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_____** **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 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 similar to morphine.

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 knowingly misrepresented that OxyContin would provide 12 hours of pain relief, while it knew 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, such as 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. They 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

II. 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 sec. 714.16 et seq. (2018) and 714.16A (2018) 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 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.

12. **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.

13. **DEFENDANT THE PURDUE FREDERICK COMPANY INC.** is a New York corporation with its principal place of business in Connecticut.

14. **DEFENDANT PURDUE PHARMA COMPANY** was formerly a Delaware general partnership, with its principal place of business in Connecticut.

15. **DEFENDANT P.F. LABORATORIES, INC.** is a New Jersey corporation with is principal place of business in New Jersey.

16. Each of the above Defendants develop, manufacture, promote, advertise, market, sell and/or distribute opioids, including OxyContin, in the 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 as assistant to the President in 1971. Beginning in the late 1970s Sackler held multiple executive positions at Purdue and related companies including heads of research and development and 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 1999 through 2018 and served as its co-chair starting in 2003. In these roles Sackler was a primary participant in and directed false, deceptive, misleading and omissive conduct and unfair practices related to the advertisement, marketing, promotion, and sale of Purdue opioids in Iowa.

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) (2018).

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 sales 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 sales 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) 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. Prior to the introduction of Purdue's OxyContin in 1996, for more than a century the medical community recognized the inherent dangers[1] of strong opioids.[2] In the latter half

[1] *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).

[2] *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").

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 harm and abuse, but have an accepted medical use, are placed in Schedule II.[3]

24. Oxycodone is a Schedule II drug, which means, by definition, it has a high potential for abuse. 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.[4] The federal Drug Enforcement Administration has characterized the pharmacological effects of oxycodone as similar to those of heroin.[5]

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.[6]

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[3] 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.)

[4] *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.

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

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

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.[7]

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.[8]

28. Opioids, such as OxyContin, are highly addictive. Some studies have found diagnosed addiction rates in a primary care setting as high as 26%.[9]

29. 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. Opioid tolerance occurs when the brain cells that have opioid receptors on them gradually become less responsive to the opioid stimulation.[10] 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.[11]

30. The most serious risks of opioids, such as addiction and death by overdose, increase substantially with higher doses.[12] Such risks rise in a dose-dependent fashion, meaning the risk increases proportionately with the dose.[13]

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[7] *Id.* at 5.
[8] *Id.*
[9] 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).
[10] Kosten & George, *supra* note 6, at 5.
[11] *Id.*
[12] Dowell *supra* note 9, 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)).
[13] Dowell, *supra* note 9, at 9, 13.

31. The risk of developing addiction also increases when opioids are used long-term.[14]

32. 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.[15] The CDC concluded that while opioids can reduce pain short-term, there is "insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."[16]

33. Opioids pose particular concerns for older adults, for whom opioid use can result in an increased risk for falls and fractures.[17] Older adults are also at greater risk of respiratory depression from opioid use.[18]

34. Veterans are also uniquely susceptible to the risks of opioid use. For example, 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.[19]

35. Oxycodone can be abused like other legal and illicit opioids including fentanyl, morphine and methadone. Abuse of oxycodone may lead to severe psychological or physical dependence.

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[14] 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).
[15] Dowell, *supra* note 9, at 9.
[16] *Id.* at 18, 20.
[17] *Id.* at 13.
[18] *Id.*
[19] *Pain Management Opioid Safety Educational Guide*, U.S. Department of Veterans Affairs (2014).

B. OxyContin

36. Purdue released OxyContin, a single agent version of oxycodone, in early 1996.[20]

37. OxyContin is an "extended-release" formulation, meaning the active ingredient – oxycodone – is released slowly, over time.[21] 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. 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 is twice as potent as morphine.[22]

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

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

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

42. 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

43. To achieve the sales it desired and position OxyContin as the leader in pain control, Purdue had to change fundamentally the way patients and health care providers perceived and used

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[20] Purdue created OxyContin following its success with MS Contin, a morphine-based extended-release product that Purdue promoted for the treatment of cancer pain.

[21] 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.

[22] *GAO Report*, *supra* at note 5, at 29.

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.

44. 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.

45. 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 the tendency of a drug to be used for non-medical reasons, even sporadically, due to underlying psychoactive effects it produces such as euphoria, sedation, or mood changes. In truth, however, *Purdue did not conduct any abuse liability studies on OxyContin before it rushed OxyContin to market.*

46. 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.

47. Purdue's failure to clinically study the abuse liability of OxyContin before it was released was unfortunately matched by Purdue's failure to put in place any post-launch program to

monitor abuse or develop a database from which it could collect and track reports of abuse or overdose.

48. Instead, Purdue was concerned with 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.

49. After the introduction of OxyContin, Purdue knew that physicians did, in fact, have a misconception about the potency of OxyContin, which is two times as potent as morphine. Purdue knew that physicians were prescribing OxyContin much earlier for non-cancer patients, where traditionally those health care providers had used much weaker opioid combination products such as Percocet. Purdue was enjoying blockbuster sales from its new product and did not want to take any action, including truthful disclosures about the nature of their product, that would decrease those sales. Accordingly, Purdue decided, *at the highest levels of the company* and approved by Sackler, that "it would be extremely dangerous at this early stage in the life of [OxyContin]...to make physicians think the drug is stronger or equal to morphine." Purdue further determined that in order to keep health care providers thinking that OxyContin was weaker than morphine and to keep physicians prescribing OxyContin much earlier for non-cancer pain, that *Purdue needed to ensure that all of its promotional pieces, articles, studies, etc. did nothing to change physicians' misperception that OxyContin was weaker than morphine*.

50. 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.

51. 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.

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

53. 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.

54. 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.

55. Purdue's sales representatives were essential in delivering Purdue's messages directly to Iowa health care providers.[23] 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.

56. 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.

57. Over the years, Purdue's sales staff made tens of thousands of calls on Iowa health care providers, sometimes visiting a single high prescriber multiple times in a month.

[23] 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 e.g. Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 Journal of the American Medical Association 1785, May 2, 2017.

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

59. 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.

60. Purdue's sales force distributed tens of thousands of promotional videos to distribute to physicians' offices, some of which were designed to be checked out and viewed by patients, including in Iowa.[24]

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

62. 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 controlled substance at free and substantially reduced cost. Purdue's patient starter coupon program for OxyContin, utilized to provide patients with a free prescription, ran intermittently for four years between 1998 and 2001.[25] By its conclusion, at least 34,000 coupons for free OxyContin prescriptions had been used nationally.[26]

63. 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

[24] *GAO Report*, *supra* note 5, at 24, 28.
[25] *Id.* at 23.
[26] *Id.*

superiority of opioids to safely treat a wide variety of pain conditions, including chronic pain.

64. Purdue funded and directed or assisted numerous professional societies, pain advocacy groups, and associations ("Third Party 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 Group publications that contained misleading and deceptive messages to Iowa prescribers.

65. The American Pain Foundation ("APF"), self-described as the nation's largest advocacy group for pain patients, was a crucial Third Party Group collaborator in Purdue's marketing efforts. Purdue made major contributions to APF[27] 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.*

66. Another significant Third Party Group 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 $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.

[27] 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.

67. 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" through direct sponsorship or financial grants, further erasing the line between medical education and pharmaceutical marketing.[28] Such funding often allowed Purdue to contribute to or control the content of health care practitioners' required continuing education content.

68. 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, 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 pain.

69. 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;

[28] *See GAO Report*, *supra* note 5, at 23.

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.

D. OxyContin Gains the Attention of Law Enforcement

70. By at least the year 2000 the risks of OxyContin gained regulatory attention. Despite the fact that from July 2001 forward the FDA required Purdue to change the OxyContin label to include a boxed warning and a statement that data are not available to "establish the true incidence of addiction in chronic patients," among other changes, Purdue continued to make false, misleading, deceptive, and omissive representations about the risks and benefits of OxyContin and engage in unfair practices related to its advertisement, marketing, promotion and sale.

71. In 2002, Dr. Paul Goldenheim, Purdue Vice President of Worldwide Research and Development and Chief Scientific Officer, among other Purdue executives, testified on Purdue's behalf before the United States Senate Committee on Health, Education, Labor and Pensions.[29] The Senate Committee was examining the effects of OxyContin and the abuse of the drug in the country. In testifying before the Senate Committee Dr. Goldenheim repeated some of Purdue's unsubstantiated claims about OxyContin, specifically that the problem of OxyContin abuse and diversion was due to "drug abusers" and people who "abuse" OxyContin, and "not patients with legitimate medical needs under the treatment of a health care professional...."[30]

72. In May 2007, The Purdue Frederick Company and three of its top executives pled guilty to felony and misdemeanor criminal charges of misbranding 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.

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[29] *OxyContin: Balancing Risks and Benefits: Hearing Before the United States Senate Committee on Health, Education, Labor, and Pensions*, 107th Cong., (February 12, 2002) (Statement of Paul Goldenheim).
[30] *Id.* at 68, 73.

E. 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.[31]

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.[32] 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.[33] One quarter of first opioid prescription fills in this group had a daily dose of more than 50 morphine milligram equivalents ("MME").[34] The CDC defines a "high" opioid dosage to be at least 50 MME and at this level, risk for an opioid overdose doubles.[35]

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.[36] Opioid pain relievers, such as oxycodone and hydrocodone, contributed to sixty percent of the drug overdose deaths in

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[31] 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.
[32] https://www.cdc.gov/drugoverdose/maps/rxstate2006.html (Last accessed March 13, 2019).
[33] *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.
[34] *Id.*
[35] *Id.*
[36] *Id.* at 4

Iowa in 2017.[37] In 2017 there were 206 opioid-related deaths (including deaths attributed to heroin) in the State, compared with 67 such deaths in 2005.[38] During the period between 2002 and 2014, there were a total of 1,239 overdose deaths due to prescription opioids in Iowa. [39]

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.[40] 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.[41]

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.[42]

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.[43]

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[37] *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).
[38] *Iowa's Opioid Crisis- An Update,* Iowa Department of Public Health, January 2019, at 6.
[39] *The Prescription Opioids Crisis, supra* note 33, at 5.
[40] *Iowa Substance Abuse Brief, supra* note 26.
[41] *The Prescription Opioids Crisis, supra* at note 32, at 5.
[42] *Iowa's Opioid Crisis, supra* note 38, at 7.
[43] Https://www.drugabuse.gov/opioid-summaries-by-state/iowa-opioid-summary (Last accessed May 1, 2019).

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 Executive Officer, Howard Udell, Purdue's Chief Legal Officer and Executive Vice 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. Purdue sales representatives told health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse;

    b. Purdue sales representatives told health care providers that OxyContin potentially creates 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 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.

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. 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 included in a section pertaining to respite periods the statement 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.

86. 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 promotion materials, symposia, clinicals, publications, conventions, or communications with the field force that would affect the unique position that OxyContin had[d] in many physicians mind" (sic).

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, 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 Medical Journal Article 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 "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 call in the last 2 days)."

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 CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR 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 Osteoarthritis Study Medical Journal Article to all of 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.

B. Purdue's Unfair and Deceptive Acts and Practices

94. Despite Purdue's judicial admissions that it promoted and marketed OxyContin with the intention to defraud and mislead in in its 2007 guilty plea agreement, Purdue continued to make false, misleading, deceptive, and omissive claims and engage in unfair practices related to the advertising, marketing, promotion and sale of OxyContin.

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 rare and had been exaggerated, and 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. Purdue developed and distributed an OxyContin marketing video titled, "*I Got My Life Back*" to thousands of prescribers, including in Iowa, in which a physician stated that opioid analgesics have been shown to cause addiction in less than one percent of patients,

a fact that the FDA found has not been substantiated.[44] *"I Got My Life Back"* was available on Purdue's *Partners Against Pain* website.

97. 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."

98. *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 more common for people addicted to OxyContin to simply swallow more tablets.

99. 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.

100. 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 addiction in opioid use when used as directed by a presciber, 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.'"

[44] *GAO Report, supra* note 5 at 25.

101. 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 Purdue-sponsored CME program 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."

102. The Federation of State Medical Boards' (FSMB) *Responsible Opioid Prescribing* made misleading and deceptive claims that addiction was unlikely to occur with opioid use, such as stating, "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.

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

104. 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 risks of addiction were 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"

105. 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.[45]

106. In its 2005 booklet titled, *Clinical Issues in Opioid Prescribing* Purdue defines, "pseudoaddiction" as a "Key Term in Pain Management" as follows:

> [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.

107. 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 who 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."

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[45] The term "pseudoaddiction" was made up in 1989 by Dr. J. David Hadox and Dr. David Weissman based on their experience with a single 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 frequently used by Purdue to promote opioid overuse and squelch health care providers' legitimate concerns about addiction.

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

109. *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 treat patients exhibiting indications of addiction as in need of more opioids, but did not disclose the lack of scientific study justifying the concept of pseudoaddiction nor that it was made up by a Purdue Vice President.

110. The concept of "pseudoaddiction" appears in Third Party 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.

111. 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."[46] An indepdendent 2015 review of medical literature mentioning pseudoaddiction concluded that "no empirical evidence yet exists to justify a clinical 'diagnosis' of pseudoaddiction."[47]

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[46] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. Journal Sentinel (Feb. 19, 2012).

[47] M. Greene & R. A. Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, 2 Cur. Addict. Rep. 310, Oct. 1, 2015.

3. Higher Doses of Opioids

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

113. Purdue trained its sales representatives to encourage Iowa health care providers to prescribe higher and higher doses of OxyContin.

114. Iowa sales representatives regularly touted the seven available strengths of OxyContin, pushed Iowa prescribers to "titrate up"- that is, to prescribe higher doses - and distributed marketing materials that encouraged increased dosages.

115. 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

116. Purdue and its sales representatives in Iowa made deceptive comparisons between OxyContin and other pain treatments, including non-opioids like NSAIDs (ibuprofen) and acetaminophen (Tylenol). These comparisons misleadingly stated or implied 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 risks of non-opioid pain relievers, while failing to disclose the significant risks associated with opioid use.

117. 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 side effects from opioids, describing them as, "constipation, nausea and vomiting, sedation (sleepiness), mental clouding and itching," and emphasized that addiction was unlikely.

118. Purdue sales representatives also made false, deceptive, misleading and omissive representations that OxyContin was superior to immediate-release opioid products, such as Vicodin or Percocet, because they contain acetaminophen, although Purdue lacked substantial medical evidence to substantiate these comparisons. 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.

5. Longer Doses of Opioids

119. Purdue made statements, and trained its sales representatives to state, that, OxyContin is appropriate for extended use in treating chronic pain, while deceptively failing to disclose the lack of scientific evidence that long-term opioid use is effective in treating chronic pain or that the longer a patient is using opioids, the higher the risk of addiction or overdose. 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 use.

120. Purdue distributed OxyContin coupons and savings cards (also known as value cards) to Iowa health care providers for distribution to patients and made the cards available on their website. The savings cards allowed patients to obtain OxyContin at a discounted price or for free 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.

121. Using coupons was a key component of Purdue's marketing strategy. Purdue knew that patients using savings cards were more likely to stay on OxyContin for longer periods of time and become more and more dependent on it.

6. Twelve Hours of Relief

122. 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.

123. 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 dosing because the twelve-hour dosing, "represents a significant competitive advantage of OxyContin over other products."[48]

124. 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.[49] Purdue also knew that health care providers, including in Iowa, were prescribing OxyContin in eight-hour intervals (e.g., three doses per day) due to OxyContin's failure to provide a full twelve hours of relief. Rather than admitting OxyContin failed to provide twelve hours of sustained pain relief, Iowa sales representatives encouraged health care

[48] April 14, 2004 Comments on Citizen Petition, Docket 2004P-0043, at 12-13.
[49] 2008 FDA Response to Citizen Petition by CT Attorney General.

providers to prescribe higher doses of the drug, without disclosing that higher doses of OxyContin pose greater risks for patients.

125. 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 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.

7. Quality of Life

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

127. 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.

128. *Responsible Opioid Prescribing* begins by stating that "[p]atients in pain who rely on opioids for analgesia and improved function deserve access to safe and effective medication..."

129. APF's *Treatment Options* repeated these false and misleading claims, stating that, when used properly, opioids "give [patients] a quality of life we deserve."

8. Vulnerable Populations: Older Patients and Veterans

130. 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 older people at lower opioid doses.

131. Purdue sales representatives specifically asked Iowa health care providers to use OxyContin in older patients without disclosing that those patients are at higher risk. 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.

132. 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.

133. For example, Purdue sponsored APF's *Exit Wounds*, a 2009 book focused on veterans, one Chapter of which is based on *Treatment Options*. *Exit Wounds* repeated false, deceptive, misleading and misleading statements about 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 that, "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 medications. When used correctly, opioid pain medications *increase* a person's level of functioning."

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

135. In 2010 Purdue introduced a reformulated version of OxyContin and discontinued marketing its original formulation of the drug.[50] The reformulated OxyContin has "abuse deterrent properties" that are 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."[51]

136. 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 by simply 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 Prescribers

137. Purdue 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

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

[51] NDA 22-272, OxyContin, Division Director Summary Review for Regulatory Action at 7 (FDA website), dated 12/30/2009

eventually subject to professional discipline by regulatory and licensing boards based on their reckless opioid prescribing practices.

138. Purdue also directed sales representatives to focus on visiting 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.

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

139. 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 advertised, marketed, promoted, and sold in Iowa.

140. Purdue is, and long has 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.

141. Richard S. Sackler had a seat on Purdue's Board from 1999 through 2018 and served as its co-chair starting in 2003.

142. Sackler began working for The Purdue Frederick Company as assistant to the President in 1971. Beginning in the late 1970s he held multiple executive positions at Purdue and related companies including the heads of the research and development and medical departments. In 1996 Sackler 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.

143. 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.

A. Sackler Perpetuated Misconceptions About OxyContin and Knew It Posed Dangerously High Risks of Abuse

144. From the initial launch of OxyContin, Sackler played a key role in developing and disseminating Purdue's false, deceptive, misleading, and omissive misrepresentation and unfair practices related to OxyContin's risk of abuse and addiction, as if he had, "dedicated [his] life to it."

145. As described above Section IV (Factual Background), Sackler was intimately involved in OxyContin's early development, sale and promotion. He knew, shortly after OxyContin's introduction in the market that prescribers had the crucial misconception that OxyContin was less potent than morphine and that health care providers were prescribing it earlier in treatment in place of weaker, opioid combination products. Sackler was informed of and approved the plan to make sure physicians weren't truthfully informed about the true potency of OxyContin. Sackler claimed that the OxyContin package insert was so full of promotional and marketing claims that it could serve as a powerful selling tool. At the company launch of OxyContin in 1996, Sackler addressed all the company's sales representatives, staff and executives in a speech in which he presciently predicted a "blizzard" of OxyContin prescriptions.

146. During the years following OxyContin's debut Sackler received many reports, including from Purdue employees and federal law enforcement, about abuse of OxyContin:

    a. A few months after the OxyContin launch in 1996, Sackler was sent a medical journal article about the abuse of Purdue's other controlled release drug, MS Contin, undercutting one of Purdue's central [mis]representations that OxyContin would have no or little abuse because of its time-release formulation;

b. In August 1996, a Purdue researcher assigned to research MS Contin abuse wrote to Sackler about his findings;

c. In February 1997, one of OxyContin's principal developers told Sackler in writing that oxycodone products were some of the most abused in the United States, and that Purdue did not have a good basis to argue that OxyContin had minimal or no potential for abuse;

d. In the same 1997 transmission to Sackler, he was told that MS Contin was being commonly abused in New Zealand;

e. In the fall of 1997, a Purdue marketing official wrote a memo to Purdue executives about discussions of OxyContin abuse he had found on the internet, stating that monitoring the online OxyContin abuse discussion "was enough to keep a person busy all day," and that Purdue had 3 such employees monitoring internet discussions of OxyContin abuse;

f. In 1998, Sackler received a Canadian medical journal article and accompanying editorial by a Canadian physician that disclosed a study of MS Contin abuse in Canada, which disclosed that MS Contin fetched the highest price per black market drugs, and that since OxyContin had then been launched in Canada, physicians expected that it too would soon be sold on the street. Purdue's top lawyer also then wrote a memo about MS Contin abuse, including street prices, and sent it to Sackler;

g. In mid-1999, when Sackler was preparing to become President of Purdue, executives were informed on numerous occasions of OxyContin misuse and abuse in multiple states;

h. In the summer of 1999, a Purdue sales representative wrote to Sackler reporting widespread abuse of OxyContin; and

i. While Sackler immersed himself in the skyrocketing sales data of OxyContin and the possibility of it becoming a billion dollar a year drug, he ignored readily available and completely alarming information, including information that Purdue subordinates were reporting, about the abuse and diversion of OxyContin. Purdue required its entire national sales force to document in writing every visit or call ("call notes") they make on health care providers. Beginning at least the year after OxyContin was launched, sales representatives began reporting, *in Purdue's own call note system*, that they were being told that OxyContin tablets were being crushed and snorted, and that they had a "street value."

j. In January 2001, while President of Purdue, Sackler received an email from a Purdue sales representative describing a community meeting at a local high school organized by mothers whose had children overdosed on OxyContin and died. 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."

k. In February 2001, a federal prosecutor reported 59 deaths from OxyContin in a single state. President Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."

147. Rather than responding to these reports by taking vigorous action to curb abuse of Purdue's highly addictive opioid products, 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."

B. Sackler Participated, Directed and Sanctioned Purdue's Aggressive OxyContin Sales Campaign

148. As an executive and a Board member, Sackler was actively and intimately involved in most, if not all of Purdue's principal business operations, including strategic planning, sales and marketing, the development of new products and technologies, finances, compensation, and company growth and forecasting. He frequently intruded upon, bypassed, and/or usurped the authority of Purdue's management including but not limited to giving his own ideas and directions to management and staff, holding his own meetings, and creating or making revisions to important company documents.

149. As a Board member and Purdue executive, Sackler requested frequent reports about Purdue's operations, including about marketing, sales and sales projections of OxyContin. Sackler continuously monitored sales and sales forecasts, asked for data on sales and marketing plans, and studied, through Purdue's own staff and marketing consultants, the best way to sell more and more opioids. As a member of the Purdue Board, Sackler approved expansions of the sales force and the marketing budget.

150. Sackler was particularly interested in, and involved himself in, the sales forecasting for OxyContin. He frequently requested and often demanded OxyContin sales data in a wide variety of forms and formats. He regularly disagreed with the sales forecasting staff's projections and assumptions, and reworked their data and analysis to modify Purdue's sales goals for OxyContin. Sackler's end goal was always to grow sales at a faster rate.

151. Sackler, as a Board member, approved plans to hire new sales representatives, hire and promote new District and Regional managers, and create sales "territories" in which representatives would target doctors. He tracked the number of Purdue sales representatives and the visits they made to urge prescribers to prescribe Purdue opioids. Sackler knew which drugs were promoted; how many visits sales representatives averaged per workday; how much each visit cost Purdue. He tracked the number of daily visits per representative, and the total number of sales visits per quarter until at least 2014.

152. Sackler was a micromanager. 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, addressing the entire national field of sales representatives, proposing cuts and other changes to the budget, involving himself in FDA and regulatory matters, engaging with sales representatives and managers, attending national sales meetings, and requesting unending briefings and data from Purdue's sales and forecasting teams.

153. In fact, Sackler's daily interactions with Purdue's management and staff were frequently unwelcome by those receiving his directions, orders, and requests, and by those in the chain of command who Sackler bypassed. Purdue staff and management appealed to executive management to stop Sackler from interfering with their work, from demanding work on weekends, and from making them perform unrealistic, unnecessary, and meaningless busywork. At times, Sackler's involvement in the day-to-day running of Purdue created

friction and concern, generating outcry among senior staff and requests that his involvement in the organization be managed.

154. As described above in Section IV, 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 less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."

155. Rather than respond to the guilty plea by revamping its aggressive sales practices Purdue and Sackler continued to authorize fraudulent, deceptive, misleading, and omissive acts that reached Iowa health care providers and patients.

156. Through Purdue staff reports to the Board, Sackler knew that Purdue distributed deceptive marketing materials, including materials sent to Iowa, that falsely claimed OxyContin would improve patients' quality of life and function, and falsely told doctors and patients that signs of addiction were actually signs of "pseudoaddiction," the solution to which was to prescribe more OxyContin.

157. Sackler's participation in Purdue's sales and promotion of OxyContin continued. Sackler attended a launch meeting for another Purdue opioid product as well as meetings with sales staff and proposed going into the field to accompany sales representatives face-to-face.

158. Sackler directly participated in promoting sales call strategy. For example, in a 2011 email exchange with the Senior Vice President for Sales and Marketing, he emphasized that sales representatives should only be calling on high prescribers.

159. The Board, including Sackler, authorized Purdue staff to hire a new staff member who would contact prescribers electronically and would promote Purdue opioids through the deceptive website *Partners Against Pain.*

160. Sackler was interested in the opioid savings cards, which Iowa sales representatives distributed to health care providers in the state and which Iowa consumers used. He sought information from the sales and marketing head and his team about the terms of the savings cards, their use, efficacy and impact on sales.

161. At a June 2012 Board meeting, Purdue staff reported to Sackler and the rest of the Board that they had expanded the use of opioid savings cards, because the latest Purdue data showed that the cards resulted in more patients staying on Purdue opioids for longer periods of time.

162. Just two months later, at a May 2013 Board meeting, staff reported to the Sacklers that they were successfully pushing opioid savings cards through direct mail and email to get patients to "remain on therapy longer."

163. In 2007, Sackler applied for a patent to treat opioid addiction. He finally received it in January 2018 and assigned it 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

164. The Sackler family, including Richard Sacker, 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.

165. 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.

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

167. Since the release of OxyContin, Purdue has faced thousands of lawsuits related to its sales and marketing practices. 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.

168. 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 continue to be a cost of doing business for Purdue. Despite this knowledge, the Sacklers continued to vote to pay themselves significant distributions and send money to offshore companies, and Purdue continued to forecast hundreds of millions of future distributions to the Sacklers.

169. 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.

170. 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 spoke with the *Washington Post* to reiterate Purdue's threat to delay scheduled trials, and ultimately delay and otherwise limit states' recovery against Purdue

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

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

VII. General Allegations

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

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

175. 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.

176. 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.

177. Omissions of material fact also violate the Consumer Fraud Act if it is intended that others rely on them. The omissions, concealments, and suppression alleged herein involved material facts and with the intent that others rely on them.

VIII. Violations of the Law

COUNT I

IOWA CONSUMER FRAUD ACT VIOLATIONS

178. The State of Iowa incorporates paragraphs 1 through 177 as if fully set forth herein.

179. Defendants' statements, acts and practices violate the Iowa Consumer Fraud Act, Iowa Code section 714.16 (2018), 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,

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

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

COUNT II

OLDER IOWANS LAW VIOLATIONS

180. Paragraphs 1 through 179 are incorporated herein by reference.

181. The Defendants' violations of the Iowa Consumer Fraud Act were committed against older Iowans within the meaning of Iowa Code Section 714.16A 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 a permanent injunction restraining Defendants and Defendants' 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 traceable to 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,

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