STATE OF WASHINGTON
KING COUNTY SUPERIOR COURT

STATE OF WASHINGTON, Plaintiff, v. PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY; DOES 1 through 99; and DOE CORPORATIONS 1 through 99, Defendants.	NO. COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF UNDER THE CONSUMER PROTECTION ACT, RCW 19.86, PUBLIC NUISANCE, AND NEGLIGENCE

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I. INTRODUCTION

1.1 On average, two Washingtonians die each day from opioid overdoses. In 2015, opioid overdoses killed 718 Washingtonians, more than either car accidents or firearms. These deaths are attributable to a flood of prescription opioids into the state over the last two decades. Hundreds of millions of prescription opioid pills have been pumped into Washington, including 112 million daily doses of prescription opioids in 2011 alone – enough for a 16-day supply for every woman, man, and child in the state. Seven Washington counties currently have more opioid prescriptions than people.

1.2 This enforcement action seeks to protect the public from deceptive and unfair marketing practices in the sale of opioids – dangerous and deadly drugs that are ravaging Washington's communities and overwhelming public resources.[1]

1.3 Defendants (collectively "Purdue"), who manufacture, sell, and market extended release opioids, have made an estimated $35 billion selling opioids and should be held responsible for the foreseeable, foreseen, and ongoing consequences of marketing opioids, particularly after it became evident that opioids had caused and were continuing a national epidemic.

1.4 This public lawsuit is unique because opioids are unique in the scope of deaths and cost. The U.S. Department of Health and Human Services reported that 33,091 people died of an opioid overdose in 2015. That year more than 12.5 million people misused prescription opioids, and the crisis cost an estimated $78.5 billion to the economy.[2]

1.5 This public lawsuit is unique because the origin of the opioid epidemic is unique. As Washington public health officials have noted, opioid use is the "worst manmade

[1] Executive Order 16-09, Addressing the Opioid Use Public Health Crisis, available at: http://www.governor.wa.gov/sites/default/files/exe_order/eo_16-09.pdf

[2] The U.S. Opioid Epidemic, US. Department of Health & Human Services, available at: https://www hhs.gov/opioids/about-the-epidemic/index.html

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epidemic in history."[3] Twenty years ago, this problem did not exist; it was created.

1.6 This public lawsuit is unique because Purdue aggressively marketed what was essentially an uncontrolled experiment on the American public. There was, and is, no reliable evidence that opioids are effective at relieving chronic pain in the long term. As evidence has mounted that, in fact, opioids are associated with poorer outcomes and unacceptably deadly side effects, Purdue has offered half-solutions and half-truths as it continues to push its pills.

1.7 This public lawsuit is unique because Purdue cloaked the sale of its products in the legitimacy of medicine. Unlike tobacco or alcohol about which no medical claims were made, patients were told by health care providers that opioids are a powerful medicine, safe to use as prescribed, and effective to relieve chronic pain. Against this message, the public had no defense.

1.8 This public lawsuit is unique because of the addictiveness of opioids. Patients quickly became dependent on opioids and, once hooked, susceptible to a host of foreseeable adverse events including addiction and death. Purdue knew of, and profited from, the addictive properties of its drugs. Purdue's marketing campaign sold the idea that dependence on opioids was an acceptable physiological reaction and that overdoses were the result of addicts misusing the drugs.

1.9 This public lawsuit is unique because Purdue's business practices were specifically aimed at expanding the most dangerous and deadly kind of opioid use—the long-term prescription of high dose opioids.

1.10 Purdue's marketing campaign in support of its opioid drugs is, and has been, deceptive. Purdue systematically overstated the effectiveness of its drugs for treating pain long-term, understated the risk of addiction, and overstated the effectiveness of risk mitigation strategies that Purdue claimed, without evidence, could render opioid use safe.

[3] Gary Franklin et al., *A Comprehensive Approach to Address the Prescription Opioid Epidemic in Washington State: Milestones and Lessons Learned*, 105 Am. J. Pub. Health 463 (2015).

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1.11 The Attorney General, on behalf of the State of Washington, asks this Court to enjoin Purdue's unfair and deceptive marketing practices related to opioids. The Attorney General further asks this Court to order Purdue to abate the public nuisance created by its marketing and business practices, to disgorge profits gained by its deceptive marketing and business practices, to impose penalties for its illegal conduct, and to award damages.

1.12 Having played a significant part in creating this crisis and profiting to the tune of $35 billion, Purdue is responsible for the costs of its conduct that are now being borne by the public.

II. PARTIES

2.1 The Plaintiff is the State of Washington. The Attorney General is authorized to commence this action pursuant to RCW 19.86.080 and RCW 19.86.140. The State, by and through the Attorney General and the Consumer Protection Division, brings this action to address practices that violate the Consumer Protection Act relating to the marketing and sale of opioid medications. The Attorney General is also authorized to bring this action pursuant to its common law and *parens patriae* authority to bring an action to abate a public nuisance and vindicate the rights of the public.

2.2 Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Connecticut. Purdue Pharma L.P. is currently registered to do business under UBI 601711150.[4]

2.3 Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Purdue Pharma Inc. was previously registered with the Washington Department of Revenue (WDOR) under UBI 602104563.

[4] Affiliated company Purdue Pharmaceutical Products L.P. is also currently registered with the WDOR under UBI 602349549.

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2.4 Defendant The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut. The Frederick Purdue Company was previously registered with the WDOR under UBI 602002636 and 600056165.

2.5 Collectively, the above-identified Defendants are referred to herein as "Purdue."

2.6 Purdue is in the business of manufacturing, promoting, marketing, and distributing opioids in the United States and in Washington. Purdue's opioid brands include, but are not necessarily limited to, the following:

a. OxyContin (oxycodone hydrochloride extended release), which is an opioid agonist tablet indicated for the "management of pain severe enough to require daily, around-the clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, OxyContin was indicated for the "management of moderate to severe pain when a continuous, around the clock opioid analgesic is needed for an extended period of time."[5]

b. MS Contin (morphine sulfate extended release), which is an opioid agonist tablet indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, MS Contin was indicated for the "management of moderate to severe pain when a continuous, around the clock opioid analgesic is needed for an extended period of time."[6]

c. Dilaudid (hydromorphone hydrochloride), which is an opioid agonist indicated for "the management of pain severe enough to require an opioid analgesic and for

[5]Highlihgts of Prescribing Information: OXYCONTIN, https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022272s006lbl.pdf (last visited Sep 27, 2017)

[6] MS Contin Label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/019516s034lbl.pdf (last visited Sep 27, 2017)

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which alternative treatments are inadequate." Prior to 2016, Dilaudid injection was indicated for the "management of pain where an opioid analgesic is appropriate."[7]

d. Dilaudid-HP (hydromorphone hydrochloride), which is an opioid agonist indicated for the "use in opioid-tolerant patients who require higher doses of opioids for the management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate."[8] Prior to 2016, Dilaudid-HP injection was indicated for "the management of moderate-to-severe pain in opioid-tolerant patients who require higher doses of opioids." Dilaudid-HP has also previously been indicated "for the relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."[9]

e. Butrans (buprenorphine), which is an opioid partial agonist transdermal patch and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Butrans was indicated for the "the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time."[10]

f. Hysingla ER (hydrocodone bitrate), which is an opioid agonist tablet indicated "for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

g. Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride), which is a combination product of oxycodone, an opioid agonist, and naloxone, an opioid

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[7] Highlihgts of Prescribing Information: DILAUDID, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019034s021lbl.pdf (last visited Sep 27, 2017)

[8] Highlihgts of Prescribing Information: DILAUDID, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019034s021lbl.pdf (last visited Sep 27, 2017)

[9] Dilaudid Label, https://www.accessdata fda.gov/drugsatfda_docs/label/2009/019034s018lbl.pdf (last visited Sep 27, 2017)

[10] Highlihgts of Prescribing Information: Butrans, https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021306s000lbl.pdf (last visited Sep 27, 2017)

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antagonist indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

2.7 In May 2007, Purdue entered into a "Consent Judgment" in an action with the State arising from unlawful marketing of OxyContin, described in further detail below.

2.8 Upon information and belief, Defendants Does 1 through 99 are individuals whose names and addresses of residence are unknown.

2.9 Upon information and belief, Defendants Doe Corporations 1 through 99 are corporations, the names and address of which are unknown.

2.10 At all relevant times, each Defendant acted individually or jointly with every other named Defendant in committing all acts alleged in this Complaint.

2.11 At all relevant times, each Defendant acted (a) as principal; (b) under express or implied agency; and/or (c) with actual or ostensible authority to perform the acts alleged in this Complaint on behalf of every other named Defendant.

2.12 At all relevant times, one or all of the Defendants acted as the agent of the others, and all Defendants acted within the scope of their agency as if acting as the agent of the others.

2.13 At all relevant times, each Defendant and its employees had awareness of the others' conduct relating to the matters alleged within the Complaint.

III. JURISDICTION AND VENUE

3.1 The State files this complaint and institutes these proceedings under the provisions of the Consumer Protection Act, RCW 19.86; the State also brings this action in its *parens patriae* capacity for the benefit of the state's residents, to protect their health and safety.

3.2 Purdue has engaged in the conduct set forth in this Complaint in King County and elsewhere in the state of Washington. Personal jurisdiction is therefore appropriate under RCW 19.86.160.

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3.3 Venue is proper in King County pursuant to RCW 4.12.020 and 4.12.025, and Superior Court Civil Rule 82 because Defendants transact business in King County by marketing and distributing the opioid products to health care providers and consumers in King County, as described more fully below.

IV. FACTS

4.1 Purdue makes and markets extended release branded opioids for the treatment of chronic,[11] long-term pain.

4.2 As set forth below, the Attorney General alleges that opioids are not effective at relieving long-term pain and that Purdue does not have sufficient evidence to make such assertions. Moreover, the risks associated with such opioid use outweigh the transient and unproven benefits of opioids.

4.3 Although the Food and Drug Administration has approved the sale of opioids, Purdue's marketing of these drugs has exceeded the labeled use and does not shield Purdue from liability for its deceptive marketing or the public nuisance created by its business model.

4.4 Washington State has a strong public policy in favor of protecting its citizens, which extends to preventing Purdue's deceptive marketing campaign and abating the public nuisance created by Purdue's opioids.

4.5 In contravention of Washington's public policy, Purdue used sophisticated and highly targeted marketing to deceive and mislead Washington health care providers into expanded and ongoing opioid prescribing in spite of massive and sustained public harms.

4.6 Using carefully selected third party materials as well as branded and unbranded marketing, Purdue disseminated deceptive and misleading statements about the effectiveness of opioids, minimized the risk of addiction, and made misleading statements about the ease with which the risk of addiction could be managed.

[11] Chronic pain means pain that lasts longer than three months.

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4.7 Washington prescribers have been directly affected by Purdue's marketing and their prescribing behaviors have changed so as to increase the prescribing of opioid pain medications.

4.8 Despite the associated risk, opioids are widely prescribed; in 2010, almost 20% of visits to the doctor for pain relief resulted in an opioid prescription.[12] This represented a 73% increase in visits resulting in an opioid prescription from 2000. Over that same period, non-opioid pain treatments remained relatively constant.[13] This means that the primary change in treating pain in the United States over the last two decades has been the increased prescription of opioids, without an impact on pain. In the last 20 years, opioid prescribing has increased by 600%.[14]

4.9 In 2012, U.S. health care providers wrote 259 million prescriptions for opioid pain medication, enough for every adult in the United States to have a bottle of pills.[15] The United States constitutes 4.6% of the world's population, but consumed 80% of the world's opioid supply in 2011.[16] Washington has 0.09% of the world's population, but in 2016 consumed 1.8% of the world's opioids.[17] This means Washington consumes nearly 20 times the opioids its population would suggest.

4.10 The result of Purdue's deceptive and unfair and negligent conduct dramatically impacted Washington State and has caused extensive public harm.

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[12] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Non-Malignant Pain in the United States*, 2000-2010, 51 Med. Care 870 (2013).

[13] *Id*.

[14] Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications* (2014), citing Leonard Paulozzi et al., *CDC Grand Rounds Prescription Drug Overdoses – a U.S. Epidemic*, 61 Morbidity and Mortality Weekly Report 10 (2012).

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

[16] Teater, *supra*, citing Daneshvari R. Solanki et al., *Monitoring Opioid Adherence in Chronic Pain Patients: Assessment of Risk of Substance Abuse*, 14 Pain Physician E119 (2011).

[17] U.S. and World Population Clock, U.S. Census Bureau, https://www.census.gov/popclock/ (last visited Sep 27, 2017).

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A. "The Science of Opioids Is Clear:" The Known, Serious, and Too-Often-Fatal Risks Far Outweigh the Unproven and Transient Benefits of Opioids for Treating Chronic Non-Cancer Pain

4.11 Opioids are a class of central nervous system depressant drugs that attach to receptors in the brain, spinal cord, and gastrointestinal tract and suppresses function. There are several different opioid molecules—morphine, hydrocodone, oxycodone, oxymorphone, hydromorphone, tapentadol, buprenorphine, and methadone being the most common.

4.12 Opioids come in two basic formulations: immediate release and extended release. Immediate release opioids deliver the full dose quickly as the pill dissolves. Extended release opioids are concentrated versions of the same active ingredients as immediate release drugs, but contained in a time-release matrix that is supposed to release the drug over time. OxyContin, for example, is oxycodone in a time-release matrix that claims to deliver the drug over 12 hours.

4.13 The immediate release opioid market is heavily generic. The extended release market has far more branded products, and Purdue's drugs compose a majority of the extended release market.

4.14 By design and marketing, Purdue's drugs are intended for long-term use, and Purdue has chosen to market them heavily for use with chronic non-cancer pain patients. As described below, long-term use, particularly in higher doses, is the most deadly and least effective opioid use.

4.15 Prescribed for pain relief, opioids also depress respiration, which is the primary mechanism by which opioids have killed thousands of Washington citizens and hundreds of thousands of Americans. It is undisputed that opioids are both addictive and deadly.

4.16 Prescription opioids constitute the largest component of the opioid epidemic,

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both in quantity and damage caused.[18] Overdose deaths parallel the prescribing of opioids.[19] In fact, filling an opioid prescription is significant risk factor for overdose.[20]

4.17 Both opioid use disorder and overdose risk are present even when opioids are taken as prescribed;[21] the opioid epidemic is not a crisis of abuse – it is a crisis of use.

1. Purdue designed and conducted an uncontrolled public health experiment on the American public about the risks of prescribing opioids for chronic non-cancer pain

4.18 In the mid-1990s, at about the time Purdue launched OxyContin, the medical community was aware of both the risks of opioids and the relative ineffectiveness of long-term opioid use. Dr. Russell Portenoy, whose theories were later adopted by Purdue, acknowledged the prevailing medical understanding regarding use of opioids long-term for non-cancer pain:

> The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effect over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutatory mood changes, but adverse effects will inevitably occur thereafter.[22]

Thus, in 1994, conventional wisdom predicted that opioids would appear effective in the short term, but prove ineffective over time with increasing negative effects.

4.19 The medical community knew from that published reports associated opioid use "with heightened pain and functional impairment, neuropsychological toxicity, prevarication

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[18] In 2015, almost half of all opioid deaths involved prescription opioids, and from 1999 to 2015, 183,000 deaths involved prescription opioids. Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*, 65 Morbidity and Mortality Weekly Report 1145 (2016).

[19] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, 16 American Journal of Transplantation 1323 (2016).

[20] Dowell, *supra* note 15, at 22-24.

[21] Letter from Janet Woodcock, MD., Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept 10, 2013). available at http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf

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

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about drug use, and poor treatment response."[23] And Dr. Portenoy noted, "the problematic nature of opioid therapy in *some patients is unquestionable*, and the potential adverse impact of all possible outcomes related to treatment, including physical dependence, deserves to be addressed."[24]

4.20 Standing against the conventional wisdom, Dr. Portenoy argued in favor of expanding the use of opioids, pointing to evidence from opioid use among cancer patients. He posited that there was a population of patients *without* cancer who could benefit from long-term opioid use. Even then, he admitted, "controlled trials suggest favorable outcomes, but are very limited. The generalizability of these data are questionable due to the brief periods of treatment and follow-up."[25]

4.21 Dr. Portenoy claimed that the lack of evidence should not stop doctors from prescribing opioids, arguing there was a lack of data

> that nonmalignant pain generally, or any patient subgroup with nonmalignant pain (such as those with neuropathic pain, low back pain, headache, or idiopathic pain), are inherently unresponsive to opioids drugs. Consequently, therapy cannot be withheld based on the a priori assumption that any particular pain or patient group will inevitably fail to benefit.[26]

4.22 Dr. Portenoy then proposed what was, in effect, an uncontrolled experiment. Expand the use of opioids and then monitor to see what would happen:

> Controlled clinical trials of long-term opioid therapy are needed, but the lack of these trials should not exclude empirical treatment when medical judgment supports it and therapy is undertaken with appropriate monitoring. If treatment is offered, documentation in the medical record of pain, side effects, functional status, and drug-related behaviors must be ongoing and explicit.[27]

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[23] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A Review of the Critical Issues*, 11 J. Pain & Symptom Mgmt. 203, 206 (1996).

[24] *Id.*

[25] *Id.* at 204.

[26] *Id.* at 206.

[27] *Id.* at 212.

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4.23 Purdue seized on the work of Dr. Portenoy. Where Portenoy proposed a clinical experiment with "appropriate monitoring," Purdue, through its marketing, expanded the "empirical treatment" to thousands of busy primary care physicians, nurse practitioners, physician assistants, and other prescribers, none of whom had Dr. Portenoy's expertise.

4.24 Purdue's business and marketing model nationalized an experiment in the absence of good evidence. Purdue hired other health care professionals that Purdue identified as "key opinion leaders" (or KOLs) and, through an extensive marketing scheme, set about convincing the rest of the medical establishment, patients, and policy makers to participate willingly in the experiment. As described below, Purdue did so by deceptively presenting the experimental *hypotheses* – that (a) opioids would be more effective than alternatives at treating chronic non-cancer pain long-term; and (b) the risks of addiction and associated problems were both slight and manageable – as *facts*. Purdue's factual claims were unsubstantiated and, unfortunately for the many Washingtonians who have suffered as a result, untrue.

2. Opioids are ineffective for pain relief and functional improvement for chronic non-cancer pain

4.25 Central to this lawsuit is the scientific fact that there is reliable evidence that opioids either relieve pain or improve function when taken long-term for chronic pain. The Centers for Disease Control (CDC) published a Guideline for Prescribing Opioids for Chronic Pain in 2016. This guideline, published after a "systematic review of the best available evidence" by an expert panel free of conflicts of interest,[28] determined that no study exists to show opioids are effective for outcomes related to pain, function, and quality of life.[29]

4.26 Purdue's decision to market opioids for long-term use despite the absence of clinical evidence and based on the hypothesis of a few cherry-picked doctors was a calculated

[28] Dowell, *supra* note 15, at 2.
[29] Dowell, *supra* note 15.

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gamble; Purdue bet that the conventional medical wisdom was wrong and that the detrimental side effects of long-term opioid use could be acceptably managed.

4.27 The scientific reality is otherwise. As Dr. Thomas Frieden, the Director of the CDC from 2011 to 2017, and Dr. Debra Houry, the Director of the National Center for Injury Prevention and Control, explained in 2016: "the science of opioids for chronic pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh unproven and transient benefits."[30]

4.28 A University of Washington pain specialist, Dr. John Loesser, explained that based on clinical experience, his clinic had developed a rule that it was not wise to use opioids for chronic pain treatments. Of Dr. Portenoy's theory that there was a population of non-cancer patients who could safely and effectively use opioids, Dr. Loesser explained,

> It did not enter our minds that there could be significant numbers of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them.[31]

4.29 On a nationwide scale, opioids did not offer a solution for what Purdue claimed was the widespread undertreatment of pain. Despite the fact that opioid prescriptions quadrupled from 1999 to 2015, the overall prevalence of patient-reported pain has remained consistent.[32] Thus, the massive expansion of prescribing opioids for pain has made little progress in reducing chronic pain.

4.30 At first blush, it may seem counterintuitive that opioids, used to treat pain for centuries, are ineffective at relieving pain. But 1994 conventional wisdom was prophetic. Opioids, when used long-term, cause tolerance, meaning larger and larger doses are necessary

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[30] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501 (2016).

[31] John D. Loeser, *Five Crises in Pain Management*, 20 Pain Clinical Updates 1 (2012).

[32] Centers for Disease Control, Injury Prevention & Control: Opioid Overdoes, Understanding the Epidemic, https://www.cdc.gov/drugoverdose/epidemic/index html (last accessed 9/6/17) citing Daubresse et al., *supra* note 12.

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to get the same effect. Long-term use also causes dependence, meaning that attempts to stop using the drug cause withdrawal symptoms.[33] In addition, long-term opioid use is associated with hyperalegisa, or heightened sensitivity to pain.[34]

4.31 While opioids may provide relief in the short term, they fail for their stated purpose of relieving pain in chronic pain conditions. In 2009, Dr. Andrea Rubenstein described a common experience for patients on long-term opioid treatment:

> 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.[35]

4.32 The 2016 CDC guideline notes 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."[36]

4.33 A 2006 Danish study found that "it is remarkable that opioid treatment of chronic non-cancer pain does not seem to fulfill any of the key outcome goals; pain relief, improved quality of life and improved functional capacity" and noted that in one study, opioid users were more likely to report pain, having more pain locations, being more depressed and physically disabled than non-opioid users."[37]

4.34 A 2006 Canadian meta-study, which noted that a majority of studies were funded by the pharmaceutical industry, still found no evidence that opioids improved function

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[33] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain*, 170 Archives of Internal Med. 1422 (2010).

[34] Marion S. Greene & R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, 2 Current Addiction Reports 310 (2015).

[35] A. Rubenstein, *Are We Making Pain Patients Worse?*, Sonoma Medicine, http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-acute-and-chronic-pain-in-orthopedics.aspx?pageid=145&tabid=747 (last visited Sep 27, 2017).

[36] Dowell, *supra* note 15, at 2.

[37] Jørgen Eriksen et al., *Critical Issues on Opioids in Chronic Non-Cancer Pain: An Epidemiological Study*, 125 Pain 172, 176-77 (2006).

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more than other non-opioid analgesics, finding instead that, "for functional outcomes the other analgesics were significantly more effective than were opioids.[38]

4.35 The deleterious effects of long-term opioid use are supported by a 2008 study which found daily opioid use at modest doses over six months is linked with self-reported poorer physical function and poorer general health.[39] Similarly, a 2008 study in the journal *Spine* found that long-term opioid users are more likely to be disabled and unable to work, as well as more likely to be addicted.[40]

4.36 A 2012 study in the Journal of Pain, which followed 69,000 women over three years, found that patients who received opioid treatment were less likely to have improvement in pain, and had worsened function.[41]

4.37 In 2012, a group of medical providers petitioned the FDA to impose limits on opioid use. The FDA considered the state of evidence and concluded that it was "not aware of adequate and well-controlled studies of opioid use longer than 12-weeks."[42] The FDA went on to note that more data was needed "on the point at which the risk of opioid use at escalating doses and longer durations of treatment may outweigh the benefits of opioid analgesic therapy."[43]

4.38 The evidence from real world opioid use similarly reflects a lack of efficacy. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, owing to greater side effects and

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[38] Andrea D. Furlan et al., *Opioids for Chronic Noncancer Pain: A Meta-analysis of Effectiveness and Side Effects*, 174 Canadian Med. Ass'n J. 1589 (2006).

[39] Rubenstein, *supra* note 35, citing citing Kathryn Sullivan Dillie et al., *Quality of Life Associated with Daily Opioid Therapy in a Primary Care Chronic Pain Sample*, 21 Journal of the American Board of Family Medicine 108 (2008).

[40] Jeffrey Dersh et al., *Prescription Opioid Dependence Is Associated With Poorer Outcomes in Disabling Spinal Disorders*, 33 Spine 2219 (2008).

[41] Frieden, *supra* note 30, citing Jennifer Brennan Braden et al., *Predictors of Change in Pain and Physical Functioning Among Post-Menopausal Women with Recurrent Pain Conditions in the Women's Health Initiative Observational Cohort*, 13 J. Pain 64 (2012).

[42] Woodcock Letter (Sept 10, 2013).

[43] Woodcock Letter (Sept 10, 2013).

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slower returns to work.[44] In addition, receiving an opioid for more than seven days increased patients' risk of being on work disability one year later; and that an opioid prescription as the first treatment for a workplace injury doubled the average length of the claim.

4.39 Thus, just as was the case with Dr. Portenoy's work in 1990s, the pattern of the opioid experiment remained the same: In the face of mounting evidence of a developing opioid epidemic, Purdue was marketing drugs for which there was no evidence of effectiveness.

3. Evidence from the last two decades has confirmed that opioids are deadly drugs with dangerous side effects, particularly in vulnerable populations

4.40 The last 20 years have proven that the conventional understanding of the danger and relative ineffectiveness of opioids was more accurate than Dr. Portenoy's hypothesis and Purdue's marketing in support of their widespread use. Opioids are massively dangerous.

4.41 Between 1999 and 2014, more than 165,000 Americans died of opioid overdose.[45] Deaths related to opioids are accelerating. In 2015, opioids killed 33,091 people and the opioid death rate increased by 15.6%.[46]

4.42 Dr. Freidan from the CDC explained, "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[47]

4.43 Aside from overdose, long-term opioid use is associated with a significant increase in mortality from other causes.[48]

4.44 Opioids are also associated with numerous other side effects including gastrointestinal impacts, delayed recovery from injury, cognitive impacts, endrocrine impacts, hyperalgesia (increased sensitivity to pain), increased risks of fractures, gastrointestinal

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[44] Gary M. Franklin et al., *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries*, 33 Spine 199 (2008).

[45] Dowell, *supra* note 15.

[46] Washington experienced a 12.5% increase in opioid death rates in 2015. Rudd et al., *supra* note 18.

[47] Frieden, *supra* note 30

[48] Wayne A. Ray et al., *Prescription of Long-Acting Opioids and Mortality in Patients With Chronic Noncancer Pain*, 315 J. Am. Med. Ass'n 2415 (2016).

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bleeding, hospitalization among the elderly, tolerance (need for increasing dose to maintain effect), dependence (causing withdrawal if stopped), and addiction.[49]

4.45 Opioids carry special risks for certain vulnerable populations. For example, opioid use during pregnancy has seen a three to- to four-fold increase between 2000 and 2009, with increased fetal, obstetrical, and neonatal abstinence syndrome risk. Neonatal abstinence syndrome may occur in up to 60-80% of infants exposed to opioids and has increased every year through 2013.[50] Of pregnant women enrolled in Medicaid from 2000 to 2007, 21.6% filled an opioid prescription during pregnancy.[51]

4.46 Opioids also pose risks for children and adolescents. Most of the use in this population is off-label as opioids are not approved for children. Use of prescription opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse. The misuse of opioids in adolescents strongly predicts the later onset of heroin use.[52] Nonetheless, the 2016 CDC guidelines found that there have been significant increases in opioid prescribing for children and adolescents, for conditions such as headaches and sports injuries.

4.47 Opioids also pose special risks for older patients as well, in part due to the decline in the ability to metabolize and excrete opioids. Older patients on opioids are particularly prone to constipation, have increased risk for falls and fractures, and have a higher risk of opioid-related adverse drug events.[53]

[49] Teater, *supra* note 14.

[50] Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on Prescribing Opioids for Pain*, 49, 3rd ed. (2015).

[51] WSAMDG, *supra*, at 42.

[52] Dowell, *supra* note 15.

[53] WSAMDG, *supra*, at 47-48.

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4. Evidence from the last two decades has confirmed that opioids are highly addictive

4.48 Opioids are also extremely addictive. Studies have found diagnosed addiction rates in primary care settings as high as 26%.[54] Among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-use disorder.[55]

4.49 Once a patient starts opioid treatment, it is extraordinarily difficult to stop. A 2017 CDC study determined that the probability of long-term use escalates most sharply after five days, and surges again when one month of opioids are prescribed.[56] A patient initially prescribed one month of opioids has a 29.9% chance of still using at one year.[57] In one study, almost 60% of patients who used opioids for 90 days were still using opioids five years later.[58]

4.50 The difficulty in stopping use is particularly true for patients first prescribed an extended release opioid. Patients who initiated treatment on an extended release opioid – such as OxyContin – have a 27.3% likelihood to be using opioids one year later, and a 20.5% likelihood of using opioids three years later.[59]

4.51 In 2013, the FDA observed that extended release opioids, like those Purdue markets, present "disproportionate safety concerns" and that the data show that the risk of misuse and abuse is greater for extended release opioids.[60] In requiring a new black-box warning on the labels of all immediate release opioids in March 2013, the FDA noted the

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[54] Dowell, *supra* note 15, at 22-24.

[55] Joseph A. Boscarino, Stuart N. Hoffman & John J. Han, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates*, 6 Substance Abuse and Rehabilitation 83 (2015); *see also* Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30 Journal of Addictive Diseases 185 (2011) (showing a 34.9% lifetime opioid use disorder).

[56] Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66 Morbidity and Mortality Weekly Report 265–269 (2017).

[57] *Id*.

[58] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26 J. Gen. Internal. Med. 1450 (2011).

[59] Shah, *supra*.

[60] Woodcock Letter (Sept 10, 2013).

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"known serious risk[] of ... addiction" which was present "even at recommended doses of all opioids."[61]

4.52 The CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" – a technical term for addiction.[62] The CDC emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[63]

4.53 Whether in the end a patient meets the clinical definition of addiction or is simply dependent and unable to stop using opioids, once opioids are prescribed for even a short period of time, patients are hooked.

4.54 Purdue's marketing strategy, and business model, relies on this fact. According to internal documents, [redacted]. Similarly, [redacted]. Purdue's profits depend on keeping continuing patients.

4.55 Marketing a substance as dangerous and addictive as opioids quickly crosses the line into an unfair trade practice. Indeed, after one Longview health care provider told a Purdue sales representative that [redacted], the sales representative was nevertheless instructed to follow up and convince the provider to [redacted] Because opioids cause tolerance and dependence, patients who take the drugs for even a short time become a physiologically captured market. If Purdue convinces a doctor and patient to start opioid treatment, Purdue knew that the patient would keep taking them.

[61] Woodcock Letter (Sept 10, 2013).
[62] Dowell, *supra* note 15, at 2.
[63] Dowell, *supra* note 15, at 21.

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5. Opioids are most dangerous when taken long-term and when taken in high doses

4.56 The risk of addiction and negative consequences increases when opioids are administered long-term.[64] In 2013, the FDA noted that the data show that risk of misuse and abuse is greatest for extended release opioids and observed that these drugs are often used chronically.[65]

4.57 One study has shown that the duration of opioid therapy is a strong risk factor for opioid use disorder, even more important than daily dose (which is itself a strong predictor of continued opioid use).[66] In fact, a study published in 2015 found that 1 in 5 patients on long-term opioid treatment will develop opioid use disorder.[67]

4.58 Higher doses of opioids are dangerous in a number of ways. A CDC clinical evidence review found that higher opioid dosages were associated with increased risks of motor vehicle injury, opioid use disorder, and overdose, and that the increased risk rises in a dose-dependent manner.[68] Another study found that higher daily doses and possible opioid misuse were also (a) strong predictors of continued use, and (b) associated with increased risk of overdoses, fractures, dependence, and death.[69]

4.59 Accordingly, the CDC recommended that physicians carefully reassess increasing opioid doses beyond 50 morphine milligram equivalents (MMEs), and avoid exceeding 90 MMEs/day.[70] Roughly translated, a single 60 mg pill of oxycodone, the active

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[64] *See e.g.* Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81 Drug and Alcohol Dependence 103, 104 (2006) (noting increased risk of addiction for long-term administration of opioids).

[65] Woodcock Letter (Sept 10, 2013).

[66] Mark J. Edlund et al., *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-cancer Pain*, 30 Clin. J. Pain 557–564 (2014).

[67] WSAMDG, *supra* note 42, citing Louisa Degenhardt et al., *Agreement between definitions of pharmaceutical opioid use disorders and dependence in people taking opioids for chronic non-cancer pain (POINT): a cohort study*, 2 The Lancet Psychiatry 314–322 (2015).

[68] Dowell, *supra* note 15, at 22-24.

[69] Edlund, *supra*.

[70] Dowell, *supra* note 15, at 22-24.

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ingredient in OxyContin, is 90 MME; a 40 mg pill is 60 MME; and a single 30 mg pill is 45 MME. Since patients take 12-hour OxyContin twice a day, a prescription for 30 mg pills of OxyContin is already at the CDC's upper threshold.

4.60 Measured against the general risk, the likelihood of developing an opioid use disorder increases threefold for acute patients prescribed even low dose opioids. For patients taking a daily dose of more than 120 MMEs over the long term, the chance of developing an opioid use disorder increases 122-fold.[71]

4.61 At high doses, patients are also at higher risk of poor functional status, increased pain sensitivity, and continuation of opioid treatment for a prolonged period.[72]

4.62 Overdose risk from opioids begins at very low doses, doubling when the daily dose is between 20 MMEs and 49 MMEs; by 100 MMEs, the risk of death increases 9-fold.[73] Recent studies of Washington workers' compensation and Medicaid populations found that nearly half of all overdose hospitalizations occur in patients who are on intermittent or lower dose opioids. [74]

4.63 Overall, 1 in every 550 patients on opioid treatment dies of opioid-related causes a median of 2.6 years after their first opioid prescription. That number increases to 1 in 32 for patients receiving 200 MMEs/day.[75]

4.64 In short, there are no safe opioid doses, but the higher the dose and the longer the treatment, the more likely serious adverse events are to occur.

6. Opioids are only moderately effective at short-term relief

4.65 Although there is evidence that opioids are effective in treating acute and short-term painful conditions, the perception of their effectiveness exceeds their actual utility.

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[71] WSAMDG, *supra* note 42, at 7-8.
[72] WSAMDG, *supra* note 42, at 13.
[73] WSAMDG, *supra* note 42, at 12.
[74] WSAMDG, *supra* note 42, at 13.
[75] Frieden, *supra* note 30.

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4.66 Even for short-term use, opioids are only modestly effective. In a 2004 meta-analysis, opioids reduced pain by only 30%, or 2 points on a scale of 1-10 over placebo for neuropathic pain conditions. For osteoarthritis, musculoskeletal pain, and mixed pain conditions, opioids provided either insignificant relief or less than the 30% reduction.[76] Even then, several studies suggest that ibuprofen and acetaminophen are better than opioids at relieving pain such as dental pain, low back pain, and moderate acute traumatic pain.[77]

7. Despite the scientific evidence, Purdue continues to market opioids for chronic non-cancer pain

4.67 Purdue's decision to promote expansive opioid use without good evidence of efficacy and in spite of the recognized risks created what Washington state public health officials have described as, "one of the worst manmade epidemics in history."[78]

4.68 Remarkably, more than 20 years after Dr. Portenoy pointed out that there were no reliable clinical trials about long-term opioid use, there are *still* no reliable clinical studies supporting the use of opioids over the long term. On the contrary, there exists a wealth of evidence establishing that opioids are both addictive and deadly.

4.69 Indeed, the original proponents of expanded opioid prescribing now admit error. Purdue key opinion leader Dr. Portenoy has admitted that he overstated opioids' benefits and downplayed their risks: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . . We didn't know then what we know now."[79]

4.70 Purdue, nevertheless, continues to market opioids as necessary to address chronic pain and that its drugs can used long-term with the appropriate patient.

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[76] Rubenstein, *supra* note 35.
[77] Teater, *supra* note 14.
[78] Franklin et al., *supra* note 3.
[79] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (last visited September 27, 2017).

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4.71 Purdue's stated motive for promoting opioids was providing pain relief, but its underlying motive was profit. Purdue's aggressive marketing of opioids for the most dangerous kind of opioid use has been exceedingly financially lucrative.

4.72 Purdue, which is a privately-owned family company, has generated an estimated $35 billion in sales since 1995, with annual revenues around $3 billion.[80] In 2012, the extended release opioid market recorded $5.2 billion in sales. OxyContin alone generated $2.8 billion, or more than half of that amount. In 2014, the total opioid market reached $11 billion and is projected to continue generating these levels of revenues.[81]

B. FDA Requirements for Promotion of Prescription Drugs

4.73 The Food and Drug Administration (FDA) regulates drugs manufactured for sale in the United States. But the FDA's regulatory scheme is limited in important ways and Purdue took advantage of those limitations. While the FDA approves drug and drug labels, the drug companies remain liable for misleading marketing under both federal and state law.

4.74 As a pharmaceutical manufacturer that markets opioids, Purdue is subject to federal rules requiring truthful marketing of prescription drugs. The Food, Drug & Cosmetic Act (FDCA) regulates the promotion of prescription drugs. 21 U.S.C. §§ 301, *et seq.* The FDA must approve a drug's label and promotional activity at the time of application.[82]

4.75 Drug companies' promotional activity can be branded or unbranded. Unbranded marketing does not refer to a specific drug, but promotes a type of treatment generally, and

[80] Alex Morrell, *The OxyContin Clan*: *The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, Forbes, July 1, 2015, https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#4348400475e0 (last visited Sept. 20, 2017).

[81] GBI Research, *Despite Substance Abuse Concerns, the US Opioid Market Will Hit $17.7 Billion by 2021*, March 31, 2016 , http://gbiresearch.com/media-center/press-releases/despite-substance-abuse-concerns-the-us-opioid-market-will-hit-177-billion-by-2021 (last visited Sept. 27, 2017).

[82] The FDCA, 21 U.S.C. § 32l(m), defined labeling to include "all labels and other written, printed, or graphic matter ... accompanying [a drug]." Title 21, Code of Federal Regulations, Section 202. l (1)(2) provided that labeling included brochures, booklets, mailing pieces, detailing pieces, bulletins, letters, motion picture films, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug which were disseminated by or on behalf of a drug's manufacturer, packer, or distributor. Such items "accompanied" a drug if they were designed for use and used in the distribution and sale of the drug.

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unbranded materials are not typically reviewed by the FDA. Moreover, by using unbranded communications, drug companies can evade the regulatory framework governing branded communications.

4.76 Conversely, branded marketing, which identifies and promotes a specific drug, such as OxyContin or Butrans, is subject to FDA review and must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[83]

4.77 The FDCA expressly prohibits the sale of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[84] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[85] Thus, Purdue's promotional materials are part of its drugs' labels and required to be accurate, balanced, and not misleading.[86]

4.78 Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to any presentation of efficacy." The FDA notes that "[b]ecause people expect to see risk information, there is no reason for them to imagine that the product

[83] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

[84] 21 U.S.C. §§ 352(a)

[85] 21 U.S.C. § 321(m) "The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.

[86] The FDCA, 21 U.S.C. § 32l(n), states that "[i]n determining whether the labeling ... [was] misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representation or material with respect to the consequences which may result from the use ... to which the labeling ... relates under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual."

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has important risks that have been omitted . . . especially if some risks are included."[87] Promotional materials or marketing that fail to present the drug's most significant risks as prominently as its benefits lack fair balance and are therefore deceptive.[88]

4.79 Purdue is also prohibited from distributing materials that exclude contrary evidence or information about the drug's safety or efficacy or that present conclusions that "clearly cannot be supported by the results of the study."[89] Pharmaceutical companies must not make comparisons between their drugs and other drugs in which they represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[90]

4.80 The public policy underpinning this regulatory framework is designed to ensure that drug companies, which are in the best position to understand the effects and risks of their drugs, are responsible for providing prescribers with the information the prescribers need to accurately assess the risks and benefits of drugs for their patients. Purdue's misbranded marketing and deceptive unbranded marketing of opioids are contrary to that purpose.

4.81 While the FDA must approve a drug's label, it is Purdue's responsibility to ensure that the material in its label is accurate and complete and to update the label[91] to reflect any new information. Promotional materials also must be submitted to the FDA when they are

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[87] FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, at 14 (2009).

[88] The State is not alleging a cause of action against Purdue for mislabeling under the Food, Drug & Cosmetic Act. The State's deception claims are alleged herein pursuant to Washington's Consumer Protection Act, RCW 19.86.

[89] 21 C.F.R. § 99.101(a)(4).

[90] 21 C.F.R. § 202.1(e)(6)(ii)

[91] *See* 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); see also *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6) (iii)(A-C) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction" or "strengthen a statement about drug abuse, dependence, psychological effect, or overdosage").

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first used or disseminated, however the FDA does not have to approve these materials in advance.

4.82 The FDA does not monitor the in-person sales representatives detailing visits to prescribers. The FDA does not ask companies to submit preplanned messages or training materials such as sales scripts, talking points, sales bulletins, or sales training videos that are provided to sales representatives for their study and use making a sales pitch to prescribers. The FDA does not require submission of any prepared text in response to unsolicited drug queries made to pharmaceutical companies by prescribers; and the FDA does not directly regulate funding for or content of continuing medical education.[92]

4.83 Critically, as Purdue's internal documents explain, in [redacted]

4.84 Thus, to avoid stifling drug development, the FDA-approved labeling does not address the most crucial component of this lawsuit—the long-term (beyond 12 weeks) use of opioid medications. Through this gap in FDA regulation, Purdue drove a multibillion dollar experiment with disastrous results.

4.85 In addition, Purdue's marketing, described below, operated outside the FDA labeling system. For example, as the FDA explained, the label is designed to encourage

[92] Jesse R. Catlin & Cornelia (Connie) Pechmann, *An Investigation of Consumer and Doctor Regulatory Beliefs and Regulatory Knowledge About Pharmaceutical Drug Promotions*, 1 J. Ass'n of Consumer Research 392 (2016); *About the Center for Drug Evaluation and Research: The Office of Prescription Drug Promotion (OPDP)*, U.S. Food & Drug Administration, https://www fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090142 htm (last visited Sep 27, 2017); U.S. Dep't of Health and Human Servs. et al., *Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices* (2011).

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prescribers to exercise "thoughtful determination" that pain is "*severe enough* to require daily, around-the-clock, long-term opioid treatment."[93] Purdue's marketing through unbranded, and therefore unregulated, materials manipulated prescribers' and patients' perception of when pain was severe enough and when opioids were required.

4.86 Similarly, the labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia, three conditions for which opioids are ineffective, but for which Purdue marketed its drugs.

4.87 Additionally, although the labels contain warnings about addiction, the severity of that risk is not quantified. Purdue's marketing, both branded and unbranded, asserted that screening, abuse deterrent formulations, or urinalysis can adequately manage the risk of developing an addiction without evidence to support those claims.

4.88 Nor do the labels address the critical issue of opioid dosage. The CDC recommends that caution be used with doses over 50 MME and recommends against 90 MME doses. As described below, Purdue's sales staff regularly visited prescribers that were writing doses far in excess of these thresholds.

C. Washington State Has a Public Policy Interest in Reducing Opioid Addiction and Abuse

4.89 In contrast to the federal labeling regulatory scheme, Washington State's consumer protection statute and common law protect consumers from the kind of marketing conduct that Purdue employed to encourage the most dangerous kind of opioid use in spite of growing and irrefutable evidence of widespread negative impacts.

4.90 Washington State has a strong public policy to preserve and protect the health and welfare of its citizens by ensuring high-quality health care and preventing abuse of prescription and non-prescription drugs.

[93] Woodcock Letter (Sept 10, 2013).

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4.91 Washington regulates the practice of medicine because "the health and well-being of the people of this state are of paramount importance." RCW 18.71.003.

4.92 Washington has a strong public policy to prevent opioid addiction and abuse. Washington has categorized opioids as Schedule II drugs, RCW 69.50.206(b)(1), meaning that they have "a high potential for abuse," which "may lead to severe psychological or physical dependence."[94]

4.93 To further its public policy, Washington has taken steps to regulate opioid use. This was prompted initially by the Washington workers' compensation system, which saw a dramatic increase in Schedule II opioid prescribing from 1996 to 2002, and a 50% increase in the average daily MME among injured workers taking these potent medications.[95] By 2000, the Department of Labor & Industries noted an alarming rise in overdose deaths.[96] A manual review of all opioid overdose death certificates by the Department of Health showed an increase in the number of overdose deaths involving prescription opioids from 24 in 1995 to 351 in 2004. By 2006, the CDC had identified Washington to be in the highest tertile of mortality (10.8 deaths/100,000)[97] from unintentional drug overdoses in the United States. At that same time, approximately 10,000 Washington patients in public insurance programs were taking at least 120 milligrams per day MED.[98] Accordingly, Washington acted.

4.94 In March 2007, the Washington State Agency Medical Directors' Group (AMDG), consisting of the medical directors for the Washington State Departments of Corrections, Social and Health Services (Medicaid), Labor and Industries, and the Health Care Authority, published its "Interagency Guideline on Opioid Dosing for Non-cancer Pain: An educational guide to improve care and safety with opioid therapy." Washington was the first

[94] RCW 69.50.205(a)(1) & (3).
[95] Franklin et al., *supra* note 3, at 464, citing to n16
[96] *Id.*
[97] Franklin et al., *supra* note 3, at 464, citing to n14.
[98] Franklin et al., *supra* note 3, at 464; Strong epidemiological studies now support a dosing threshold or range around 80 to 100 milligrams per day. Franklin et al., *supra* note 3, at 465, citing to n27-29.

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jurisdiction in the country to issue guidelines recommending caution in using high dose opioids.[99]

4.95 The 2007 AMDG guidelines were relatively simple, with modest recommendations. Noting that increasing opioid doses may not improve pain control and function, the guideline recommended the lowest possible effective dose, and monitoring of function rather than pain scores. If function did not improve, if adverse effects occurred, or if there were drug-seeking behaviors, the guidelines recommended discontinuing opioids. The guidelines proposed a 120 MME dose as threshold for seeking specialized care.

4.96 Purdue's response to these modest 2007 guidelines was to participate in a "Pain Care Forum" subcommittee on Washington State with representatives from other pharmaceutical manufacturers, key opinion leaders like Dr. Scott Fishman, professional associations like the American Academy of Pain Medicine, and members of pain advocacy groups to revise and oppose the AMDG guidelines. The American Academy of Pain Medicine issued a position statement opposing the guideline because recommending a consultation could impair "legitimate patients…appropriate dosing with opioids."[100]

4.97 In a letter to the AMDG, Purdue explained its position regarding opioids, offering its "extensive experience with clinical issues regarding pain management due to our portfolio of pain medications." Purdue explained that OxyContin's "safety and efficacy" was established, and defended the use of more than 120 MME per day. Purdue also advised that drug-seeking behaviors could be misinterpreted and constituted "pseudoaddiction" rather than addiction. Finally, Purdue wrote that even when an opioid "causes significant adverse effects that are not otherwise manageable, this does not preclude a trial of another opioid."[101]

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[99] Franklin et al., *supra* note 3, at 464, citing to n18. In 2006 a consortium of all WA agencies that purchase or regulate health care (the Agency Medical Directors' Group (AMDG) collaborated with 15 WA pain management experts (the Clinical Advisory Group) to develop an opioid prescribing guideline.

[100] "A Position Statement from the American Academy of Pain Medicine" available at: http://www.painmed.org/files/washington-state-amdg-opioid-guidelines-statement.pdf.

[101] Letter from Lally Samuel, RPh, MS, Purdue, to Gary Franklin, MD, MPH (May 9, 2007).

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4.98 In 2009, the Washington Attorney General's office funded a study on how the AMDG guideline was functioning. Among the findings from the study was that Schedule II opioids represented the largest increase in opioid prescriptions from 1996 to 2008, and the average daily dose of long-acting opioids, like those sold by Purdue, had steadily increased from the late 1990s.

4.99 In 2010, the AMDG issued updated guidelines that provided tools for calculating dosages, screening for substance abuse, mental health, and addiction, clinical tools, and patient education materials and resources.

4.100 Also in 2010, the Washington Legislature began enacting legislation to address the threat opioids posed to public health. Public testimony, as summarized by non-partisan legislative staff, revealed the concerns motivating lawmakers:

> Over the last decade we've seen a huge increase in the dosing levels of narcotics and that has driven a dramatic increase in dependency, addiction, overdoses, deaths, and bad interaction with other drugs. This is a public health emergency. More people die from prescription drug overdoses in this state than in car accidents. We have to change prescribing practices, through education and setting guidelines, to help practitioners who are under pressure to increase doses well beyond what is safe and useful. The rampant use of opiods [*sic*], sold as prescriptions, means that kids think these are safe and are using them straight out of their parents' medicine cabinets. . . . We have to stop drug surfing and find ways to assist practitioners and pharmacists who feel at risk because the demand for these drugs is so high.

4.101 This public testimony about the burgeoning opioid epidemic resulted in a strong bi-partisan consensus to confront the public health problems caused by opioid use. The Senate voted 36-12 and the House of Representatives voted 96-1 to require Washington medical boards to adopt new regulations.

4.102 In accordance with the Legislature's directive, those agencies promulgated new standards for opioid prescriptions for the treatment of chronic non-cancer pain. The Department of Health explains that:

> The boards and commissions are committed to protecting and improving the health of people in Washington State. The pain management rules' goals are to

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> keep patients safe, and to give practitioners who prescribe opioids the best practices in pain management. A key component of the rules is to encourage practitioners to become better educated in the safe and effective uses of these powerful drugs.

4.103 As it had with the first set of guidelines, Purdue opposed Washington's efforts to urge caution. As discussed below, Purdue partnered with the American Pain Foundation and provided significant material support to the Washington Pain Alliance to oppose the new regulations in Washington State.

4.104 The new guidelines had a significant effect. Prescription opioid overdose death rates in Washington declined by 27% from 2008 to 2012, and overdose hospitalization rates declined for the first time in 2012. The percentage of Washington residents who have used prescription pain medication nonmedically in the past year declined from 6.2% in 2009-2010 to 5.1% in 2011-2012.

4.105 Unfortunately, although Washington has seen a decline in prescription overdose deaths, it has been more than offset by a corresponding rise in heroin overdose deaths. The rise in illicit opioid deaths is a foreseeable consequence of Purdue's manipulation of the opioid market. Nearly 80% of heroin users report using prescription opioids before beginning heroin use.[102] Having created physically dependent patients through widespread opioid prescribing, efforts to restrict prescribing inevitably pushed those patients into finding alternate sources of opioids.

4.106 In June 2015, the AMDG released another update to the Interagency Guidelines. Washington Secretary of Health John Wiseman noted that "Washington and many other states are in the midst of an epidemic of opioid misuse, abuse, and overdose," and warned that "[a]lthough opioids can be a useful option for pain management, their inappropriate use can result in significant harms, including addiction and death." He therefore urged prescribers to

[102] *Prescription Opioids and Heroin*, National Institute on Drug Abuse, https://www.drugabuse.gov/publications/research-reports/prescription-opioids-heroin (last visited Sept 20, 2017).

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"help us improve the health of Washington residents by following this updated AMDG evidence-based practice guideline."[103]

4.107 The 2015 AMDG guidelines recommend reserving opioids for acute pain resulting from severe injuries or medical conditions when alternatives are ineffective or contraindicated. Even then, opioids should be prescribed at the lowest necessary dose and for the shortest duration and should not be prescribed at all for low back pain, headaches, or fibromyalgia. Long-term opioid use is not recommended unless there is sustained clinically meaningful improvement in function, and, even then, it is to be carefully monitored.

4.108 In 2016, Governor Jay Inslee issued an executive order recognizing that medically prescribed opioids have contributed to an opioid epidemic that is devastating Washington communities and families, and overwhelming law enforcement, health care, and social service providers. Governor Inslee directed state agencies to prevent inappropriate opioid prescribing, reduce opioid misuse and abuse, expand treatment resources, and use data to detect and intervene to prevent mortality. At the same time, Washington created an interagency opioid working plan to implement the Governor's order.

4.109 In addition to medical guideline and legislative action, Washington's consumer protection laws also prohibit Purdue from engaging in unfair or deceptive acts or practices in the conduct of any trade. As is detailed below, Purdue's marketing was both deceptive and misleading and, in the context of the addictive and deadly properties of opioids, unfair to the citizens of Washington.

D. Purdue Used Sophisticated Branded and Unbranded Marketing Targeted at Washington Health Care Providers and Patients to Boost Opioid Prescribing and Its Own Profits

4.110 Purdue engaged in a marketing campaign to deceive health care providers and patients into believing that opioids in general and Purdue drugs in particular were effective and

[103] WSAMDG, *supra* note 42.

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safe, and should therefore be widely prescribed. Upon information and belief, Purdue centrally developed its marketing strategies and materials, which were deployed at the local level in Washington and nationwide.

4.111 Russell Gasda, a current Purdue executive and former Vice President for Sales and Marketing, testified regarding Purdue's message when marketing any drug. He explained that "[redacted]" The marketing "[redacted]"

4.112 He also testified that "[redacted]" Thus, "[redacted]"

4.113 Finally, he explained that "[redacted]"

4.114 Purdue knew that its in-person marketing worked. The effects of sales calls on prescribing behavior are well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling of sales calls.[104] A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical

[104] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221–227 (2009).

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sales representatives were allowed to detail prescribers.[105] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures.[106]

4.115 Purdue's deceptive opioid marketing focused on convincing doctors that (a) opioids were effective at relieving pain and improving function; (b) the adverse effects of opioids (including addiction) were overstated and could be managed; and (c) in light of (a) and (b), opioids were a superior option to other pain treatments.

4.116 Purdue pushed this central, deceptive message in ways strategically designed to deceive health care providers and patients. As discussed below, Purdue authored and disseminated both its own branded materials, as well as unbranded materials from third-party groups that Purdue funded but which were designed to look independent. Purdue followed these materials with one-on-one visits to health care providers to persuade them to prescribe more Purdue opioids.

1. Purdue chased growth by promoting both opioids generally and its brand-name drugs in particular

4.117 Purdue's marketing strategy encompassed promotion of both (a) opioid therapy in general, and (b) its own opioids – MSContin, OxyContin, Butrans, and Hysingla – in particular. Promotion of opioids in general was important to Purdue's business plan and marketing strategy for several reasons.

4.118 First, by deceptively changing the medical community's and public's perception of opioids as a class of drugs, Purdue also sought to change the perception of its own opioid products, which were part of that larger class. Although Purdue would not capture *all* the

[105] Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. Am. Med. Ass'n 1785 (2017).
[106] *Id.*

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benefits of its investment in general opioid re-education, it would profit handsomely by increased prescriptions of its own brand-name drugs.

4.119 Second, once health care providers initially prescribed immediate-release opioids – often generics – to treat a patient's pain, Purdue sought to [redacted]. Indeed, Purdue's 2015 marketing plan noted that, [redacted] and that "[redacted]"

4.120 Purdue carefully coordinated its sponsored Continuing Medical Education courses (CME) marketing with its one-on-one sales representative visits to maximize conversions to OxyContin and its other extended release opioids. For example, following a campaign on the [redacted] Purdue made sure to have its sales representatives re-enforce the message. As Purdue explained to its sales force in an [redacted]

[redacted]

4.121 Purdue trained its sales representatives to [redacted]

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4.122 Accordingly, Purdue sales representatives' call notes for Washington health care providers [redacted]. For example:

a. [redacted] This question was repeated [redacted] times in the call notes during a [redacted] period from [redacted] detailing one pain specialist who prescribed significant numbers of opioids. Starting with the next sales visit, Purdue's sales representative began focusing on [redacted].

b. [redacted] This sentence was repeated in call notes with the same pain specialist [redacted] times in less than [redacted] from [redacted].

4.123 Purdue sales representatives are specifically trained to ask these questions in trainings like [redacted]

4.124 Purdue also trained its sales representatives to handle the [redacted].

4.125 Purdue sales representatives were then trained that [redacted] Purdue therefore inserted its sales representatives directly into prescribers' decision-making process concerning the type and dose of opioid to prescribe – upon information and belief, these conversations that took place without the patient present.

4.126 In addition to persuading health care providers [redacted], Purdue also undertook efforts to persuade health care providers to [redacted]

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[redacted]

4.127 As part of this effort, and to gain market share, Purdue commissioned a 2016 marketing study to [redacted] As discussed below, Purdue targeted Washington prescribers with the strategies for spreading its deceptive message that were recommended in the marketing study.

2. Purdue continued to selectively support and disseminate misleading materials from third party groups

4.128 Purdue has an active grant program supporting third party organizations. From 2006 to the end of 2016, Purdue provided more than $[redacted] in direct grants including:

a. $[redacted] to the [redacted];

b. $[redacted] to the [redacted];

c. $[redacted] to the [redacted];

d. $[redacted] to the [redacted];

e. $[redacted] to the [redacted];

f. $[redacted] to the [redacted];

g. $[redacted] to the [redacted];

h. $[redacted] to the [redacted];

i. $[redacted] to the [redacted];

j. $[redacted] to the [redacted];

k. $[redacted] to the [redacted]; and

l. $[redacted] to the [redacted].

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4.129 On information and belief, many of these grants were targeted for specific purposes to assist Purdue's marketing efforts. For example, pharmaceutical companies, including Purdue, provided almost all of the funding for the American Pain Foundation (APF), which offered publications for health care providers, patients, policymakers and journalists.[107] APF's materials, discussed below, contain misrepresentations about opioids' efficacy and safety.

4.130 Purdue Executive Pamela Bennett explained the company's support for APF as follows: [redacted]

4.131 [redacted]

4.132 [redacted], the President of American Academy of Pain Management, Dr. Perry Fine, the President of APF, Dr. Scott Fishman, and the President of the American Pain Society, Dr. Seddon Savage, wrote

[107] Charles Ornstein & Tracy Weber, *The Champion of Painkillers*, Propublica, Dec. 23, 2011, https://www.propublica.org/article/the-champion-of-painkillers (last visited Sept. 27, 2017).

[108] The Attorney General does not assert a claim based on Purdue's representations to government officials or regulators.

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an editorial in the Seattle Times asserting it was unreasonable to recommend that primary care physician consult with a specialist before prescribing high dose opioids.[109]

4.133 This article failed to disclose that Dr. Fishman was a consultant for Purdue Pharma and that Dr. Fine was on the advisory board for Purdue.[110]

4.134 As part of the same effort to maintain robust opioid sales in Washington, [redacted]

4.135 In addition to selecting and funding third parties to conduct such campaigns, Purdue also incorporated apparently neutral entities in its direct marketing to Washington prescribers.

4.136 In 2009, the American Academy of Pain Medicine and American Pain Society issued Clinical Guidelines (2009 APS Guidelines). These guidelines claimed that opioid treatment for chronic pain "can be an effective therapy for carefully selected and monitored patients with chronic non-cancer pain." The guidelines cautioned, however, that to be safe and effective, such treatment required "clinical skills and knowledge in both the principles of opioid prescribing and on the assessment and management of risks associated with opioid abuse, addiction, and diversion." [111]

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[109] Perry G. Fine, Scott M. Fishman, & Seddon R. Savage, *Bill to Combat Prescription Abuse Really Will Harm Patients in Pain*, Seattle Times, Mar. 16, 2010.

[110] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 J. Am. Med. Ass'n 1445 (2011).

[111] Roger Chou et al., *Clinical Guidelines for Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 J. Pain 113 (2009). Of the 21 members of the APS panel, 6 disclosed payments from Purdue, and only 6 claimed no conflicts of interest. Dr. Russell Portenoy and Dr. Perry Fine were both on the panel.

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4.137 Purdue incorporated and disseminated these guidelines without disclosing its contributions to both the American Academy of Pain Medicine and the American Pain Society. For example, Purdue's Partners Against Pain website incorporated sections of a 2001 APS consensus statement about addiction to bolster Purdue's position that drug-seeking behavior in chronic pain patients should be interpreted as "pseudoaddiction" rather than addiction. As discussed below, "pseudoaddiction" is an unvalidated theory Purdue used to mislead prescribers about the risks of opioid use.

4.138 When Washington prescribers contacted Purdue for information about its opioids, Purdue [redacted].

4.139 [redacted].

4.140 Although Washington's AMDG guidelines were available, Purdue did not recommend Washington prescribers consult them. Nor did Purdue notify the prescribers that only skilled clinicians should be prescribing extended release opioids like OxyContin, Butrans, or Hysingla.

4.141 Purdue's promotion of these guidelines is particularly troubling in light of [redacted].

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[redacted]

4.142 Purdue funded and acted through these third-party groups because doctors were conditioned to trust them – more so than branded marketing material – when making prescribing decisions.

4.143 Indeed, a 2016 Purdue-commissioned marketing study of doctors recommended that [redacted]

4.144 By using third party materials and detailing visits to disseminate its messaging, Purdue was able to exert significant and unidentified influence over prescribers. For example:

a. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain, while those reading the non-industry-funded CME mentioned the risks of death and addiction much more frequently. Critically, *neither* group could accurately identify whether the article they read was industry-funded, illustrating health care providers' trouble screening and accounting for source bias.[112]

b. A recent study of the effect of regulatory beliefs on the persuasive value of pharmaceutical marketing found that doctors inaccurately believed that the FDA regulates

[112] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut, June 25, 2010, http://pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf (last visited September 27, 2017).

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continuing education programs, which could lead to doctors scrutinizing the information presented at industry-funded CMEs less carefully than they otherwise might.[113]

c. Indeed, following one CME presentation [redacted]

3. Purdue engaged in deceptive in-person marketing to Washington health care providers

4.145 Purdue marketed its brand-name opioids, such as OxyContin, MS Contin, Butrans, and Hysingla, directly to health care providers in Washington through in-person visits from sales representatives, also known as "detailers." These sales representatives misleadingly portrayed the risks and benefits of opioids – particularly Purdue-branded drugs – for the treatment of chronic non-cancer pain, and worked systematically to increase prescriptions of Purdue opioids.

4.146 Purdue's former Vice President for Marketing explained [redacted],

[redacted]

(Emphasis added.)

4.147 Upon information and belief, Purdue carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of Purdue's drugs in

[113] Catlin, *supra* note 92.

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particular and opioids in general. To ensure that sales representatives delivered the desired messages to prescribers, Purdue directed and monitored its sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' call notes from each visit. Purdue likewise required its sales representatives to use sales aids reviewed, approved, and supplied by the company and forbade them from using promotional materials not approved by the company's marketing and compliance departments. Purdue further ensured marketing consistency nationwide through national and regional sales representative training.

4.148 Purdue's sales representative or detailer call notes were intended to [redacted]

4.149 Upon information and belief, Purdue sought to establish, and did establish, the same prominence in the market and medical community with respect to opioids in general as with its brand-name opioids.

4.150 It did so for a reason: studies indicate that marketing can and does impact doctors' prescribing habits,[114] and also indicate that face-to-face "detailing" – which Purdue engaged in heavily, as described below – has the greatest influence.

4.151 In addition to "handling" the "objections" of health care providers who were not inclined to prescribe opioids, Purdue sought to become a "resource" and a source of information to which health care providers looked in making prescribing decisions. They did

[114] *See, e.g.*, Puneet Manchanda & Pradkeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 Mktg. Letters 129 (2004) (detailing impacts prescriptions written); Ian Larkin et al. *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33 Health Aff. 1014 (2014) (academic medical centers that restricted direct promotion by sales representatives resulted in 34% decline in on-label use of promoted drugs); *see also* Van Zee, *supra* note 104 (increase of OxyContin prescriptions 1997 to 2002 correlated with doubling of Purdue's sales force and trebling of sales calls).

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so by delivering and discussing the sort of deceptive unbranded materials described below directly to Washington prescribers to help "educate" them one-on-one. Purdue's call notes for Washington prescribers include the following examples:

a. One sales representative made a note to [redacted]

b. [redacted]

c. [redacted]

4.152 Purdue distributed other purportedly third-party materials, [redacted]

4.153 Purdue pursued a two-pronged strategy for targeting health care providers. Purdue targeted primary care physicians, physician assistants, and nurse practitioners, who were least likely to have the training and experience to evaluate Purdue's marketing claims. Purdue also promoted marketed OxyContin, Butrans, and Hysingla for chronic non-cancer pain to the highest opioid prescribers, who often worked at "pain clinics" and who accounted for an outsized portion of opioid prescriptions.

4.154 As the practice of medicine has changed, so too has Purdue's marketing strategy and efforts. As nurse practitioners and physicians assistants became more active in prescribing opioids, Purdue shifted resources to follow them. [redacted]

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[redacted]

4.155 Finally, both third-party materials and Purdue-branded educational resources were targeted at patients, and designed to persuade patients through misleading statements, that opioids were both effective and safe. Purdue created and disseminated marketing materials directly to patients, such as patient brochures and branded public-facing websites like HysinglaER.com, encouraging consumers to seek out Purdue opioids from their health care providers. Upon information and belief, Purdue also disseminated nonbranded marketing materials directed toward patient consumers, such as the website *In The Face of Pain*, *Partners Against Pain* "Pain Management Kits," patient comfort assessment guides, and other resources guiding patients to use opioids. [redacted] Similarly, as discussed below, various third party groups produced patient guides and pamphlets that Purdue either distributed or sponsored.

E. Using These Marketing Channels, Purdue Disseminated Deceptive Statements and Assertions Designed to Increase Opioid Prescriptions

4.156 As described in more detail below, Purdue engaged in numerous deceptive or unfair acts and practices designed to convince health care providers to continue prescribing

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opioids despite the lack of evidence of effectiveness and despite the risks of opioid use, including without limitation:

a. Marketing Purdue's opioid drugs, both directly and indirectly through third party groups, as a solution to the undertreatment of pain and either stating directly, or implying, that opioids are effective to treat or relieve long-term chronic pain;

b. Marketing Purdue's opioid drugs, both directly and indirectly through third party groups, for the treatment of specific pain conditions including neurological pain, headaches, low back pain, and fibromyalgia, despite evidence that opioids were not effective at treating these conditions;

c. Selectively supporting third party groups and employing unbranded marketing to promote and defend the long-term use of opioids and at higher doses as an effective pain relief tool for the treatment of chronic pain;

d. Misrepresenting and making unsubstantiated claims that, and the extent to which, opioids improve function;

e. Misrepresenting the truth and making unsubstantiated claims about how (and how frequently) opioids lead to addiction and the extent to which addiction risk can be managed and addiction prevented;

f. Misleadingly using terms like addiction, dependence, tolerance, physical dependence, and "pseudoaddiction" to persuade health care providers and patients that the addiction risk of opioids could be successfully managed;

g. Misrepresenting and making unsubstantiated claims that increased doses of opioids do not pose significant additional risks;

h. Misrepresenting and making unsubstantiated claims about the challenges entailed in managing withdrawal;

i. Misrepresenting and making unsubstantiated claims regarding the factors for comparing the risks and benefits of opioids with those of alternative forms of pain

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treatment; and

j. Marketing Purdue's abuse deterrent formulations of opioid medications as a means of reducing abuse and addressing the opioid epidemic without any evidence to support such a claim. Purdue intended prescribers and policy makers to believe these abuse deterrent formulations were safer than opioids without these formulations.

4.157 Purdue's impact on the marketing of opioids has been significant. As Purdue's internal documents observed [redacted] Purdue has dominated the market for opioid marketing since the 1990s.

1. Purdue's deceptive acts or practices relating to opioids' ability to improve function

4.158 Consistent with Purdue's marketing strategy described above, Purdue made deceptive and unsubstantiated claims regarding the efficacy of opioids in general and its own drugs in particular.

4.159 Opioids may initially improve function by providing pain relief in the short term, but as explained above there is no evidence that opioids improve patients' function in the long-term.

4.160 Despite the lack of evidence of improved function long-term, Purdue deceptively promoted opioids as improving function and quality of life without disclosing the lack of evidence for this claim. For example:

a. Purdue sponsored The Federation of State Medical Boards' *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve

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function." In fact, on the first page, *Responsible Opioid Prescribing* represents that patients "rely on opioids for . . . improved function."[115] Purdue provided $800,000 dollars in various grants in support of various Federation initiatives related to opioids, including $100,000 to disseminate *Responsible Opioid Prescribing* and $50,000 to fund Dr. Scott Fishman's production of the book. Also according to the Federation, more than 15,000 copies of the book were distributed to Washington prescribers by 2012.[116]

b. Purdue sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs *(e.g.*, aspirin or ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids.

c. Purdue sponsored APF's *A Policymaker'* s *Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that "multiple 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. But in fact, the sole reference for these claims (i) noted the absence of long-term studies and (ii) actually stated that "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."[117]

d. Purdue sponsored *Exit Wounds*, which taught veterans, another vulnerable population, that opioid medications "increase your level of functioning."

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[115] Scott M. Fishman, *Responsible Opioid Prescribing*, Federation of State Medical Boards, Waterford Life Sciences (2007).

[116] Letter from Humayun J. Chaudhry, DO, FACP, Federation of State Medical Boards, to Sen. Max Baucus and Charles Grassley, (June 8, 2012).

[117] Furlan et al., *supra* note 38.

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e. Purdue sponsored a CME entitled *Managing Patient's Opioid Use: Balancing the Need and the Risk*, which made unsubstantiated and false claims about improved functionality. One copy provided to Purdue as part of a funding request stated, in the context of promoting opioids for chronic non-cancer pain relief, that effective pain control [redacted] The presentation explained that prescribers should conduct [redacted] Upon information and belief, these deceptive statements about opioids' ability to improve function were included in the final presentation.

4.161 Purdue also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved (1) providing oxycodone for 30 days, and then (2) randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients advanced to the second phase of the study, and most participants who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) caused by the opioid or because the opioid provided ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results ... should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[118] Yet the authors concluded that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when

[118] Jacques R. Caldwell et al., *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 26 J. Rheumatology 862 (1999).

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managing patients with opioids longterm."[119] This statement is not supported by the data, because (a) a substantial number of patients dropped out because of adverse effects, (b) there was no reported data regarding addiction, and (c) the study was not long-term.

4.162 As noted above, the available evidence indicates opioids are not effective to treat chronic non-cancer pain – indeed, they may harm patients' health.[120] Thus, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[121] Similarly, a 2014 internal Purdue study of [redacted] Purdue's efficacy claims to the contrary were misleading.

4.163 Indeed, there is evidence that these unsubstantiated and false efficacy claims influenced health care providers. For example, a 2016 marketing study commissioned by Purdue found that [redacted] (Emphasis added.) The same study noted that health care providers [redacted]

[119] *Id.*

[120] *See, e.g.* Furlan et al., *supra* note 38. Furlan noted that even those studies that did show efficacy did not typically show data on opioid addiction, and also pre-screened the study pool to remove patients who might have been more prone to addiction; *see also* Dersh et al., *supra* note 40.

[121] *See* Friedan, *supra* note 30, at 1503.

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[redacted]

2. Purdue deceptively claimed OxyContin was effective for 12 hours

4.164 In addition to claiming efficacy for long-term pain relief, Purdue also deceptively promoted OxyContin as delivering a full 12 hours of "steady state" pain relief. This meant that OxyContin was purportedly both (a) more effective than immediate-release opioids, and (b) less likely to result in crashes and cravings that lead to addiction and abuse. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

4.165 OxyContin has been FDA-approved for twice-daily "Ql2"-dosing frequency since its debut in 1996. Purdue chose to submit OxyContin for approval with 12-hour rather than 8-hour dosing, and then made the 12-hour claim central to its marketing campaign.[122]

[122] Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," Purdue has conducted no such studies.

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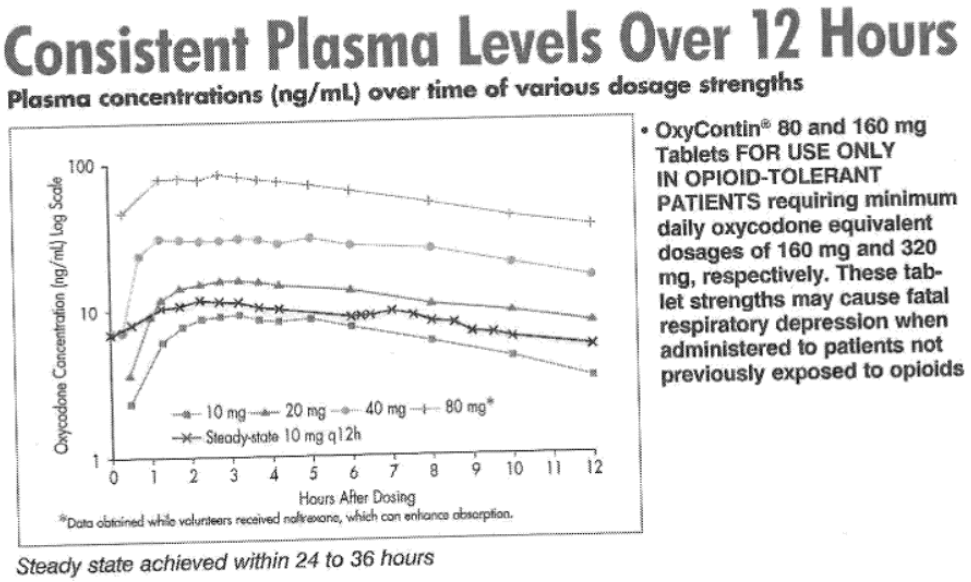
4.166 Purdue promoted OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake up to take a third or fourth pill. The advertising claimed that OxyContin provides "Consistent Plasma Levels Over 12 Hours" and included a chart depicting plasma levels on a logarithmic scale. The chart deceptively concealed the steep decline in OxyContin's effectiveness over 12 hours by manipulating the scale of the chart's Y-axis to make 10 mg appear to be half of 100 mg. This sleight of hand manipulated the curve and made the absorption rate appear more steady or consistent than it really was.



4.167 Purdue senior medical director, Dr. J. David Haddox, told a reporter in 2001 that "[a] lot of these people say, 'Well, I was taking the medicine like my doctor told me to,' and then they start taking them more and more and more….I don't see where that's my problem."[123]

[123] Quoted in Harriet Ryan et al., *"You Want A Description of Hell?" OxyContin's 12-Hour Problem*, Los Angeles Times, May 5, 2016.

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4.168 In fact, upon information and belief, Purdue knew, according to its own research during the development of OxyContin and after, that the drug wears off in under 6 hours in one quarter of patients and in under 10 hours in more than half. The FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience "end of dose failure" with little or no pain relief at the end of the dosing period.[124] In a 2013 public hearing, Dr. David Egliman testified:

> Now, why did we get to a Q12 dose? It wasn't because of the data on efficacy of the drug. It was because Purdue Pharma needed something to distinguish is drug from other short-acting narcotics, and this became the main marketing device to increase profits. On the other hand, the data showed something else. As you can see, at 10 milligrams, the OxyContin product release was effective for less than six hours in at least 25 percent of patients. And the 20 and 30 milligram dose were effective for less than 10 hours in at least 50 percent of patients. Other Purdue studies, all of them in fact, allowed rescue or short-acting oxy to cover patients who had pain breakthrough before 12 hours. However, this does not—and this information is omitted from the label.[125]

4.169 Nevertheless, Purdue still emphasized 12-hour dosing in detailing visits to Washington prescribers, though that often did not match the physicians' anecdotal experience. Purdue was also aware of the common practice of prescribing OxyContin more frequently than 12 hours to address end-dose failure experienced by the patients, up to three or four doses per day:

a. One Washington prescriber reported to a Purdue sales representative that [redacted]

[124] 2008 FDA response to Citizen Petition by Connecticut Attorney General.

[125] Testimony of David Egilman, *Impact of Approved Drug labeling on Chronic Opioid Therapy* at 91:6-11, FDA Center for Drug Evaluation and Research Public Hearing (Feb. 8, 2013), https://wayback.archive-it.org/7993/20170113151848/http:/www fda.gov/downloads/Drugs/NewsEvents/UCM342713.pdf (last visited Sept. 27, 2017).

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b. Four years later, a sales representative asked a Washington prescriber [redacted] The prescriber responded that he [redacted]

4.170 Purdue did promote a "solution": increase the dosage of the opioid, rather than the frequency, even though higher dosing carries higher risks of addiction and overdose. Purdue's solution exposed patients to higher highs and lower lows, increasing their craving for their next pill. But sales representatives were trained to reassure prescribers that there is no ceiling on the amount of OxyContin a patient could be prescribe. And many prescribers followed the recommendation of the sales representatives to increase the dose rather than the frequency:

a. When a prescriber reported to the sales representative [redacted]

b. A sales representative asked one Washington high prescriber [redacted]

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4.171 These 12-hour pain relief misrepresentations are particularly dangerous because when a patient is inadequately dosed, they begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose -- a cycle that fuels addiction. Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

4.172 Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day-which converts to the 90 milligrams of morphine equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[126]

4.173 According to a *Los Angeles Times* article, a West Virginia circuit court judge in a November 2004 order denying summary judgment found that "[m]ost of the patients in the clinical trials required additional medication, so called 'rescue medications,' that accompanied their 12-hour OxyContin dose…Purdue could have tested the safety and efficacy of OxyContin at eight hours, and could have amended their label, but did not."[127]

4.174 Instead, Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price. 12-hour dosing set OxyContin apart from its competitors, and from less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours), and explained that "Purdue has always trained its sales force to promote q12h dosing only" because "[t]he 12 hour dosing schedule represents a significant competitive advantage of OxyContin over other products."[128]

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[126] Ryan et al., *supra* not 123.

[127] *Id*. citing to *West Virginia v. Purdue Pharma L.P.*, Order Deying Purdue Pharma's Motion for Summary Judgment on Preemption (Circuit Court of McDowell County, WV Nov. 5, 2004).

[128] April 14, 2014 Comments on Citizen Petition Docket #2004P-0043, at 12-13.

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4.175 Purdue's 12-hour dosing efficacy claims misrepresent the duration of pain relief from OxyContin and fuel the cycle of addiction with crashes and cravings. To fix a misleading marketing campaign, Purdue's solution was to make the drug more deadly by encouraging physicians to titrate doses up. Purdue had every opportunity to correct its labeling to reflect appropriate dosing for OxyContin and chose not to do so, all to support its misleading claim that OxyContin was unique amongst opioids and therefore worth the price.

4.176 Purdue's claims that opioids improve function are unsubstantiated and misleading because they have not been demonstrated by substantial evidence or substantial clinical experience. But more than being unsubstantiated, those claims were and are untrue.

3. Purdue's deceptive acts or practices relating to opioid addiction and opioid harms

4.177 Consistent with the marketing strategy described above, Purdue also sought to mislead health care providers and patients about the adverse effects of opioids, particularly the risk of addiction. For example, as the United States Department of Justice found in resolving criminal charges against Purdue in 2007, sales representatives had "falsely told some health care providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids."[129]

4.178 Purdue funded, influenced and distributed third party publications of doctor and patient "educational" materials that misled their target audiences about the additional danger of prescription opioids. Indeed, many of these publications sought to turn the tables and asserted that doctors who did not treat patients' pain complaints with opioids were failing their patients, while those who prescribed long-term opioid treatment were following the compassionate (and professionally less risky) approach. For example:

[129] *United States v. The Purdue Frederick Company, Inc., et al.*, 1:07-cr-00029 (W.D. Va.), Criminal Information, ¶ 24.

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a. Upon information and belief, Purdue maintained a website, *In the Face of Pain*, from 2008 through 2015, which asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. The website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013.[130] Purdue omitted this material fact from the site.[131] Purdue deactivated *In the Face of Pain* in the face of an investigation, and later settlement, by the New York Attorney General.[132]

b. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. The *Treatment Options* guide also states "[d]espite the great benefits of opioids, they are often underused," and emphasized that "[r]estricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction." The brochure also explained that opioids' "under-use has been responsible for much unnecessary suffering."

c. Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans 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 so low as to be immaterial.

d. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids would become addicted. It also misleadingly concluded that "[u]nfortunately, too many

[130] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151 (August19, 2015).
[131] *Id.*
[132] *Id.*

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Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include ... misconceptions about opioid addiction."[133]

e. *Providing Relief, Preventing Abuse,* a pamphlet published by Purdue in 2011 for prescribers and law enforcement, includes pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." But it is uncommon for opioid addicts to resort to these extremes – they more typically become dependent and addicted to swallowing pills as Purdue designed and intended the drug to be ingested. Purdue sales representatives gave the pamphlet *Providing Relief, Preventing Abuse* to prescribers in Washington, including, by way of example, [redacted].

4.179 In fact, as discussed above, up to 26% of opioid users and as many as 30% or even 40% of long-term opioid users experience problems with addiction. Purdue's representations that the risk of addiction was either low or acceptable were misleading.

4. Purdue's deceptive acts or practices relating to managing addiction and abuse risks

4.180 Purdue knew it probably could not persuade doctors to disregard the risk of opioid addiction entirely, and therefore sought to reassure them that doctors could effectively manage risks and prevent addiction in their patients by using tools that Purdue and its third-party groups provided.

4.181 Purdue deceptively claimed that screening patients could effectively manage addiction risk. For example:

a. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

[133] This claim also appeared in a 2009 publication by APF, *A Reporter's Guide.*

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b. Purdue sponsored a 2011 webinar taught by Dr. Webster entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

c. On information and belief, Purdue sales representatives gave the *Partners Against Pain* "Pain Management Kit," which contained several "drug abuse screening tools," to Washington prescribers. These screening tools included the "Opioid Risk Tool" – a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease."

d. Purdue also promoted the Opioid Risk Tool in CME material, including a 2013 CME entitled *Is It Pain?* And upon information and belief, a Purdue sales representative [redacted]

4.182 Purdue's deceptive statements about prescribers' ability to manage the risk of addiction and prevent abuse by their patients influenced Washington prescribers. Indeed, Purdue sales call notes for Dr. Dillinger – whose prescribing habits were profitable to Purdue but problematic for the public health, as discussed below – report his statement that he [redacted]

4.183 Convincing prescribers that they could effectively manage risk and prevent addiction was essential to Purdue's marketing strategy of increasing the number of prescriptions of opioids and its own branded drugs. It was also unsubstantiated.

4.184 A 2014 Evidence Report by the Agency for Healthcare Research and Quality (AHRQ) "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" and identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring

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instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[134]

4.185 Similarly, the evidence shows that methods for preventing abuse and addiction when prescribing opioids to high-risk patients – like those with a documented predisposition to substance abuse – such as patient contracts, more frequent refills, and urine drug screening often do not work in the real world.[135]

4.186 Even if these risk mitigation strategies did work, prescribers to which Purdue marketed often did not use them. In practice, opioids are all too often prescribed to patients at serious risk for addiction or who are already addicted to opioids – often at high doses.[136] In the call notes and medical board actions described in this complaint, pain sufferers frequently have a history of substance abuse or current substance abuse issues and were still prescribed opioids. Purdue knew that this was a common practice, and continued marketed to prescribers who were doing so.

5. Purdue petitioned the FDA to prohibit generic versions of Oxycontin's original formulation, arguing that it presented a public health risk outweighing its benefits

4.187 In 2010, Purdue introduced a reformulation of OxyContin and discontinued marketing its original formulation. This meant that other manufacturers could petition the FDA for permission to make generic OxyContin. The FDA's regulations required it to determine whether original OxyContin was voluntarily withdrawn from sale for "safety or effectiveness

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[134] *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, Agency for Healthcare Res. & Quality, Sept.19, 2014.

[135] Michael Von Korff et al., *Long-Term Opioid Therapy Reconsidered*, 155 Annals of Internal Med. 325 (2011); Laxmaiah Manchikanti et al., *American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 Pain Physician S1 (2012).

[136] Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307 J. Am. Med. Ass'n 940 (2012). In addition to studies, a review of Purdue call notes and MQAC disciplinary actions reveal that health care providers regularly prescribe opioids to patients with a history of substance abuse and/or current substance abuse issues.

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reasons" before approving an Abbreviated New Drug Application ("ANDA") – basically, a generic version.[137]

4.188 Generic OxyContin was a threat to Purdue's bottom line, and the company therefore implemented a cynical strategy: it submitted a citizen petition to the FDA on July 13, 2012, arguing that original OxyContin was actually *unsafe*. Purdue argued that if generic original OxyContin were allowed, "abuse of extended release oxycodone could return to the levels experienced prior to the introduction of reformulated OxyContin." In short, Purdue argued that the very same high OxyContin abuse rates that it caused and enabled through the deceptive marketing described above were an unacceptable public health crisis, and the drug that caused it should be banned – but only after Purdue had profited handsomely from creating the crisis.[138]

4.189 Purdue's petition to the FDA confirms that the company's epiphany was prompted not by a newfound concern for the public health, but by a desire to continue reaping blockbuster profits. By blocking generic versions of original OxyContin, Purdue maintained the dominant market position for extended release oxycodone under its well-established OxyContin brand name. And Purdue's hired consultant explained to the FDA that allowing original OxyContin generics would "substantially reduce[]" the "incentives to invest in the significant research and development necessary to bring tamper-resistant products to market." Making its own deadly-but-profitable product safer apparently ranked lower on the list of motivations.

4.190 On April 18, 2013, the FDA found that Purdue had voluntarily withdrawn original OxyContin from sale for safety reasons, closing the door on generic manufacturers. The agency explained that considering OxyContin:

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[137] 21 C.F.R. § 314.161.

[138] Indeed, Purdue unfairly ramped *up* its deceptive promotion of original OxyContin from 2007-2009, a time when it knew original OxyContin was unsafe and being abused at unconscionable rates.

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> has long considered the abuse potential of a drug in numerous regulatory contexts. Where appropriate, FDA may take into account abuse potential as part of the safety profile of a drug when weighing its benefits and risks. In this case, FDA has considered the abuse potential as part of the Agency's determination of whether the original formulation of OxyContin was withdrawn from sale for reasons of safety or effectiveness. This approach is particularly appropriate here in light ***of the extensive and well-documented history of OxyContin abuse.***
>
> Original OxyContin has the same therapeutic benefits as reformulated OxyContin. Original OxyContin, however, poses an increased potential for abuse by certain routes of administration, when compared to reformulated OxyContin. Based on the totality of the data and information available to the Agency at this time, ***FDA concludes that the benefits of original OxyContin no longer outweigh its risks***.[139]

4.191 The FDA's proper refusal to allow easily-abused generic OxyContin onto the market has had the unintended consequence – by the FDA – of further lining Purdue's pockets. First, Purdue enjoyed protection from generic competition for years while deceptively promoting and profiting from an admitted easily-abused drug and fueling an abuse and addiction crisis. Second, that very Purdue-fueled abuse crisis served as the justification for further competitive protection for – and associated profits from – reformulated OxyContin.

6. Purdue deceptively claimed that abuse deterrent formulations could lower opioid risk

4.192 The 2010 reformulation instituted what Purdue calls "abuse deterrent" formulations of its extended release opioids. Because Purdue's extended release opioids are essentially very large doses of opioids placed in a timed-release matrix designed to release the drug over time, if the time release formulation can be defeated, then the user can get the concentrated dose all at once. In addition, by dissolving the drug, the user can inject it directly into the bloodstream to receive a high. The abuse deterrent formulations were designed to make opioid pills harder to crush, dissolve, or otherwise manipulate so as to defeat this problem.

[139] Federal Register, Vol. 78, No. 75, Thursday, April 18, 2013, Notices, at 23273.

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4.193 As Purdue's website explains, abuse deterrent formulations "are designed to provide pain relief when taken as directed while also deterring abuse by snorting and injection" and are "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."[140]

4.194 As Purdue was the first opioid manufacturer to create an FDA-approved abuse deterrence formula, it has featured prominently in Purdue's marketing of its drugs. A 2014 marketing plan defined [redacted] A 2015 marketing plan, for example, emphasized [redacted] Purdue's strategic plan for 2015 [redacted] A 2016 marketing analysis [redacted].

4.195 A 2014 Marketing document displays how Purdue used abuse deterrence to distinguish its drugs. [redacted]"

4.196 Most opioids that are abused, however, are swallowed whole, and oral ingestion is equally risky. In fact, studies suggest that only about 10% to 20% of all opioid users snort or

[140] *Opioids with Abuse Deterrent Properties*, Purdue Pharma, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties (last visited 9/17/17).

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inject pills, and there is no evidence that orally administered opioids are less addictive.[141] In its 2012 medical office review of Purdue's application to include abuse deterrence in its FDA label for OxyContin, the FDA noted that the vast majority of deaths were associated with oral consumption and that only 2% of deaths linked to OxyContin were associated with recent injection and 0.2% with snorting the drug.[142] The CDC also observed that abuse deterrent technologies do not prevent overdose through oral intake.[143]

4.197 Purdue's efforts to associate abuse deterrent formulas with safety have borne fruit. In a 2016 survey, 46% of physicians surveyed erroneously stated that abuse deterrent formulations were less addictive than non-abuse deterrent formulations.[144]

4.198 The 2016 CDC guideline found no evidence or studies to support the notion that abuse deterrent formulations have any effectiveness as a risk mitigation strategy for deterring or preventing abuse. The CDC noted the exception was a study that suggested that the abuse deterrent formulation was associated with increased uses of other opioids, including heroin.[145]

4.199 After being informed of a newspaper story critical of Purdue's marketing of abuse deterrent formulation in late 2016, Purdue [redacted]

4.200 In 2016, The Pharmaceutical Manufacturing Research Services, Inc. filed a citizen's petition with the FDA, asking the FDA to withdraw its approval of abuse deterrent labeling on OxyContin. The petition asserted that, in fact, it was "exceedingly easy" to extract the active ingredient from OxyContin via small volume extraction. In fact, it is easier to extract

[141] Catherine S. Hwang et al., *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32 Clinical J. Pain 279 (2016).
[142] FDA_2013summary review, Reference ID 325870, 4-5.
[143] Dowell, *supra* note 15, at 2.
[144] Hwang et al., *supra* note 143.
[145] Dowell, *supra* note 15, at 2.

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the active ingredient from OxyContin than it is to extract from Opana, Endo Pharmaceutical's extended release drug,[146] which was so unsafe that the FDA requested it be removed from the market. [147]

4.201 Since the introduction of the reformulated OxyContin, there is little to no data to suggest that it has had meaningful reduction in abuse.[148] And, in fact, as noted above, despite the introduction of abuse deterrent formulas in 2010, opioid deaths have continued to accelerate.

7. Purdue's deceptive acts or practices relating to the significant additional risks posed by increased opioid doses

4.202 Because Purdue urged doctors to respond to evidence of addiction by increasing opioid dosage, it had to convince those doctors that the escalated doses were safe. It did so through deceptive marketing materials. For example:

a. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose, regardless of the dose currently prescribed, and that opioids have "no ceiling dose."

b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinite ones, but did not disclose the risks from high-dose opioids. This publication is still available online.

c. Purdue sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013.[149] The 2013 version remains available for CME

[146] February 19, 2016 Citizen Petition, Pharmaceutical Manufacturing Research Services, Inc.

[147] *FDA Requests Removal of Opana ER for Risks Related to Abuse*, FDA, June 8, 2017, https://www fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm (last visited Sept. 27, 2017).

[148] *Id.*

[149] AMA Education Center, Module 02 – Pain Management – Overview of Management Options, https://cme.ama-assn.org/activity/1296783/detail.aspx (last visited Sept. 27, 2017).

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credit. The CME was edited by Dr. Portenoy, among others, and upon information and belief taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

4.203 Furthermore, Purdue knew or should have known that the prescribers targeted by sales representatives – high volume pain clinics, primary care physicians, nurse practitioners, and physician assistants – frequently had limited resources or time to scrutinize Purdue's claims or conduct the necessary research about the efficacy and risks of high doses of extended release opioids themselves. In fact, Purdue was aware that prescribers often relied upon Purdue sales representatives and the materials that they provided as "***someone they can look to for the information they need to make prescribing decisions.***"

4.204 Purdue sales representatives took the opportunity, when visiting with at least one Washington prescriber, to "discuss proper titration to get adequate analgesic effect" – that [redacted] Purdue's visual aids prompt health care providers to titrate, or adjust doses up, not down:

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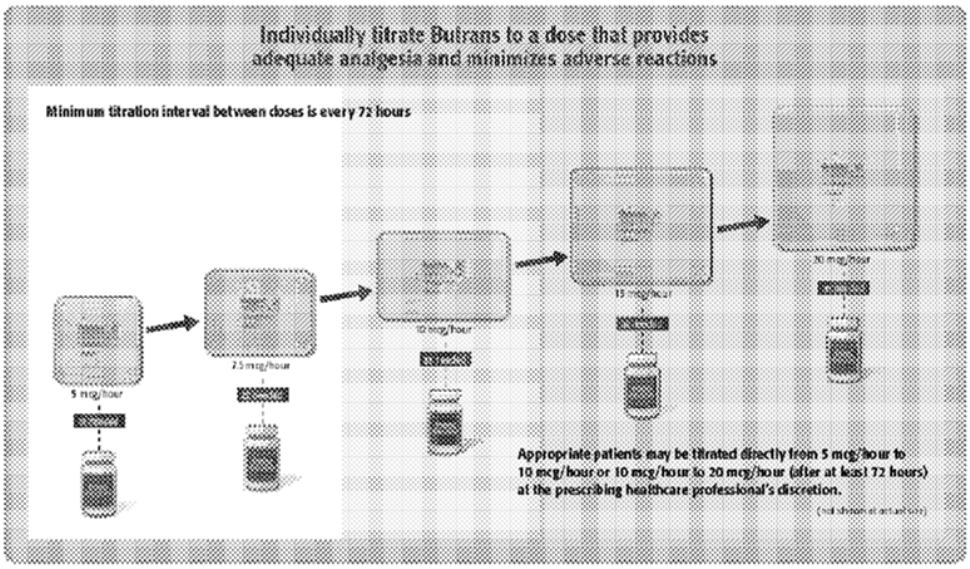

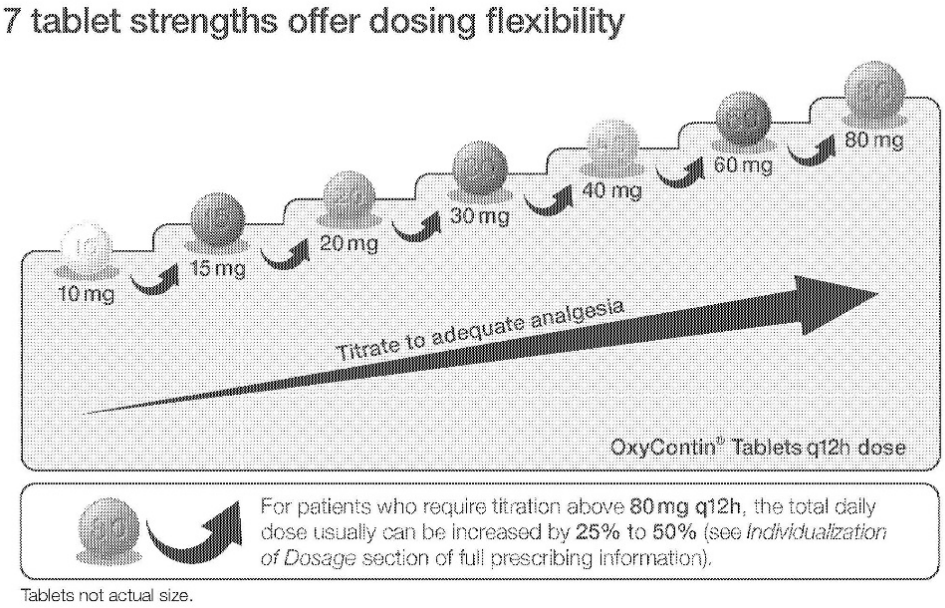

4.205 Purdue sales representatives [redacted] By beginning sales pitches with the appropriate dose of branded opioids, Purdue sales representatives shifted the discussion from "should this

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patient be taking opioids chronically?" to "which Purdue opioid is easier for your patient to use long-term?"

8. Purdue's deceptive acts or practices relating to myths like "pseudoaddiction"

4.206 Purdue downplayed the problem of addiction by simply re-labeling it. According to Purdue, the signs of addiction are actually the product of untreated pain, which should be treated by prescribing even more opioids.

4.207 The term "pseudoaddiction" was coined by Dr. J. David Haddox, and popularized for opioid treatment for chronic pain by Purdue. "Pseudoaddiction" was meant to differentiate between "undertreated pain" and "true addiction" – as if the two were mutually exclusive.

4.208 Purdue promoted the concept of "pseudoaddiction" while failing to disclose that it was not substantiated by competent scientific evidence. For example:

a. Purdue sponsored the Federation of State Medical Boards' *Responsible Opioid Prescribing* (2007), which claimed that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are not signs of genuine addiction, but only signs of "pseudoaddiction."

b. Purdue also posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on the Partners Against Pain website in 2005, and upon information and belief circulated this pamphlet after 2007. The pamphlet represented that conduct like "illicit drug use and deception" was not evidence of "true" addiction, but instead an indication of "pseudoaddiction" caused by untreated pain. It explained: "Pseudoaddiction 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. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

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c. Purdue sponsored *A Policymaker's Guide to Understanding Pain & Its Management*, 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. A 2010 Purdue "Training Guide for Healthcare Providers" on OxyContin taught that "[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior."

e. Purdue disseminated the Definitions Related to the Use of Opioids for the Treatment of Pain section of an APS consensus statement though the Partners Against Pain website. APS defined pseudoaddiction in the same terms endorsed by Purdue:

> Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused…. Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated. Physical dependence on and tolerance to prescribed drugs do not constitute sufficient evidence of psychoactive substance use disorder or addiction. They are normal responses that often occur with the persistent use of certain medications.…A patient who is physically dependent on opioids may sometimes continue to use these despite resolution of pain only to avoid withdrawal. Such use does not necessarily reflect addiction.

f. Purdue sponsored *Exit Wounds*, which sought to reassure veterans about addiction concerns by explaining that although they may become physically dependent on opioids, they will not become addicted:

> Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., swearing, rapid heart rate, nausea, diarrhea, goose bumps, or anxiety) if a drug medication is suddenly stopped or the dose is lowered too quickly. . . . Physical dependence is normal. This does not mean you are addicted.

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> Opioid medications can, however, be abused or used as recreational drugs, and some people who use drugs in this way *will* become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing them harm.

(Emphasis in original.)

g. Purdue directly disseminated materials about "pseudoaddiction" to all Washington prescribers. Following the entry of a 2007 Consent Judgment discussed further below, Purdue was obligated to provide information about abuse and diversion to prescribers. [redacted] Under the guise of education, Purdue sent annual "Dear Healthcare Provider" letters to all Washington health care providers who prescribed opioids, and enclosed two copies of *Providing Relief, Preventing Abuse*. Purdue represented that "[t]he brochure contains important information" about topics like "definitions related to the use of opioids for the treatment of pain," as well as [i]ndicators of possible abuse" and "[s]trategies for identifying opioid abusers." Various editions of *Providing Relief, Preventing Abuse* contained deceptive statements about "pseudoaddiction."

h. The 2008 edition of *Providing Relief, Preventing Abuse* explained that the term "pseudoaddicton"

> describes the misinterpretation by members of the health care team of relief-seeking behaviors in a person whose pain is inadequately treated as though they were drug-seeking behaviors as would be common in the setting of abuse. The lack of appropriate response to the behaviors can result in an escalation of them by the patient, in an attempt to get adequate analgesia.

i. The 2008 edition of *Providing Relief, Preventing Abuse* further explained that "[p]seudoaddiction can be distinguished from addiction in that the behaviors resolve when pain is effectively treated."

j. By 2011, Purdue had revised the brochure, and the second edition of *Providing Relief, Preventing Abuse* explained that

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> [s]ome patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. The term *pseudoaddiction* has emerged in the literature to describe the inaccurate interpretation of these behaviors in patients who have pain that has not been effectively treated. Pseudoaddiction behaviors can be distinguished from addiction by the fact that, when adequate analgesia is achieved, the patient who is seeking pain relief demonstrates improved function, uses the medications as prescribed, and does not use drugs in a manner that persistently causes sedation or euphoria.

k. By 2014, the term "pseudoaddiction" no longer appeared in *Providing Relief, Preventing Abuse*, but the brochure included an "Other Considerations" section that taught "[s]ome patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment."

l. The 2007 Purdue-sponsored book *Responsible Opioid Prescribing* warns doctors to "[b]e aware of the distinction between *pseudoaddiction* and addiction."[150] (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."[151] This confusion arises because the "same behavioral signs [of pseudoaddiction] can also indicate addiction."[152]

i. Prescribers were instructed to tell pseudo- from "true" addiction by "observing as closely as possible the functional consequences of opioid use. Whereas pseudoaddiction resolves when the patient receives adequate analgesia, addictive behavior does not."[153]

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[150] *Responsible Opioid Prescribing* (2007), at 62 (emphasis in original).
[151] *Id.*
[152] *Id.*
[153] *Id.*

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ii. In short, to tell whether a patient is addicted to opioids, doctors are to give the patient more opioids and then see if he keeps engaging in "demanding or manipulative behavior" *after* his demands are met or the manipulation has achieved its desired result.[154]

iii. Other examples of addiction-indicating behavior listed in the book – such as "[b]ought pain medications from a street dealer" and "[t]ried to get opioids from more than one source"[155] – are likely to cease if a single doctor is willing to provide all the opioids the patient needs to satisfy his needs.

iv. Conversely, the more extreme examples of addiction-indicating behavior listed in the book – such as "[s]tole money to obtain drugs," "[p]erformed sex for drugs," and "[p]rostituted others for money to obtain drugs" – are more indicative of the patient's financial ability to buy prescription opioids than his underlying need for, and dependence on, opioids.

m. Thus, the difference between "pseudoaddiction" and "true" addiction is really whether the patient has (a) a doctor willing to prescribe more opioids until "need" is met, and (b) the insurance and money to pay for those opioids without resorting to theft or prostitution. As long as doctors follow Purdue's instructions and increase opioid doses, they will see very few patients who are "addicted" to opioids as Purdue trained them to understand the condition.

4.209 Purdue's efforts to promote "pseudoaddiction" successfully convinced Washington opioid prescribers to ignore the fact that their patients were addicted. For example, sales call notes reflect that [redacted]

[154] *Id.*
[155] *Responsible Opioid Prescribing* (2007), at 63.

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[redacted].

4.210 In fact, Purdue KOL Dr. Lynn Webster acknowledged: "[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 we are debunking as a concept."[156]

9. Purdue's deceptive acts or practices relating to the management of withdrawal

4.211 Purdue also downplayed the impact of addiction by representing that physical dependence on opioids is not the same as addiction and could be addressed by gradually tapering patients' dosage to avoid withdrawal. Purdue downplayed the difficult and painful effects that many patients experience when dosages are lowered or opioids are discontinued, which decrease the likelihood those patients will be able to stop using opioids. For example:

a. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught 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. A 2010 Purdue "Training Guide for Healthcare Providers" on OxyContin 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."

[156] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel, Feb. 19, 2012.

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4.212 In fact, as discussed above, it is very difficult to stop using opioids once they have been prescribed. It is not, as Purdue implied, a simple matter to taper the drug and stop using opioids.

10. Purdue's deceptive acts or practices relating to the comparison between the risks and benefits of opioids and those of alternative forms of pain treatment

4.213 As the final element of its marketing plan – after misrepresenting opioids' efficacy and adverse effects – Purdue presented a misleading comparison between the risks and benefits of opioids and other pain treatment methods by influencing and controlling marketing materials that (a) omitted known risks of chronic opioid treatment; and (b) emphasized or exaggerated risks of competing products. These practices had the capacity to deceive prescribers and patients, who would then be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs. For example:

a. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some opioids differ from NSAIDs in that they have "no ceiling dose as there is with the NSAIDs" and are therefore the most appropriate treatment for severe pain. *Treatment Options* attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the true figure was closer to 3,200 at the time.[157] *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," but omitted any corresponding warning about the long-term risks of opioids.

b. Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings about potentially fatal interactions between opioids and anti-anxiety medicines called

[157] Robert E. Tarone et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17 (2004).

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benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder – the target audience for *Exit Wounds*.

c. The Purdue-Sponsored CME *Managing Patient's Opioid Use: Balancing the Need and the Risk* contains a deceptive assertion in its very title. Rather than framing the question whether to prescribe opioids properly – as a weighing of the potential benefits and risks, as well as an analysis of other pain treatment options – the presentation implicitly tilts the scales by presenting a "need" for opioids that may or may not exist.

d. The 2007 Purdue-sponsored book *Responsible Opioid Prescribing* represents on Page 1 that "[p]atients in pain who rely on opioids for analgesia" should not be deprived of "optimal pain-relief."

e. [redacted]

4.214 These claims were not supported by competent scientific evidence. As explained above, comparisons between Purdue's drugs and other drugs cannot represent or suggest that Purdue's drug is safer or more effective than its competitor unless it has been demonstrated by substantial evidence or clinical trials. Purdue's [redacted].

4.215 In that same presentation, [redacted] Yet in a detailing visit to a Washington prescriber, one sales representative told the prescriber [redacted]

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4.216 Similarly, Purdue paid lip service to the rule that for [redacted] Yet a Purdue sales representative [redacted]

4.217 Purdue's campaign worked, and opioids replaced other, safer options in health care providers' pain treatment repertoires. For example, a study of 7.8 million doctor visits between 2000 and 2010 found that while prescriptions for NSAIDs and acetaminophen fell from 38% to 29%. Opioid prescriptions increased from 11.3% to 19.6% of visits, driven primarily by the decline in NSAID prescribing.[158]

F. Purdue's Misconduct Stretches Back Two Decades and Continued Despite a Consent Judgment Regarding the Marketing of OxyContin

4.218 Purdue's marketing campaign to convince prescribers and patients that long-term opioid use was effective for long-term treatment of pain and that its risks could be safely managed is not new. Purdue's aggressive marketing extends back more than two decades. From the beginning, Purdue employed a wide variety of marketing strategies to accomplish its goal of recklessly increasing opioid sales.

4.219 In 1995, as Purdue prepared to launch OxyContin, it conducted market research and determined that the "biggest negative of [OxyContin]" was the abuse potential." Beginning

[158] Daubresse et al., *supra* note 12. For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady; *see also* John N. Mafi et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173 J. Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

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in 1995, Purdue employees set about marketing OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance.[159] For example, Purdue created and maintained public facing websites, such as "Partners Against Pain," as well as brochures and videotapes for patients in which Purdue asserted that the risk of addiction from OxyContin was small.[160]

4.220 From the beginning, much of Purdue's marketing was directed at prescribers. By 2000, Purdue had approximately 94,000 doctors on its physician call list.[161] Purdue also recruited and paid respected health care professionals as "speakers" who presented Purdue-approved programs to other prescribers at lunch and dinner events. From 1996 to 2001, Purdue held more than 40 national conferences and more than 5,000 physicians, pharmacist, and nurses attended these speaker conferences.[162] In addition to speaker programs, Purdue targeted doctors with "educational" programing and funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants by July 2002.[163]

4.221 Purdue also paid for direct advertising to physicians in medical journals and distributed thousands of videos, many of which made the claim that addiction occurred in less than 1% of patients.[164] This claim came from a 1980 one-paragraph letter to the editor of the New England Journal of Medicine. It was not a study and did not support the assertion that addiction occurred in less 1% of patients. Despite that, after Purdue began aggressively utilizing the letter as "evidence" that opioids were not addictive, citations to this article in

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[159] *United States v. Purdue Frederick Co., Inc.*, 495 F.Supp.2d 569, 571 (W.D. VA 2007); *United States v. Purdue Frederick Co., Inc. et. al.* Case 1:07-cr-00029-JPL, Dkt. 5-2, at 5-6.

[160] Van Zee, *supra* note 104.

[161] *Id.*

[162] *Id.*

[163] Van Zee, *supra* note 104.

[164] Purdue admitted it distribute 14,000 copies of *From on Paint Patient to Another: Advice from Patients Who Have Found Relief*for doctors to make available to patients, and 15,000 copies of *I Got My Life Back: Patients in Pain Tell Their Story*. Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem. Washington DC; General Accounting Office: December 2003 Publication GAO-04-110, 24-27.

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medical literature exploded: the article has been cited 608 times. More than 70% of these citations claimed that it was evidence that addiction was rare, and 80% failed to accurately describe the one paragraph letter.[165]

4.222 The impact of Purdue's efforts to disseminate this letter can be measured. The other 11 letters published in the same issue of the journal were only cited a median number of 11 times.[166]

4.223 The marketing materials from the early 2000s had a long tail. As illustrated by the longevity of the 1980 one-paragraph letter, misrepresentations that make it into the scientific literature continued to be cited long after publication. Similarly, prescribers trained at Purdue CMEs continue practicing. These early manipulations of prescribers provided fertile ground for Purdue's later, more nuanced misrepresentations like "pseudoaddiction."

1. Purdue admitted its marketing conduct was unlawful in 2007 and promised to take corrective action

4.224 In 2007, Purdue Pharma and several Purdue executives entered in a guilty plea to a criminal charge of Misbranding and paid $634 million dollars in fines related to the marketing campaign for OxyContin.[167]

4.225 At the same time, Washington brought an action against Purdue related to the marketing campaign for OxyContin. The State alleged that Purdue aggressively promoted OxyContin as a first line response to pain and a powerful and effective pain reliever,[168] While minimizing the risks of abuse, dependence, addiction, and diversion. In videos and pamphlets

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[165] Pamela T.M. Leung et al., Correspondence, *A 1980 Letter on the Risk of Opioid Addiction*, 376 New Eng. J. Med. 2194 (2017).

[166] *Id.*

[167] *United States v. Purdue Frederick Co., Inc.*, 495 F.Supp.2d 569, 571 (W.D. VA 2007); *United States v. Purdue Frederick Co., Inc. et. al.* Case 1:07-cr-00029-JPL, Dkt. 5-2.

[168] *State v. Purdue*, Cause No. 07-2-00917-2, Complaint for Injunctive and Other Relief Under the Consumer Protection Act, ¶¶ 26-27, filed May 9, 2007.

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for doctors, Purdue directly and falsely asserted that fewer than 1% of opioid using patients become addicted.[169] Washington further alleged that

> Purdue could have used the prescribing data to readily identify potential sources of abuse and diversion…For years Purdue did not take those steps…Purdue sales representatives instead targeted the highest prescribers and encouraged them to prescribe more OxyContin, in larger doses, to more patients. Purdue's marketing practices thus exacerbate the abuse and diversion risks.[170]

4.226 Purdue entered into a Consent Judgment with Washington in 2007 to resolve these allegations. In that Consent Judgment Purdue agreed, inter alia,

a. Not to market OxyContin with any claim that is false, misleading or deceptive;

b. Not to misrepresent the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence, relating to the Off-Label uses of OxyContin;

c. To establish, implement, and follow an OxyContin abuse and diversion detection program to internally report apparent pattern of excessive numbers of patients, atypical patterns of prescribing techniques or locations, information that a Health Care Professional or their patients are abusing or diverting medications, sudden unexplained changes in prescribing, disproportionate number of patients paying in cash, multiple allegations of overdose and "take such further steps as may be appropriate based on the facts and circumstances

d. To provide written, non-branded education information to all health care professionals related to detecting and preventing abuse and diversion of opioid analgesics.[171]

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[169] State v. Purdue, Cause No. 07-2-00917-2, Complaint for Injunctive and Other Relief Under the Consumer Protection Act,, ¶ 40-41, filed May 9, 2007.

[170] State v. Purdue, Cause No. 07-2-00917-2, Complaint for Injunctive and Other Relief Under the Consumer Protection Act, ¶ 48, filed May 9, 2007.

[171] *State v. Purdue*, Cause No. 07-2-00917-2, Consent Judgment, at 2-14, filed May 9, 2007.

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2. Despite its Promises of Reform, Purdue Continued its Unfair Practice of Marketing Opioids to, and Concealing from Oversight, its Highest Prescribers

4.227 The 2007 Consent Judgment required Purdue, among other things, to:

> establish, implement and follow an OxyContin abuse and diversion program consisting of internal procedures designed to identify potential abuse or diversion of OxyContin in certain settings (the "OxyContin Abuse and Diversion Detection Program"). The OxyContin Abuse and Diversion Detection Program will apply to Purdue employees and contract or third-party sales representatives, including Medical Liaisons, who contact practicing Health Care Professions in person or by telephone for the purpose of promoting OxyContin. That Program directs those persons to report to the Office of the General Counsel situations [suggestive of OxyContin abuse or diversion].

4.228 The Consent Judgment set out a non-exhaustive list of examples of situations that raise an inference of abuse or diversion, and which needed to be reported by sales representatives and subsequently investigated. These situations include (a) excessive numbers of patients for the practice type, which could be indicated by long lines, "standing-room-only" capacity, and brief interactions between prescriber and patient; (b) "an atypical pattern of prescribing techniques or locations"; (c) credible information "that a Health Care Professional or their patients are abusing or diverting medications"; (d) unexplained and unjustified changes in prescribing or dispensing patterns; (e) a disproportionate number of patients paying for office visits or medications with cash; (f) "multiple allegations that individuals from a particular practice have overdosed"; or (g) "unauthorized individuals signing prescriptions or dispensing controlled substances."

4.229 When the OxyContin Abuse and Diversion Detection Program turned up information suggesting abuse or diversion, Purdue promised to:

> conduct an internal inquiry which will include but not be limited to a review of the Health Care Professional's prescribing history . . . and shall take such further steps as may be appropriate based on the facts and circumstances, which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities.

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4.230 Even apart from the Consent Judgment, Purdue had an obligation to monitor and report suspicious conduct to the federal Drug Enforcement Administration ("DEA"). See 21 U.S.C. § 823(e); 21 C.F.R. 1301.74(b).[172]

4.231 Upon information and belief, Purdue's implementation of the OxyContin Abuse and Diversion Detection Program failed to meet minimal standards of diligence and effectiveness, and Purdue routinely failed to (a) detect or investigate potential abuse or diversion, and (b) take appropriate action to stop it.

4.232 For example, in the 10 years following entry of the Consent Judgment, the Consumer Protection Division of the Attorney General's Office has been unable to find evidence of a single instance in which Purdue provided notice of potential diversion or abuse to Washington State authorities such as the Washington Attorney General's Office or the Medical Quality Assurance Commission.

4.233 Purdue failed to investigate and take action in instances that reasonably would raise an inference of abuse or diversion – in other words, where it had information that its product was likely harming the public health. The following are offered by way of example only – upon information and belief, Purdue unfairly continued to market to these opioid prescribers and concealed them from the scrutiny of regulators while collecting the profits from their excessive and dangerous prescription volumes.

3. Dr. Delbert Whetstone

4.234 Dr. Delbert Whetstone was an osteopathic physician who practiced owned and operated Doctors Osteopathic Care, located at 9629 Evergreen Way, Suite 102 in Everett, Washington.

[172] For the avoidance of confusion, the State does not allege a cause of action under these or other federal laws.

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4.235 On [redacted], a Purdue sales representative [redacted] The [redacted] also described:

[redacted]

4.236 An internal Purdue report rephrases the foregoing as [redacted] The same report notes that [redacted].

4.237 The [redacted] report was [redacted]

4.238 Purdue was again alerted to diversion and abuse of OxyContin by Dr. Whetstone and [redacted]

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4.239 All of this is particularly astonishing [redacted].

4.240 Despite these clear indications of diversion, Purdue did not alert Washington authorities. Instead, it chose to remain silent and reap the profits from what turned out to be exactly what it looked like – an organized criminal enterprise to procure OxyContin and distribute it on the black market, thereby poisoning an entire community. Its economic incentive to do so was clear: an internal Purdue document shows [redacted].

4.241 On October 8, 2010, the U.S. Department of Justice filed a complaint against Dr. Whetstone for structuring financial transactions to avoid reporting requirements. The complaint was supported by an investigation by the U.S. Drug Enforcement Administration (DEA), and alleged that the DEA executed a search warrant on October 5, 2010 for Dr. Whetstone's offices, where it found an account statement reflecting a balance of $447,697.89, as well as a history of daily (and twice-daily) deposits just below $10,000. The DEA also found $46,784.00 in cash in a locked filing cabinet.

4.242 This cash was generated by illegal and voluminous prescriptions of OxyContin. An undercover DEA agent obtained three OxyContin prescriptions from Dr. Whetstone in December 2009 and January 2010. Dr. Whetstone never physically examined the undercover officer, though he falsely entered such an examination in his chart. The undercover officer's second and third encounters with Dr. Whetstone, during which he obtained additional OxyContin prescriptions, lasted 49 seconds and 72 seconds, respectively.

4.243 The DEA's review of prescription data revealed that Dr. Whetstone wrote prescriptions for 87,977 80 mg tablets of OxyCotnin (a dose popular for illicit street sales)

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during a 10-month period in 2009.[173] By way of comparison, the Providence Regional Medical Center, Everett's largest hospital, ordered only 13,400 of those tablets during the same period.

4.244 On December 22, 2010, a federal grand jury returned an indictment against Dr. Whetstone for structuring transactions to avoid reporting requirements.

4.245 On February 27, 2012, the government filed an Information charging Dr. Whetstone with distribution of a controlled substance. The next day, Dr. Whetstone pleaded guilty to (a) Structuring Transactions to Avoid Reporting Requirements, and (b) Distribution of a Controlled Substance – the latter of which means that he knowingly and intentionally prescribed a controlled substance (OxyContin), and that the prescription was outside the scope of professional practice and not for a legitimate medical purpose.

4.246 In sentencing Dr. Whetstone, U.S. District Court Judge Robert Lasnik "Judge Lasnik noted that "[n]ever once did I hear you address what happened to these individuals who are addicted to the drugs you were putting them on," or "What happened to the people who went out in the community and sold those drugs to people who were pathologically addicted to those drugs, who then broke into pharmacies, who then broke into houses, who then stole cars, who then robbed people to keep this habit going?"

4.247 Judge Lasnik concluded by telling Dr. Whetstone that "the community was harmed by your practice of medicine."

4.248 Documents produced by Purdue [redacted]. But by then Purdue had reaped its profits from the illicit sale and distribution of OxyContin, the damage to the community had been done, the DEA had conducted its undercover investigation, and Dr. Whetstone was under federal indictment.

[173] Looking at Dr. Whetstone's opioid prescriptions more broadly, he issued 5,189 prescriptions for oxycodone products (308,466 tablets) during the same 10-month time period.

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4. Dr. Frank Li and Seattle Pain Center

4.249 During Purdue's sales representatives' frequent visits to the Seattle Pain Center, they often noted circumstances that should have led Purdue to discontinue sales calls and report Dr. Li and his staff to the appropriate authorities. Instead, it unfairly continued to target him for detailing visits that incited him to prescribe even more opioids, with disastrous consequences for the public health.[174]

4.250 Purdue's sales call notes repeatedly reference how busy Dr. Li and his staff were – which, combined with the exceptionally high opioid prescription numbers discussed below, should have been another red flag that OxyContin and other opioids were likely being abused. On [redacted] sales call notes reflect that the [redacted] This was a trigger specifically identified in the Consent Judgment as requiring investigation and potential action. There is no indication that such action was taken.

4.251 That Seattle Pain Center's lobby and schedule were so congested is particularly troubling given its practice – again, noted by Purdue – of writing prescriptions for [redacted] This revelation should also have raised red flags about whether Seattle Pain Center had implemented adequate practices and procedures to detect diversion and abuse.

4.252 Full lobbies and a packed opioid-prescribing schedule were fully consistent with Pain Relief Center's business model as Dr. Li explained it to Purdue. Purdue's sales call notes reflect that Dr. Li was [redacted] and he sought information from Purdue about [redacted]

[174] Purdue's extensive and successful marketing efforts aimed at Dr. Frank Li and the Seattle Pain Center are set forth in more detail below to illustrate how Purdue's deceptive marketing practices affected Washington health care providers.

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[redacted]. Conversely, Dr. Li did [redacted]

4.253 The alarm should also have been sounded as the result of three interactions between Purdue and Dr. Li in [redacted]:

a. On [redacted], following Purdue's reformulation of OxyContin, Dr. Li [redacted] By itself, this would not necessarily be cause for concern. But the following calls should have cast this inquiry in a very different light and revealed a serious abuse and diversion problem.

b. On [redacted], Dr. Li [redacted] and the sales representative had to remind him [redacted].

c. Potentially even more troubling, on the same call Dr. Li noted that OxyContin [redacted].

d. Even worse yet, on the same call Dr. Li [redacted]

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[redacted]

e. On [redacted], the Purdue sales representative learned from a physician assistant [redacted]

4.254 If that were not enough, as discussed below, Seattle Pain Center's patients died at an alarming rate -- 60 between 2010 and 2015 – all too often of overdose. Some of these deceased patients were treated with OxyContin, MS Contin, and Dilaudid. Purdue either (a) designed and implemented a monitoring system that failed to detect these tragedies, or (b) ignored them and continued to promote OxyContin and its other products to the Seattle Pain Center without reporting the issue to authorities even as the clinic's body count continued to rise.

4.255 Despite all this, Purdue [redacted] It did not report him to Washington authorities, but instead unfairly encouraged more prescribing and remained silent in order to reap profits that cost Washingtonians their lives.

5. Advanced Registered Nurse Practitioner Patricia Yetneberk

4.256 Patricia Yetneberk was an advanced registered nurse practitioner who practiced in Snoqualmie, Washington.

4.257 A red flag should have been raised with respect to Ms. Yetneberk, who [redacted]

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[redacted]. This was at least the second time Ms. Yetneberk had described this practice – earlier sales notes state that:

[redacted]

4.258 The sales representative nevertheless continued to [redacted]. Rather than ceasing promotion and alerting authorities to this troubling misuse of OxyContin, after Ms. Yetneberk's second statement, the sales representative [redacted] representative [redacted]

4.259 After Purdue introduced reformulated OxyContin – which was designed to be resistant to being ground up and smoked – Ms. Yetneberk [redacted]. Ms. Yetneberk [redacted] it [redacted] that [redacted]

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[redacted]. But rather than discontinue its marketing efforts or reporti this disturbing information, Purdue unfairly continued to market OxyContin and other prescription opioids to Ms. Yetneberk.

4.260 Purdue's sales notes also repeatedly reference [redacted] None of these reports were flagged by the sales representative as problematic.

4.261 Purdue's incentive to ignore these red flags and continue to target Ms. Yetneberk with sales pitches was clear. Upon information and belief, at her peak in [redacted] when Ms. Yetneberk agreed to disciplinary action through the Washington Nursing Care Quality Assurance Commission (NCQAC). These detailing visits worked: Upon information and belief, from 2007 to 2016, Ms. Yetneberk wrote more than [redacted] times the OxyContin prescriptions of the next highest prescriber, despite the 2014 MQAC discipline that prevented her opioid prescribing during the final two years of the period.

G. Washington Prescribers and Their Patients Have Been Directly Affected by Purdue's Marketing

4.262 Purdue's marketing has been effective in changing the prescribing patterns of health care providers both nationally and in Washington. These methods were specifically

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tailored to deceive health care providers and increase opioid prescriptions, including prescriptions of Purdue products.[175]

4.263 Purdue's misrepresentations about the safety and efficacy of extended release opioids encouraged health care providers to prescribe and patients to take increasing numbers of opioids for the treatment of chronic pain.

4.264 Between January 2007 and November 2016, Purdue sales representatives documented [redacted] to Washington individual prescribers and clinics. Between 2009 and 2010, Purdue [redacted] its sales force in Washington from [redacted] to [redacted]. In 2011 alone, [redacted] Purdue sales representatives made [redacted] detailing visits or the equivalent of more than [redacted] every business day that year.

4.265 The significant time and resources devoted to detailing prescribers in Washington indicates that Purdue recognized the effectiveness of in-person marketing.

4.266 The following examples illustrate the interaction between Purdue's misrepresentations, delivered through "educational" materials and personal sales calls, and opioid prescribing practices.

1. Dr. Donald Dillinger

4.267 Purdue targeted Dr. Donald Dillinger, an Everett physician who ran a pain management clinic in Everett, with marketing including the following:

a. [redacted];

b. [redacted];

c. [redacted];

[175] Purdue also gave out "swag." According to the DEA, Purdue's use of branded promotional items was unprecedented among Schedule II opioids, and was an indicator of Purdue's aggressive and inappropriate marketing of OxyContin. GAO, *OxyContin Abuse and Diversion and Efforts to Address the Problem*, at 25 (2003).

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d. [redacted]

e. [redacted]

f. [redacted]

g. [redacted]

h. [redacted]

i. [redacted].

4.268 Purdue's use of key opinion leaders and presentations at conferences and CMEs was successful at influencing Washington prescribers. For example, Purdue sales call notes reveal that Dr. Dillinger [redacted] And following a [redacted] Dr. Dillinger reported to Purdue that [redacted]

4.269 Purdue sales representatives conducted numerous sales calls and check-ins with Dr. Dillinger. [redacted]:

a. [redacted] then [redacted]

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[redacted]

b. [redacted].

c. [redacted].

d. [redacted]

e. [redacted]

f. [redacted]

[redacted] (Emphasis added.)

4.270 Purdue's efforts to change Dr. Dillinger's prescribing practices were successful. For example, Purdue sales call notes reflect:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

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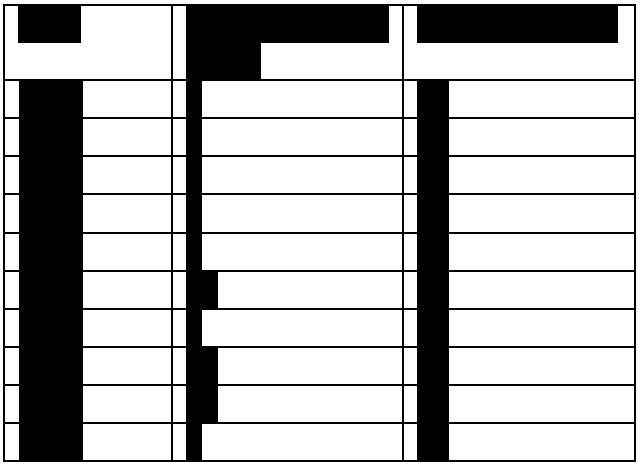
f. [redacted]

g. [redacted]

4.271 From 2007 through 2016, Dr. Dillinger wrote [redacted] prescriptions of OxyContin – [redacted] times more than the average Everett prescriber, and nearly [redacted] times as many as the next highest in his community. But rather than viewing this pattern as a cause for concern, Purdue saw an opportunity for profit.

4.272 Indeed, Purdue's efforts to influence Dr. Dillinger intensified as his prescriptions of OxyContin began increasing in 2008 when it likely identified him as a high prescriber, and continued after his peak OxyContin prescription year of 2010. As set forth in the chart below, Purdue contacted Dr. Dillinger just [redacted] times per month in [redacted], but increased to [redacted] times per month by [redacted], the year after his OxyContin prescribing peak:



4.273 Indeed, Purdue's efforts were so successful that its sales call notes [redacted]

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4.274 As a result of this relentless marketing, Dr. Dillinger prescribed OxyContin at extremely high rates. According to data produced by Purdue, Dr. Dillinger issued between approximately [redacted] and [redacted] opioid prescriptions – including generic drugs – each month from [redacted] through [redacted]. As described above, Dr. Dillinger's OxyContin prescriptions increased regularly from [redacted] through [redacted] – a period when he received regular sales visits from Purdue representatives [redacted]. As Purdue brought new opioids to market and [redacted], Dr. Dillinger's [redacted] declined, but his overall opioid prescriptions, including prescriptions of generics, [redacted]

4.275 Once Dr. Dillinger became a reliable Purdue opioid subscriber, Purdue [redacted]. Dr. Dillinger consulted with primary care physicians (PCPs) who referred patients to him. Purdue's sales call notes reflect the following:

a. [redacted]

b. Asking (i) [redacted]; (ii) [redacted]; (iii) [redacted]; (iv) [redacted]; (v) [redacted]; (vi) [redacted]; (vii) [redacted]

4.276 This strategy of obtaining [redacted] of opioid prescribing practices is consistent with Purdue's research, which found that [redacted]

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[redacted] The report noted that [redacted]

4.277 Purdue's marketing report recommended that Purdue [redacted] because [redacted] Indeed, call notes with Dr. Dillinger reflect that he [redacted]; Purdue then attempted to use Dr. Dillinger to [redacted].

4.278 Purdue's efforts to recruit Dr. Dillinger [redacted]:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

4.279 Dr. Dillinger's opioid prescription practices, encouraged by Purdue, did not end well. On August 23, 2017, Washington Department of Health, Medical Quality Assurance Commission ("MQAC") issued its Findings of Fact, Conclusions of Law, and Final Order (the

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"Final Order") *In the matter of Donald Stephen Dillinger, License No. MD.MD.00017867,* Master Case No. M2015-280. The Final Order found that the Department of Health proved by "clear and convincing evidence" that Dr. Dillinger engaged in improper treatment of patients with opioids, including by:

a. Failing to document required information in the patient treatment plans.

b. Failing to "obtain informed consent and to discuss the risks and treatment regarding his opioid treatment."

c. Failing "to update and enforce written agreements for treatment that outlined the [patients'] responsibilities."

4.280 The Final Order details Dr. Dillinger's treatment of several patients, who are designated by letter to protect their identities. For example:

a. Dr. Dillinger failed to address indications that Patient B was misusing or diverting prescription opioids, and notes that when Patient B complained that Fentanyl patches were falling off, Dr. Dillinger switched her to OxyContin. Dr, Dillinger then prescribed her a three-month supply of opioids while she would be out of town without putting any procedures in place to ensure they were not abused or diverted.

b. Patient C had a history of obtaining "street drugs," and at several points sought additional opioids from Dr. Dillinger by explaining that her prescriptions were either lost or stolen. Dr. Dillinger did not recognize these incidents as red flags for diversion and abuse.

c. Similarly, Patient E reported five (5) incidents of drug theft from 2006 to 2011, but Dr. Dillinger took no precautions to prevent diversion or abuse. Nor did Dr. Dillinger take action when Patient E tested positive for cocaine, when she was incarcerated, or when she experienced deep vein thrombosis caused by injecting drugs into the femoral artery.

d. Dr. Dillinger began treating Patient F after she failed a urinalysis and her previous health care provider refused to continue treating her with opioids. Dr Dillinger's

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charts reveal that he did not contact Patient F's previous provider, and did not institute additional controls when she reported her opioid medications stolen.

4.281 Among other conditions, the Final Order imposed three years of oversight, permanently restricted Dr. Dillinger "from the practice of treating chronic pain patients," prohibits him from prescribing "more than three-days of opioid medication in the treatment of non-chronic pain patient[s]," and requires him to register with the Washington Prescription Monitoring Program, or "PMP."

2. Dr. Frank Li and the Seattle Pain Center

4.282 A Statement of Charges was filed against Dr. Frank Li, owner and operator of the Seattle Pain Center, providing further, tragic examples of the damage wrought upon Washington citizens by Purdue's misinformation campaign about the benefits and risks of opioids, and the resulting prescription patterns.[176] His license was summarily suspended.

4.283 Despite its name, the now-shuttered Seattle Pain Center operated clinic locations throughout Western Washington – in Seattle, Renton, Everett, Tacoma, Olympia, Poulsbo, and Vancouver – in addition to a location in Spokane.

4.284 Upon information and belief, Seattle Pain Center represented itself as a pain treatment center focused on "finding treatment alternatives to narcotic pain medications" by incorporating "emerging best practices." It employed five physicians and numerous mid-level practitioners, such as Advanced Registered Nurse Practitioners (ARNPs) and Physician Assistants (PAs), often newly licensed and with little experience.[177] In reality, Seattle Pain

[176] On July 13, 2016, MQAC lodged a Statement of Charges against Dr. Li under Master Case No. M2016-705.

[177] Purdue sales representatives targeted [redacted]. For example, sales call notes reflect plans to [redacted] and [redacted] as well as the [redacted]

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Center's prescribers often used opioids as the exclusive method to treat chronic non-cancer pain without even exploring other treatment options.

4.285 Seattle Pain Center's opioid prescriptions were extraordinarily high. For example, from [redacted] to [redacted], Dr. Li alone wrote [redacted] OxyContin prescriptions. Most Seattle Pain Center locations closed in July 2016, after the Washington State Medical Commission suspended Dr. Li's license.

4.286 Seattle Pain Center was also the target of a concerted marketing effort by Purdue to promote its brand-name drugs and opioids in general. Dr. Li and Seattle Pain Center staff received numerous sales calls and visits, including lunches. Purdue also invited Dr. Li, at his request, to dinner programs. Finally, Purdue supplied Dr. Li and the mid-level practitioners he employed with its "educational" materials promoting opioids, including [redacted]. Sales call notes reflect Seattle Pain Center's reliance on Purdue's materials:

a. [redacted]

"

c. [redacted]

d. [redacted]

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e. [redacted]

f. [redacted]

g. [redacted]

h. [redacted]

4.287 As a result, Seattle Pain Center's practices were consistent with the false, and dangerous, misrepresentations about opioid treatment pushed by Purdue directly and through its KOLs and Front Groups.

4.288 Purdue promoted opioids as effective at treating chronic non-cancer pain, and superior to other options. Upon information and belief, Seattle Pain Clinic routinely prescribed opioids without exploring other treatment options. For example, MQAC alleged:

a. "[Dr. Li] treated Patient A with an aggressive regimen of oxycodone without conducting an objective physical examination" and "without crucial consideration of physical co-morbidities . . . ."[178]

b. "Patient P was maintained on an oxycodone regimen on his request, and there was no documented objective diagnosis, review of prior medical records, or risk assessments."

4.289 Purdue downplayed the risks of long-term opioid use. Upon information and belief, Seattle Pain Center routinely provided its patients with opioids for years, often without creating any plan to wean or discontinue the use of opioids. For example, MQAC alleged:

[178] MQAC noted that "Patient A died 12 days after filling her prescription for oxycodone."

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a. "SPC treated Patient P's chronic pain by prescribing oxycodone at 180 [morphine equivalent dose] for greater than two years without evidence of improvement" and without "implement[ing] an opioid exit strategy."

b. For two years, "[Dr. Li] and SPC providers prescribed [Patient Q] escalating monthly doses of oxycodone HCL and OxyContin."

4.290 Purdue promoted the myth of "pseudoaddiction" that should be treated with additional opioids, as well as the notion that there was no "ceiling" for opioid doses, such that patients could simply be prescribed additional opioids when they developed tolerance. Upon information and belief, Seattle Pain Center routinely increased opioid doses of its patients, even with signs of addiction or abuse. For example, MQAC alleged:

a. "[Dr. Li] and SPC providers continued to escalate Patient A's opioid dose despite Patient A's known overuse of Percocet, doctor-shopping for medications, requests for early refills, and repeated presence of alcohol in her UDS."

b. "SPC providers prescribed increasing methadone doses of 30 mg to 40 mg daily even after Patient C admitted to taking more pills than prescribed, and had a history of overdose, and continued to smoke marijuana."

c. "Patient H had four SPC office visits where [Dr. Li] and a PA he supervised prescribed increasing doses of [Purdue drug] MS Contin and oxycodone at each visit despite awareness of Patient H's high risk factors for opioid misuse."

d. "SPC providers . . . continued prescribing hydromorphone at escalating doses."

e. "[I]n less than six months Patient M was switched from morphine to an escalated dose of prescribed methadone."

f. "SPC providers documented multiple aberrant behaviors of drug-seeking, but deemed the conduct not egregious and maintained Patient N on escalating opioid doses."

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4.291 Purdue downplayed the danger of opioid abuse and promoted the notion that it could be curtailed using tools presented by its KOLs and Front Groups. Upon information and belief, Seattle Pain Clinics routinely prescribed opioids despite evidence of its patients' actual or potential abuse. For example, MQAC alleged that "SPC providers initiated an opiate regimen of morphine, [Purdue drug] Dilaudid, and Flexeril despite Patient D's history of critical opioid risk factors . . . ."[179]

4.292 Seattle Pain Clinic's profligate prescribing practices had deadly consequences. Upon information and belief, Sixty (60) of its patients died between 2010 and 2015. MQAC investigated eighteen (18) of these deaths, and found that sixteen (16) of them "listed acute drug intoxication as a cause or likely contributing cause of death." In short, these Seattle Pain Clinic patients died of overdose – often shortly after filling their final prescriptions for opioids. For example, MQAC alleged that:

a. "Patient G died 15 days after filling her last prescriptions of morphine and [Purdue drug] Dilaudid prescribed by SPC."

b. "Patient O filled her final methodone prescription from SPC just five days prior to her death" from "acute combined hydrocodone, hydromorphone, and methadone intoxication."

3. Advanced Registered Nurse Practitioner Kelly Bell

4.293 Kelly Bell was an advanced registered nurse practitioner in Vancouver, Washington who regularly treated patients complaining of pain with opioids, including OxyContin.

4.294 Purdue aggressively targeted Ms. Bell with medical "education" materials designed to persuade her to prescribe opioids for pain, as discussed above. For example, Purdue Sales representative call notes reflect discussions and [redacted] that included

[179] MQAC noted that "Patient D died nine days after filling his last prescription from SPC."

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[redacted] and [redacted] as well as [redacted]

4.295 Purdue's efforts to "educate" Ms. Bell were successful. As noted above, sales call notes reflect that [redacted]. On [redacted] – i.e., that she would prescribe them opioids in the amounts they desired.

4.296 Purdue's "education" efforts also touched on applicable regulations, with call notes indicating plans to [redacted]

4.297 Purdue's education efforts successfully primed Ms. Bell to reject the opioid prescribing recommendations in Washington's Agency Medical Director's Group Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain. Sales call notes reveal that the sales

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representative and Ms. Bell had a [redacted]

4.298 The results of Purdue's re-education efforts were huge amounts of opioids pumped into Ms. Bell's patients and the Vancouver community, and significant profits for Purdue. For example, an internal Purdue study of Ms. Bell's prescriptions [redacted]

4.299 Indeed, Ms. Bell wrote so many prescriptions for so many opioids that she met resistance from insurance companies who balked at paying for the flood of drugs. Purdue's sales call notes reflect that:

a. [redacted]

b. [redacted]

c. [redacted]

4.300 Ms. Bell's high opioid prescription rate also put a strain on her patients' digestive tracts from opioid-induced constipation. This resulted in [redacted]. Senokot is a laxative produced and sold by Purdue. Purdue's sales call notes reflect [redacted] during a [redacted]-month stretch. For example, [redacted]

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4.301 Despite Ms. Bell's alarmingly high opioid and OxyContin prescription rates, Purdue unfairly continued to call her and promote its products – and reap the profits from her prescriptions – until [redacted] before Washington's Nursing Care Quality Assurance Commission (NCQAC) filed a statement of charges against her. The Statement of Charges alleged that Ms. Bell "prescribed extremely high doses of opioids" to patients to treat "complaints of chronic, non-cancer pain" without engaging in "appropriate assessment or appropriate ongoing monitoring." This put patients "at risk of serious physical harm or death."

4.302 Ms. Bell entered into an Agreed Order with NCQAC in which she admitted putting patients at risk of "moderate to severe harm" and that her treatment of chronic non-cancer pain fell below the standard of care for a "reasonably competent advanced registered nurse practitioner and a reasonably competent registered nurse in the state of Washington." The Agreed Order also suspended Ms. Bell's privilege to prescribe all Schedule II drugs indefinitely.

4. Prescribers outstripping their peers

4.303 Purdue methodically tracks prescriptions and sales of its branded opioids in Washington by prescriber, drug strength, pill quantity, days supplied, pharmacy, personal identifying information of the patient, and many other factors. For example, Purdue has precise data itemizing the number of OxyContin, Butrans, and Hysingla prescriptions written in Washington [redacted].

4.304 Using these granular sales data, Purdue undertook a business practice of marketing aggressively to the highest decile prescribers of Purdue branded opioids in Washington. In a 2014 internal marketing document, [redacted] In 2016, Purdue's data showed [redacted]. In a 2011 document,

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Purdue found [redacted].

4.305 [redacted].

4.306 This carefully considered marketing strategy established an insidious group of local Purdue-targeted prescribers and pharmacists who wrote and dispensed prescriptions for Purdue opioids at a rate vastly exceeding peers in their locality or their specialty. For example, between 2008 and 2016:

a. [redacted] This physician's rate [redacted]

i. [redacted]

ii. [redacted]

b. [redacted]

[180] The number of prescriptions of OxyContin, Butrans, and Hysingla attributed to prescribers in this section were calculated from commercial prescriber data produced by Purdue to the Consumer Protection Division in response to a civil investigative demand.

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i. [redacted]

ii. [redacted]

iii. [redacted]

4.307 Purdue's two-pronged strategy of marketing to primary care physicians, physician assistants, and nurse practitioners, and to pain clinics resulted in a noticeable and alarming trend of outlier prescribers in geographically disparate Washington cities and towns who flooded the state with opioid prescriptions. For example:

a. Arlington, WA has a population of approximately 19,000 people. Two providers in [redacted]. The next two highest prescribers of those same Purdue opioids in Arlington [redacted]

b. In Olympia and Yelm, [redacted] Olympia has a population of approximately 51,000 and Yelm has a population of fewer than 9,000. [redacted]

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[redacted]

c. Similar patterns of local clinics prescribing vastly more Purdue opioids than their next highest-prescribing competitors in that locality are repeated in [redacted], in [redacted] in [redacted], in [redacted], and all over the state.

4.308 The prescribers and clinics listed above demonstrate how effectively Purdue targeted its deceptive practices at Washington health care providers, and Purdue's significant influence on their opioid prescribing habits.

H. Opioids Have Severely Impacted Washington State

4.309 Opioid use, morbidity, and mortality have increased exponentially nationwide and across Washington State in the years since Purdue first began aggressively marketing opioids for long-term use. Prescriptions and sales of opioids in Washington skyrocketed more than 500% between 1997 and 2011.[181]

4.310 In 2011, at the peak of overall sales in Washington, more than 112 million daily doses of all prescription opioids were dispensed in the state – enough for a 16-day supply for every woman, man, and child in the state. Since 2011, sales of extended release opioids have plateaued somewhat, although there were still more than 18.2 million daily doses of oxycodone distributed in 2015.

4.311 Nearly one-fourth of all Washington residents received at least one opioid prescription in 2014.[182] Even as prescription rates decline, in 2016 there were still seven

[181] Franklin et al., *supra* note 3.

[182] *PDMP County Profiles 2014: Executive Summary*, Washington State Department of Health, http://www.doh.wa.gov/Portals/1/Documents/2600/PMPcountyProfiles/630-126-CountyProfilesExecutiveSummary2014.pdf (last visited Sept. 27, 2017).

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counties in which enough opioid prescriptions were dispensed for every person in that county to have one.[183]

4.312 According to the CDC, between 1999 and 2015 more than 194,000 people died in the United States from prescription-related overdoses. There have been more than 10,000 deaths attributable to any opiate in Washington alone since turn of the 21st century.[184]

a. Overall, the majority of drug overdose deaths in Washington (more than 6 out of 10) involve an opioid.[185]

b. Overdose deaths – specifically opioid overdose – have overtaken those causes that have traditionally had the highest rates of accidental death. In 2015, the number of overdose deaths in Washington (718) surpassed both the number of deaths in car accidents (592) and from firearms – suicide, homicide, and accidental (714).

c. Drug-caused deaths involving opioids increased 31% statewide, with increases in most counties. The total number of drug-caused deaths involving opioids in 2013 was 718, with 7595 deaths total from 2006–2016.[186] The annual rate of opioid deaths has not changed from 2008 to 2013. A similar pattern emerges with prescription-type opioids peaking between 2008–2010, while heroin continued increasing through 2013.

d. In King County, prescription-type opioid trends are down somewhat from peaks around 2010, however prescription-type opioid-involved deaths are persisting at

[183] The CDC data show the estimated rate of opioid prescriptions per 100 U.S. residents in 2016, including rates of 150.9 in Asotin County; 119.9 in Columbia County; 119.7 in Clallam County; 119 in Garfield County; 118 in Pend Oreille County; 113 in Grays Harbor County; and 102.4 in Benton County. CDC U.S. Prescribing Rate Maps. https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html (last visited Sept. 27, 2017).

[184] Center for Health Statistics, Washington State Department of Health.

[185] Rudd et al., *supra* note 18.

[186] *DOH Opioid-Related Deaths in Washington State, 2006-2016*, Washington State Department of Health, https://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf (last visited Sept. 27, 2017).

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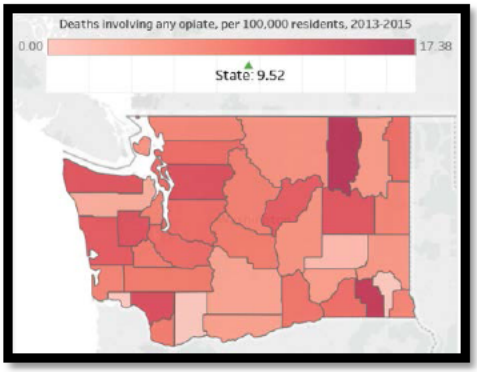
elevated rates and are second only to heroin in terms of most common drugs identified in fatal overdoses.[187]

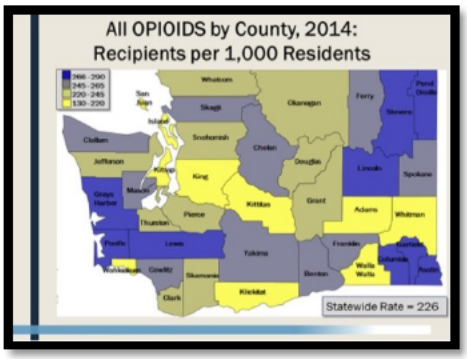
4.313 Geographic areas with higher per-capita rates of opioid prescribing show a strong correlation with higher overdose rates.

4.314 The death rates in Washington are geographically disparate and are concentrated in the counties with the highest rates of opioid prescriptions. For instance:

a. In 2014, Pend Oreille County in the northeastern corner of the state had a rate of opioid substance use of 282.3 patients prescribed opioids per 1,000 residents and a corresponding 10.10 deaths attributable to any opioid per 100,000 residents between 2013-2015. That overdose death rate was a more than 200% increase from 2002-2004. Similarly, Cowlitz County in the southwestern corner of the state had a rate of opioid substance use of 273 patients prescribed opioids per 1,000 residents and a corresponding 13.49 deaths attributable to any opioid per 100,000 residents between 2013-2015. This pattern can be seen repeated in many Washington counties.

4.315 Clallam, Cowlitz, and Snohomish counties have opioid overdose rates higher than the state average. While not located in the one of the four corners, Snohomish County has experienced a 23.7% increase in deaths involving any opiate between 2002-2004 and 2013-2015.





[187] ADAI 2016 Drug Use Trends in King County, Washington (July 2017) Contributors: Caleb Banta-Green, Jason Williams, Robyn Smith, Brad Finegood, Laurie Sylla, Richard Harruff, Joe Tinsley, Meaghan Munn, Julia Hood, Susan Buskin, Sara Glick, Steve Freng, Fiona Couper, Ed Suzuki, Johnny Ohta, Jim Pugel, Mary Taylor

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4.316 The scope of human suffering and economic cost of opioids on Washington reverberates far beyond overdose mortality rate. The State spends significant public resources on medical services, law enforcement, corrections, workers' compensation, diversion programs, prosecution, probation, treatment, and child welfare.

a. The cumulative rate of opioid-related inpatient hospital and clinic stays increased by 60.1 percent in Washington between 2009 and 2014, the fourth greatest increase in the nation.[188] That rate of 313.2 opioid-related inpatient stays per 100,000 in population placed Washington eighth in the nation.[189]

b. The Washington State Toxicology Laboratory, housed within Washington State Patrol, has received a significant increase in the number of cases submitted for testing in recent years by approximately 1,000 cases per year since 2013. The increased caseload results in a backlog of samples waiting to be tested.

c. Crime lab data for police evidence testing for opioids indicate an 85% increase statewide between 2002-2004 and 2011-2013, with increases in most counties. Police evidence testing results show that oxycodone has consistently been the most common prescription-type-opioid detected in all years.[190]

d. Publicly funded drug treatment admissions for opioids as the primary drug increased 197% statewide, with increases in 38 of 39 counties.[191]

4.317 Deceptive and unfair marketing of opioids by Purdue also has a significant detrimental impact on children in Washington. Adolescent misuse of prescription-type-opioids is very important because it is the peak period in life when people first misuse opioids.[192] The

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[188] HCUP Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009-2014 (Dec 2106, revised Jan 2017), at *7-8.

[189] HCUP Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009-2014 (Dec 2106, revised Jan 2017), at *5.

[190] ADAI Opioid Trends Across Washington State (April 2015) ADAI-IB 2015-01.

[191] ADAI Opioid Trends Across Washington State (April 2015) ADAI-IB 2015-01.

[192] Opioid Trends in Pierce County (February 2017), citing to Meier et al., 2012.

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overprescribing of opioids for chronic pain has given young children access to opioids, nearly all of which were prescribed for adults in their household or to the children by dentists.

a. The 2016 Healthy Youth Survey revealed that a significant portion of Washington students misuse prescription drugs – about 4,500 twelfth graders use prescription opioids to get high in any given month, and about 3,600 have tried heroin at least once.[193]

b. Washington dentists are the biggest prescribers of opioids to youth, prescribing more than 13,000 pills to youth age 14-19 in one six-month period in 2015. For comparison, emergency medicine providers, the second highest prescribers, issued prescriptions for approximately 2,500 pills in the same period.

c. While Healthy Youth Survey data for King County tenth graders indicate a significant decline in the proportion reporting past month use of prescription-type-opioids to get high, that decline is being offset somewhat by increased rates of heroin use. In 2006, 10% of King County tenth graders reported past month use of prescription-type-opioids to get high; that number has steadily declined in bi-annual surveys to 4% in 2014 and the same proportion in 2016.[194] However, in 2016 there was a strong association between reporting use of prescription-type-opioids to get high and having ever used heroin (26%), compared to only 2% reporting ever having used heroin if they had not used prescription-type- opioids to get high.

4.318 Even infants have not been immune to the impact of opioid abuse and overprescription. There has been a dramatic increase in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome (NAS), which can occur in an infant exposed in utero to addictive, illegal or prescription drugs.

a. Neonatal abstinence syndrome (NAS) can occur in an infant exposed in utero to addictive, illegal or prescription drugs. Babies born with NAS may experience a

[193] 2016 Washington State Healthy Youth Survey. Data Brief: Prescription Drugs and Opiates. http://www.doh.wa.gov/Portals/1/Documents/8350/160-NonDOH-DB-Opiates.pdf.

[194] 2016 Washington State Healthy Youth Survey www.askhys net

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variety of withdrawal symptoms, medical complications and have prolonged hospital stays. According to the Centers for Disease Control and Prevention, the incidence rate of NAS in Washington State increased from a rate of 1.5 for every 1,000 hospital births in 1999 to a rate of 7.9 for every 1,000 hospital births in 2013. In Washington, prenatal exposure to opioids increased from 11.5 percent of all drug-exposed neonates in 2000 to 24.4 percent in 2008, and 41.7 percent of infants diagnosed with NAS were exclusively exposed to opioids.[195]

4.319 Opioid use has had a significant impact on Washington's child welfare system. Parental substance abuse is a major risk factor for child fatalities, child maltreatment, and involvement with the child welfare system.

a. From calendar year 2013 to 2016, the Office of the Family & Children's Ombuds identified 33 maltreatment related fatalities of children ages 0 to 3 years where a caregiver's opiate use was a known risk factor.[196]

b. Upon information and belief, a review of a representative sample of dependency petitions filed 2014-2016 in Snohomish County found that in more than 95% of cases where children were removed from the home due to parental drug use, the drug involved was an opioid.

c. Children removed from their home as a result of parental substance abuse are likely to remain in foster care longer and have significantly higher rates of adoption than those in foster care for other reasons.[197] A higher rate of adoption indicates that children

[195] August 2017 WA Office of the Family and Childrens' Ombuds report "Child Fatalities and Near Fatalities in Washington State" p.21-22, citing to Neonatal Abstinence Syndrome: How States Can Help Advance the Knowledge Base for Primary Prevention and Best Practices of Care, (2014) http://www.astho.org/prevention/nas-neonatal-abstinence-report (last visited Sept. 27, 2017).

[196] Office of the Family and Childrens' Ombuds "Child Fatalities and Near Fatalities in Washington State" (August 2017), p.21

[197] 2017 WA Child and Family Ombuds report p.21, citing to Family-Based Recovery: An Innovative In-Home Substance Abuse Treatment Model for Families with Young Children, By Hanson, Karen E.; Saul, Dale H.; Vanderploeg, Jeffrey J.; Painter, Mary; Adnopoz, Jean

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removed from their homes remain in foster care longer and are less likely to exit from foster care to reunification with biological parents.

4.320 The initial rise in prescription-type opioids came while heroin deaths, crime lab cases, and treatment rates were on the decline, and the recent decline for prescription-type opioids comes as heroin returns to prominence. Since the statewide peak in 2011, the number of prescriptions of extended release opioids has declined and correspondingly so has the rate of overdose deaths attributed to prescription opiates. The overall rate of overdose in Washington State, however, has stayed relatively flat through 2015 because of an increase in heroin use and overdose deaths attributed to heroin.

4.321 Many individuals who use heroin, and the majority of young adults who use heroin, report using prescription-type opioids prior to switching to heroin.[198]

4.322 The Evergreen Treatment clinic in Seattle currently treats 1400 people with opioid use disorder, 95% of whom are active heroin users. According to anonymous incoming patient surveys, 90% of patients started using with prescription opioids.

4.323 Five percent of Pierce County 10th graders reported lifetime heroin use and current painkiller use "to get high" in 2014. While most students report using neither, 3% had tried heroin, 4.4% reported current painkiller use only, and 1% reported both. To illustrate the association between heroin and other opioids, among those who have tried heroin, the current painkiller use rate is 34.7% versus 4.5% among those who report no lifetime heroin use. Nearly one in five students who report painkiller use in the past month report ever using heroin.[199]

4.324 Heroin indicators remain at high levels in 2016 across all measures:

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[198] K. Michelle Peavy et al., *"Hooked on" Prescription-Type Opiates Prior to Using Heroin: Results from a Survey of Syringe Exchange Clients*, 44 JOURNAL OF PSYCHOACTIVE DRUGS 259–265 (2012); Emily R. Cedarbaum & Caleb J. Banta-Green, *Health behaviors of young adult heroin injectors in the Seattle area*, 158 DRUG AND ALCOHOL DEPENDENCE 102–109 (2016).

[199] Opioid Trends in Pierce County (February 2017), p. 5

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a. Heroin deaths more than doubled between 2010 and 2015.[200]

b. Heroin was the most common drug reported as primary in 2016, accounting for 31% of all treatment admissions, a numerical and proportional increase compared to 2012.[201]

c. There were more than four calls per day to King County's Recovery Helpline seeking assistance regarding heroin.[202] Heroin-related calls to the Recovery Helpline have consistently been the most common drug for calls regarding young adults. There were 476 calls in 2016, similar to prior years. For adults 26 and older, heroin was consistently the second most common substance reported in calls to Recovery Helpline, and there were a total of 1,179 calls in 2016 similar to the prior year.

d. For adults ages 18-25 admitted to treatment, heroin was numerically and proportionally much more common than other drugs, with a relatively large proportion, 19%, of admissions for heroin ages 18-25.[203]

e. In Pierce County, a recent rise in police evidence testing cases and drug overdose deaths is being driven by increases in heroin use over the past few years.[204] Correspondingly, treatment admissions in Pierce County for heroin and first admissions for heroin have risen precipitously since 2013.

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[200] Washington State Department of Health. (2017). Opioid-related Deaths in Washington State, 2006-2016. Retrieved from http://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf

[201] ADAI 2016 Drug Use Trends in King County, Washington (July 2017) Contributors: Caleb Banta-Green, Jason Williams, Robyn Smith, Brad Finegood, Laurie Sylla, Richard Harruff, Joe Tinsley, Meaghan Munn, Julia Hood, Susan Buskin, Sara Glick, Steve Freng, Fiona Couper, Ed Suzuki, Johnny Ohta, Jim Pugel, Mary Taylor

[202] ADAI 2016 Drug Use Trends in King County, Washington (July 2017) Contributors: Caleb Banta-Green, Jason Williams, Robyn Smith, Brad Finegood, Laurie Sylla, Richard Harruff, Joe Tinsley, Meaghan Munn, Julia Hood, Susan Buskin, Sara Glick, Steve Freng, Fiona Couper, Ed Suzuki, Johnny Ohta, Jim Pugel, Mary Taylor

[203] ADAI 2016 Drug Use Trends in King County, Washington (July 2017)

[204] Opioid Trends in Pierce County (February 2017)

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4.325 The staggering rise in use of heroin and heroin-related overdose deaths is a predictable result from the declining opioid prescriptions rates across the state.[205]

4.326 Purdue's business model depends on creating addicts to fuel its sales of branded extended release opioids, because according to internal documents, [redacted] When dependent users are unable to obtain prescription opioids they turn to illicit sources of opiates such as heroin.

I. Purdue Is Responsible for Washington's Opioid Crisis

4.327 As detailed in this complaint, the impacts of opioids on Washington are inextricably linked with Purdue's marketing campaign designed to convince prescribers, patients, and the public that opioids were an effective medical solution for chronic pain.

4.328 When evidence of the widespread impacts opioids were having on Washington and across the nation, Purdue carefully packaged and targeted its messages to convince prescribers that the risks of addiction were overstated and could be managed.

4.329 As a result of Purdue's efforts, opioid use has grown to epidemic proportions and the death rates continue to rise while Purdue continue to market and sell drugs that it knows are deadly.

4.330 The Attorney General asks the court to stop Purdue's deceptive marketing and order legal and equitable remedies to begin addressing the opioid epidemic.

V. FIRST CAUSE OF ACTION
(VIOLATIONS OF THE CONSUMER PROTECTION ACT, RCW 19.86)

5.1 The State incorporates Paragraphs 1.1 through 4.330 herein as if set forth in their entirety.

5.2 RCW 19.86.020 prohibits "unfair" or "deceptive" acts or practices in trade or commerce.

[205] Franklin et al., supra note 3, citing to n45-47

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5.3 The marketing, distribution, and sale of opioids to health care providers and consumers in Washington constitutes "trade" or "commerce" defined by RCW 19.86.010(2).

5.4 Purdue engaged in numerous deceptive acts or practices, including the following:

a. Marketing opioids, including its own drugs, both directly and indirectly through third party groups, as a solution to the undertreatment of pain and either stating directly or implying that opioids are effective to treat or relieve long-term chronic pain and improve function and quality-of-life.

b. Misrepresenting and making unsubstantiated claims that, and the extent to which, opioids improve function over the long term.

c. Misrepresenting the truth and making unsubstantiated claims about how (and how frequently) opioids lead to addiction and the extent to which addiction risk can be managed and addiction prevented.

d. Misleadingly using terms like addiction, dependence, tolerance, physical dependence, and "pseudoaddiction" to persuade health care providers and patients that the addiction risk of opioids could be successfully managed.

e. Misrepresenting and making unsubstantiated claims that increased doses of opioids do not pose significant additional risks.

f. Misrepresenting and making unsubstantiated claims regarding the factors for comparing the risks and benefits of opioids with those of alternative forms of pain treatment.

g. Marketing Purdue's abuse deterrent formulations of opioid medications as a means of reducing abuse and addressing the opioid epidemic without any evidence to support such a claim.

5.5 Purdue engaged in numerous unfair acts or practices, including the following:

a. Marketing and selling opioids for long-term use in treating chronic pain without sufficient evidence of efficacy, while also understating the risk of addiction and the

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ease with which addiction could be treated.

b. Influencing health care providers' prescription decisions for particular patients in sales calls for which the patient was not present.

c. Encouraging health care providers to ignore or reject regulatory guidance from the Washington's Agency Medical Director's Group, thereby undermining Washington's public policy to diminish the amount of addictive and dangerous opioids prescribed to its residents.

d. Targeting and encouraging health care providers with high rates of opioid prescription through in-person detailing, dissemination of educational materials and programs, and third party materials containing misleading statements about the efficacy and risks of opioids. This targeted marketing sought to cause high volume prescribers to continue prescribing at those rates and encouraging additional prescriptions despite observing indications that the health care provider was not meeting the standard of care, and/or that opioids were being diverted or abused, thereby harming the public health.

e. Failing to report and/or concealing from relevant law enforcement and medical regulators suspicious, excessive, and illegal opioid prescribing practices, while profiting from inflated prescriptions of OxyContin and other Purdue-branded opioids.

5.6 Purdue's unfair and deceptive conduct in the marketing, distribution, and sale of opioids to health care providers and consumers in Washington affects the public interest because the opioids were marketed and issued to numerous consumers in Washington, injured numerous Washington consumers, created a public health crisis and a public nuisance, were part of Purdue's very business model and regular course of business operations, and were repeated.

VI. SECOND CAUSE OF ACTION (PUBLIC NUISANCE)

6.1 The State incorporates Paragraphs 1.1 through 5.6 herein as if set forth in their entirety.

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6.2 RCW 7.48.120 provides that:

> [n]uisance consists in unlawfully doing an act, or omitting to perform a duty, which act or omission either annoys, injures or endangers the comfort, repose, health or safety of others, offends decency, or unlawfully interferes with, obstructs or tends to obstruct, or render dangerous for passage, any lake or navigable river, bay, stream, canal or basin, or any public park, square, street or highway; or in any way renders other persons insecure in life, or in the use of property.

6.3 Pursuant to RCW 7.48.130, a "public nuisance" is a nuisance that "affects equally the rights of the entire community or neighborhood, although the extent of the damage may be unequal."

6.4 Finally, RCW 7.48.010 defines an "actionable nuisance" to include "whatever is injurious to health or indecent or offensive to the senses."

6.5 Through the actions described above, Purdue has contributed to and/or assisted in creating and maintaining a condition that is unreasonable and harmful to the health of Washingtonians and/or interferes with the comfortable enjoyment of life in violation of Washington law. For example:

a. Opioid use, abuse, and overdose deaths have increased throughout the state.

b. Locations such as the offices of high-prescribing health care practitioners and the pharmacies at which their patients fill opioid prescriptions have attracted drug dealers and addicts.

c. Locations such as abandoned homes and some public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to over-prescribing, and the foreseeable failure to safely dispose of opioids.

d. The greater demand for emergency services, law enforcement, addiction treatment, and social services places an unreasonable burden on State and local resources.

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e. Expanding the market for prescription opioids to primary care patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury.

f. The creation of additional illicit markets in other opiates, particularly heroin. Many users who were initially dependent on prescription opioids and then were unable to obtain or afford prescription opioids turned to heroin as an alternative, fueling a new heroin epidemic in the process.

g. Increased health care costs for individuals, families, and the State.

h. Purdue also interfered with enjoyment of the public right by failing to report suspicions of illicit prescribing to the State, law enforcement, or the Board of Medicine, allowing health care providers who were profitable to Purdue but problematic for the public health to continue prescribing increasing numbers of opioids throughout the state.

6.6 The public nuisance created by Purdue's actions is substantial and unreasonable – it has caused significant harm to communities across Washington, outweighing any offsetting benefit. Purdue knew or should have known that its sales and promotion of long-term opioid use for chronic pain would create a public nuisance.

6.7 Purdue's actions described above were a substantial factor in opioids becoming widely available, used, and all too often abused. These actions were a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic non-cancer pain, and in distorting the medical standard of care for treatment of chronic pain that resulted in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment.

6.8 But for Purdue's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. Purdue's actions have and will continue to injure and harm many residents

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throughout the state, including patients with chronic non-cancer pain who take opioids, their families, and their communities at large.

6.9 The public nuisance and associated financial and economic losses were foreseeable to Purdue, who knew or should have known that its unfair business practices and deceptive statements regarding the risks and benefits of opioids were creating a public nuisance. As alleged herein, Purdue engaged in and disseminated widespread deceptive promotion of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death.

6.10 The intent of Purdue's sale of extended release opioids and the promotion of opioids was for health care providers to prescribe opioids for treatment of long-term chronic pain, for patients to fill those prescriptions, and then to keep filling those prescriptions at higher and higher doses. A reasonable person in Purdue's position would foresee not only a vastly expanded market for chronic opioid therapy, but also the other likely and forseeable result of Purdue's conduct – the widespread problems of opioid addiction and abuse. In fact, Purdue was on notice and aware of signs that health care providers were prescribing unreasonably higher numbers of opioids and that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

6.11 Purdue's business practices generated a new and very profitable circular market with the promotion of opioids – providing both the profitable supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

6.12 Purdue is liable for a public nuisance because they acted without express authority of a statute in knowingly promoting off label opioid prescribing; in engaging in a pattern of conduct that overstated the benefits of long-term opioid use, misrepresented the duration of efficacy of extended release opioids, failed to disclose the lack of evidence supporting long-term use of opioids, and misrepresented the serious risk of addiction from legitimate and prescribed use

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of opioids; and in creating and maintaining the prescription and sale of opioids for long-term treatment of chronic pain at such volumes and degree as to create an epidemic.

6.13 The health and safety of Washington residents, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the State, whose duty to protect the health, safety, and well-being of its residents is paramount. Washington and its residents have a right to be free from conduct that endangers their health and safety. Purdue's deceptive marketing and unfair business practices interfered in the enjoyment of this public right by the State and its citizens.

6.14 Pursuant to RCW 7.48.020 and 7.48.180, the State seeks an order that provides for abatement of the public nuisance Purdue has created, enjoining Purdue from future violations of RCW chapter 7.48, and awards the State damages in an amount to be determined at trial.

VII. THIRD CAUSE OF ACTION (COMMON LAW NEGLIGENCE)

7.1 The State incorporates Paragraphs 1.1 through 6.14 herein as if set forth in their entirety.

7.2 Under Washington law, a cause of action arises for negligence when defendant owes a duty to a plaintiff and breaches that duty, and proximately causes the resulting injury.

7.3 Purdue owed a duty of care to the citizens of Washington, including but not limited to exercise reasonable care in the marketing and sale of a highly addictive drug like opioids. Purdue knew or should have known that its affirmative conduct in aggressive and misleading marketing and sale of opioids created an unreasonable risk of harm.

7.4 A reasonably prudent manufacturer would be aware that aggressively marketing opioids for chronic pain would result in the severe harm of addiction for large numbers of Washingtonians and that increasing the numbers of prescription opioids available in the market would lead to massive harm to the public including increased hospitalizations, overdoses, and deaths.

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7.5 In fact, Purdue was aware from internal sales data, adverse event reports, publicly available studies and reports, and other sources that the rapid expansion of prescription products, including its specific opioid products, was causing the massive public harm that was reasonably foreseeable. Purdue failed to take reasonable steps in response to that information, choosing instead to offer inadequate measures to mitigate risk while continuing to aggressively market drugs in such a way as to ensure high prescribing of opioids continued

7.6 A reasonably prudent manufacturer of opioids could reasonably foresee that long-term use of opioids at increasing dosages was a particularly addictive and dangerous use of opioids and that aggressively marketing opioids for long-term treatment of chronic pain would make opioids more dangerous and deadly.

7.7 In fact, Purdue was aware from internal sales data, adverse event reports, publicly available studies and reports, and other sources that its aggressive marketing was expanding the use of opioids for long-term treatment of chronic pain conditions and was causing massive public harm.

7.8 A reasonably prudent manufacturer of opioids could reasonably foresee that aggressive, targeted marketing of opioids would lead to increased opioid prescriptions. A foreseeable consequence of expanded opioid prescriptions is the expansion of use of illicit and diverted opioids.

7.9 In fact, Purdue was aware from internal sales data, adverse event reports, publicly available studies and reports, and other sources that its aggressive, targeting marketing of opioids was causing increased opioids prescriptions in Washington state and was fueling a massive increase in heroin use and the diversion of opioid pain medications. Even knowing that, Purdue continue its marketing of these drugs.

7.10 By misrepresenting the addictive nature of opioids, aggressively promoting its opioids, and opioids generally, for long-term treatment of chronic pain, Purdue breached its duty of reasonable care as a manufacturer of dangerous opioids and increased the risk for public harm ,

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7.11 As set forth above, and incorporated by reference, Purdue's misrepresentations include the deceptive conduct described above.

7.12 Purdue's conduct was a proximate cause of increased opioid prescribing along with the inevitable and foreseeable consequences and public harms.

7.13 As a direct and proximate cause of Purdue's unreasonable and negligent conduct, Washington has suffered and will continue to suffer harm, and is entitled to damages in an amount determined at trial.

VIII. PRAYER FOR RELIEF

Wherefore, the State prays for the following relief:

8.1 A declaration that Defendants' acts described above are unfair or deceptive acts or practices in trade or commerce, affecting the public interest, and in violation of the Consumer Protection Act, RCW 19.86;

8.2 An injunction pursuant to RCW 19.86.080(1) enjoining Defendants and from engaging in any acts that violate the Washington Consumer Protection Act, including, but not limited to, the unfair and deceptive acts and practices alleged herein;

8.3 An order necessary to restore to any person an interest in any moneys or property, real or personal, which may have been acquired by means of an act prohibited by the Consumer Protection Act, pursuant to RCW 19.86.080(2);

8.4 An award of a civil penalty in the amount of $2,000.00 for each and every violation of Washington's Consumer Protection Act, pursuant to RCW 19.86.140;

8.5 An award of the State's reasonable costs and attorney's fees incurred in this action, pursuant to RCW 19.86.080(1);

8.6 An order requiring Defendants to abate the public nuisance that they created;

8.7 An award of damages in an amount determined at trial for injury sustained by the State as a result of Defendants' unreasonable and negligent conduct;

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8.8 Equitable relief requiring restitution and disgorgement of the revenues wrongfully obtained from sale of extended release opioids as a result of Defendants' wrongful conduct;

8.9 An award of pre-judgment and post-judgment interest, as provided by law; and

8.10 Any other and further relief the Court deems just and equitable.

JURY DEMAND ENDORSEMENT

Plaintiff, State of Washington, demands a trial by jury on public nuisance and negligence claims to the maximum number of jurors permitted by law.

DATED this 28th day of September, 2017.

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