IN THE SUPERIOR COURT FOR THE DISTRICT OF COLUMBIA
CIVIL DIVISION

DISTRICT OF COLUMBIA
a municipal corporation,
441 4th Street, N.W.
Washington, D.C. 20001

Plaintiff,

v.

PURDUE PHARMA L.P.
One Stamford Forum
Stamford, Connecticut 06901

and

PURDUE PHARMA INC.
One Stamford Forum
Stamford, Connecticut 06901

and

RICHARD S. SACKLER, M.D.
5310 N. Ocean Dr. #801
Riviera Beach, FL 33404

Defendants.

Civil Action No. _____

Judge: _____

JURY TRIAL DEMANDED

REDACTED COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

Plaintiff District of Columbia ("District"), by and through its Attorney General, brings this action against Defendants Purdue Pharma Inc. and Purdue Pharma L.P. ("Purdue"), and Richard S. Sackler, M.D. ("R. Sackler") (collectively "Defendants") for Purdue and R. Sacklers' violations of the District's Consumer Protection Procedures Act ("CPPA"), D.C. Code § 28-3901, *et seq*. In support of its claims, the District states as follows:

Introduction

1. Defendant Purdue has been one of the leading pharmaceutical companies in the nation, influencing how doctors and patients view and use opioid medications. R. Sackler actively participated in directing the conduct of Purdue. The District alleges that Defendants gained influence over the opioid market in part through deceptive practices that have misled consumers about the benefits of opioids, as well as the potential harms that are inextricably intertwined with opioid use. As detailed below, some of these deceptive practices include false claims that opioids are not addictive, and that cases of addiction only arise when opioids are abused; and that opioids are better for treating a variety of conditions that are in fact more effectively alleviated by less harmful medications.

2. Defendants also engaged in reckless practices to prolong the time that patients ingest opioids as well as the doses that patients consume - both harmful practices with limited proven efficacy, and great potential harm to the patient. They encouraged these practices in spite of the dangers, and without adequately warning consumers and doctors about the momentous risks, including overdose and death.

3. In May 2007, the District entered into a Consent Judgment with Purdue over the District's allegations that Purdue had engaged in deceptive acts or practices in its marketing, promotion and sale of OxyContin, Defendants' best-selling opioid.

4. This Complaint, which focuses on many of the same deceptive acts and practices that were the subject of the 2007 Consent Judgment, concerns Purdue's activities after May 2007 ("the Post-Judgment Period").

Defendants Sold and Promoted Their Opioids in the District

5. Defendants have continued to actively market and sell opioids in the District in the Post-Judgment Period.

6. Defendants' sales representatives visited doctors, pharmacies, hospitals, insurance companies, and veterans' facilities in the District in the Post-Judgment Period.

7. From 2007 to 2015, Defendants' sales representatives made at least 8,037 visits to District health care providers.

8. Defendants marketed the opioids Butrans, Dilaudid, Hysingla ER, MS Contin, OxyContin, and Ryzolt in the District in the Post-Judgment Period.

9. Focusing only on Defendants' sales in the District from 2008-2017 of *one* of its opioids, Oxycodone, it sold: 2,312,245 units of 10 mg OxyContin; 2,817,436 units of 20 mg OxyContin; 2,317,695 units of 40 mg OxyContin; and 1,948,367 units of 80 mg OxyContin.[1]

10. Additionally, in the Post-Judgment Period, Defendants continued to blanket the District with other forms of promotion of its opioids, including but not limited to its distribution of publications, its third-party sponsored websites that were regularly accessed by people in the District, and through medical education programs held in the District.

Background on Opioids

11. Opioids are dangerous narcotics that can be deadly, causing patients to stop breathing and suffocate.

12. Opioids are also highly addictive. Over 70 percent of those who become opioid dependent begin with prescription pain medications. Americans consume over 90 percent of the world's pharmaceutical opioids. Patients using opioids for more than a few days can experience severe withdrawal symptoms, including anxiety, insomnia, pain, blurry vision, rapid heartbeat, chills, panic attacks, nausea, vomiting, and tremors. Opioid withdrawal symptoms can last up to one month. The first phase (acute withdrawal) begins about twelve hours after the last opioid use, peaks at around three to five days, and can go on for up to four weeks. Withdrawal can last so long and be so painful that it is difficult to stop taking opioids. In addition, opioids act on the brain and body in ways other than withdrawal that create addiction and maintain addiction.

[1] The District does not have complete sales data after 2017, although Purdue continued to do business in the District after 2017.

13. Patients who take prescription opioids for longer periods of time or in higher dosages increase their risk of opioid use disorder (addiction), overdose, and death. Because of the inherent risks of taking opioids, prior to 1996 before OxyContin, physicians traditionally have reserved opioids for treating short-term severe pain, or for patients near the end of life.

14. Most patients taking opioids experience side effects. According to the Center for Disease Control ("CDC"), 96% of people who take opioids for chronic pain experience side effects. Opioid use is associated with significant harms including accidental overdose, addiction, diversion and accidents involving injuries. Adverse events from opioid use include constipation, nausea, respiratory depression, sedation, myocardial infarction, endocrinological effect (erectile dysfunction or testosterone replacement), hyperalgesia (increased sensitivity to pain), and heightened fracture risk.

15. Surprisingly, given these significant and sometimes devastating side effects, research has shown that opioids have limited efficacy for long-term use.

16. As early as 2000, and continuing to the present, numerous peer-reviewed studies conducted by independent researchers have concluded that: (1) [f]or functional outcomes, …other [non-addictive] analgesics were significantly more effective than were opioids; (2) increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater healthcare utilization; and (3) opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.

17. In 2014, the Agency for Healthcare Research and Quality ("AHRQ") (which is part of the federal Department of Health and Human Services) issued a report, citing studies conducted from 2000-2009, in which it wrote: "Although randomized trials show short-term, moderate improvements in pain in highly selected, low-risk populations with chronic pain, such

efficacy-based evidence is of limited usefulness for informing long-term opioid prescribing decisions in clinical practice."

18. AHRQ concluded: "Evidence on long-term opioid therapy for chronic pain is very limited, but suggests an increased risk of serious harms that appears to be dose-dependent." Specifically, their research showed that high-doses are associated with increased risk.

19. The CDC came to the same conclusions, in its CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016 ("*CDC Guideline*"). The CDC did a comprehensive survey of the research on opioids to conclude that there is "no evidence of a long-term benefit of opioids in pain and function **versus no opioids** for chronic pain with outcomes examined at least 1 year later; extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose and motor vehicle injury; and extensive evidence suggests some benefits of nonpharmacological and nonopioid treatments compared with long-term opioids therapy, with less harm." (emphasis added). In other words, the long-term use of opioids has been shown to do more harm than good, and people may do better on alternate therapies.

Defendants Promoted Opioid Use by Making Assessment of Pain a Central Part of the Assessment of Care

20. Defendants changed the landscape for how doctors, patients and treatment facilities view and use opioids.

21. Before the 1990s, opioids were not widely prescribed because it was correctly believed that their use involved serious risks, including addiction, withdrawal, and overdose, that were not justified by the benefits. Opioids typically were used only to treat short-term, acute pain or for palliative care.

22. In 1996, Defendants released OxyContin, its best-selling drug. To coincide with OxyContin's release, Defendants funded a national campaign targeted at health care providers to make pain the fifth "vital sign" – an indicator doctors should monitor at every doctor's visit alongside blood pressure, temperature, heartbeat, and breathing.

23. Defendants provided substantial funding to support the American Pain Society's *Pain as the 5th Vital Sign* campaign. In 1999, the Veterans Health Administration adopted this concept in its facilities nationwide, and thereafter, *Pain as the 5th Vital Sign* spread to the private sector.

24. Purdue worked with the Joint Commission on the Accreditation of Healthcare Organizations ("JCAHO"), which accredits hospitals across the United States. In 2001, JCAHO issued new pain treatment standards that called for assessment of pain in all patients and in each physician-patient interaction. JCAHO made accreditation decisions contingent on institutions implementing the new pain standards. Purdue worked closely with JCAHO to promote the new pain standards. Purdue was exclusively licensed to distribute certain educational videos about how to comply with the new standards and Purdue sponsored various guides and summits for implementing the new JCAHO standards.

25. Both the *Pain as the 5th Vital Sign* campaign and the JCAHO pain standards have been widely integrated into medical practice in the District and nationally.

26. Defendants' aggressive marketing campaign changed how patients with pain are treated. Before the introduction of OxyContin in 1996, the opioid market was for post-surgical, end-of-life, or cancer pain. By 2012, opioids were among the most prescribed drugs; approximately 90% of prescription opioids were given for chronic pain conditions, and only 10% of prescription opioids were dispensed for post-surgical, palliative, and cancer pain treatments. This was an almost complete reversal of long-standing medical practice.

Defendants Created Fear that Pain was Undertreated

27. Defendants not only changed the standards for assessing care by including a persistent reference to pain, they also fostered a fear that the under-treatment of pain was a scourge plaguing society.

28. In 2001, Defendants created a website, www.inthefaceofpain.com. Although Purdue's name appeared at the bottom of the webpages, it presented itself as a neutral source of information about pain and pain advocacy.

29. The website argued that pain was undertreated, and urged patients and advocates to "overcome" the "fear of producing addiction" and the "concern about analgesic side effects."

30. A central part of the website was written and video testimonials from several dozen "advocates" whose faces appeared on the website. Many of these advocates were paid by Purdue. Neither the payments, nor the advocates' connection to Purdue was disclosed in the website. These testimonials also appeared on YouTube.

31. One testimonial on the site proclaimed: "There is no debate among public health experts about the fact that pain is under-treated. Under-treatment of pain has been recognized as a public health crisis for decades. The consequences are often catastrophic for patients." Another 'advocate' pronounced: "I believe people should not live or die with uncontrolled pain because of unrealistic fears or mistaken beliefs about available treatments."

32. The New York Attorney General brought an action against Purdue alleging in part that the website deceived consumers by creating the false impression that the information on the website was neutral and unbiased.

33. Purdue entered into an Assurance of Discontinuance with the New York Attorney General's Office in August 2015 in which it agreed to disclose the payments made by Purdue to persons providing testimonials.

34. In October 2015 Purdue shut down the inthefaceofpain website.

35. People in the District accessed this website 2,353 times between 2010 and October 2015.

Jurisdiction

36. This Court has jurisdiction over the subject matter of this case pursuant to D.C. Code §§ 11-921, 28-3909 and 47-2853.28.

37. This Court has personal jurisdiction over Defendants pursuant to D.C. Code § 13-423(a)(1), (a)(2), (a)(3) and (a)(4).

Parties

District of Columbia

38. Plaintiff the District of Columbia, a municipal corporation empowered to sue and be sued, is the local government for the territory constituting the permanent seat of the government of the United States. The District brings this action through its chief legal officer, the Attorney General for the District of Columbia. The Attorney General has general charge and conduct of all legal business of the District and all suits initiated by and against the District and is responsible for upholding the public interest. D.C. Code § 1-301.81(a)(1). The Attorney General is also specifically authorized to enforce the CPPA. *See* D.C. Code § 28-3909.

Purdue

39. Defendant Purdue Pharma Inc. is a drug company incorporated in New York with its principal place of business in Connecticut. It acts as the main operating company for the Purdue business, including opioid prescription medications. It is responsible for promoting and selling Purdue's opioid drugs.

40. Defendant Purdue Pharma L.P. is a limited partnership established in Delaware with its principal place of business in Connecticut. Purdue Pharma Inc. is the general partner of Purdue Pharma L.P.

41. Purdue Pharma L.P. employs the sales representatives and pays doctors to promote Purdue's opioids.

42. Purdue Pharma Inc. and Purdue Pharma L.P. share the same physical offices, the same CEO, and many of the same officers. The companies are referred to throughout the Complaint as "Purdue."

43. Purdue is owned through holding companies and family trusts for the benefit of the families of Mortimer and Raymond Sackler, who started and developed the Purdue companies. R. Sackler is one of the beneficiaries of these holding companies and trusts.

44. Members of the Sackler family held either all of the seats on the Board, or a majority of the seats on the Board from 1990 to 2018.

45. At all times material to this Complaint, Purdue acting alone or in concert with others, has marketed, promoted, offered for sale or sold opioids in the District of Columbia.

Richard Sackler

46. Defendant Richard S. Sackler. M.D. ("R. Sackler") is the son of one of the founders of Purdue, Raymond Sackler. R. Sackler has held various positions at Purdue, including: Vice President of the Medical Department in the 1980's; Director of Sales and Marketing in the early 1980's; Staff Assistant to Mortimer and Raymond Sackler; President from late 1999 to 2003; Co-Chairman of the Board from at least January 1, 2005 until May 11, 2007; and Board member from 1990 until mid-2018.

47. At all times material to this Complaint, R. Sackler, acting alone or in concert with others, has formulated, directed, controlled, had the authority to control, participated in, or with knowledge approved of the acts or practices of Purdue, including the unlawful acts and practices set forth in this Complaint.

48. The Purdue Board met formally at least quarterly.

49. Starting in January 2013, [redacted]

50. R. Sackler was an engaged and demanding participant in managing Purdue's business.

51. As late as 2014, R. Sackler was involved in hiring decisions beyond those at the top level of management, such as the VP of Human Resources.

52. During the post-Judgment period, R. Sackler repeatedly impelled Purdue management to increase the sale of Purdue's opioids.

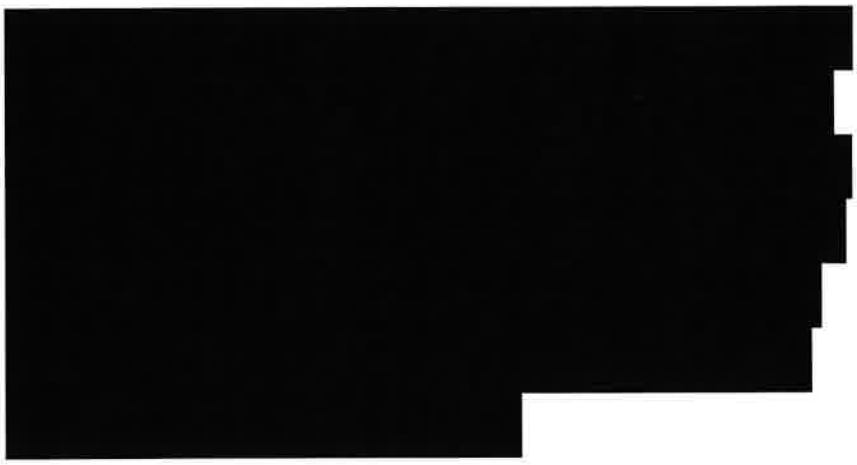
a. The Purdue Board set the targets in the budgets for sales, not management.

ii. [redacted]

iii. Significantly, it was the budget that drove the sales targets for the representatives. Defendants' ten-year plan contained the directive: [redacted]

b. R. Sackler aggressively pushed Purdue management for reports on the sales of opioids, sometimes asking for reports over the weekend, other times following up his initial request for information with a reminder five minutes later.

c. R. Sackler required management to create very individualized reports for him, directing the composition of the report in minute detail. For instance, in one email dated February 14, 2008, he directs:



d. Purdue employees carried out R. Sackler's requests for new analyses of sales data, even when they did not agree with the need to do the analysis. In response to one of these requests from R. Sackler, a Purdue employee wrote:

e. Although the 2007 Consent Judgment required Purdue to cease compensating its sales representatives *solely* on the basis of OxyContin sales, in the Post-Judgment Period, Purdue continued to compensate its salespeople largely based upon their sales.

f. Purdue salespeople were incentivized to increase sales with bonuses which frequently either made up a significant percentage of a salesperson's income, or even exceeded the salesperson's base salary.

i.

ii. Purdue's top sales people whom they called "Toppers" were also rewarded with additional incentives, such as trips to resorts with their spouses.

iii. The Board reviewed the structure of the bonuses for Purdue's sales force.

[redacted]

53. R. Sackler and the rest of the Purdue Board were actively involved in shaping the messages that Purdue sales representatives provided during their sales calls.

a. Defendants hired consultants to help Purdue increase the sale of OxyContin by working on the messaging, prescriber targeting, salesforce execution, developing medical/scientific support and working on converting patients to OxyContin from other medications.

b. The Board reviewed specific marketing messages designed to increase sales.

c. The Board reviewed specific marketing strategies to increase sales, such as generating substantial opinion leader dialogue on the value of OxyContin's abuse deterrent formulation (ADF), which Purdue released in 2010.

d. The Board reviewed specific tactics for challenging legislation that imposed restrictions on opioid prescribing and dispensing policies.

e. The Board reviewed messaging plans to switch patients taking immediate release opioids onto extended release opioids such as Butrans and OxyContin.

54. R. Sackler was involved in forming strategies that Purdue used to combat bad press that Purdue received about its opioids.

a. In 2001, he received an email from a Purdue employee reporting that a community meeting that was intended to cover pain management was [redacted] by two mothers whose children had died from their use of OxyContin. The Purdue employee reported "Statements were made that OxyContin sales were at the expense cf [of] dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor." The employee continued, [redacted]

[redacted] R. Sackler received this email and responded by endorsing the creation of a work-group to address this.

b. Subsequently, Defendants created two programs to work with law enforcement, The Law Enforcement Liaison & Education ("LELE"), and Crime Stoppers.

[redacted]

d. R. Sackler was involved in ensuring that internet ads for Purdue products were only linked to positive stories about opioids, not "about how useless or damaging or dangerous is our product that we are trying to promote."

e. In 2018 in response to the wave of lawsuits against Purdue, management at Purdue noted that its strategy to combat bad press included:

[redacted]

Mortimer Sackler, a Board member, advised that Purdue should also:

f. [redacted]

55. In 2009, [redacted]. It was very important to Defendants to obtain a label for reformulated OxyContin that would allow them to promote it for a wide variety of uses.

a. R. Sackler worked on the strategy [redacted].

b. In a speech, R. Sackler subsequently touted the approved label as [redacted]

56. Between 2008 and 2016, members of the Sackler family, including R. Sackler, received billions of dollars in distributions from Purdue from its opioid sales.

57. In sum, R. Sackler was involved in overseeing and directing the business of Purdue, including but not limited to by: making hiring decisions, setting the budgets (and therefore the goals) for opioids sales, analyzing (and criticizing) the work of Purdue employees, setting bonuses for Purdue employees, shaping opioid sales messages and tactics, forming press and public relations strategies, fighting legislation that would hurt Purdue's business, working with third parties to promote Purdue's messages, and even helping to negotiate with the FDA over label changes for Purdue's opioids.

Defendants Failed to Disclose and Misrepresented the Addictive Qualities of its Opioids

58. Defendants disseminated a narrative in the District during the Post-Judgment Period, that opioids are rarely addictive.

59. For example, in its *Resource Guide for People with Pain*, it conflated the concept of addiction with getting "high." "Knowledge is power. 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.'"

60. Addiction does not require that a patient become "high."

61. In 2009, Defendants funded a book, *Exit Wounds, A Survival Guide to Pain Management for Returning Veterans and Their Families ("Exit Wounds"),* which was packaged as the story of a wounded veteran, but which promoted the benefits of opioids and the dangers of other types of medications. That publication repeated Purdue's claim that addiction to opioids was unlikely: "Long experience with opioids shows that 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; . . ." (emphasis in original).

62. Defendants repeated the claim that addiction was rare in *Opioid Prescribing: Clinical Tools and Risk Management Strategies.* In this Purdue-funded publication prescribers were advised that "addiction is rare in patients who become physiologically dependent on opioids while using them for pain control."

63. Part of their subterfuge included implying that addicts were people who injected opioids.

64. In 2010, Defendants rolled out a reformulated version of OxyContin, which it claimed had "abuse deterrent" properties, and withdrew its earlier version of the drug. Defendants touted the reformulation as less likely to cause abuse because it was harder to crush and then inject. However, the most common form of abuse was simply swallowing the pills, and the "abuse deterrent" version had no impact on that form of ingestion.

65. Almost half of physicians surveyed in 2014 falsely believed that abuse deterrent formulations of opioids were less addictive. *Clinical Journal of Pain,* 2016 Apr; 32(4): 279-84. https://www.ncbi.nlm.nih.gov/pubmed/26102320.

66. R. Sackler was aware of the addictive nature of opioids. R. Sackler is a medical doctor, who learned about the addictive properties of opioids in medical school, prior to working at Purdue.

Defendants Shifted the Blame of Addiction to Patients through the Concept of Pseudo-Addiction

67. Rather than acknowledging that some patients had become addicted to their opioids, Defendants promoted the concept that patients were experiencing "pseudoaddiction." Defendants represented that pseudoaddiction was the fault of predisposed or irresponsible patients, not the opioids themselves. This concept encouraged prescribers to provide their struggling patients with even more opioids, by claiming that these patients simply needed higher doses of opioids.

68. Defendants distributed hundreds of copies of *Providing Relief Preventing Abuse, A Reference Guide to Controlled Substance Prescribing Practices ("Providing Relief, Preventing Abuse")* in the District in the Post-Judgment Period. That publication contains the claim that addiction "is not caused by drugs." Instead "it is triggered in a susceptible individual by exposure to drugs, most commonly through abuse."

69. *Providing Relief, Preventing Abuse*, declared that, "The term pseudoaddiction has emerged in the literature to describe the inaccurate interpretation of [drug-seeking] behavior in patients who have pain that has not been effectively treated."

70. Defendants repeated this claim in *Responsible Opioid Prescribing*, which Defendants provided to *every* licensed Doctor in the District. This publication again placed the blame on the character of the patient, not the nature of the drug. It told doctors that only "a small minority of people seeking treatment may not be reliable or trustworthy" and not suitable for opioids.

71. In a presentation intended for law enforcement, *Abuse and Diversion,* Defendants again asserted that addiction was not a by-product of opioids, but was instead due to genetic traits of individual users: "Addiction involves innate and acquired biologic factors. Each person

has a particular underlying genetic risk for developing addiction if exposed to a certain type of drug in a certain environment. Although the choice to try a drug may be voluntary, the effects of the drug can be influenced profoundly by genetic factors."

72. This narrative, that addiction was caused by a weakness in the patient, not the properties of the drug, was repeated in visits between Purdue sales representatives and District Doctors. For instance, in one visit in 2011, a Doctor asks if patients can get addicted to Butrans. Rather than stating that addiction is a risk of opioid use, the representative reframed the issue as one of misuse or abuse. [redacted]

73. In a sales call in 2010 to the Washington DC VA Medical Center, a Purdue representative reports laying out the pseudoaddiction concept: " [redacted]

74. Despite their contrary statements, Defendants were always aware that there was a risk of addiction that could be created by the drug itself, (iatrogenic addiction), and that it was not just a risk for people with a genetic predisposition to addiction.

Defendants' Deceptive Comparisons of Opioids to Other Medications

75. FDA Guidelines, 21 C.F.R. § 202.1(e)(6)(ii), provide that an advertisement is false, lacking in fair balance or otherwise misleading if it makes comparison claims about a drug, unless there is substantial evidence or clinical trials to support such claims.

76. Defendants' own internal training materials stated that its employees [redacted]

77. Comparison claims include claims about fewer pills or reduction in number of tablets or claims such that a drug has "lower abuse potential." A problematic comparison can be

express or implied. For instance, implied claims can include asking whether a patient can benefit from ingesting opioids rather than acetaminophen.

78. Yet, in its publications, and in sales calls, Defendants repeatedly made such comparison claims.

79. Call notes for Defendants' representatives in the District make numerous references to the convenience of taking few pills, including:

80. Defendants also made statements about the benefits of their opioids compared to over-the-counter medications such as acetaminophen.

81. Specifically, Defendants pointed to the danger of ingesting high doses of acetaminophen, compared to high doses of opioids.

82. In *Exit Wounds*, for instance, Defendants warned that the combination of opioids with acetaminophen can cause liver damage. It continued, "For severe pain, pure opioids are used because their doses can be gradually increased over time if the pain intensifies." It did not compare the possibility of liver damage to the possibility of death, overdose, fractures, or the other well-documented side-effects of taking high doses of opioids.

83. Similarly, the 2011 edition of *Responsible Opioid Prescribing,* suggests that opioids are safer than NSAIDs. "Factors contributing [to] the rise in opioid prescribing included the introduction of long-acting formulations and novel delivery systems, as well as prescriber

concerns over the dangers of non-opioid analgesics such as nonsteroidal anti-inflammatory drugs (NSAIDS)." (NSAIDs include medications such as aspirin and ibuprofen.)

84. This Purdue publication proceeds to argue that clinicians need to keep the risk of opioids in perspective, as they routinely use other 'dangerous treatments' such as NSAIDs, chemotherapy and insulin. The publication neither points out the differences between opioids and efficacious and potentially life-saving drugs such as insulin and chemotherapy, or the likelihood and severity of side effects from opioids compared to NSAIDs.

85. Although Defendants regularly promoted the advantages of their opioids over NSAIDs, R. Sackler was aware that in fact NSAIDs provide better relief for certain conditions.

87. Even though they had no evidence that their opioids were better than other drugs, Defendants attempted to switch patients from other medications onto their opioids. In 2016, recognizing that doctors were trying to prescribe fewer opioids, Defendants funded "switch research" to "understand what triggers prescribers to switch patients" from NSAIDs to opioids.

88. Defendants deceptively compared their opioids to other medications including but not limited to by: touting the convenience and the reduction of pill burden for their long-acting opioids, claiming that their opioids were superior to over-the-counter medications, and warning of the dangers of over-the-counter medications. They made these claims even though they knew that they had no drugs for which they had the substantiation to make such comparison claims.

Defendants' Deceptive Statements about the Benefits and Uses of Opioids

89. Defendants aggressively marketed their opioids as the solution for a wide spectrum of chronic pain.

90. In *Exit Wounds*, Defendants extolled the benefits, and minimized the risks of opioid use. "The pain-relieving properties of opioids are unsurpassed; they are today considered the "gold standard" of pain medications, and so are often the main medications used in the treatment of chronic pain. Yet, despite their great benefits, opioids are often underused. For a number of reasons, healthcare providers may be afraid to prescribe them, and patients may be afraid to take them."

91. *Exit Wounds* even claims that opioids are mostly free from side-effects. "The good news is that, with the exception of constipation, most side effects [from the use of opioids] disappear after a few days for most (not all) people."

92. Defendants specifically promoted opioids for conditions that they have not been shown to be effective for, such as the treatment of osteoarthritis.

93. The one study that Defendants conducted on the use of Butrans to treat this common condition "failed to show efficacy."

94. Defendants even used patient profiles in their sales materials, including hypothetical patients, "Pam," "Carol," and "Maggie," all of whom were depicted as suffering from osteoarthritis, which Defendants used to encourage doctors to prescribe opioids for this condition.

95. Defendants' research showed that patient profiles were particularly effective in influencing the prescribing practices of physicians.

96. Call notes from Purdue's sales representatives in the District show that they repeatedly promoted opioids for the treatment of osteoarthritis:

[redacted]

[redacted]

97. Defendants also claimed that their opioids could improve a patient's quality of life.

98. Defendants made these claims even though they had no drugs that met the FDA standards for making such a claim.

[redacted] In the District, a manager advised [redacted]

100. Defendants marketing and promotion of opioids to treat conditions such as osteoarthritis and to improve a patient's quality of life lacked substantiation, and were deceptive.

Defendants Pushed to Increase Patients' Time on Opioids in Spite of the Increased Danger to the Patients

101. Although Defendants aggressively promoted their opioids for long-term use they had no studies to support the efficacy of such use.

102. Rather, as noted above (¶¶ 16-19), extensive research has shown that opioids have limited or no efficacy for long-term use.

103. Nonetheless, Defendants pushed for long-term use of their opioids. Defendants' training materials for sales representatives promoting OxyContin set the explicit goals of [redacted]

104. One way that Defendants created more long-term users of opioids was through their promotion of patient savings cards. In 2012, Defendants' internal research showed that:

a. 60% more patients remained on OxyContin after 90 days when they redeem a savings card, compared to patients who do not.

b. [redacted]

105. The patient savings card program became a central part of Purdue's marketing and sales strategy. Defendants' comprehensive campaign included using telemarketers to call doctors, banner ads, Mediscript Rx pads with information about the savings cards, a co-pay calculator for doctors to use with patients, and an emailing initiative.

106. The Purdue Board received regular reports about the patient savings card program and campaigns.

107. Defendants' efforts to extend average treatment duration succeeded. A national study of tens of thousands of medical and pharmacy claims records published in the *Journal of General Internal Medicine* in 2011, found that two-thirds of patients who took opioids for 90 days were still taking opioids five years later.

108. Defendants' success is also demonstrated in District workers' compensation data.

109. Most workers' compensation recipients in the District who were prescribed opioids used opioids for an extended period of time. Workers' compensation claim data from 2011-2015 shows that over half of the District's workers' compensation claimants who were prescribed opioids used the drug for more than a year. Thirty-eight percent of the claimants used opioids for more than six years.

110. Analyses of workers' compensation claims have shown that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. [2]

[2] Jeffrey A. White *et al.*, *The Effect of Opioid Use on Workers' Compensation Claims Cost in the State of Michigan*, 54(8) J. of Occupational & Environ, Med. 948-953 (2012).

111. In their push to increase the length of time that consumers took opioids, Defendants failed to disclose that there was no evidence supporting the efficacy of long-term use of opioids.

Defendants Pushed to Increase Patients' Doses of Opioids in Spite of the Increased Danger to Patients

112. Higher dose opioids pose a greater risk of addiction and adverse side effects, including overdose and death.

113. Defendants made more money from their higher dose opioids, than their lower dose opioids.

114. First, Defendants charged much more for their higher dose opioids. For instance, in 2015, the price that Defendants charged for 100 tablets of OxyContin, ranged from $269.17 for 10 mg tablets, to $1500.18 for 80 mg tablets.

115. Second, Defendants knew that patients who were on higher doses of opioids would take the drugs for a longer period of time. "There is a direct relationship between OxyContin LOT [length of treatment] and dose." Their research showed that you could almost double the number of patients who stayed on opioids longer than 30 days, if they were taking an 80 mg dose compared to a 10 mg dose.

116. The *CDC Guideline* cautions against the use of high-dose opioids, stating that the: "Benefits of high-dose opioids for chronic pain are not established."

a. More specifically, they advise against prescribing opioids in amounts above 50 MME/day. "Most experts agreed that, in general, increasing dosages to 50 or more MME/day increases overdose risk without necessarily adding benefits for pain control or function."

b. And, their caution against prescribing over 90 MME/day is even more severe. "Clinicians should avoid increasing opioid dosages to $\geq$ 90 MME/day or should carefully justify a decision to increase dosage to $\geq$ 90 MME/day . . ."

117. In 2016, after the rollout of the *CDC Guideline*, [redacted]

119. Defendants closely examined what even a 1% shift in decreases in doses would do to their bottom line. According to their internal research, "a small shift [of 1%] of roughly 15k prescriptions from 20 mg or 15 mg down to 10 mg has a $2MM impact."

120. In line with these financial incentives, Defendants created a sales campaign entitled "*Individualize the Dose,*" to encourage physicians to put their patients on higher doses of opioids, in spite of the increased risk and lack of demonstrated benefit.

121. The "*Individualize the Dose*" campaign featured 7 doses of OxyContin: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg, which encouraged physicians to continually 'titrate' the dose. Titration is the process of gradually increasing a dose of a drug until the side-effects become intolerable.

122. Defendants even used the *Individualize the Dose* campaign to push for prescriptions well above 90 MME (which is equivalent to 60 mg of opioids). "For patients who require titration above 80 mg q12h, the total daily dose usually can be increased by 25% to 50%."

123. Patients who are titrated to 80 mg q12h are receiving 160 mg of opioids per day. This is equivalent to 240 MME per day. Increasing that dose by 50% would equal 360 MME per day, which is four times higher than the dose that the CDC cautioned against exceeding.

124. And R. Sackler pushed to incentivize the sale of higher dose opioids, in spite of the increased risk: "Let's measure our performance by Rx's by strength, giving higher measures to higher strengths . . .."

125. Defendants' training materials made the goal of keeping patients on opioids longer, by increasing the dose, explicit. [redacted]

[redacted]

126. And, ignoring the research on the dangers of high-dose opioids, Defendants trained their sales representatives not to fear pushing for high-dose prescriptions: [redacted]

127. Purdue coached its sales representatives on ways to overcome concerns that doctors had about the dangers of prescribing opioids, and on ways to manipulate a physician into agreeing to prescribe its opioids.

128. A sales representative who promoted to doctors in the District was criticized by her supervisors for not being aggressive enough in pushing Purdue's opioids. [redacted]

129. In their push to put consumers on higher doses of opioids, Defendants failed to disclose either the lack of benefits or the risks of taking high doses of opioids.

Violations of the Consumer Protection Procedures Act

130. The District re-alleges and incorporates by reference paragraphs 1 through 129, as if fully set forth herein.

131. The CPPA is a remedial statute that should be broadly construed. It establishes a right to truthful information from merchants about consumer goods and services that are or would be purchased, leased or received in the District of Columbia.

132. Consumers purchase Purdue opioids that Defendants offer for personal or family purposes and, therefore, these services are consumer goods.

133. Defendants, in the ordinary course of business, offer to sell or supply consumer goods and, therefore, are merchants.

134. Merchants who violate the CPPA may be subject to restitution, damages, civil penalties, temporary or permanent injunctions, the costs of the action, and reasonable attorneys' fees. D.C. Code § 28-3909.

Count I

135. Defendants' representations to consumers, both express and implied, that its opioids were suitable for the treatment of conditions such as osteoarthritis, or are the "gold-standard" of pain treatment, represent that goods or services have a source, sponsorship, approval, certification, accessories, characteristics, ingredients, uses, benefits, or quantities that they do not have and were unlawful trade practices that violate the CPPA, D.C. Code §28-3904(a).

136. Defendants' representations to consumers, both express and implied, that its opioids were superior to other opioids or over-the-counter medications are representations of material facts that had a tendency to mislead consumers, and were unlawful trade practices that violate the CPPA, D.C. Code § 28-3904(e).

137. Defendants' representations to consumers, both express and implied, that addiction to opioids is rare, or is the result of a genetic predisposition, or that the issue is actually 'pseudoaddiction' fail to state a material fact if such failure tends to mislead and were unlawful trade practices that violate the CPPA, D.C. Code § 28-3904(f).

Count II

138. The District re-alleges and incorporate by reference paragraphs 1 through 129 as if fully set forth herein.

139. Defendants' representations to consumers, both express and implied, that long-term use of opioids was appropriate or beneficial, when Defendants had no evidence to support such claims, and when Defendants failed to disclose the risks of long-term ingestion of opioids, were failures to state material facts that had a tendency to mislead, and were unlawful trade practices that violate the CPPA, D.C. Code § 28-3904(f).

140. Defendants' representations to consumers, both express and implied, that high doses of opioids are appropriate or beneficial, when Defendants had no evidence to support such claims, and when Defendants failed to adequately disclose the risks of the ingestion of high

doses of opioids, were failures to state material facts that had a tendency to mislead, and were unlawful trade practices that violate the CPPA, D.C. Code § 28-3904(f).

PRAYER FOR RELIEF

WHEREFORE, the District respectfully requests that this Court enter a judgment in its favor and, pursuant to the District of Columbia Consumer Protection Procedures Act, D.C. Code § 28-3909(a), grant the following relief:

(a) Permanently enjoin Defendants' violations of the District of Columbia Consumer Protection Procedures Act, D.C. Code § 28-3901, *et seq.*;

(b) Order Defendants to disgorge all revenues, profits and gains achieved in whole or in part through violations of the Consumer Protection Procedures Act;

(c) Order the payment of statutory civil penalties in the amount of $5,000 per violation for Defendants' violations of the District's consumer protection laws;

(d) Award the District the costs of this action and reasonable attorneys' fees incurred by the District in connection with the investigation and litigation of its claims;

(e) Grant such further relief as the Court deems just and proper.

JURY DEMAND

The District demands a trial by jury.

Dated: June 3, 2019

Respectfully submitted,

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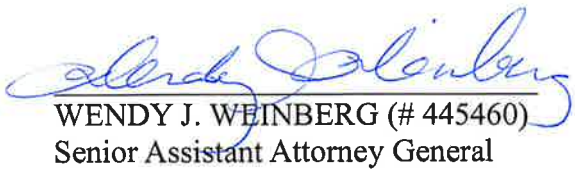

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