STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY

STATE OF WISCONSIN,
17 West Main Street
Post Office Box 7857
Madison, WI 53707-7857,

Plaintiff,

v.

Case No. 19-CX-_____

Complex Forfeiture: 30109

PURDUE PHARMA L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431,

PURDUE PHARMA INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431, and

RICHARD S. SACKLER
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431,

Defendants.

COMPLAINT

The State of Wisconsin, by its attorneys, Attorney General Joshua L. Kaul, and Assistant Attorneys General Laura E. McFarlane, Jennifer L. Vandermeuse, and Shannon A. Conlin, brings this action against the Defendants named above and alleges as follows:

INTRODUCTION

1. The United States and the State of Wisconsin are suffering from an opioid epidemic. The public health crisis has taken the lives of hundreds of thousands of Americans, including thousands of Wisconsinites.

2. From 1999, the number of drug overdose deaths in the United States involving an opioid increased by almost 500%, from 8,048 in 1999 to 47,600 deaths in 2017.

3. For the first time since World War I, the United States has sustained a multi-year decline in life expectancy, which has been directly linked to the opioid crisis.

4. From 2000 to 2017, Wisconsin has lost over 7,500 of its citizens to overdoses involving opioids. The rate of opioid overdose deaths in Wisconsin has almost tripled since 2006 when the rate was 5.9 deaths per 100,000 persons. In 2017 alone, there were over 900 opioid overdose deaths in Wisconsin.

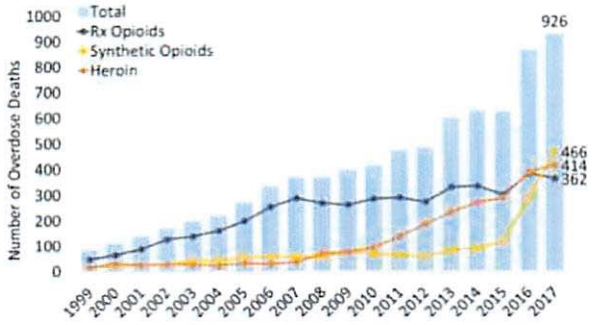
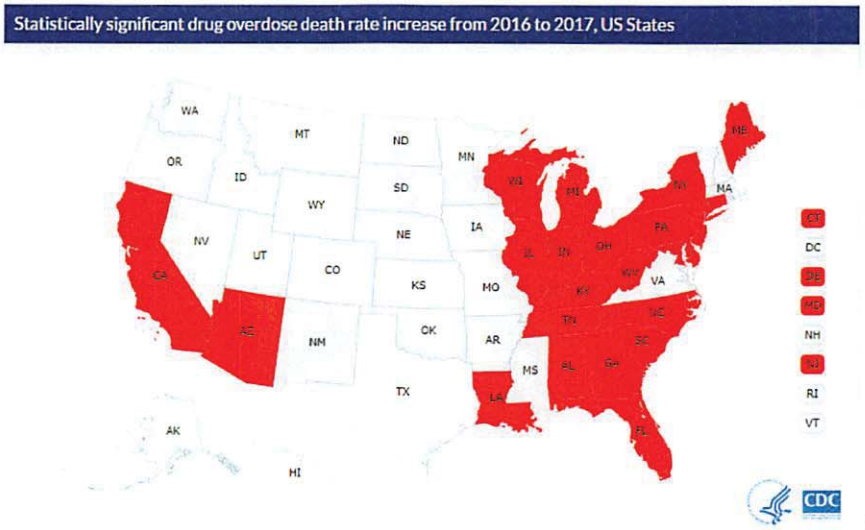


Figure 1. Number of overdose deaths involving opioids in Wisconsin, by opioid category. Drug categories presented are not mutually exclusive, and deaths might have involved more than one substance. Source: CDC WONDER [1]

[1] Wisconsin Opioid Summary, National Institute on Drug Abuse, https://www.drugabuse.gov/opioid-summaries-by-state/wisconsin-opioid-summary (last visited May 15, 2019).

5. According to the Centers for Disease Control and Prevention, the drug overdose death rate in Wisconsin increased by 24.5 percent from 2015 to 2016, and it rose by another 9.8 percent from 2016 to 2017.



[2]

6. In Wisconsin, the risk of illicit opioid overdose is linked to past usage of prescription opioids. Approximately three out of four heroin users report having abused prescription opioids prior to using heroin. In fact, once patients stopped taking prescription opioids, heroin overdose occurred after six months on average.

7. According to the Wisconsin Department of Health Services ("DHS"), opioid overdose deaths represent the "tip of the iceberg" of the total opioid harm in Wisconsin. For example, in 2014, DHS reports there were nearly 3,000 hospital encounters for opioid overdoses. In 2017, an estimated 1.7 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.

---

[2] Drug Overdose Deaths, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited May 15, 2019).

8. The Centers for Disease Control and Prevention estimates that the total economic burden of prescription opioid misuse nationally is $78.5 billion a year, which accounts for the costs of health care, lost productivity, addiction treatment, and criminal justice involvement.

9. An example of the impact of the crisis comes from Wisconsin Rapids, Wisconsin. Rebecca P. was prescribed pain medication in 2013 due to complications during labor for her fifth child. Her doctors prescribed her pain medication for five months before she became addicted, and even then, her doctors continued to prescribe her pain medication for two years. In January 2015, Rebecca began using heroin. Due to her addiction, Rebecca became homeless and her five children were placed in the foster care system.

10. Another example comes from Crandon, Wisconsin. Matthew E. was first prescribed opioids as a teenager to treat an ingrown toenail infection. Over the next seven years, Matthew became addicted to his prescription pain medication and eventually, heroin. After spending five months in jail and completing a drug treatment program, Matthew temporarily stopped using drugs, but he was unable to stay clean for long – he relapsed on opioids and died of a drug overdose at the age of 25. For the last two years of his life, Matthew recorded his daily drug use and attempts to quit in two spiral-bound journals. His journal entries document one common theme – the only thing holding him back in life was "dope."

11. The opioid crisis was not inevitable. The crisis, in part, is a direct and foreseeable result of Defendants' conduct. As set forth below, Defendants undertook

a concerted and successful effort to change the public's understanding – and to increase the use – of opioids, misleadingly downplaying the risks and overstating the benefits of those drugs.

PARTIES

12. Plaintiff State of Wisconsin is a sovereign state of the United States of America, with its principal offices located in Madison, Wisconsin.

13. Defendant Purdue Pharma L.P. is a foreign limited partnership organized under the laws of Delaware, with its principal place of business in Stamford, Connecticut.

14. Defendant Purdue Pharma Inc. is a foreign corporation organized under the laws of New York, with its principal place of business in Stamford, Connecticut.

15. Purdue Pharma Inc.'s purpose includes, but is not limited to, manufacturing, sales, distribution, and research and development with respect to pharmaceutical products, directly or as the general partner of a partnership engaged in those activities.

16. Purdue Pharma L.P. is in the business of manufacturing, marketing, promoting, and selling Purdue's drugs, including by employing the sales representatives and paying health care providers to promote Purdue's drugs.

17. Purdue Pharma Inc. is the general partner of, and ultimately controls, Purdue Pharma L.P. At all relevant times, Purdue Pharma Inc. has supervised and managed the operations and affairs of Purdue Pharma L.P.

18. Purdue Pharma Inc. controlled Purdue Pharma L.P. as its general partner and is liable for the misconduct of the partnership. Purdue Pharma Inc. is also the general partner of Purdue Holdings L.P., which holds the sole limited partnership interest in Purdue Pharma L.P.

19. Purdue Pharma Inc. and Purdue Pharma L.P. shared the same physical offices, the same CEO, and many of the same officers.

20. Purdue Pharma Inc. and Purdue Pharma L.P. acted together to carry out all of the misconduct alleged in this Complaint.

21. Purdue Pharma Inc. and Purdue Pharma L.P. are collectively referred to as "Purdue." For purposes of this Complaint, any reference to the acts and practices of Purdue shall mean that such acts and practices are by and through the acts of Purdue's members, owners, directors, employees, salespersons, representatives, and/or other agents.

22. At all relevant times, Purdue has been controlled by members of a single family, the Sacklers, who are the intended beneficiaries of Purdue's profit distributions. Those distributions have amounted to billions of dollars.

23. Defendant Richard S. Sackler became a member of the Purdue Pharma Inc. board in 1990 and became its co-chair in 2003, which he remained until he left the board in 2018. He was also its president from 1999 through 2003. Richard S. Sackler resides in New York, Florida, and Texas.

24. Defendant Richard S. Sackler directed the deceptive sales and marketing practices within Purdue. Defendant Richard S. Sackler sanctioned,

controlled, or had the ability to control, the acts and practices that form the basis for the violations alleged below.

JURISDICTION, VENUE, AND TOLLING

25. This action is brought pursuant to Wis. Stats. §§ 100.18(11)(d) and 100.182(5)(a) to enjoin and restrain violations of Wis. Stats. §§ 100.18(1) and 100.182, Wisconsin laws prohibiting false, deceptive, and misleading representations. This action is further brought pursuant to the Attorney General's authority under Wis. Stats. §§ 823.01 and 823.02, as an action to enjoin and abate a public nuisance.

26. This Court has personal jurisdiction over Purdue pursuant to Wis. Stats. §§ 801.05(1)(d), (3), and (4), and over Richard S. Sackler pursuant to Wis. Stats. §§ 801.05(3) and 801.05(4). Purdue, pursuant to Richard S. Sackler's active control and direction, has engaged in substantial business contacts within the State of Wisconsin and has directed Purdue's deceptive marketing practices at all times relevant to this Complaint. Purdue's multi-pronged marketing campaign was targeted at all states, including Wisconsin. Richard S. Sackler exercised a high level of control over the deceptive marketing enterprise and business contacts targeted at all states, including Wisconsin, was aware of and sanctioned the deceptive marketing practices, and willingly participated in the revenue derived from these practices. The Defendants' acts, conducted both within and outside the State of Wisconsin, were a cause of the in-state injuries alleged in this Complaint.

27. Venue for this action properly lies in Dane County, Wisconsin pursuant to Wis. Stat. § 801.50(2)(a).

28. The State of Wisconsin, Purdue Pharma Inc., and Purdue Pharma L.P. entered into a written agreement tolling any applicable statutes of limitation during the time period between December 23, 2016, and May 13, 2019.

FACTUAL ALLEGATIONS

I. Opioid Crisis Background.

29. Opioids are a class of drugs associated with the chemicals found in the opium poppy plant. They are known as either opiates, semi-synthetic opioids, or synthetic opioids. Opiates are chemicals that are naturally derived from the opium poppy plant. There are four opiate chemicals that are used by the medical industry, with the two most popular being morphine and codeine. Semi-synthetic opioids are manmade chemicals that are derived from naturally occurring opiates, and include legally manufactured drugs such as oxycodone, hydrocodone, and buprenorphine, as well as heroin. Synthetic opioids are manmade and mimic the effects of opiates but are not derived from the opium poppy. Synthetic opioids include drugs such as fentanyl and methadone.

30. The dangers of opioids have long been known in the United States. In 1908, President Theodore Roosevelt appointed an Opium Commissioner who stated that opium was "the most pernicious drug known to humanity."

31. Opioids are powerful drugs as they attach to receptors on nerve cells in the brain, spinal cord, and other organs. This allows them to block pain messages sent from the body to the brain.

32. When the opioids attach to the receptors, they cause a large amount of dopamine to be released in the pleasure centers of the brain – effectively causing a rush of extreme pleasure and well-being throughout the body.

33. The additional dopamine that opioids create in the body is dangerous as it can cause extreme sleepiness, confusion, nausea, vomiting, constipation, and can even slow down the respiratory system enough to cause death by suffocation.

34. When the state of euphoria wears off, the desire to bring it back – by taking the opioid again – inevitably sets in. Repeated use of opioids, however, creates tolerance – requiring the user to take ever higher doses to achieve the same euphoric effect, as the body defensively produces more and more of a stimulating chemical called noradrenaline to counteract the sedating effects of the opioids. Once tolerance sets in, physical withdrawal and dependence come with it, because when the opioids leave the body, the excess noradrenaline remains, causing jitters, anxiety, muscle cramps, and diarrhea.

35. As a result of this powerful combination of physical and psychoactive reactions, anyone who uses opioids, even for a short time, may develop opioid use disorder, commonly known as addiction. Opioid use disorder is a condition in which the brain literally changes – prefrontal regulatory circuits are impaired, and normal reward and emotion response mechanisms become skewed – making it extraordinarily difficult for the people it affects to voluntarily reduce their drug-taking behavior, despite knowing the potentially catastrophic consequences.

36. Prescription opioids are available in both immediate release and extended release formulas. Immediate release, as the name suggests, are drugs that immediately enter the bloodstream. Extended release, on the other hand, are concentrated doses of the immediate release versions, but contained in a delivery system designed to release the drug over time.

37. Extended release formulations of opioids are considered dangerous as they present serious risks of misuse, abuse, NOWS (neonatal opioid withdrawal syndrome), addiction, overdose, and death.

38. Prior to 1996, health care providers were reluctant to prescribe opioids as awareness of the proven risks associated with the drugs, established within the medical and scientific communities, kept the prescriptions tightly restricted to a relatively narrow population of patients for whom the benefits were deemed to outweigh the dangers – people battling acute cancer pain or advanced HIV or for end-of-life palliative care.

39. In 1996, the medical community's understanding of appropriate prescribing of opioids changed dramatically with the introduction of OxyContin by Purdue and its corresponding deceptive marketing campaign.

II. Purdue and OxyContin.

40. In 1952, Arthur, Raymond, and Moritmer Sackler bought Purdue Frederick, a small patent-medicine company based in Greenwich Village. At the time, Purdue Frederick made laxatives and earwax remover.

41. In 1990, members of the Sackler family incorporated Purdue Pharma Inc. in the State of New York. The following year, 1991, members of the Sackler family incorporated Purdue Pharma L.P. in the State of Delaware. Purdue Pharma Inc. is the general partner of Purdue Pharma L.P. Both Purdue Pharma Inc. and Purdue Pharma L.P. operate out of Stamford, Connecticut.

42. Since its incorporation, members of the Sackler family have retained a voting majority on the Purdue Pharma Inc. board.

43. Purdue entered the opioid business in the 1980s when it acquired a Scottish drug producer that had developed MS Contin, a sustained-release technology suitable for morphine. "MS" is short for morphine sulfate, and "Contin" is short for "continuous."

44. Purdue had a great deal of success with MS Contin. MS Contin was considered the default option for cancer patients eligible for opioid treatments.

45. MS Contin became the engine of then-unprecedented growth and financial success for Purdue and members of the Sackler family.

46. By the late eighties, Purdue's patent for MS Contin was about to expire and Purdue was concerned about preserving and expanding the gains the company had made with MS Contin. Around that time, Richard S. Sackler became more involved in the management of the family businesses. According to a long-time Purdue sales representative, Richard S. Sackler wanted Purdue to be big – "*really* big."

47. Purdue knew that once its competitors could sell generic versions of MS Contin, it would lose its space in the market for treating cancer patients. Purdue recognized the opportunity to go laterally with MS Contin to non-cancer pain indications whereby Purdue would convince health care providers to prescribe the drug for patients for whom opioids were traditionally thought of as inappropriate.

48. Purdue recognized, however, that any generic competition would engulf even an expanded market for MS Contin. As a result, Purdue developed a controlled-release formulation of the synthetic opioid oxycodone, which was later named "OxyContin." Once Purdue patented this new formulation, the branded drug could be "positioned against numerous analgesics in non-cancer painful indications including chronic non-malignant pain" and thereby avoid the consequences when generic competition arrived "to crush all of the MS Contin eggs."

49. Prior to Purdue's introduction of OxyContin, oxycodone had been used in other prescription pain relievers such as Percodan and Percocet. However, neither Percodan nor Percocet are pure oxycodone. Instead, each drug only contains a small amount of oxycodone and is blended with a higher concentration of over the counter pain relievers. Milligram for milligram, oxycodone is about fifty percent stronger than morphine.

50. Purdue's oxycodone drug, OxyContin, was not blended with over-the-counter pain relievers. Instead, OxyContin was pure oxycodone with a time-release formula similar to that of MS Contin.

51. OxyContin was made available with doses as low as 10 milligrams, but Purdue also made available higher and more potent doses of 20, 40, 80, and even 160 milligrams.

52. Purdue and Richard S. Sackler were well aware of the financial gains they were about to make with the launch of OxyContin. At the OxyContin launch party, Richard S. Sackler asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. He then said, "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white...."

53. Prior to launching OxyContin, Purdue was aware of the common concern within the medical community that opioids had a high abuse potential and, as a result, should not be used to treat chronic pain.

54. In order to combat the concerns about opioids being abused, Purdue deployed a marketing campaign that sought to increase sales of OxyContin, while changing the accepted norms about opioid prescribing.

55. One key marketing ploy initiated by Purdue to make health care providers more comfortable with prescribing dangerously high dosages of opioids was to create the narrative of an "epidemic" of untreated pain in America, where as many as 100 million adults were allegedly suffering silently.

56. Purdue developed an aggressive marketing scheme to fundamentally change opioid prescribing norms by using seemingly independent practitioners and medical societies, as well as an army of sales representatives and unbranded "patient

advocacy" websites, to spread Purdue's deceptive claims, all with the goal of increased sales and profit for Purdue, and ultimately, financial gain for members of the Sackler family.

57. Purdue paid physicians around the country, including in Wisconsin, significant sums of money to act as speakers, Key Opinion Leaders, and/or consultants.

58. Another crucial, and complementary, marketing channel for Purdue was the use of Front Groups over whose publications Purdue exercised editorial input and control. Many of these Front Groups had seemingly independent and innocuous names – leading consumers and the health care community to believe they were independent and trustworthy sources of medical knowledge.

59. Those Front Groups include, but are not limited to, the following:

a. American Pain Foundation ("APF");

b. American Academy of Pain Medicine ("AAPM") and American Pain Society ("APS");

c. Academy of Integrative Pain Management ("AIPM");

d. U.S. Pain Foundation ("USPF");

e. American Geriatrics Society ("AGS");

f. Pain Care Forum ("PCF"); and, among others,

g. American Chronic Pain Association ("ACPA").

60. Purdue compounded the effect of the deceptive "educational" materials generated by Key Opinion Leaders and Front Groups by directly disseminating them

through hundreds of sales representatives deployed around the country, including in Wisconsin, to promote Purdue's products and opioids directly to health care providers.

61. Sales representatives were encouraged by a lucrative bonus system to increase sales of OxyContin in their territories. In 2001, for example, although the average sales representative's annual salary was $55,000, annual bonuses averaged $71,500, with a range of $15,000 to nearly $240,000. Purdue paid $40 million in sales incentive bonuses to its sales representatives that year.

62. Purdue was deliberate in who its sales representatives would target. Those targets included health care providers not typically associated with prescribing opioids, such as primary care providers and others unfamiliar with pain management. Purdue also analyzed prescribing patterns of health care providers in order to identify the highest volume opioid prescribers so they could be targeted to switch their patients to Purdue's opioids and then "titrate" their patients to higher doses.

63. Purdue also disseminated misleading materials directly to consumers and health care providers in Wisconsin through its unbranded pain management advocacy websites, *In The Face of Pain*, http://www.inthefaceofpain.com, and *Partners Against Pain*, http://www.partnersagainstpain.com.

64. Throughout its multi-pronged marketing campaign that was targeted at all states, including Wisconsin, Purdue made many misrepresentations about OxyContin including its addictive and abuse qualities as well as it being less likely to cause tolerance and withdrawal.

65. Behind closed doors, Richard S. Sackler perpetuated harmful misconceptions about opioid abusers and addicts being responsible for the opioid crisis. For example, in 2001, an acquaintance of Richard S. Sackler's wrote him an email that read "[a]busers die, well that is the choice they made, I doubt a single one didn't know of the risks." Richard S. Sackler responded by saying, "[a]busers aren't victims; they are the victimizers." When asked about a Time magazine article on OxyContin, Richard S. Sackler responded by saying that when he is "ambushed by 60 Minutes" he can't easily get the concept of addicts being criminals because "calling drug addicts 'scum of the earth' will guarantee that I become the poster child for liberals who want to do just want [sic] to distribute the blame to someone else...."

66. Purdue's marketing efforts were highly effective. Although research demonstrated that OxyContin was comparable in efficacy and safety to other available opioids, Purdue's marketing catapulted OxyContin to blockbuster drug sales. Sales escalated from $44 million (316,000 prescriptions dispensed) in 1996 to a 2001 and 2002 combined sales of nearly $3 billion (over 14 million prescriptions).

67. This dramatic increase in sales resulted in enormous financial gain for Purdue and members of the Sackler family. It also led to increased opioid abuse, diversion, and addiction.

68. Soon after OxyContin was brought to market, users discovered that an OxyContin tablet, when softened up with water or saliva, could be crushed to yield its full oxycodone dose all at once. By 2004, OxyContin had become a leading drug of abuse in the United States.

69. In 2007, Purdue Frederick (and individual executives) pled guilty to a federal felony based on its marketing practices.

70. Purdue Frederick specifically 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 medications."

71. Purdue Frederick also admitted that this deceptive marketing and advertising occurred through misstatements by its own trained sales representatives who mischaracterized the risks of OxyContin addiction and abuse.

72. The plea agreement plainly stated, "Purdue is pleading guilty as described above because Purdue is in fact guilty." Purdue Frederick was ordered to pay $600 million in sanctions and the individual defendants were ordered to pay $34.5 million.

73. Also in 2007, Purdue Pharma L.P., Purdue Pharma Inc., and Purdue Frederick Company entered into a civil Consent Judgment with the State of Wisconsin, along with 25 other states and the District of Columbia, concerning its marketing and promotion of OxyContin, and alleged violations of state consumer protection laws, including Wis. Stat. § 100.18(1). As part of the Consent Judgment, Purdue Pharma L.P., Purdue Pharma Inc., and Purdue Frederick Company paid the states $19.5 million.

74. The Consent Judgment prohibited Purdue from making any false, misleading, or deceptive claims in the promotion or marketing of OxyContin or any

controlled-release drug distributed by Purdue that contains oxycodone as an active pharmaceutical ingredient.

75. The Consent Judgment also prohibited Purdue from misrepresenting any such drug's potential for abuse, addiction, or physical dependence. In addition, Purdue was required to implement and maintain an OxyContin Abuse and Diversion Detection Program to identify potential abuse or diversion of such drugs, including the identification and reporting of problematic prescribing behaviors.

III. The Defendants' Deceptive Practices Continued.

76. Despite the criminal sanctions and the terms of the states' consent judgments, Purdue persisted, although more surreptitiously, in its deceptive marketing and promotion of its prescription opioid products.[3]

77. Since May 8, 2007, Purdue has continued to use its same multi-pronged approach to disseminate false, deceptive, and misleading information about opioid prescribing and its brand-name opioids, namely OxyContin, MS Contin, Butrans, and Dilaudid, Hysingla, and Ryzolt. Specifically, Purdue has continued to rely upon Key Opinion Leaders, Front Groups, sales representatives, and "patient advocacy" websites to mislead health care providers and consumers about its prescription opioids.

78. Although Purdue has continued to use the same avenues of deception, including targeting high volume prescribers known to Purdue to be problematic,

[3] Due to the Consent Judgment between the State of Wisconsin and Purdue, the claims in this Complaint are limited to actions after the Consent Judgment, effective May 8, 2007.

Purdue has relied more heavily on its Front Groups the last few years to mislead the public and influence public policy and public opinion.

79. Through widely available public information as well as documents Purdue received related to abuse and diversion of Purdue opioids, Purdue knew or should have known of the hazards of opioid use, as well as the abuse and addiction related to its products. Yet Purdue continued its deceptive marketing of opioids in Wisconsin.

80. Purdue's activities were a substantial factor in creating the public health crisis in Wisconsin and the injuries alleged in this Complaint.

81. While having actual or constructive knowledge of the risks posed by its products, Purdue continued to resist efforts to place reasonable restrictions on opioid prescription activity that could have reduced the scale of the opioid crisis.

82. In February 2018, the Senate publication *Fueling an Epidemic* revealed that Purdue had been the single largest funder of organizations that served as Front Groups or that otherwise advanced Purdue's interests, spending over $4.15 million between January 2012 and March 2017 on twelve different organizations that were examined by the Senate committee.

83. In promoting its prescription opioids,[4] Purdue misrepresented the potential for addiction, the concept of "pseudoaddiction," the additional risks associated with increased doses, the ability to mitigate the risk of addiction, the

[4] When reference is made to promotion of opioids by Purdue, that promotion is attributed to Purdue's direct and indirect marketing through Purdue's sales representatives, speakers, Key Opinion Leaders, websites, and through the dissemination of materials created with Front Groups.

benefits of its prescription opioids, the efficacy of its prescription opioids, the ability to control the effects of withdrawal, and the risks for senior citizens.

A. Purdue Misrepresented the of Risk of Addiction.

84. Despite medical evidence to the contrary, Purdue misled health care providers and consumers about the risk of addiction associated with opioids.

85. For example, Purdue trained its sales representatives to represent that the risk of addiction "is less than one percent."

86. By way of unbranded marketing, Purdue funded and sponsored its Front Groups' efforts to provide "educational" publications that downplayed the risk of addiction. Examples of the Front Groups' misrepresentations include, but are not limited to, the following:

a. Purdue sponsored the American Pain Foundation's ("APF") *Treatment Options: A Guide for People Living with Pain* (2007), which maintained that addiction was rare and limited to extreme cases, such as unauthorized dose escalations, obtaining opioids from multiple sources, or theft. *Treatment Options* also stated that "[d]espite the great benefits of opioids they are often underused," and "[r]estricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction."

b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Risk & Its Management* (2011), which claimed that "less than 1 percent of

children treated with opioids become addicted" and that pain is undertreated due to "[m]isconceptions about opioid addiction."

c. Purdue sponsored APF's *Exit Wounds* (2009), which targeted the veteran community and claimed that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the rate is immaterial.

d. The APF publication *Getting the Help You Need* claims, "[s]tudies and clinical practice have shown that the risk of addiction is small when [opioids] are appropriately prescribed and taken as directed," and "[u]nless you have a past or current history of substance abuse, the chance of addiction is low when these medications are prescribed properly and taken as directed."

e. In the "Commonly Asked Questions and Answers" section of the APF website, APF claims, "addiction is very rare when pain medicines are properly prescribed and taken as directed," and "[k]eep in mind, pain medicine in and of itself does not cause someone to become addicted."

87. These materials were distributed nationwide, including in Wisconsin.

88. On the *In the Face of Pain* website, between 2008 and 2015, Purdue asserted that policies limiting access to opioids are "at odds with best medical

practices" and encouraged consumers to be "persistent" in finding doctors who will treat their pain.

89. Purdue deactivated *In the Face of Pain* in conjunction with its 2015 settlement with the State of New York Attorney General.

90. Purdue published its *Resource Guide for People with Pain*, which falsely assured consumers and health care professionals that, although many people "believe that opioid medications are addictive," "the truth" is that if these medications are properly prescribed and taken as directed, they "give relief – not a 'high.'"

91. In fact, prescription opioids are well-known to be highly addictive. Studies have found diagnosed addiction rates in primary care settings as high as 26%.

92. While not all people who become addicted to opioids remain on prescription opioids – many, for instance, may move on to heroin or other street drugs – the majority of persons addicted to opioids first took opioids pursuant to a prescription.

93. In 2016, the Centers for Disease Control and Prevention issued its Guideline for Prescription Opioids for Chronic Pain ("CDC Guideline"). The CDC Guideline was created to advise health care providers about the appropriate prescribing of opioids and was based upon a review of clinical evidence available at the time.

94. The CDC Guideline found "insufficient evidence to determine how harms of opioids differ depending on past or current substance abuse."

95. Purdue itself has acknowledged the risks associated with OxyContin. Purdue discontinued the marketing and sale of its original formulation of OxyContin upon its introduction of a reformulation in 2010. This meant that other manufacturers could petition the FDA for permission to make generic versions of OxyContin, but before approving a generic version, the FDA's regulations required it to determine whether the original formulation of OxyContin was voluntarily withdrawn from sale for "safety or effectiveness reasons."

96. Purdue, in response to the FDA, submitted a citizen petition to the FDA on July 13, 2012, arguing that if generic OxyContin were allowed, "abuse of extended release oxycodone could return to the levels experienced prior to the introduction of reformulated OxyContin." Essentially, Purdue acknowledged that the product it had marketed, sold, and profited from (to the tune of billions of dollars) as the opioid crisis grew had such a significant risk of abuse that it should be banned.

97. On April 18, 2013, the FDA, at Purdue's urging, found that Purdue had voluntarily withdrawn the original formulation of OxyContin from sale for safety reasons "in light of the extensive and well-documented history of OxyContin abuse," thereby closing the door on generic manufacturers.

98. The release of this reformulation, covered by a new patent, allowed Purdue to keep its highly-profitable and heavily marketed drug "on-brand," ensuring that it could continue to charge a premium, rather than have prices slip in the face of competition from generic versions produced by other manufacturers.

99. Purdue's misrepresentations about the risk of addiction led health care providers – including those in Wisconsin – to prescribe opioids when they otherwise would not have, and led health care providers and consumers to believe that the risk of addiction from prescription opioids was low.

B. Purdue Misrepresented the Concept of "Pseudoaddiction."

100. Purdue repeatedly misrepresented that many individuals showing signs of addiction were actually experiencing the unsubstantiated concept of "pseudoaddiction."

101. Drs. J. David Haddox and David Weissman, a Medical College of Wisconsin physician, coined the catchphrase "pseudoaddiction" in a 1989 paper where they described a situation in which a doctor might mistakenly identify a patient exhibiting the signs of compulsive drug-seeking behavior as a drug addict, when in fact that behavior might be "pseudoaddiction" and actually reflect the plight of a patient who was receiving inadequate medication to treat their pain. According to Drs. Haddox and Weissman, the solution was to treat such patients with more opioids.

102. The problem with the catchphrase "pseudoaddiction" is that it was not the product of a medical study of patients over time, nor has it been substantiated. Instead, it was a theory that Dr. Haddox based on his analysis of a single patient's behavior.

103. Notably, Dr. Haddox would go on to become a vice president of Purdue.

104. The concept of "pseudoaddiction" shows how the seemingly-independent Key Opinion Leaders were misused. A study that reviewed academic medical publications discussing "pseudoaddiction" determined that "[o]f the 224 articles, none exist that attempted to empirically validate the concept of pseudoaddiction," and those that considered "pseudoaddiction" as a "genuine clinical phenomenon" were funded by opioid manufacturers, including Purdue.

105. That same study concluded the following:

> The existence of pseudoaddiction, and its distinction from true addiction, is understood by proponents as being based on the patient's reported motivation for pain relief (e.g., if their behavior results from pain, then they have pseudoaddiction, not addiction). The reliability of this conceptualization seems to hinge on the assumption that addiction and pain do not co-occur...However, it is not the case that pain and addiction are mutually exclusive conditions, and no clear evidence exists that having pain protects against the genesis or expression of addiction.

106. Despite there being no scientific basis to support the concept of "pseudoaddiction," Purdue relied on the concept throughout its marketing efforts.

107. Purdue's sales representatives, when discussing abuse, addiction, and diversion with health care providers, across the country, including in Wisconsin, informed providers about "pseudoaddiction" and how to distinguish it from "true addiction."

108. Purdue also marketed the false concept of "pseudoaddiction" to health care providers and consumers through methods including, but not limited to the following:

a. Purdue sponsored the publication *Responsible Opioid Prescribing* (2007), which warned doctors to "[b]e aware of the distinction between *pseudo addiction* and addiction." (emphasis in original). It explains that "[p]atients who are receiving an inadequate dose of opioid medication often 'seek' more pain medications to obtain pain relief," and "[t]his is called pseudoaddiction because healthcare practitioners can mistake it for the drug-seeking behavior of addiction." This confusion arises because the "same behavioral signs [of pseudoaddiction] can [also] indicate addiction." The publication suggested that, in order to tell whether a patient is addicted to opioids, the provider should give the patient more opioids and see if he continues engaging in "demanding or manipulative behavior" after his demands are met.

b. Purdue made similar representations in its pamphlet *Clinical Issues in Opioid Prescribing* (2008), directed at health care providers but also available on its *Partners Against Pain* website, where it explained "[p]seudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is untreated....Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief." This pamphlet also stated that "pseudoaddiction" is

distinguishable from true addiction "in that the behaviors resolve when the pain is effectively treated."

c. Purdue sponsored the publication of *A Policymaker's Guide to Understanding Pain and Its Management* (2011), which deceptively promoted the concept of "pseudoaddiction" by explaining that "[p]atients with unrelieved pain may become focused on obtaining medications and may otherwise seem inappropriately 'drug seeking,' which may be misidentified as addiction by the patient's physician."

d. Purdue also published the pamphlet *Providing Relief, Preventing Abuse*, which initially, in 2008, described "pseudoaddiction" as "the misinterpretation by members of the health care team of relief-seeking behaviors in a person whose pain is inadequately treated as though they were drug-seeking behaviors as would be common in the setting of abuse," and in the 2011 edition explained that "[t]he term *pseudoaddiction* emerged in the literature to describe the inaccurate interpretation of these behaviors...."

109. These materials were distributed nationwide, including in Wisconsin.

110. One of Purdue's Key Opinion Leaders, Dr. Lynn Webster, acknowledged that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication. It led us down a path that caused harm. It is already something that we are debunking as a concept."

111. The CDC Guideline confirms the invalidity of "pseudoaddiction" as a concept, explaining that "patients who do not experience clinically meaningful pain relief early in treatment (i.e. within 1 month) are unlikely to experience pain relief with longer-term use." The CDC Guideline went on to advise that prescribers should "reassess[] pain and function within 1 month" to decide whether to "minimize the risks of long-term opioid use by discontinuing opioids." Thus, the CDC Guideline advises that physicians should consider *discontinuing* opioid use for those patients who are exhibiting behaviors that indicate ineffective pain relief, not *increase* their doses.

112. Purdue's misrepresentations about "pseudoaddiction" led health care providers – including those in Wisconsin – to prescribe opioids when they otherwise would not have, and led health care providers and consumers to believe that "pseudoaddiction" was a scientifically verified concept.

C. Purdue Misrepresented the Safety of Increased Doses of Opioids.

113. In addition to recommending that health care providers respond to identifiable signs of addiction by increasing opioid dosages, Purdue misrepresented to health care providers and consumers – including those in Wisconsin – that they could increase opioid dosages indefinitely without added risk.

114. For example, Purdue funded or sponsored third-party efforts, including, but not limited to, the following:

a. APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that "physical dependence is normal" and not a sign of

addiction, that some patients need a larger dose because of their worsening pain, and that certain opioids have "no ceiling dose."

b. APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011) explained that dose escalations are "sometimes necessary," even indefinite ones.

c. Purdue sponsored a Continuing Medical Education ("CME") course entitled *Overview of Management Options* edited by Key Opinion Leader Dr. Portenoy that taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses. The program appears to still be available for CME credit online.

d. In addition, on Purdue's *In the Face of Pain* website, Purdue encouraged patients to be "persistent" in finding doctors who will treat their pain, and promoted the position that if a patient's doctor does not prescribe what is, in the patient's opinion, a sufficient dosage of opioids, he should find another doctor who will.

115. These materials were distributed nationwide, including in Wisconsin.

116. Purdue's sales representatives also carried this message in Wisconsin, making sure that patients were receiving "appropriate doses" of their pain medications (with no indication that any dose might be too high).

117. Purdue's misrepresentations led health care providers – including those in Wisconsin – to increase the dosages of opioids when they otherwise would not have,

and led health care providers and consumers to believe that higher doses were safe and appropriate.

D. Purdue Misrepresented the Ease of Preventing or Mitigating the Risk of Addiction.

118. In addition to downplaying the risk of addiction and mischaracterizing the signs of addiction, Purdue also misrepresented the ease of preventing addiction.

119. Purdue sought to reassure health care providers that any risk of addiction could be managed by using tools provided by Purdue or Front Groups.

120. Specifically, Purdue falsely claimed that screening could manage addiction risks. Examples of publications making these false statements include, but are not limited to, the following:

a. APF's *Treatment Options: A Guide for People Living with Pain* (2007) informed patients that so-called "opioid agreements" between doctors and patients could "ensure that you take the opioid as prescribed." Opioid agreements are written or oral agreements between a prescribing provider and a patient regarding how the patient will use the prescribed opioids.

b. Purdue sponsored a 2011 webinar taught by Key Opinion Leader Dr. Webster entitled *Managing Patient's Opioid Use: Balancing the Need and the Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

121. Purdue's sales representatives gave health care providers in Wisconsin the Partners Against Pain "Pain Management Kit," which contained several "drug abuse screening tools," including the "Opioid Risk Tool" ("ORT").

122. The ORT is a five-question screening tool that identifies, through patient self-reporting, whether there is a personal history of substance abuse, sexual abuse, or "psychological disease."

123. According to Purdue, this tool could be used to predict and manage the risk of opioid addiction.

124. Purdue also promoted the ORT in CME materials, including a 2013 CME entitled *Is It Pain?*

125. Through the materials described above, Purdue sought to convince health care providers and consumers throughout the country, including in Wisconsin, that addiction risk could be managed in order to increase the overall number of prescriptions for their opioid products.

126. The CDC Guideline claims, "the body of evidence" is insufficient to support "the effectiveness of use of risk assessment tools and mitigation strategies in reducing harms," including "improving outcomes related to overdose, addiction, abuse, or misuse."

127. Purdue's misrepresentations regarding the ease of preventing or mitigating the risk of addiction led health care providers – including those in Wisconsin – to prescribe opioids when they otherwise would not have, and led

providers and consumers to believe that the use of the ORT and other tools meaningfully reduced the risk of addiction.

E. Purdue Misrepresented the Benefits of its Prescription Opioids.

128. Purdue not only misrepresented the risks associated with using prescription opioids, but also misleadingly touted their benefits, including their superiority over other non-opioid products such as NSAIDs.

i. Purdue misrepresented the Abuse-Deterrent Properties of its Prescription Opioids.

129. In 2010, Purdue introduced a reformulation of its flagship opioid, OxyContin, that it labeled "abuse deterrent" because, as compared to the original formulation, the pills were harder to dissolve, crush, or otherwise manipulate to defeat their extended release character.

130. Purdue's website stated that the abuse-deterrent formulation was "intended to help deter the abuse, misuse, and diversion of these prescription pain medications, while ensuring that patients in pain continue to have appropriate access to these important therapies."

131. Key Opinion Leaders gave presentations on behalf of Purdue that claimed the abuse-deterrent formulas "make opioids you prescribe harder to abuse and make all clinicians part of the solution to prescription opioid abuse."

132. Purdue's efforts to characterize its abuse-deterrent formulation as safer proved effective. A 2014 survey found that 46% of physicians surveyed believed that abuse-deterrent formulations were less addictive than non-abuse-deterrent formulations.

133. The CDC Guideline, however, found no evidence or studies in support of the claim that abuse-deterrent formulas have any effectiveness as a risk mitigation strategy for deterring or preventing abuse or addiction.

134. Moreover, in response to negative press coverage about the marketing of its abuse-deterrent formula, Purdue prepared company talking points that admitted "[t]he current FDA-approved products with abuse-deterrent properties address abuse through certain routes, but they only make abuse more difficult, not impossible, and they provide no deterrence against swallowing the intact tablet."

135. Purdue's misrepresentations regarding the abuse-deterrent properties of its prescription opioids led health care providers – including those in Wisconsin – to prescribe opioids when they otherwise would not have, and led health care providers and consumers to believe that use of the abuse-deterrent formulas reduced the risk of abuse and addiction.

ii. Purdue Misrepresented the Superiority of Prescription Opioids to Other Pain Treatment Options.

136. Purdue misrepresented its branded opioids, and prescription opioids in general, as superior to other pain treatment options such as NSAIDs.

137. NSAIDs (nonsteroidal anti-inflammatory drugs) are a drug class that reduce inflammation, pain, and fever by reducing the body's production of prostaglandins. Commonly known NSAIDs are Aspirin, Ibuprofen (Motrin, Advil), and Naproxen (Aleve).

138. Specifically, Purdue presented misleading comparisons between the risks and benefits of opioids and NSAIDs.

139. For example, Purdue touted its products' lack of a "dose-ceiling" as compared to NSAIDs or other medications in publications including, but not limited to, the following:

a. APF's *Treatment Options: A Guide for People Living with Pain* (2007) claims that certain opioids have "no ceiling dose as there is with NSAIDs. As pain worsens, these medications continue to be useful unless side effects occur."

b. APF's *Exit Wounds* (2009) claims that NSAIDs "have an important limitation, called a 'dose ceiling.' Taking doses above the ceiling will significantly raise the risk of serious side effect, such as kidney failure, which can be life-threatening."

c. Purdue distributed a letter to doctors entitled *Maximum Dose of OxyContin Tablets* which claimed, "when used appropriately, there is no established or fixed upper limit on the dosage of full, single entity, opioid agonists such as oxycodone."

d. In a 2010 version of the *Maximum Dose* letter, Purdue explicitly compared its product to other pain treatment options saying, "[l]ike all pure opioid agonist analgesics, with increasing doses there is increasing analgesia, unlike with mixed agonist/agonists or non-opioid analgesics, where there is a limit to the analgesic effect with increasing doses."

140. These materials were distributed nationwide, including in Wisconsin.

141. Purdue made these superiority claims despite the absence of any scientific evidence that higher doses of opioids are more effective for treating pain, and while minimizing the risks associated with higher dosages (including, as described in this Complaint, an increased risk of addiction).

142. In addition, Purdue misrepresented the risks of other non-opioid drugs such as NSAIDs or acetaminophen, relative to the risks posed by prescription opioids.

143. For example, APF's *Exit Wounds* (2009) lists the "serious side effects" of NSAIDs, such as gastrointestinal bleeding, decreased kidney function, and possible risk of stroke or heart attack, and highlights that higher doses of acetaminophen can cause "possible liver damage." When discussing the side effects of opioids, however, *Exit Wounds* downplays the risk – limiting the claimed side effects of opioids to "constipation, nausea and vomiting, sleepiness, mental cloudiness, itching, dizziness and difficulty urinating" – of which "most side effects disappear after a few days for most (not all) people."

144. APF's *Treatment Options: A Guide for People Living in Pain* (2007) claims that "NSAIDs can cause life-threatening side effects in some persons," and attributes "10,000 to 20,000 deaths each year because of the side effects of this class of medications." The actual number of deaths associated with the side effects was around 3,200 at the time. APF did not, however, make any reference to the known severe and life-threatening side effects of prescription opioids or the number of deaths caused by them.

145. Purdue has targeted NSAIDs as a key opportunity for growth, even setting goals of conversion from NSAIDs to its branded opioids.

146. Purdue's sales representatives made misleading comparisons between Purdue's extended-release opioid products and immediate-release, or short-acting, opioid products, as well as competing extended-release opioids, when targeting Wisconsin health care providers.

147. Purdue's claims of superiority in safety or efficacy were not supported by scientific evidence, and were intended to increase the sales of its products.

148. Despite Purdue's claims, prescription opioids are no more effective than NSAIDs, acetaminophen, or other non-opioid options for the treatment of chronic pain.

149. In fact, the National Safety Council states that, even in cases of acute pain, no scientific evidence supports a preference for opioids over NSAIDs, and "the evidence seems to indicate that NSAIDs are more effective for severe pain."

150. Moreover, according to the CDC Guideline, when opioids are prescribed for chronic pain, "they should be combined with non-pharmacologic and non-opioid pharmacologic therapy, as appropriate, to provide greater benefits to patients in improving pain and function."

151. Purdue's misrepresentations about the superiority of its opioids led health care providers – including those in Wisconsin – to prescribe opioids when they otherwise would not have, and led providers and consumers to believe that the use of opioids was better and/or safer than the use of other non-opioids such as NSAIDs.

F. Purdue Misrepresented the Efficacy of its Prescription Opioids.

152. Along with repeatedly misrepresenting the risks associated with opioid use, and deceptively highlighting the benefits of its products, Purdue also marketed its drugs as a solution to the undertreatment of pain, effective to treat or relieve long-term chronic pain and improve overall function.

153. As described above, Purdue set out in its marketing campaign to change the prevailing medical standards on the use of prescription opioids such as OxyContin for the treatment of chronic pain, and it continued to make misleading claims even after it pled guilty to a federal crime and entered into consent judgments in 2007.

154. For example, APF's *Exit Wounds* (2009) claimed, "pain relieving properties are unsurpassed; they are today considered the 'gold standard' of pain medications, and so are often the medications used in treatment of chronic pain. Yet, despite their great benefits, opioids are often underused."

155. Purdue marketed its products for long-term use, and specifically for the treatment of "chronic pain," despite a lack of evidence as to the effectiveness of long-term opioid use and its knowledge of this evidentiary deficiency.

156. The CDC Guideline concluded that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least a year later."

157. There is also no evidence that the increase in prescription opioid use has resulted in less pain for patients. In fact, despite a 600% increase in opioid

consumption over the last 20 years, overall patient-reported pain has remained consistent.

158. In addition to misrepresenting the efficacy of its prescription opioids for the treatment of chronic pain, Purdue misrepresented that opioids increase long-term functionality.

159. Purdue's misrepresentations about functionality include, but are not limited to, the following:

a. Purdue's publication *Responsible Opioid Prescribing* (2007) claimed that "[w]hile significant pain worsens function, relieving pain should reverse that effect and improve function."

b. APF's *Treatment Options: A Guide for People Living with Pain* (2007) claimed that opioids, when used properly, "give [patients] a quality of life we deserve."

c. APF's *Exit Wounds* (2009) claimed that if opioids are taken properly they can "increase a person's level of functioning."

d. APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011) claimed that opioids are "often a necessary part" of a plan "to restore functioning and improve quality of life." The Guide also misleadingly claimed that "[m]ultiple clinical studies have shown that long-acting opioids, in particular are effective in improving" "[d]aily function," "[p]sychological health," and "health-related quality of life for

people with chronic pain," with the implication that these studies presented claims of long-term improvement.

e. Purdue sponsored a CME presentation entitled *Managing Patient's Opioid Use: Balancing the Need and the Risk*, which made unsubstantiated and false claims about improved functionality.

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

160. These materials were distributed nationwide, including in Wisconsin.

161. Purdue's sales representatives made misleading statements about opioid use improving quality of life directly to Wisconsin health care providers during sales calls.

162. Purdue made these misrepresentations without any reliable scientific evidence that long-term use of opioids improve function or quality of life, while minimizing any risks.

163. Indeed, the CDC Guideline stresses that "[w]hile benefits for pain relief, function, and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."

164. Purdue's misrepresentations about the efficacy of prescription opioids led health care providers – including those in Wisconsin – to prescribe opioids when

they otherwise would not have, and led providers and consumers to believe that opioids were effective, even preferred, for improving functionality and quality of life.

G. Purdue Misrepresented the Ability to Control the Effects of Withdrawal.

165. In an attempt to downplay the risk associated with opioid dependence, Purdue misrepresented the risks of withdrawal and the ability to control the effects of withdrawal.

166. Purdue's misrepresentations about withdrawal include, but are not limited to, the following:

a. In APF's *A Policymaker's Guide to Understanding Pain & Its Management*, APF claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use, even gradual tapering off.

b. Similarly, Purdue's *Training Guide for Healthcare Providers* (2010) claimed that patients who were physically dependent on opioids, but who had not developed an "addiction disorder" "[c]an generally discontinue their medicine with mild to no withdrawal syndrome once their symptoms are gone by gradually tapering the dosage according to their doctor's orders."

167. These materials were distributed nationwide, including in Wisconsin.

168. In reality, it is very difficult to stop using opioids once they have been prescribed. Repeated exposure to escalating doses of opioids alters the brain so that

it functions more or less normally when the drugs are present and abnormally when they are not. The alternation to the brain occurs when the user experiences opioid tolerance, meaning the user needs to take higher and higher doses to achieve the same opioid effect.

169. When the opioids are not present to suppress the brain cells' enhanced activity, the body responds by triggering jitters, anxiety, muscle cramps, and diarrhea.

170. Purdue's misrepresentations about the ability to control the effects from withdrawal led health care providers – including those in Wisconsin – to prescribe opioids when they otherwise would not have, and led health care providers and consumers to believe that they could manage the effects of withdrawal from opioids with little problem.

H. Purdue Misrepresented the Risks of Opioids for Senior Citizens.

171. Purdue focused much of its deceptive marketing on senior citizens by claiming senior citizens are lower risk patients.

172. For example, Purdue supported the American Geriatrics Society's 2009 *Guidelines for the Pharmacological Management of Persistent Pain in Older Persons*, which misrepresented that the risk of addiction was "exceedingly low in older patients with no current or past history of substance abuse."

173. Purdue's sales representatives targeted elderly patients in their marketing phone calls to health care providers.

174. Despite Purdue's claims, senior citizens have an increased risk for the most dangerous side effect of opioids – respiratory depression. Senior citizens are also more likely to experience complications from falls (fractures and hospitalizations) caused by the cognitive impairment that is associated with opioid use. For example, a 2010 paper reported that elderly patients who used opioids had a significantly higher rate of deaths, heart attacks, and strokes than users of NSAIDs.

175. Purdue's misrepresentations about the risks of opioids for senior citizens led health care providers – including those in Wisconsin – to prescribe opioids more than they otherwise would have, and led health care providers and consumers to believe that there are few risks associated with opioid use by senior citizens.

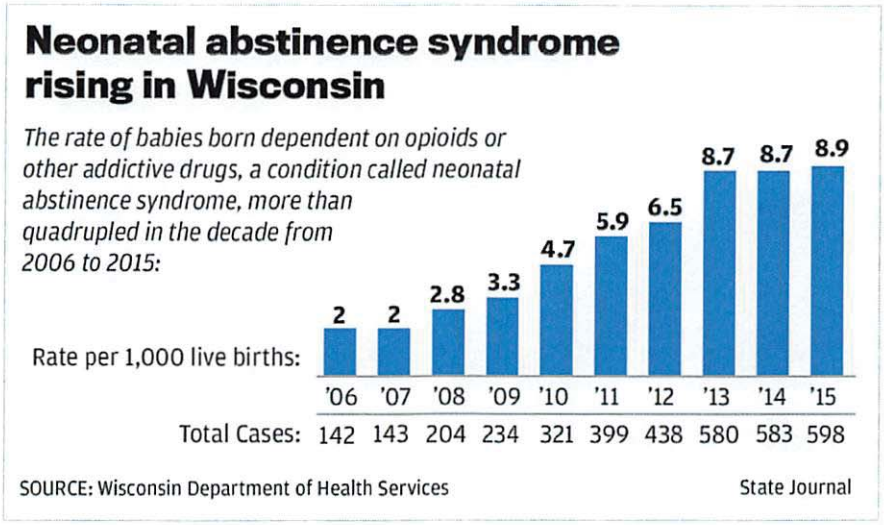
IV. The Defendants' Actions Have Had Severely Harmful Consequences for the State of Wisconsin.

176. Without the Defendants' unreasonable actions, opioid use and abuse would not have become so widespread in Wisconsin, and some of the harm resulting from the opioid crisis would have been averted.

177. In 2017, more people died in Wisconsin from an opioid overdose than from motor vehicle accidents, suicide, or firearms. That year alone, Wisconsin lost 916 of its citizens to the opioid epidemic.

178. A study of the health care costs for a person who abused opioids between 2012 and 2015 found that the cost was $14,810 more than spending on a comparable person who did not abuse opioids.

179. The rate of babies born addicted to opioids and other addictive drugs in Wisconsin quadrupled between 2006 and 2015. As of 2015, roughly 9 out of every 1,000 babies born in Wisconsin were born with neonatal abstinence syndrome.



[5]

180. The opioid crisis, which was in-part created and maintained by the Defendants' actions, has had a severe and harmful impact on Wisconsin's labor market and economy. Between 1999 and 2015, the volume of prescription opioids per capita in Wisconsin rose 425 percent, around 11 percent annually. This rise in opioid use was associated with a 2.1 percentage decline in the state's labor force participation rate of prime-age workers, slowing annual real gross domestic product growth by 0.8 percentage points. In summary, between 1999 and 2015, Wisconsin has lost 45,200 workers due to opioids.

[5] David Wahlberg, *Babies dependent on opioids: Wisconsin sees surge in infants born with addiction*, Wisconsin State Journal, Feb. 12, 2017, https://madison.com/wsj/news/local/health-med-fit/babies-dependent-on-opioid-wisconsin-sees-surge-in-infants-born/article_1da6faee-827d-5435-aada-23a1d5fc8024.html.

181. The decline in Wisconsin's labor force due to the opioid epidemic has cost the State approximately $37 billion in real economic output.

182. In 2015 alone, the opioid crisis cost Wisconsin an estimated $10 billion in health care, criminal justice services, and worker productivity.

183. These costs do not include the nonmonetized impacts that the opioid epidemic has had on Wisconsin's citizens. Those impacts include, but are not limited to, decreased quality of life, emotional burdens, and loss of perceived community well-being.

V. Richard S. Sackler Was Actively Involved in Purdue's Deceptive Marketing, Which Targeted Wisconsin.

184. Wisconsin's consumer protection statutes, including Wis. Stats. §§ 100.18 and 100.182, allow for personal liability against individual wrongdoers when the individual is responsible for devising the unfair practice.

185. Further, in Wisconsin, an individual is personally responsible for his own tortious conduct. A corporate officer or agent cannot shield himself from personal liability for a tort he personally commits or participates in by hiding behind the corporate entity; if he is shown to have been acting for the corporation, the corporation also may be liable, but the individual is not thereby relieved of his own responsibility.

186. Richard S. Sackler was actively involved in the day-to-day operations of Purdue.

187. Richard S. Sackler exercised control over Purdue, and controlled or sanctioned the misconduct described in paragraphs 1 - 183 above.

188. Through Purdue's national marketing strategy, deceptive marketing materials were circulated in Wisconsin by virtue of Richard S. Sackler's control.

189. Through Purdue's national marketing strategy, Richard S. Sackler knowingly and intentionally sent or caused to be sent sales representatives and marketing materials to promote opioids to prescribers in Wisconsin thousands of times.

190. Through Purdue's national marketing strategy, Richard S. Sackler knew and intended that the sales representatives and marketing materials in Wisconsin would unfairly and deceptively promote opioid sales that are risky for patients.

191. Through Purdue's national marketing strategy, Richard S. Sackler knew and intended that the prescribers and patients in Wisconsin would rely on Purdue's deceptive sales campaign to prescribe and take Purdue opioids. Securing that reliance was a purpose of the sales campaign.

192. Through Purdue's national marketing strategy, Richard S. Sackler knew and intended that staff reporting to him would reinforce these misleading acts through thousands of additional acts in Wisconsin, including by sending deceptive publications to Wisconsin.

193. During the period relevant to this Complaint, Purdue informed Richard S. Sackler of reports about abuse and diversion of Purdue opioids. Richard S. Sackler failed to take appropriate action to remedy the reported abuse.

194. Through widely available public information as well as documents Purdue received and reported to Richard S. Sackler related to abuse and diversion of Purdue opioids, Richard S. Sackler knew or should have known of the hazards of opioid use, as well as the abuse and addiction related to its products. Yet Richard S. Sackler pushed Purdue to continue its deceptive marketing of opioids nationwide, including in Wisconsin.

195. Richard S. Sackler's activities were a substantial factor in creating and maintaining the public health crisis in Wisconsin and the injuries alleged in this Complaint.

196. While having actual or constructive knowledge of the risks posed by its products, Richard S. Sackler has continued to resist efforts to place reasonable restrictions on opioid prescription activity that could have reduced the scale of the opioid crisis and the injuries alleged in this Complaint.

197. Richard S. Sackler knowingly and intentionally took money and derived a financial benefit from Purdue's deceptive business and opioid sales in Wisconsin.

198. Richard S. Sackler knowingly and intentionally sought to conceal his misconduct.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
Violation of Wis. Stat. § 100.18(1)

199. The State of Wisconsin incorporates by reference the allegations in paragraphs 1 through 198 of the Complaint.

200. Through the conduct described above, Purdue and Richard S. Sackler, made untrue, deceptive, or misleading representations in their marketing, promotion and sale of opioids in Wisconsin.

201. Through the conduct described above, Purdue and Richard S. Sackler, in an effort to sell their opioids, directly and indirectly, made, published, disseminated, circulated, and placed before the public advertisements, statements, and representations that contained assertions, representations and statements of fact that were untrue, deceptive, and misleading.

SECOND CAUSE OF ACTION
Violation of Wis. Stat. § 100.182(2)

202. The State of Wisconsin incorporates by reference the allegations in paragraphs 1 through 198 of the Complaint.

203. Through the conduct described above, Purdue and Richard S. Sackler made untrue, deceptive or misleading representations material to the effects of the opioids they were advertising in Wisconsin.

THIRD CAUSE OF ACTION
Public Nuisance

204. The State of Wisconsin incorporates by reference the allegations in paragraphs 1 through 198 of the Complaint.

205. Through the conduct described above, Purdue and Richard S. Sackler were substantial participants in creating and maintaining a public nuisance in Wisconsin.

206. Under Wisconsin law, a public nuisance is defined as a condition or activity that substantially or unduly interferes with the use of a public place, the activities of an entire community, or a public right, common to all members of the public. The opioid crisis is a public nuisance, consisting of widespread addiction, overdose, illness and death in Wisconsin. The Defendants' conduct constitutes a substantial and unreasonable interference with the Wisconsin citizenry's right to public health and safety.

207. Each Defendant knew or should have known that the public nuisance was resulting from, or was substantially certain to result from, their conduct described above.

208. Each Defendant knew or should have known of the existence of this public nuisance in Wisconsin, could have abated it within a reasonable period of time, had a duty to act, and failed to do so.

209. Each Defendant's conduct was a substantial cause of the existence of the public nuisance, which was a substantial factor in causing injury to the people of State of Wisconsin.

210. The injuries that each Defendant caused in Wisconsin have been significant, including but not limited to: (a) opioid addiction, overdose, and death; (b) health care costs of individuals, children, families, and employers within Wisconsin; (c) loss of productivity and harm to Wisconsin's economy; and (d) public costs associated with efforts in Wisconsin to abate the nuisance and support public health, safety, and welfare.

211. The injury to the Wisconsin public that resulted from this public nuisance continues through the present.

212. Defendant Richard S. Sackler is liable because he had actual or constructive knowledge of the public nuisance, and participated in, approved, directed, controlled, or otherwise had the ability to control the acts and practices that form the basis of the conduct that gave rise to the creation or maintenance of this public nuisance.

RELIEF REQUESTED

213. WHEREFORE, the State of Wisconsin respectfully requests that:

A. Pursuant to Wis. Stats. §§ 100.18(11)(d) and 100.182(5)(a), the Court permanently enjoin and restrain the Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in untrue, misleading, and deceptive practices in the marketing, promotion, selling and distributing of their opioid products;

B. Pursuant to Wis. Stat. § 100.26(4), the Court order the Defendants to pay civil penalties in the amount of not less than $50 nor more than $200 for each and every violation of Wis. Stats. §§ 100.18(1) and 100.182(2);

C. Pursuant to Wis. Stat. § 100.261, the Court order the Defendants to pay all consumer protection surcharges;

D. Pursuant to Wis. Stat. § 100.263, the Court order the Defendants to pay costs and reasonable attorneys' fees incurred by the State of Wisconsin in connection with the investigation and litigation of this matter;

E. Pursuant to Wis. Stat. § 100.263, the Court order the Defendants to pay the amount reasonably necessary to remedy the harmful effects of their violations of Wis. Stats. §§ 100.18(1) and 100.182(2);

F. Pursuant to Wis. Stat. § 100.264, the Court order the Defendants to pay supplemental forfeitures for violations against elderly or disabled persons;

G. The Court order the Defendants to abate the nuisance, to reimburse the cost of Wisconsin's abatement efforts, and to pay compensatory damages for harms caused by the nuisance; and

H. That the Court grant such further relief as the Court deems necessary or appropriate to remedy the effects of the Defendants' conduct.

THE STATE HEREBY DEMANDS A TRIAL BY A TWELVE-PERSON JURY

[Signatures On Following Page]

Dated this 16th day of May, 2019.

Respectfully submitted,

JOSHUA L. KAUL
Attorney General of Wisconsin

Electronically signed by:

s/ Laura E. McFarlane
LAURA E. MCFARLANE
Assistant Attorney General
State Bar #1089358

JENNIFER L. VANDERMEUSE
Assistant Attorney General
State Bar # 1070979

SHANNON A. CONLIN
Assistant Attorney General
State Bar # 1089101

Attorneys for State of Wisconsin

Wisconsin Department of Justice
Post Office Box 7857
Madison, Wisconsin 53707-7857
(608) 266-8911
(608) 266-2250 (Fax)
mcfarlanele@doj.state.wi.us