContin was better than immediate-release oxycodone in its efficacy or adverse events.

133. Purdue's later internal training documents repeatedly acknowledge that, regardless of the FDA's prohibition on comparative claims, Purdue did not have the data necessary to make comparative claims about OxyContin. For example, in a 2011 sales representative training document, Purdue admitted:

> Statements cannot represent or suggest that a drug is safer/more effective (or make any other sort of comparative claim) unless there is substantial evidence/clinical trials supporting the statement.
>
> **We have no drugs that satisfy this standard**. (Emphasis in original).[84]

134. Despite Purdue's knowledge that it was prohibited from claiming that OxyContin is safer or more effective than other drugs since 1995, Purdue and its sales representatives in Iowa made deceptive comparisons between OxyContin and other pain treatments, including but not limited to non-opioids like NSAIDs (ibuprofen) and acetaminophen (Tylenol). These comparisons misleadingly stated or implied that OxyContin was superior because it was safer, more effective or equally effective and/or otherwise superior to non-opioid pain relievers, although Purdue knew it lacked medical evidence to support these claims. Purdue misleadingly emphasized the "toxicity" of non-opioid pain relievers, while failing to disclose the significant risks associated with opioid use.

[84] PWG 190160.

135. Purdue sales representatives also made false, deceptive, misleading and omissive representations that OxyContin was superior to immediate-release combination opioid products, such as Vicodin or Percocet, because the latter contain acetaminophen, although Purdue lacked substantial medical evidence to substantiate these comparative claims. Sales representatives regularly told Iowa health care providers that OxyContin was superior to immediate-release combination opioid products because it was more convenient, did not pose a risk of liver toxicity, and was less prone to abuse and addiction.

136. Iowa sales representatives regularly encouraged prescribers to use OxyContin in place of immediate-release opioids. For example:

    a. In an October 1999 visit an Iowa sales representative was encouraged to have a prescriber "think of Oxy instead of Vico even for short term pts."[85]

    b. A May 2006 call note described an Iowa sales representative's exchange with the prescriber: "He then had brought up the short-acting agents and I asked him when would he consider switching a patient to Oxycontin. he said when a patient is taking 5-6 a day. I told him that with Oxycontin you don't have the tylenol toxicity to worry about. The worst side effect is constipation…."[86]

    c. Another Iowa May 2006 note describing a sales call states: "Used sales aid to show advantage of moving those patients when they are taking 4-6 vicodin a day. Reminded of toxicity issues with combination products."[87]

[85] PIA 6518, line 6867 (10/14/1999).
[86] PIA 2, line 1229 (5/17/2006).
[87] PIA 2, line 1065 (5/2/2006).

d. A March 2007 Iowa call note states: "I then went on to let him know the benefits of oxycontin, such as the q12 hour dosing and the fact that there is no acetemetphen [*sic*] toxicity."[88]

e. In a May 2007 sales call, the representative asked the prescriber if she was aware of "patients that are on Vicodin that are still having around the clock pain, the benefits of oxycontin being less pills, no APAP, and a better nights sleep, and that 8 Vicodin is equal to 20mg q12 hours of oxycontin."[89]

f. Finally, after a December 2012 sales visit, a Purdue manager pushed the Iowa sales person to focus on positioning OxyContin as superior to immediate-release opioids products, writing, "would you agree your next call objective would [be] to continue breaking down the [short-acting] opioid to gain commitment?"[90]

137. Purdue's misleading comparisons between opioids and non-opioid pain treatments were reiterated in APF's *Treatment Options*, which stated that opioids had "no ceiling dose as there is with NSAIDs," and emphasized that NSAIDs posed "serious" and "life-threatening" side effects. By contrast, *Treatment Options* understated the side effects from opioids, describing them as "constipation, nausea and vomiting, sedation (sleepiness), mental clouding and itching," and emphasized that addiction was unlikely.

5. Longer Doses of Opioids

138. Purdue made statements, and trained its sales representatives to state, that OxyContin is appropriate for extended periods of time in treating chronic pain, while deceptively failing to disclose the lack of scientific evidence that long-term opioid use is effective in treating

[88] PIA 2, line 5103 (3/27/2007).
[89] PIA 2, line 5566 (5/2/2007).
[90] PIA 2, line 47162 (12/19/2012).

chronic pain, or that the longer a patient is using opioids, the higher the risk of addiction, overdose, and opioid-induced hyperalgesia. Purdue sales representatives used and distributed marketing materials that implied opioid use could continue unabated and without risk for months or years, without disclosing the lack of evidence supporting such long-term use.

139. Coupons (also known as "savings cards" or "value cards") were a key component of Purdue's marketing strategy to encourage long-term use of OxyContin. Purdue knew that patients using savings cards were more likely to stay on OxyContin for longer periods of time and become more dependent on it. In 2011 the company's internal data showed that providing consumers with coupons that covered part of their out-of-pocket cost for an opioid prescription encouraged patients to stay on opioids longer: 60% more patients remained on OxyContin after 90 days when a savings card was redeemed.[91] Purdue focused on increasing utilization of the patient savings program as one of three 2012 "strategic initiatives." In 2013, Purdue planned to increase the maximum patient assistance from $70 to $90 per prescription to increase sales growth by $19.7 million, increase net sales growth by $5.7 million, and to yield 32,000 new prescriptions.[92]

140. Purdue distributed OxyContin coupons to Iowa health care providers for distribution to patients and made the cards available on their website. Purdue sales representatives distributed savings cards to hundreds of Iowa prescribers and between 2006-2016, over 10,000 OxyContin savings cards were used by Iowa consumers.[93] The savings cards allowed patients to obtain OxyContin, a Schedule II drug with a high potential for abuse

[91] PPLPC 12000382119.
[92] PWG 163700.
[93] PIA 5657.

and which can cause severe psychological or physical dependence, for free or at a discounted price for periods ranging from 30 days to up to a year, during which time patients were susceptible to becoming dependent upon or addicted to it.

141. Purdue sales representatives encouraged Iowa prescribers to give out the savings cards to patients. Representatives encouraged prescribers to hand out savings cards even to consumers using generic products, presumably in an effort to drive those patients to eventually become consumers of the OxyContin brand. Iowa call notes show:

    a. In a January 2007 call, the sales representative described her call on an Iowa doctor as follows: "Briefly talked to him … about the savings cards and reminded him of the value they are to patients…asked him to start giving the savings cards out to the patients that are on the generic because they will eventually be able to use them."[94]

    b. In another January 2007 sales call record, the Iowa sales representative said: "Talked to her about the savings cards and reminded her that she had them…I told her even to begin giving them to her patients even if they are on a generic because they will eventually benefit from it."[95]

6. Twelve Hours of Relief

142. Purdue made misleading and deceptive statements that OxyContin provided a full twelve hours of pain relief with no "peaks and valleys," and that this long-lasting effect resulted in improved pain control, more convenience for patients, and less euphoria.

143. Twelve-hour dosing was a significant market advantage for Purdue. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued FDA approval to allow more frequent

[94] PIA 6519 line 18317 (1/4/2007).
[95] PIA 6519 line 18319 (1/4/2007).

dosing because the twelve-hour dosing "represents a significant competitive advantage of OxyContin over other products."[96]

144. In fact, Purdue knew that substantial numbers of OxyContin patients would experience "end-of-dose" failure with little or no pain relief during the last hours of the twelve-hour period.[97]

145. Purdue also knew that health care providers, including in Iowa, were prescribing OxyContin in eight-hour intervals (i.e., three doses per day) due to OxyContin's failure to provide a full twelve hours of relief. As early as May 1996 - just months after OxyContin's premiere - one Iowa prescriber told a Purdue sale representative that OxyContin only lasts for 9-10 hours when treating chronic back pain patients.[98]

146. Rather than admitting OxyContin failed to provide twelve hours of sustained pain relief, Iowa sales representatives encouraged health care providers to prescribe higher doses of the drug, without disclosing that higher doses of OxyContin pose greater risks for patients. For example:

a. In response to an Iowa physician's question about prescribing OxyContin every 8 hours, the Purdue sales representative advised that the doctor could "titrate if [OxyContin was] not lasting a full 12h."[99]

b. In August 2007, an Iowa prescriber "asked about q8 dosing as an option" and the Purdue sales representative, "[e]ncouraged her to increase dosing strength…."[100]

[96] April 14, 2004 Comments on Citizen Petition, Docket 2004P-0043, at 12-13.
[97] 2008 FDA Response to Citizen Petition by Connecticut Attorney General.
[98] PIA 6518, line 2428 (5/10/1996).
[99] PIA 6519, line 14832 (3/15/2006).
[100] PIA 2, line 6955 (8/30/2007).

c. In a December 2010 sales call, a prescriber told the sales representative about a patient who said they "need another dose of oxycontin after 6-8 hours."[101]

d. In a sales call in April 2012 with an Iowa doctor, a sales representative described a detailing visit: "OxyContin- discussed dosing and he said he tries to keep patients on q12h dosing but has gone to q8. Encouraged q12h and the possibility of increasing the dose for better coverage."[102]

147. Purdue's misrepresentations about twelve-hour dosing are particularly dangerous. Patients who experience end-of-dose failure suffer the symptoms of opioid withdrawal -such as intense flu symptoms, vomiting, body aches, nausea, and anxiety - relieved only by taking their next dose. This pattern often results in patients taking their next dose early, leading them into the cycle of addiction and abuse.

7. Quality of Life

148. For years Purdue made false, deceptive, misleading, and omissive statements that OxyContin was superior to other pain treatments because it provided better quality of life, sleep, and function, although Purdue knew it lacked the scientific evidence necessary to support such a claim.

149. Iowa sales representatives made false, deceptive, misleading and omissive representations to Iowa health care providers that long-term use of OxyContin would improve not only their patients' pain, but their quality of life, sleep, and function. For example:

a. In a June 2006 sales call, an Iowa sales representative reported: "Had a great discussion with [an Iowa physician] about OxyContin not only improving the patients pain, but their quality of life….I led into just like those patients with OA

[101] PIA 2, line 25208 (12/15/2010).
[102] PIA 2, line 39171 (4/6/2012).

and RA whose quality of life could be improved with just 10-20 mg q12 hours of OxyContin.[103]

b. The same sales representative described the following interaction with an Iowa doctor later that month: "I had a great conversation with him about Oxycontin and where he uses it in his practice….I told him that I know that he has patients in his practice with OA that he knows and trusts that could benefit from 10-20mg q12 hours of Oxycontin per PI and that it would improve their quality of life- mood, sleep and pain."[104]

c. In a July 2006 call, an Iowa sales representative "[t]old [the prescriber] I was here to talk to him about OxyContin and he asked me why I didn't sell one of the easier to sell drugs….I told him because I like the challenge of selling this drug…I told him that it wasn't all about just pain, that it was alos [*sic*] about quality of life. I told him that I was going to continue to work on him.[105]

d. In reviewing a March 2013 call, a Purdue manager coached the sales representative in a future call to: "Ask dr if he is able to suggest to his pts, is there something you've been able to do prior to the pain that you would like to do again? It's a quality of life measurement for the pt rather than number of pills taken daily."[106]

149. APF's *Treatment Options* repeated theses false and misleading claims that opioid use would improve a patient's quality of life, stating that when used properly opioids "give [patients] a quality of life we deserve."

[103] PIA 2, line 1556 (6/15/2006).
[104] PIA 2, line 1620 (6/22/2006).
[105] PIA 2, line 1932 (7/26/2006).
[106] PIA 2, line 48747 (3/21/2013).

150. After years of promoting OxyContin as improving patients' quality of life, Purdue's internal training documents admit that Purdue does not have the data necessary to make claims about quality of life in promoting OxyContin. In a 2012 Guidelines on Product Promotion, Purdue admitted:

> You cannot make a quality of life claim unless supported by substantial evidence.
>
> - We have no drugs that meet this standard.

Purdue also stated "You cannot ask a question of the [health care provider] that causes him/her to make a quality of life conclusion about a Purdue product.[107]

8. Vulnerable Populations: Older Patients and Veterans

151. Purdue targeted OxyContin marketing at older patients, those in nursing homes, and those suffering from osteoarthritis and rheumatoid arthritis, even though opioid use poses heightened risks for such patients, such as respiratory depression, falls, and fractures. Due to these increased risks associated with treating elderly patients with controlled substances, the FDA recommends starting elderly patients at lower opioid doses.

152. In addition to targeting older patients through prescribers, Purdue reached the elderly directly with targeted advertising and promotional materials aimed at senior citizens, even going so far as to hand out compact discs to patients containing swing music from the 1930s and 1940s ("Get into the Swing with OxyContin!").[108]

153. Purdue sales representatives specifically asked Iowa health care providers to use OxyContin in older patients without disclosing that those patients are at higher risk, and told providers that elderly patients were better because their risk for misuse and addiction

[107] PVT 58330.
[108] PDD 9520506456; PDD 952056457.

was lower. For example, in a 2006 call, an Iowa sales representative reported "Dr. came into display…said he just doesn't have the population to write much LA opiods [*sic*]…Asked when he would use and he said he does have a few pts on LA opiods [*sic*] and they are OA or elderly back pts. Agreed that those were ideal pts because they are low risk/high benefit."[109]

154. Sales representatives emphasized to prescribers that OxyContin was covered by Medicare, the government health insurance program for older adults and disabled people, and encouraged them to prescribe it for those patients, without disclosing OxyContin's risks for this population.

155. Purdue directed false, deceptive and misleading claims about opioid use at veterans, a population that is particularly vulnerable to the risks of opioid addiction, misuse, abuse and death.

156. For example, Purdue sponsored APF's *Exit Wounds*, a 2009 book focused on veterans, in which one chapter is based on *Treatment Options*. *Exit Wounds* repeated false, deceptive, misleading and misleading statements about the use of opioids for chronic pain, as follows:

a. Claims that NSAIDs "alone are not effective treatments for pain;"

b. Warns of the dangers of "undertreated pain;"

c. Holds up opioids as the "gold standard of pain medications" and "despite their great benefits, opioids are often underused;" and

d. Asserts that "[l]ong experience with opioids shows the people who are not predisposed to addiction are unlikely to become addicted to opioid pain

[109] PIA 2, line 4008 (1/3/2007).

medications. When used correctly, opioid pain medications *increase* a person's level of functioning."

157. *Exit Wounds* failed to warn about the dangers that opioids present or address the common and dangerous practice of combining opioids with benzodiazepines, known particularly to impact veterans.

9. "Abuse-Deterrent" OxyContin Formulation

158. In 2010 Purdue introduced a reformulated version of OxyContin and discontinued marketing its original formulation of the drug.[110] The reformulated OxyContin has "abuse deterrent properties" that are claimed to be more resistant to abuse from snorting or injecting the drug. However, the FDA found that the reformulation of OxyContin "will have no effect on abuse by the oral route (the most common mode of abuse) and that, "[w]hile reformulation is harder to crush or chew, possibility mitigating some accidental misuse, oxycodone HCI is still relatively easily extracted."[111]

159. Purdue made statements, and trained its sales representatives to state, that the reformulation of OxyContin released in 2010 was effective in reducing opioid abuse. Purdue failed to disclose that the most common method of opioid abuse is simply by swallowing more tablets, rather than injecting or snorting the drug. Iowa sales representatives touted the abuse-deterrent formulation in their detailing visits to Iowa prescribers.

10. Targeting High "Core" Prescribers

[110] Once Purdue received FDA approval for reformulated OxyContin, it submitted a Citizen's Petition to the FDA on July 13, 2012, arguing that if other pharmaceutical companies were permitted to manufacture a generic version of the earlier formulation of OxyContin, "abuse of extended release oxycodone could return to the levels experienced prior to the introduction of reformulated OxyContin."

[111] NDA 22-272, OxyContin, Division Director Summary Review for Regulatory Action dated 12/30/2009 at 7, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000SumR.pdf.

160. Purdue and its sales force targeted high opioid prescribers in Iowa, including physicians, nurse practitioners and other health care providers, known as "core" prescribers. Iowa sales representatives visited high prescribers multiple times per month. Many of those high prescribers were eventually subject to professional discipline by regulatory and licensing boards based on their reckless opioid prescribing practices.

161. Purdue also directed sales representatives to focus their sales calls on family health practitioners, who were most likely to treat patients with chronic pain but many of whom were without adequate training in pain management and addiction.

162. Dr. A. was one of the highest OxyContin prescribers in Iowa: between 2006 - 2016, he wrote over 2,200 prescriptions for OxyContin, the majority between 2010 and 2016.[112]

163. Purdue realized Dr. A. was a huge revenue source. Sales representatives detailed Dr. A. almost 300 times between 2010 and 2017, often 3, 4 or 5 times a month.[113] In 2012, a Purdue manager told the Iowa sales representatives assigned to Dr. A. to keep up the pace, saying, "Dr is one of your highest potential HCP's ….Frequency is key with this HCP."[114] When a new sales representative was assigned to detail Dr. A. in 2014, the manager reiterated "He is one of your top targets….Nice job getting him to think about the patient that is 65 years or older."[115]

164. In 2018, the Iowa Board of Medicine alleged that Dr. A. engaged in improper pain management in the treatment of multiple patients between 2011-2016 and cited him for failure to provide appropriate pain management. Dr. A. agreed not to prescribe, administer

[112] PIA 1, Tab 1, line 453.
[113] PIA 2.
[114] PIA 3, line 1072 (11/14/2012).
[115] PIA 3, line 1300 (4/1/2014).

or dispense controlled substances for the treatment of chronic pain, among other terms of his three-year probation, including compliance with a monitoring program and chart audits.

165. Dr. B. was another high OxyContin prescriber in Iowa. Between 2006-2016, Purdue sales representatives visited Dr. B. over 280 times.[116] Dr. B. wrote 1,500 OxyContin prescriptions during that period, making him one of the most prolific prescribers in the State.[117]

166. Purdue sales staff focused on getting their sales message to Dr. B regardless of his response. After reviewing a 2009 sales call by a sales representative, a supervisor advised, "Continue to work on refining the opening probes. You should be able to maneuver around any answer you get. Make sure to always be positioning…."[118]

167. Purdue management directed the Iowa sales staff to focus their sales calls on Doctor B. In January 2011, a Purdue manager told the sales representative that Dr. B. "…is someone you can follow up with weekly and maybe twice a week."[119] Iowa sales representatives followed that directive. Between 2011-2016, they made approximately 200 visits to Doctor B.'s office, often 3, 4 or even 5 times a month.[120] During those visits, the sales representatives distributed misleading materials, such as *Providing Relief, Preventing Abuse.*

168. Purdue's visits to Dr. B. stopped in early 2016, shortly before the Iowa Board of Medicine cited him for failure to provide appropriate pain management to multiple patients between 2010-2015. The Board prohibited Doctor B. from prescribing,

[116] PIA 2; PIA 4767.
[117] PIA 1, Tab 1, line 4215.
[118] PIA 3, line 260 (8/3/2009).
[119] PIA 2, line 20935 (1/24/2011).
[120] PIA 2; PIA 4767.

administering, or dispensing controlled substances for the treatment of chronic pain, ordered him to pay a $5,000 penalty and placed him on 5 years of probation, among other things. Only then did Purdue place Dr. B. on the "Region Zero" list of prescribers which it claimed it would not call.[121]

169. Iowa family medicine practitioner Dr. C. wrote 885 prescriptions for OxyContin between 2006-2016. During the period from 2010-2017 Purdue sales representatives visited Dr. C. over 95 times.[122]

170. In 2017, the Iowa Board of Medicine brought a Statement of Charges against Dr. C. alleging professional incompetency, inappropriate prescribing, improper pain management and unethical or unprofessional conduct. The Board charged Dr. C. with 30 separate bases for alleged violations of the law: that he indiscriminately or promiscuously prescribed controlled substances to numerous patients resulting in serious harm to patients and the public, including overdose deaths; that Dr. C. continued to prescribe large quantities of potentially lethal medications to patients despite evidence of abuse, misuse or diversion; that the doctor routinely provided early refills to patients despite evidence of abuse, misuse or diversion; and that Dr. C. frequently wrote multiple prescriptions for high dose opioids to patients simultaneously to be filled at multiple pharmacies. In February 2018 Dr. C. entered into a settlement with the Board, in which he was permanently prohibited from prescribing, administering, or dispensing controlled substances for the treatment of chronic pain, and his Iowa medical license was indefinitely suspended.

171. Family medicine practitioner Dr. D. is another example of Purdue targeting high prescribers who engaged in problematic conduct. From 2006-2010 (when the Iowa Board

[121] PIA 2802, line 3.
[122] PIA 2; PIA 6517.

of Medicine prohibited Dr. D. from prescribing controlled substances for the treatment of chronic pain), Dr. D. wrote 771 OxyContin prescriptions.

172. Purdue sales representatives called on Dr. D. 60 times during those four years. Although call notes repeatedly raised red flags about Dr. D., Purdue continued to push him to write more OxyContin prescriptions. In November 2007, a Purdue salesperson submitted a "Report of Concern" to Purdue about "the investigation surrounding [Dr. D.'s] practice and prescribing habits."[123] The sales representative briefly paused calling on Dr. D, but began again in April 2008.[124]

173. In December 2008, Dr. D. told the same sales representative that he "fired" 25 patients for abusing, though "he did not say what medication they were taking." Apparently the representative did not ask about what drug those "fired" patients were taking, and continued to call on Dr. D.[125]

174. Purdue reviewed Dr. D. again in April 2010, but decided to continue calling on him.[126]

175. In 2010, the Iowa Board of Medicine placed Dr. D. on probation and prohibited him from prescribing, administering, or dispensing controlled substances for the treatment of chronic pain. Despite this censure, Purdue still continued to call on Dr. D. to promote its laxative products until he voluntarily surrendered his medical license in 2012 after a clinical competency evaluation revealed "significant deficiencies."

[123] PIA 2, line 8004 (11/16/2007).
[124] PIA 2, line 9362 (4/4/2008); PIA 2802, line 34.
[125] PIA 2, line 12235 (12/4/2008).
[126] PIA 2802, line 34.

VI. Richard S. Sackler Was A Primary Participant in Purdue's Unlawful Conduct

176. Defendant Richard S. Sackler played an active and central role in the management of Purdue throughout the period it developed OxyContin and while it was deceptively advertised, marketed, promoted, and sold in Iowa.

A. Sackler's Role at Purdue

177. Purdue has long been a closely held, family-owned company. The Sackler family has owned and controlled Purdue for decades. Eight members of the Sackler family held the majority of seats on its Board of Directors until 2018.

178. Richard S. Sackler was on Purdue's Board from 1995 through 2018 and served as its co-chair starting in 2003.[127]

179. Sackler began working full-time for The Purdue Frederick Company as assistant to the President in 1971 after completing medical school. Beginning in the late 1970s he became the head of research and development at Purdue Frederick. He held that position until approximately 1982 or 1983, when he became the Medical Director at Purdue Frederick. He continued to oversee research and development as Medical Director.[128]

180. Sackler became Purdue Frederick's head of marketing and sales in 1983 or 1984. His title was Vice President of Marketing and Sales, a job he held until sometime in 1986. In that position he was "actively involved" in the day-to-day management of marketing and sales at Purdue Frederick and developed a "very significant" understanding for Purdue's marketing and sales.[129]

[127] [ ]
[128] PWG 4812428.
[129] PWG 4812426; PWG 4812429.

181. From 1986 until at least 2002, Purdue's subsequent head of Marketing and Sales reported directly to Sackler.[130] Since at least 1986, Sackler has been involved in the general management of Purdue Frederick.[131]

182. Sackler was the Senior Vice President of Purdue Pharma since shortly after that company was formed in 1991, until 1999 when he became its President.[132]

183. In 1995, six months before OxyContin was launched, Sackler was the only Senior Vice President at Purdue Frederick and Purdue Pharma. The only two company executives who held positions higher than his were two of the company's founders: his uncle Mortimer Sackler, Chairman of the Board of Directors, and his father Raymond Sackler, President.

184. In 1996 Sackler was Senior Vice President responsible for Marketing and Sales, the position he held at the time OxyContin was launched in 1996. In 1996, 1997, 1998 and part of 1999, Sackler remained as third in command and the only Senior Vice President of Purdue Frederick and Purdue Pharma.[133]

185. In 1999, Sackler became President of Purdue Pharma and served in that position until 2003.

186. His duties and responsibilities as President were fundamentally the same as his duties as Senior Vice President, as they "didn't change much."[134]

187. Michael Friedman, the Executive Vice President and Chief Operating Officer of Purdue, reported to Sackler while he was the President.[135]

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[130] PWG 4812426; 4812430-31.
[131] PWG 4812431.
[132] PWG 4812416; PWG 4812420.
[133] PKY 181872609; PKY 18187261; PKY 181872633; PKY 181872635; PKY 181872669; PKY 181872672; PKY 181872726; PKY 181872730.
[134] PWG 004812420; PWG 004811492; PWG 004811493.
[135] PWG 4812417; PWG 4812418.

188. Dr. Paul Goldenheim, the Group Vice President of Scientific and Medical Affairs, headed the Purdue department that had responsibility to make sure the marketing department's promotional materials were medically accurate. Goldenheim reported directly to Sackler from 1985 until 2003, at which time Goldenheim began reporting to Friedman, who was Chief Executive Officer at that time.[136]

189. Sackler is named as an inventor on dozens of patents relating to oxycodone and other pain medications, including patents issued as late as 2016. Most of these patents were assigned to Purdue.

B. Sackler Was a Primary Participant in the Marketing and Sale of OxyContin

i. Pre-Launch Period

190. Before the 1996 launch of OxyContin, Sackler played a key role in developing and disseminating Purdue's false, deceptive, misleading, and omissive misrepresentations and unfair practices related to OxyContin's risk of abuse and addiction.

191. Sometime shortly after 1985, Sackler met with Dr. Robert Kaiko, Purdue Frederick's head of clinical pharmacology. Kaiko told Sackler that Purdue Frederick should pursue making a controlled-release oxycodone product.[137] On behalf of Purdue, Sackler approved the idea and told Kaiko that Purdue would devote resources to develop an extended release oxycodone product.[138] This was the beginning of Purdue's OxyContin.

192. As early as 1993, more than two years before OxyContin was released, Sackler was being provided with updates on the plans for how it would be marketed, including that the principal initial market for OxyContin would be in cancer pain patients.[139]

[136] PWG 3804166; PWG 3804167.
[137] PWG 4812440; PWG 4812441; PWG 4812442.
[138] PWG 4812443.
[139] PDD 1701825444.

193. As Purdue was refining OxyContin in early 1994, Sackler asked other high-level company executives whether Purdue should study the abuse liability of OxyContin, and how much such studies would cost.[140] At the time, executives were discussing whether it would be possible to get the FDA to place OxyContin on a lower DEA schedule if Purdue were to conduct studies which demonstrated that OxyContin had lower abuse liability.[141] Kaiko replied to Sackler and other executives: "I believe that OxyContin may prove to have less abuse liability with acute dosing, but not with repeated dosing."[142] While no abuse liability studies were conducted by Purdue, Purdue still claimed that it "believed" that OxyContin has less abuse potential due to its extended release formulation.

194. Sackler was involved in planning the marketing for OxyContin even before its approval by the FDA and launch. In January 1995, Sackler proposed to Friedman, head of Sales and Marketing, that Purdue "co-promote" OxyContin with another pharmaceutical company.[143] Ultimately, Purdue chose Abbott to co-promote OxyContin with Purdue.

195. In March 1995, Sackler asked Friedman to set up a meeting with the other top executives to review the OxyContin marketing research and status.[144] He was also keeping tabs on sales representatives' visits to certain hospitals Purdue supplied, as well as the quantity of Purdue products physicians were using, as opposed to competitors' products.[145]

196. In July 1995 Sackler reviewed the OxyContin materials that the sales representatives would use in making sales pitches to health care providers across the country. Sackler then prepared a memorandum to Friedman, suggesting substantive changes to the launch

[140] 8813070821; 8813082443.
[141] 2992903.1.
[142] 2992903.1.
[143] PPLPC 42000000021.
[144] PPLPC 42000000056.
[145] PPLPC 42000000060.

materials. Of particular note, Sackler told Friedman that Purdue should avoid the words "opioid" and "narcotic" and instead used the word "analgesic" in OxyContin promotional pieces.[146]

197. Around this time Sackler was involved, perhaps as an originator, in the creation of a Purdue website called *Partners Against Pain* (partnersagainstpain.com), where medical professionals and patients could access information regarding pain control and Purdue printed and video materials.[147] The *Partners Against Pain* website debuted in 1997.

198. During the same period Sackler tracked Purdue's involvement with various Third Party Front Groups and Purdue's plans to hold lectures on OxyContin for health care providers attending various conferences and annual meetings.[148]

199. In August 1995, Sackler suggested to the head of Marketing and Sales that Purdue produce advertisements that would be aimed directly at patients.[149]

200. At the same time, Sackler was involved in the creation of OxyContin's Package Insert[150] and the FDA's approval of it.[151]

ii. Early OxyContin Sales

201. OxyContin was approved by the FDA in late 1995 and launched for sale in January 1996.

202. Sackler was the keynote speaker at Purdue's 1996 National Sales meeting where he told Purdue's entire sales force that:

[146] PPLPC 420000000120; PPLPC 420000000121.
[147] PPLPC 42000000070.
[148] PPLPC 42000000084.
[149] PPLPC 420000000169; PPLPC 420000000170.
[150] The "package insert" for a prescription drug is written for health care providers and must contain a summary of essential scientific information needed for the safe and effective use of the prescription drug; be informative and accurate and neither promotion in tone nor false or misleading; and be updated when new information becomes available that causes labeling to become false, inaccurate or misleading. *See* 21 C.F.R. §2016.56(a).
[151] PPLPC 420000000178.

> [T]he 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 white flag.

Sackler also told all the sales representatives and staff that Purdue "had the most powerful selling package insert in the category and in the industry."[152] He further told all of the Purdue field force that the Purdue team working on the Package Insert (of which he was a part) made the label "a more potent selling instrument."[153]

203. Sackler was active in Purdue's public relations efforts for OxyContin in 1996, as he recommended the company prepare one or more press releases regarding OxyContin, its uses, "success," and tremendous reception.[154] Sackler got the marketing department's agreement to proceed with press releases. In Sackler's words:

> I want to signal the licensing in market for the product around the world, get an audience for our patent infringement suits so that we are feared as a tiger with claws, teeth and balls, and build some excitement with prescribers that OxyContin Tablets is [*sic*] the way to go.[155]

204. In the Fall of 1996, Sackler came up with the idea, soon implemented by Purdue's marketing department, to put the company's websites (URLs) on all Purdue's products, including OxyContin,[156] directing all OxyContin consumers to Purdue's websites.

205. Throughout his career as a Purdue executive, Sackler was heavily involved in sales forecasting and strategic planning. By example, at the end of 1996 after reviewing Purdue's "7-Year Strategic Plan," Sackler directed changes to sales forecasting figures and

[152] PWG 4812568.
[153] PWG 4812568.
[154] PWG 4811735.
[155] PWG 4811734.
[156] PPLPC 18000001669.

sales forecasting.[157] Sackler's work on the 7-Year Strategic Plan was not welcomed by Friedman, who told Sackler "I refuse to respond to this."[158]

206. In late 1996 Sackler reviewed the draft OxyContin visual sales aids used by Purdue's sale representatives with health care providers, as well as the current draft marketing strategy for OxyContin.[159]

207. Sackler was actively involved in most, if not all, of Purdue's principal business operations. He engaged on a daily basis with members of the Purdue management team and staff in a myriad of ways, including but not limited to: giving them orders and directions; making demands; asking questions; disagreeing with their decisions; criticizing their work and company results; modifying and editing their work product; reviewing and reworking sales data and forecasts; and proposing cuts and other changes to the budget. Sackler's participation in the day-to-day running of Purdue was so involved that in late 1996 Friedman wrote to Sackler:

> You need a vacation and I need a vacation from your email. Today you sent messages that: announced your "personal disappointment" with the Abbott arrangement; expressed your fears that we would be embarrassed by the way we have handled Nakahara and we will not; communicates to the organization that you think our forecast for OxyContin is a silly number and it is not….
>
> In all honesty, I am very disappointed that you feel it is necessary to: harass me with this level of follow up, utilize this manner of indirect communication, and challenge my judgement about matters that are within my expertise and well under control.[160]

[157] PPLPC 39000000153.
[158] PPLPC 42000000756.
[159] PPLPC 39000000155; PPLPC 39000000156.
[160] PWG 4811694.

208. In January 1997, Sackler suggested to other senior executives at Purdue that the company "may need to start a campaign to focus attention on the untreated patient in severe pain who is mobilized and given his life back by our products."[161] This idea for the *I Got My Life Back* campaign, *see* Section V(B)(1) *supra*, was made in response to a pharmacy benefits manager who didn't want OxyContin approved because of concerns with its abuse potential.[162]

209. At the same time, Sackler also recommended to the other Purdue executives to "plan a presentation about addiction" that could be presented by Purdue personnel. Sackler wanted a "convincing presentation that [controlled-release] products are less prone to addiction potential, abuse or diversion than [immediate-release] products."[163]

210. In an effort to increase sales and incentivize Purdue's massive sales force, in January 1997 Sackler wrote, upon reviewing the daily and month end sales numbers for OxyContin:

> IT WOULD BE A GREAT SALES MOTIVATOR FOR THE [SALES FORCE] TO HAVE THE ABSOLUTELY BIGGEST NUMBER FOR OXY FOR THE FIRST MONTH OF 1997. PLEASE CONSIDER WHAT CAN BE DONE. WOULD WHOEVER READS THIS FIRST CONFERENCE CALL THE OTHERS. I WOULD EVEN STAY OPEN AN EXTRA HOUR TO MAKE WONDERS HAPPEN.[164]

211. In his increasing quest for higher and higher OxyContin sales, in the United States and abroad, Sackler was excited about the idea that it might be possible to sell OxyContin as an unscheduled (uncontrolled) drug in Germany, if Purdue could provide German regulators with support for Purdue's claim that OxyContin had a "very low abuse

[161] PPLPC 13000018287.
[162] PPLPC 13000018287.
[163] PKY 181133741.
[164] PWG 4811699.

potential."[165] Kaiko told Sackler in early 1997 "I don't believe we have a sufficiently strong case to argue that OxyContin has minimal/or no abuse potential." Kaiko also reminded Sackler that "oxycodone containing products are still among the most abused opioids in the United States" and that Purdue's controlled-release morphine product MS Contin "is the most common sources [*sic*] of parenterally abused morphine/heroin" in New Zealand.[166]

212. In early 1997, Sackler's involvement in OxyContin was so substantial that he wanted to change the shape and size of the OxyContin 160 mg dose tablet.[167]

213. Sackler frequently bypassed Friedman to seek information directly from lower-level staff, creating enough tension that Friedman wrote at one point: "You are absolutely torturing me."[168]

214. Sackler, still concerned about getting OxyContin unscheduled in Germany, wrote other Purdue executives in March 1997, still pushing the argument that OxyContin was less likely to be abused because of its controlled-release formula. The head of the Purdue Medical department replied: "We do not have any abuse liability studies. I think this is a dead end."[169]

215. Sackler was involved in the decision-making process as to what studies Purdue would conduct concerning OxyContin. He told Friedman in May 1997:

> If a study is going to address a question that has already been settled and there is a risk that a different result might occur, then this is a PROBLEM if such a contradictory result could embarrass our marketing or regulatory posture… .[170]

[165] PWG 4812818.
[166] PWG 4812817.
[167] PPLPC 39000000265.
[168] PPLPC 39000000270.
[169] PWG 4811772.
[170] PPLC 39000000429.

216. Later in 1997, Sackler participated in a conspiracy among Purdue executives to downplay the strength and potency of OxyContin. After Sackler was sent the results of various physician focus groups that Purdue had conducted, he originally asked Friedman to put some materials together that would change physicians' misperception that OxyContin was not as strong as MS Contin.[171]

217. Sackler received two sets of minutes from the Phase IV OxyContin Tablets Team in May 1997. The minutes reported, again, that doctors in the focus groups incorrectly believed that OxyContin was not as effective as morphine, and that physicians wrongly perceived that OxyContin was "a weaker opioid than MS Contin."[172] After Sackler asked Friedman to address these issues, Friedman wrote:

> My purpose in writing this memorandum is to clarify our position on the very complex issues raised…during the Phase IV team meeting and which were the subject of Dr. Richard's [Sackler] inquiry.
>
> We are well aware of the view, held by many physicians, that oxycodone is weaker than morphine. We all know that this is the result of their association of oxycodone with less serious pain syndromes. This association arises from their extensive experience with and use of oxycodone combinations to treat…"less serious" [pain]. This "personality" of oxycodone is an integral part of the "personality" of OxyContin.
>
> When we launched OxyContin, we intentionally avoided a promotional theme that would link OxyContin to cancer pain.…
>
> …[W]e have been successful beyond our expectations in the non-malignant pain market. Doctors use the drug in non-malignant pain because it is…less threatening to them, and their patients, than that of the morphine alternatives.

[171] PWG 3806701.
[172] PKY 183294357; PKY 183294362.

> ….While we might wish to see more of this product sold for cancer pain, it would be extremely dangerous, at this early stage in the life of this product, to tamper with this "personality," to make physicians think the drug is stronger or equal to morphine….[173]

218. Sackler told Friedman "I agree with you"[174] in response to this proposal to intentionally mislead and/or defraud the American public about the true strength of OxyContin.

219. The OxyContin product manager advanced the fraudulent plan, again with Sackler's express written approval:

> Since oxycodone is perceived as being a "weaker" opioid than morphine, it has resulted in OxyContin being used much earlier for non-cancer pain. Physicians are positioning this product where Percocet, hydrocodone, and Tylenol with Codeine have been traditionally used. Since the non-cancer pain market is much greater than the cancer pain market, it is important that we allow this product to be positioned where it currently is in the physician's mind.[175]

220. Sackler, Purdue's third in command, again approved Purdue's fraudulent marketing plan, writing "I think you have this issue well in hand. If there are developments, please let me know."[176] Purdue's deceptive plan was put in motion. The entire Phase IV OxyContin Team, composed of Purdue executives and employees from Purdue's medical, clinical, legal, research, sales, and marketing departments, were instructed that "we….do not want to say OxyContin is as 'powerful' as morphine" as the company developed "future marketing programs, symposia, clinical study manuscripts, and any other items that discusses the use of OxyContin." Sackler received a copy of that directive.[177]

[173] PWG 3806689.
[174] PWG 3806689.
[175] PWG 4398560.
[176] PPLPC 39000000528.
[177] PWG 4812966; PWG 4812967.

221. In the summer of 1997, when Purdue was seeking regulatory protection of OxyContin in France, Sackler asked for, received, and made comments and suggested changes to Purdue's submission, including inserting the text from OxyContin's United States' Package Insert into the French application.[178]

222. By the Fall of 1997, Sackler was directing the sales and financial departments how to collect and report OxyContin sales data, which once again drew a rebuke from Friedman.[179]

223. In May 1999, Sackler boasted to a colleague about the substantial role he played in OxyContin:

> You won't believe how committed I am to make OxyContin a huge success. It is almost that I dedicated my life to it. After the initial launch phase I will have to catch up with my private life again. [180]

224. In July 1999, Sackler went on sales calls at Sloan Kettering Memorial Cancer Center and talked to hospital oncologists about the benefits of OxyContin.[181]

225. Sackler immersed himself in the skyrocketing OxyContin sales data and the possibility of it becoming a billion dollar a year drug. At the same time, he ignored readily available reports, including information that Purdue subordinates and sales staff were reporting, about the abuse and diversion of OxyContin. Purdue required its entire national sales force to document in writing every visit or call they made on health care providers. Beginning at least the year after OxyContin was launched, sales representatives began reporting, *in*

[178] PDD 1706195615; PDD 1706195616; PDD 1706195617; PDD 1706195618.
[179] PPLPC 18000003166.
[180] The initial launch of OxyContin occurred more than 3 years earlier in January 1996. In fact, Sackler was so committed to Purdue that he was even a training source for Purdue's national sales force. Sackler was listed as medical personnel that sales representatives could call *on nights and weekends* with any product-related medical questions. PKY 180429714-720.
[181] 8855673789.

Purdue's own call note system, that they were being told that OxyContin tablets were being crushed and snorted, and had a "street value."

226. In November 1999, Sackler boasted to the entire Purdue sales force at their annual national meeting that "We have redefined and have borne a new, major pharmaceutical market, the analgesic market."[182]

227. Sackler commonly gave instructions directly to Purdue subordinates while bypassing those subordinates' supervisors and the chain of command, such that Sackler was often admonished for it. As one example, in April 2001 the head of the medical department told Sackler:

> Richard, you are giving too many instructions to too many people about the same topic…There are so many crossed wires here. PLEASE!!![183]

228. As President, Sackler's direct involvement in Third Party Front Groups was apparent by April 2001, when he set the goals for and set up meetings between Purdue and the leaders of the American Pain Society, the American Pain Foundation, and other front groups:

> I want the meeting to be in Stanford if possible, or NYC as a fallback. 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.[184]

iii. Sackler and Purdue Knew About OxyContin Abuse and Diversion Earlier Than They Admitted

229. Sackler and Purdue became aware early in the promotion of OxyContin that MS Contin, its controlled-release morphine product, was being diverted and abused.[185] Purdue did not

[182] 380284.1.
[183] PPLPC 45000004929.
[184] PPLPC 45000004929.
[185] Purdue's public position historically was to deny knowledge of MS Contin abuse, and therefore claim it had no reason to suspect OxyContin diversion and abuse.

share that information with government regulators, its massive sales force, or the public. It did not stop the way it was promoting its controlled-release products or take steps to curb the abuse. Purdue soon learned that OxyContin was being diverted and abused. Instead of taking action, alerting regulators, changing its training and promotion, and devising ways to stop diversion and abuse, Purdue wanted to sell more OxyContin. Accordingly, Purdue and its executives lied in every public statement they made about when Purdue learned that OxyContin was being abused. While Purdue was marketing OxyContin as less abuseable and addictive than other drugs, its executives and owners knew about growing diversion and widespread abuse of OxyContin.

230. On August 28, 2001 a hearing was held before the United States House of Representative subcommittee on Oversight and Investigations on OxyContin Abuse. Friedman, then Purdue's Chief Operating Officer, testified and claimed, falsely, that reports of OxyContin abuse and diversion began "early in the year 2000."

231. Friedman testified again in February 2002, accompanied by Udell and Goldenheim, before a United States Senate Committee on Health, Education, Labor and Pensions. Again, he falsely claimed:

> It was early in April of 2000 that Purdue was first alerted to reports of abuse and diversion of OxyContin by accounts in Maine newspapers claiming that OxyContin was the subject of recreational use in Maine. Purdue immediately implemented a response team that included some of the Company's top executives and scientists….[186]

232. Sackler has testified falsely, under oath, that he first learned of OxyContin abuse in May 2000.[187]

[186] Paul Goldenheim has also falsely testified that he became aware of reports of OxyContin abuse and diversion starting sometime in 2000.
[187] PWG 4812601.

233. Purdue knew, as it was public knowledge even years before OxyContin was released, that oxycodone-containing drugs were among the most abused Schedule II narcotics.

234. During the first years of OxyContin sales, Purdue and Sackler were aware of abuse and diversion of MS Contin. For example:

a. In May 1996, five months after OxyContin was unleased, Sackler and Howard Udell, Purdue's General Counsel, were sent a medical journal article about MS Contin abuse, titled "Recovery of Morphine from a Controlled Release Preparation," which described how drug abusers were injecting MS Contin after extracting its morphine.[188]

b. In March 1998, Udell sent Sackler and other Purdue executives a memo titled "MS Contin Abuse" which included recent newspaper articles detailing the sale of MS Contin for illicit use on the Canadian[189] black market, and noted that a nearly identical article appeared on the front page of the Vancouver Sun on the same day.[190]

c. In 1998 Purdue was aware of a medical journal article in the July 1998 issue of Canadian Medical Association Journal that included discussion of the street value of controlled-release opioids, particularly MS Contin, which fetched the highest price on the street/black market.[191] An accompanying editorial by Dr. Brian

[188] Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. Times, May 29, 2018; Barry Meier, *Pain Killer*, 177 (Random House 2018).
[189] Among hundreds of other related entities, the Sackler family also owns Purdue Pharma Canada.
[190] Meier, *Pain Killer supra* note 188, at 179-80; *The Weekly, Episode 10: A Secret Opioid Memo That Could Have Slowed an Epidemic,* N. Y. Times, August 16, 2019. Udell quoted the article in his memo: "a prescription of 30 pain-killing morphine MS Contin 60-mg tablets – known as 'purple peelers' – cost $58 from a pharmacy but fetches about $1,050 on the black market at $35 a tablet."
[191] Meier, *Origins of an Epidemic supra* note 188; *see also* Canadian Medical Ass'n. Journal, July 28, 1998; 159 (2).

> Goldman, a sometimes Purdue-paid speaker, warned: "now that [Purdue's] controlled-release oxycodone has been licensed in Canada, we can expect that it and other controlled-release opioid analgesics will also find their way onto the black market."[192]

235. Purdue quickly became aware of OxyContin abuse. By the Fall of 1997, Purdue had several employees monitoring the internet and drug "chat rooms" for mention of OxyContin.[193]

236. By at least October 1998, Purdue hired Fleishman-Hillard ("FH"), a public relations firm, to conduct a public relations/communications plan, including internet monitoring.[194] In 1999, FH reported to Purdue about internet mentions of the abuse, diversion, addiction, and misuse of OxyContin. FH reported to Purdue about the popularity of OxyContin as a highly favored drug of abuse, that OxyContin's controlled-release component was easily defeated, and that it was being snorted and injected. These reports were sent to senior Purdue executives.[195]

237. On June 1, 1999, a Purdue paralegal's internal memo to Udell addressed the first two FH "Issues Monitoring Reports" stating: "My own [internet] research has shown … numerous discussions of misuse and abuse of Purdue products, in particular, OxyContin."[196] Udell sent the memo to Friedman, who sent it on to Mark Alfonso, Purdue's Executive Director of Marketing.[197]

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[192] Canadian Medical Ass'n. Journal, July 28, 1998; 159 (2).
[193] Meier, *Pain Killer, supra* note 188, at 179; Meier, *Origins of an Epidemic supra* note 188.
[194] PDD 1502308346.
[195] PDD 1502308346; PKY 183050152; PKY 181024496.
[196] PKY 182895879; PKY 182895880.
[197] PKY 182895879; PKY 182895880.

238. As of June 1999, FH and one or more Purdue representatives were monitoring RxNews.net[198] and receiving information about people crushing and snorting OxyContin, which was sent to Purdue.[199]

239. In early July 1999, one of Purdue's top marketing executives wrote a "HIGH" Importance email about the abuse of OxyContin to Friedman, Udell, and Goldenheim, among others and promised the executives that "we will keep you informed as we get more information" about the abuse of OxyContin. [200]

240. Later that month, the Purdue paralegal sent Udell another article from RxNews.net as follows:

> A state wide drug analyst today indicated a problem with OxyContin. Seems the drug is now being injected and causing a "speed" type high, and the abusers are later following it with an oral dose to bring them down.
>
> I continue to see OxyContin increase in abuse with our doctor shoppers and sellers. I suspected the trend was temporary, but appears to be a valid trend.[201]

241. Udell sent this information to the heads of Purdue's marketing and medical departments, among others.[202] All of these people reported to Richard Sackler.

242. A June and July 1999 FH report that RxNews.net was seeing "a lot of abuse of MS Contin and that OxyContin is "more frequently…a drug of choice,"[203] was shared with Purdue's medical clinical, and legal department executives.[204]

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[198] RxNews.net was created by or before February 1999. It was dedicated to open and anonymous discussions about prescription drug abuse and operated by an Ohio police officer.
[199] 3166940.1; PKY 181386416.
[200] PKY 181386416.
[201] 3167811.1.
[202] 2257388.1.
[203] PKY 181024496.
[204] PKY 181024488.

243. At some time after the launch of OxyContin, Purdue created an OxyContin crisis management team, comprised of some of the company's "top executives and scientists." Contrary to Friedman's congressional testimony, it wasn't organized in response to an April 2000 Maine newspaper story about OxyContin abuse. By August 1999 *at the latest*, Purdue's OxyContin crisis management team was already holding meetings.[205] A separate OxyContin medical risk group headed by former FDA reviewer Curtis Wright was also in operation.[206] On August 1, 1999, internal emails show that not only were Purdue's executives aware of ongoing OxyContin abuse, but that by their own admission they had "been anticipating" it.[207] Contrary to the later sworn testimony of Purdue executives, by August 1, 1999, Purdue had knowledge of OxyContin abuse through its "spontaneous reporting system," through its own call note system, through the internet watch Purdue had set up with FH, and through Purdue's own employees, including in the legal department, monitoring the internet and documenting OxyContin abuse for Purdue executives.[208] The Chief Operating Officer asked Alfonso for an update on Purdue's "crisis management effort" on August 1, 1999.[209]

244. Throughout August and September 1999 FH reported to Purdue on more internet discussions about chewing and snorting OxyContin and how to extract its oxycodone. For example, Friedman forwarded to Sackler an FH email message with the subject line, "Another 'Snorting Oxy' Message from Deja.com" which included the quote:

> …What's realy [*sic*] good is to chew some and snort some. The best ones for snorting are the 40 mg ones cuz you're not snorting lots of filler. ¼ of a 40 mg Oxy is equal to the oxy in 2 percs! If you eat

[205] PDD 8801146522.
[206] 2294634.
[207] 2294634.
[208] 2294634.
[209] 2294634.

> some (well chewed, washed down with a beer) and wait 20 minutes and then snort some – you'll feel the rush!..[210]

245. Intracompany emails establish that this OxyContin abuse information was disseminated to Purdue executives at the highest levels of the legal, medical and marketing departments.[211]

246. Former FDA reviewer and Purdue executive Curtis Wright asked another Purdue executive if there was a way to "wipe out" messages about OxyContin abuse on the internet.[212]

247. In October 1999, Udell circulated among Purdue executives an RxNews.net story about a massive arrest of drug dealers in Virginia, which story indicated that OxyContin "is becoming the drug of choice by abusers. We've seen an increase in thefts and most relate back to OxyContin."[213]

248. In November 1999 FH sent more OxyContin abuse information to Alfonso, including the street price of OxyContin in the northeast United States, which was shared intracompany with Sackler and other Purdue executives.[214]

249. In December 1999, Purdue knew from RxNews.net that MS Contin was being heavily abused in New Zealand, that MS Contin and OxyContin had been "greatly diverted and abused" by injection and snorting, respectively, and that MS Contin was $60.00 per pill on the street.[215] Udell was also informed that MS Contin was being abused by people who removed the pill's coating, crushed the tablets into a powder, then snorted it, and that OxyContin was the "preferred drug" to abuse.[216]

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[210] PKY 181018182.
[211] PDD 1701044070 (1975656.1); PDD 8801174655; PDD 8801174656.
[212] 8100236084.
[213] PDD 8801185570.
[214] PDD 8801173893.
[215] 3099613.1 (8810343458).
[216] 3099613.1 (8810343458).

250. In the face of these growing and alarming reports of OxyContin abuse and diversion, as President of Purdue Sackler was focused on how to increase OxyContin sales. In mid-2000, when he was advised about the continuing abuse of OxyContin in Virginia, West Virginia and eastern Kentucky, responded in part "This is an issue that if it grows could reduce our growth."[217]

251. In January 2001, Sackler received an email from a Purdue sales representative describing a community meeting at a local high school organized by mothers whose had children who died from overdoses of OxyContin. The sales representative wrote: "Statements 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." In February 2001, a federal prosecutor reported 59 deaths from OxyContin in a single state. Sackler wrote to other Purdue executives: "This is not too bad. It could have been far worse."

252. Sackler chose a deliberate strategy of demonizing the victims. In February 2001, he wrote in an email: "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."

iv. Sackler Remained a Primary Participant As a Purdue Board Member and Owner

253. As described above in Sections IV and V, in 2007 the Purdue Board, including Sackler, decided that The Purdue Frederick Company would pay nearly $700 million in criminal fines and plead guilty to a felony for intentionally defrauding doctors and patients about OxyContin. As part of the plea agreement, Purdue admitted that its supervisors and employees "with the intent to defraud or mislead, marketed and promoted OxyContin as

[217] PDD 8801150089.

less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."

254. However, as described above in Section V, Purdue continued to engage in false, misleading, deceptive and unfair conduct in the sales and marketing of OxyContin. Similarly, Sackler continued to be a primary participant in all of Purdue's principle operations, including sales and marketing.

255. The pattern of Sackler bypassing upper management to engage directly with Purdue staff persisted as well. Throughout 2006-2007 Friedman regularly asked Sackler to stop going around him and communicating directly with the company's staff, stating at one point: "I am asking, and will not ask again, that you work through me."[218]

256. No aspect of OxyContin promotion was too small for Sackler's input. In 2008, he suggested to Purdue that it purchase laser pointers to give out to physicians as gifts.[219]

257. In early 2008 Sackler's reach into the company operations continued. During that time he contacted upper-level staff by email and phone on a weekend with specific, detailed questions about OxyContin insurance coverage[220] and directed Russell Gasdia, then

[218] PPLPC 39000168383. Friedman, the head of Sales and Marketing and later Purdue's Chief Operating Officer, commonly expressed frustration to Sackler about Sackler's involvement in the day-to-day running of the company. By example, in February 2006 Friedman wrote in an email message to Sackler "Once again, at least copy me on your inquiries to my subordinates and their subordinates." PPLPC 39000136129. In a November 2006 email message Friedman summarized the issue: "the ongoing disagreement between [him and Sackler] regarding your frequent interactions with my subordinates. You influence priorities with your communications and undermine the direction I give people." PWG 4476877. In February 2007 Friedman reacted to Sackler posing questions to Russell Gasdia, the head of Sales and Marketing, saying "Why do you do this? I have repeatedly asked you not to go around me because this behavior undermines my authority and as a consequence impairs my ability to do my job." PWG 4524971. Later that month Friedman told Sackler "I think your involvement at this level of detail and calling [an employee] to your office for a review, without notifying me is wrong." PWG 4536803.

[219] PPLPC 530000027178; PPLPC 530000027179; PPLPC 530000027180; PPLPC 530000027181.
[220] PPLPC 120001715002; PPLPC 1200171503; PPLPC 1200171504.

Purdue's Vice-President of Sales and Marketing, to "be the hammer" when talking with vendors to get "100% of people covered second or third tier at a minimum."[221]

258. Sackler was particularly interested in the opioid savings cards, which Iowa sales representatives distributed to health care providers in the state and which Iowa consumers used. In early 2008, he sought information from Gasdia and his team about the terms of the savings cards, their use, efficacy and impact on sales.[222]

259. In March 2008, Sackler wrote to Purdue executives, Gasdia, and Board members asking for detailed information about a new savings card program, as he was "eager to find way to build our Rx loyalty to OxyContin tablets and continue the positive trend in Rx growth that began to falter about 6-8 months ago."[223]

260. Later in the same month he directed upper-level staff to provide him with detailed sales forecast data and create new graphs to his specifications. He circulated the new data to other Board members and directed the issue be placed high on the Board agenda: "This is a vital issue for us."[224]

261. He also asked Gasdia for specific details about the "status of covered lives" with OxyContin.[225]

262. Sackler continued to carefully monitor OxyContin sales. In June 2009, he asked sales staff how a competing drug company had increased sales: "What is happening???"[226]

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[221] PWG 4335517. Gasdia forwarded this directive to another executive to share his frustration: "This is unrealistic. We never were at 100 percent and will not be….Some of the things they ask for are not good for us and impact bigger issues." PWG 4335517.
[222] PPLPC 12000168321; PPLPC 12000068322.
[223] PWG 4335376. Gasdia was concerned, and responded to Purdue's CEO saying "I know it is tricky, but Dr. Richard has to back off somewhat. He is pulling people in all directions, creating a lot of extra work and increasing pressure and stress."
[224] PPLPC 12000174153; PPLPC 1200174154; PPLPC 23000164605.
[225] PPLPC 12000179679; PPLPC 1200179680.
[226] PWG 4334672.

263. In July 2009, Sackler directed that a, "program to boost OxyContin tablets and oxycodone [extended-release] prescriptions rather than watch them languish" be added to the agenda for a Board of Directors meeting.[227] Later that summer he invited other Board members to an August 2009 meeting for a "presentation of all the efforts Sales and Marketing [*sic*] is doing and planning to do to reverse the decline in OxyContin tablets market."[228]

264. In late 2009, Sackler told staff to send him weekly reports on OxyContin sales. Although no other Board members or executives received such reports, Purdue created one for him.[229] Sackler also had Purdue staff undertake a series of specific tasks related to OxyContin sales and marketing, including identifying specific programs that the Sales and Marketing Department would implement to "profitably grow the extended-release oxycodone market and OxyContin in light of competition."[230]

265. In December 2009, Sackler attended a 2010 Sales Forecast meeting with sales and marketing staff.[231] The next month, in response to a weekly sales report for another Purdue product, Sackler directed staff to create additional charts to compare the new product to OxyContin and other drugs. Gasdia was frustrated with Sackler's continual data requests and again asked Purdue's CEO: "Can you help with this? It seems like every week we get one off requests from Dr. Richard…."[232]

266. In early 2010, Sackler he asked for and received the 2010 OxyContin Marketing Plan to prepare for a 2010 Sales Forecast Review meeting. Weeks later, he was once again disputing the OxyContin growth forecast and asking for more materials, including the

[227] PWG 4335536; PWG 4335537.
[228] PPLPC 12000234970; PPLPC 12000234971.
[229] PPLPC 22000283690; PPLPC 22000283691; PPLPC 22000283692.
[230] PPLPC 12000249328.
[231] PWG 4820572.
[232] PWG 4334388.

"marketing program overview." Upon its receipt, he requested even more data.[233] In March 2010, Sackler directed staff to provide him with monthly reports on the sales of OxyContin and its competitors.

267. In January 2011, Sackler attended the national launch meeting for Butrans, Purdue's new opioid (a buprenorphine patch), where he addressed the entire sales force directly and met with sales representatives.[234]

268. Throughout 2011 Sackler was very involved in Butrans sales forecasting and promotion, including closely monitoring weekly sales trends, accompanying sales representatives on detailing visits to health care providers, and planning to visit with District Managers.[235]

269. In early 2012, staff provided updated information about Butrans sales to Sackler, who responded "This is bad." Gasdia told Purdue's CEO "Anything you can do to reduce the direct contact of Richard into the organization is appreciated."[236]

270. In March, Sackler directed upper-level Purdue staff to get him a spreadsheet showing monthly prescription data for all extended-release opioids starting in 2000 and to meet with him two days later.[237] A couple of weeks later, the same staff member provided Sackler with an "updated draft of the OxyContin market events project," which contained up-to-date information about the sales force expansion.[238]

[233] PDD 9316101376; PDD 9316101377.
[234] PWG 4461680.
[235] For example, Sackler questioned the contents of the "contraindications" section of the Butrans label (PPLPC 1000091102); suggested that he go into the field with Purdue sales representatives (PWG 4460294; PPLPC 12000329722); and considered attending conventions to meet with prescribers and sales representatives (PWG 4335243).
[236] PPLPC 12000368569.
[237] PPLPC 12000369328.
[238] PWG 4520708.

271. For another meeting the next month, Sackler wanted to discuss with Gasdia a "sudden decline in OC sales in the past year or two and corrective action."[239]

272. In June 2014, Gasdia left Purdue. He warned his replacement that Sackler managed the sales operation intensely: "There are times this becomes a tennis match with Dr. Richard."[240]

273. In January 2015, Sackler sought a meeting with Purdue staff to go over a broad range of sales information, including information about Purdue's OxyContin sales with detailed past and future projections of market share, and one staff member's "study on the history of OxyContin tablets from launch to the present…."[241]

274. In 2007, Sackler applied for a patent to treat opioid addiction, which he finally received in January 2018 and assigned to Rhodes Pharmaceuticals, a different company controlled by the Sackler family, instead of Purdue. Sackler's patent application admits that opioids are addictive. The application describes people who become addicted to opioids as "junkies" and asks for a monopoly on a method of treating addiction.

C. Richard Sackler Has Benefited Directly From Purdue's Misconduct

273. The Sackler family, including Richard Sackler, through their ownership and control of the Purdue entities, have directed Purdue and its associated companies to distribute billions of dollars generated from the sale of OxyContin to the Sackler family, including Richard Sackler.

[239] PWG 4334207.
[240] PPLPC 12000483223.
[241] PPLPC 22000797066.

274. According to publicly available information, Purdue's annual revenue averaged about $3 billion, mostly from the sale of OxyContin, and Purdue has made more than $35 billion since releasing OxyContin in 1995.

275. Illustrating both their control of Purdue and their incentive to sell as much OxyContin as possible, and by any means necessary, the Sackler dominated-Board has paid the Sackler family, including Richard Sackler, billions of profits stemming from the sale of OxyContin.

276. Since the release of OxyContin, Purdue has faced thousands of lawsuits related to its sales and marketing practices and OxyContin's addictiveness. In January 2007 alone, Purdue settled more than 1,000 pending lawsuits of the nearly 1,400 cases pending against it at that time, according to public reports. For that year, Purdue's legal fees were reported to be almost half a billion dollars.

277. By 2014, the Sacklers knew that state Attorneys General were investigating Purdue, commencing actions against it, and that settlements and/or judgments against Purdue would be forthcoming. Despite this knowledge, Sackler continued to vote to pay himself and other Sackler family members significant distributions and send money to offshore companies, and Purdue continued to forecast hundreds of millions of future distributions to the Sacklers.

278. Purdue has settled lawsuits with the States of West Virginia, Kentucky, and Oklahoma after years of protracted litigation with those states. In October 2019, Purdue is currently scheduled to face trial in federal court on the first of thousands of lawsuits filed by counties, municipalities, hospitals and others, and trial dates have been set against Purdue in numerous states, including Washington, South Carolina, New Jersey, Alaska and Missouri.

These cases, commenced by state Attorneys General in 2017 and 2018, represent the culmination of investigations started years earlier during the post-2007 conviction wave of litigation against Purdue.

279. In the face of these mounting lawsuits and liabilities, Purdue began threatening to commence bankruptcy proceedings by at least March 2019. "As a privately-held company, it has been Purdue Pharma's longstanding policy not to comment on our financial or legal strategy," Purdue said in a statement. Less than ten days later, however, Purdue's President and CEO publicly reiterated Purdue's threat to delay scheduled trials, and ultimately delay and otherwise limit states' recovery against Purdue

280. Despite being involved in nearly two decades of litigation involving Purdue's misconduct relating to the sale, marketing and risks of OxyContin, and in the face of mounting liabilities to the states, including Iowa, Purdue – at the Sacklers' direction – continued to pay the Sacklers hundreds of millions of dollars each year in distributions for no consideration and in bad faith.

281. Now, when faced with the reality that Purdue – and the Sacklers – will finally be held accountable for their misconduct, Purdue has publicly admitted that it cannot pay its threatened liabilities and is threatening to commence bankruptcy proceedings.

VII. General Allegations

282. Neither all nor any part of an application for injunctive relief has been presented to and refused by any court or justice pursuant to Iowa Rule of Civil Procedure 1.1504.

283. In any action by the state, no security is required of the state pursuant to Iowa Rule of Civil Procedure 1.207.

284. Although it is not necessary to establish reliance, damages or intent to deceive to obtain injunctive relief or reimbursement under the Iowa Consumer Fraud Act, establishing these factors, particularly intent, is nevertheless relevant *inter alia* to the Court's determination of the appropriate scope of injunctive relief and the appropriate amount of civil penalties.

285. The acts and practices of Defendants in violation of subsection (2)(a) of the Consumer Fraud Act as alleged herein were such as would in fact induce reliance, would in fact cause damage, and/or were in fact intentional.

286. Omissions of material fact also violate the Consumer Fraud Act where others rely on them. The omissions, concealments, and suppression alleged herein involve material facts and with the intent that others rely on them.

VIII. Violations of the Law

COUNT I

IOWA CONSUMER FRAUD ACT VIOLATIONS

287. The State of Iowa incorporates paragraphs 1 through 286 as if fully set forth herein.

288. Defendants' statements, acts and practices violate the Iowa Consumer Fraud Act, Iowa Code section 714.16 (2019), including but not limited to:

a. Defendants' representations, made by it and through Third Party Groups and KOLs, regarding the claimed safety, efficacy, uses, non-addictiveness, side effects, lack of withdrawal symptoms, superiority profile, and claimed benefits of opioids and OxyContin were false, deceptive, fraudulent, and omissive, and constitute unlawful practices under the Iowa Consumer Fraud Act.

b. Defendants' acts, conduct, practices, and statements in concealing, suppressing and omitting material facts, including but not limited to failing to disclose necessary

and truthful information about the risks, dangers, appropriate uses, addictiveness, and side effects regarding opioids and OxyContin in particular, constitute unlawful practices under the Iowa Consumer Fraud Act.

c. Defendants' acts, conduct, practices, and statements in concealing, suppressing and omitting material facts, including but not limited to failing to disclose the lack of clinical data to substantiate many of its claims about opioids and OxyContin in particular constitute unlawful practices under the Iowa Consumer Fraud Act.

d. Defendants' unfair practices of creating and disseminating seemingly truthful but incomplete and biased branded and unbranded promotional materials for OxyContin and opioid use, disguised as patient, health care provider, and regulatory education constitute unlawful practices under the Iowa Consumer Fraud Act.

e. Defendants fraudulently stated that the controlled-release formulation of OxyContin made it both less prone to abuse and rarely addictive, and that they had no knowledge of the abuse and diversion of OxyContin until some time in the middle of the year 2000. These statements were false and fraudulent as Defendants knew about OxyContin abuse and diversion but continued to claim and market the drug as having nearly nonexistent potential for abuse and addiction, and, as such, constitute unlawful practices under the Iowa Consumer Fraud Act.

f. Because some of Defendants' Consumer Fraud Act violations were committed against older persons they give rise to the additional penalties provided for in Iowa Code section 714.16A (2019).

COUNT II

OLDER IOWANS LAW VIOLATIONS

289. Paragraphs 1 through 288 are incorporated herein by reference.

290. The Defendants' violations of the Iowa Consumer Fraud Act were committed against older Iowans within the meaning of Iowa Code Section 714.16A (2019) and give rise to penalties as set forth in that provision.

PRAYER

Plaintiff, the State of Iowa, requests the Court grant the following relief:

A. Pursuant to Iowa Code section 714.16(7), enter permanent injunctive relief restraining Defendants and Defendants' past and present directors, officers, principals, partners, owners, shareholders, employees, agents, servants, representatives, subsidiaries, affiliates, successors, assigns, merged or acquired predecessors, parent or controlling entities, and all other persons, corporations and other entities acting in concert or participating with Defendants who have actual or constructive knowledge of the Court's injunction, from engaging in the fraudulent, deceptive, misleading and omissive representations and unfair practices alleged in this Petition or otherwise violating the Iowa Consumer Fraud Act, expanding their provisions as necessary by including *inter alia* such "fencing in" provisions as are reasonably necessary to ensure that Defendants and other enjoined persons and entities do not return to the unlawful practices alleged herein, or commit comparable violations of law.

B. Pursuant to Iowa Code section 714.16(7), enter judgment against Defendants for restitution of all amounts necessary to restore to Iowans all money acquired by means of acts or practices that violate the Consumer Fraud Act.

C. Pursuant to Iowa Code section 714.16(7), enter judgment against Defendants for such additional amounts as are necessary to ensure complete disgorgement by Defendants of all ill-gotten gains resulting from the unlawful practices alleged herein.

D. Pursuant to Iowa Code section 714.16(7), enter judgment against each Defendant for up to forty thousand dollars per violation of the Iowa Consumer Fraud Act.

E. Pursuant to Iowa Code section 714.16A enter judgment against each Defendant for a civil penalty of five thousand dollars to be added to each civil penalty imposed under the Iowa Consumer Fraud Act.

F. Award Plaintiff interest as permitted by law.

G. Pursuant to Iowa Code section 714.16(7) enter judgment against Defendants for attorney fees, state's costs and court costs.

H. Retain jurisdiction as necessary to ensure full compliance with the Court's rulings.

I. Grant such additional relief as the Court deems just and equitable.

Respectfully submitted,

THOMAS J. MILLER
IOWA ATTORNEY GENERAL

Jessica Whitney
Special Assistant Attorney General

Amy Licht
Mariclare Thinnes Culver
William Pearson
Assistant Attorneys General

Hoover Building, 2nd Floor
1305 East Walnut Street,
Des Moines, IA 50319

Phone (515) 281-5926
jessica.whitney@ag.iowa.gov
amy.licht@ag.iowa.gov
mari.thinnesculver@ag.iowa.gov
william.pearson.ag.iowa.gov