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**SEVENTH JUDICIAL DISTRICT COURT  
CARBON COUNTY, UTAH**

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<p><b>STATE OF UTAH,</b></p> <p>Plaintiff,</p> <p>v.</p> <p><b>PURDUE PHARMA L.P., PURDUE PHARMA INC., and THE PURDUE FREDERICK COMPANY,</b></p> <p>Defendants.</p>	<p><b>COMPLAINT</b></p> <p>Case No. _____</p> <p>Discovery Tier 3</p> <p>Jury trial demanded.</p> <p>Judge: _____</p>
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Plaintiff, the State of Utah, through its Attorney General, Sean D. Reyes, brings this Complaint for compensatory damages, restitution, disgorgement, abatement, injunctive relief, civil penalties, and punitive damages against Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company ("Purdue").

## Introduction

1. Opioid abuse and addiction is a national public health crisis. According to the Centers for Disease Control (“CDC”), over 63,000 American’s died of a drug overdose in 2016, of which 66.4 percent (42, 249) involved opioids. The number of deaths and the prevalence of opioids were both worse in 2016 than a year prior.<sup>1</sup>

2. Utah is not immune from the effects of this opioid crisis. According to the Centers for Disease Control and Prevention (“CDC”), Utah lost 1,884 people to drug overdose death between 2014 and 2016, and the “main driver” of these deaths was prescription and illicit opioids. In 2016, there were 466 opioid-related overdose deaths in Utah—a rate of 16.4 deaths per 100,000, which is much higher than the national rate of 13.3 deaths per 100,000.<sup>2</sup>

3. Purdue’s misconduct, including its consistent failure to comply with its legal obligations, has led to an epidemic of prescription opioid abuse in Utah. This epidemic resulted in a nearly 600% increase in prescription opioid-related deaths in Utah between 1999 and 2007,<sup>3</sup> 466 prescription opioid-related deaths in Utah in 2016 alone,<sup>4</sup> and millions drained annually from State resources.

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<sup>1</sup> Ctr. for Disease Control & Prevention, Morbidity and Mortality Weekly Report, March 30, 2016, *Overdose Deaths [I]*, 2015-2016, [https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a1.htm?s\\_cid=mm6712a1\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a1.htm?s_cid=mm6712a1_w). According to The Council of Economic Advisers of the United States, over 50,000 Americans died of a drug overdose in 2015, of which 63 percent (33,091) reportedly involved opioids.

<sup>2</sup> National Institute on Drug Abuse, Opioid-Related Overdose Deaths, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/utah-opioid-summary>.

<sup>3</sup> Ctr. Disease Control & Prevention, Morbidity and Mortality Weekly Report, Feb. 19, 2010 59(06), *Adult Use of Prescription Opioid Pain Medications --- Utah, 2008*, [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5906a1.htm?s\\_cid=mm5906a1\\_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5906a1.htm?s_cid=mm5906a1_w).

<sup>4</sup> *Utah Opioid Summary*, Nat’l Inst. on Drug Abuse, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/utah-opioid-summary>.

4. This epidemic has drained State resources for the criminal justice,<sup>5</sup> education,<sup>6</sup> social services and welfare,<sup>7</sup> and healthcare systems.<sup>8</sup> Prescription opioid abuse costs the citizens and State of Utah approximately \$238 million in healthcare costs each year.<sup>9</sup>

5. Prescription opioids are powerful pain-reducing medications. They include non-synthetic derivatives of the opium poppy (also called “opiates,” such as codeine and morphine), partially-synthetic derivatives (such as hydrocodone and oxycodone), and fully-synthetic derivatives (such as fentanyl and methadone).

6. When used properly, and under appropriate medical supervision, prescription opioids can help manage pain for certain patients. Despite their potential beneficial uses, these drugs can also cause addiction, overdose, and death, even when used properly. When used to treat chronic pain – or when used for non-medical purposes – those risks are amplified.

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<sup>5</sup> *The High Price of the Opioid Crisis*, Pew Charitable Trusts July 2017, [http://www.pewtrusts.org/~media/assets/2017/07/highpriceofopioidcrisis\\_infographic\\_final.pdf?la=en](http://www.pewtrusts.org/~media/assets/2017/07/highpriceofopioidcrisis_infographic_final.pdf?la=en). In 2015, \$7.6 billion was spent nationally on criminal justice costs associated with prescription opioid abuse, and 96% of the costs fell to state and local governments.

<sup>6</sup> *Id.* at 24. In 2005, approximately 12.2% of federal government education spending “was spent coping with the impact of substance abuse and addiction.”

<sup>7</sup> The Nat’l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets* 27 (2009), <http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets>. In 2005, state governments spent 27% of the amount they spend on healthcare to fund the social services related to substance abuse.

<sup>8</sup> Matric Global Advisors, *Health Care Costs from Opioid Abuse: A state-by-state analysis* 5 (2015), [http://drugfree.org/wp-content/uploads/2015/04/Matrix\\_OpioidAbuse\\_040415.pdf](http://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf); Kohei Hasegawa et al., *Epidemiology of Emergency Department Visits for Opioid Overdose: A population-based study*, 89 *Mayo Clinic Proceedings* 462, 465, 467 (2014) (there are about two times as many opioid overdoses in Emergency Departments among publicly-insured individuals than among individuals with private insurance and publicly-insured individuals are approximately twice as likely to have a second visit to the Emergency Departments for opioid overdose as are privately-insured individuals); Cong. Research Serv., *Medicaid’s Federal Medical Assistance Percentage (FMAP)* 14–15 (2016), <https://fas.org/sgp/crs/misc/R43847.pdf> (the State of Utah pays for approximately 30% of publicly-funded healthcare expenses).

<sup>9</sup> *Id.*

7. Purdue has engaged, and continues to engage, in an aggressive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids. Utah law prohibits suppliers from using misleading or deceptive practices to market their products. Nonetheless, Purdue disseminated misstatements through multiple channels, representing opioids as useful in treating chronic pain long-term, and as having low addiction risk. This campaign included websites, promotional materials, conferences, guidelines for doctors, and other vehicles. Several Utah doctors were consultants for Purdue, wrote promotional materials supporting opioids as the best approach to pain management, and prescribed lethal amounts of opioids to Utah residents from a Salt Lake “pain clinic.”<sup>10</sup>

8. Purdue’s marketing campaign enabled Purdue to overcome the longstanding medical consensus that opioids were unsafe for the treatment of chronic pain. Purdue’s campaign resulted in a significant increase in the number of opioids prescribed nationwide. In fact, between 1999 and 2016, the number of opioids prescribed nationwide quadrupled.<sup>11</sup> Not surprisingly, deaths from prescription opioid use also quadrupled over the same period.<sup>12</sup> Between 2002 and 2015, the number of opioid prescriptions dispensed in Utah jumped up by over one million. In

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<sup>10</sup> Deseret News, *The untold story of how Utah doctors and Big Pharma helped drive the national opioid epidemic*, (Oct. 26, 2017), <https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html>.

<sup>11</sup> Li Hui Chen et al., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat’l Ctr. for Health Statistics Data Brief (Sept. 2014), <https://www.cdc.gov/nchs/data/databriefs/db166.pdf>; Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity and Mortality Weekly Report 1445 (Dec. 30, 2016), <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

<sup>12</sup> *Drugs Involved in U.S. Overdose Deaths, 2000-2016*, Ctr. Disease Control & Prevention WONDER, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>.

2015 Utah providers wrote 73.1 opioid prescriptions per 100 persons, compared to the national average of 70 opioid prescriptions per 100 persons.<sup>13</sup>

9. Prescription opioids are no less addictive than heroin. No other medication routinely used for a nonfatal condition kills patients so frequently.<sup>14</sup>

10. The increase in opioid prescriptions to treat chronic pain correlates with an increase in the number of people seeking prescription opioids for non-medical purposes and becoming addicted.<sup>15</sup> Nationally, the number of people who take prescription opioids for non-medical purposes is now greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.<sup>16</sup> In Utah alone, data from the Substance Abuse and Mental Health Services Administration indicates that from 2012-2014, an average of 7.65% of 18 - 25 year-olds used prescription opioids for non-medical purposes.<sup>17</sup>

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<sup>13</sup> National Institute on Drug Abuse, Opioid-Related Overdose Deaths, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/utah-opioid-summary>.

<sup>14</sup> Thomas R. Frieden and Debra Houry, *New England Journal of Medicine*, *Reducing the Risks of Relief, the CDC Opioid-Prescribing Guideline*, at 1503 (Apr. 21, 2016).

<sup>15</sup> Chronic pain is often defined as any pain lasting more than 12 weeks. National Institutes of Health, NIH MedlinePlus, Spring, 2011, <https://medlineplus.gov/magazine/issues/spring11/articles/spring11pg5-6.html>.

<sup>16</sup> Substance Abuse and Mental Health Servs. Admin., *Results from the 2015 National Survey on Drug Use and Health: Detailed Tables*, <https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf>.

<sup>17</sup> Substance Abuse and Mental Health Servs. Admin., *2012-2014 National Survey on Drug Use and Health Substate Age Group Tables* 143 (2015), <https://www.samhsa.gov/data/sites/default/files/NSDUHsubstateAgeGroupTabs2014/NSDUHsubstateAgeGroupTabs2014.pdf> (in Utah, 4.15% of people age 12-15, and 3.03% of people 26+, engage in the non-medical use of prescription pain relievers).

11. This increase in non-medical demand and addiction has corresponded with an increase in “diversion.” Diversion occurs when the prescription opioid supply chain breaks and the drugs are transferred from legitimate channels to illegitimate ones.

12. The legitimate supply chain for prescription opioids begins with the manufacture and packaging of the pills. Manufacturers, including Purdue, then transfer the pills to distribution companies. Distributors then supply opioids to pharmacies and other healthcare providers, which then dispense the drugs to consumers. Diversion to illicit use can occur anywhere in the supply chain, from a distribution truck or pharmacy robbery, to a curious teenager taking pills a parent absentmindedly left accessible.

13. Of the 2.2 million opioid prescriptions issued in Utah in 2015 (nearly one prescription per Utah resident), studies suggest that as many as 281,600 of those prescriptions were diverted to non-medical uses.<sup>18</sup>

14. The extent to which opioids are diverted into illicit use is even more concerning because Utah has the second highest high-dosage opioid prescription rate in the United States.<sup>19</sup>

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<sup>18</sup> *Opioid Pain Reliever Prescriptions*, Nat’l Inst. on Drug Abuse, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/utah-opioid-summary>. The studies estimate that the percentage of prescription opioids that are diverted to illegitimate purposes ranges from 1.9 percent to 12.8 percent of total prescriptions. B.L. Wilsey et al., *Profiling Multiple Provider Prescribing of Opioids, Benzodiazepines, Stimulants, and Anorectics*, 112 *Drug and Alcohol Dependence* 99 (2010) (estimating that 12.8% of prescriptions are diverted); N. Katz et al., *Usefulness of Prescription Monitoring Programs for Surveillance—Analysis of Schedule II Opioid Prescription Data in Massachusetts, 1996–2006*, 19 *Pharmacoepidemiology and Drug Safety* 115 (2010) (estimating the diversion rate at 7.7% when defining likely diversion as patients that obtain opioids from at least 3 prescribers and at least 3 pharmacies in a year); D.C. McDonald & K.E. Carlson, *Estimating the Prevalence of Opioid Diversion by “Doctor Shoppers” in the United States*, 8 *PLoS ONE* (2013) (estimating the diversion rate at 1.9% of all prescriptions and 4% of total grams dispensed).

<sup>19</sup> *Annual Surveillance Report of Drug-Related Risks and Outcomes: United States, 2017*, Ctr. Disease Control & Prevention, 9 <https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf>.

15. In 2016, Carbon County had the highest opioid prescribing rate in Utah, at 176 prescriptions per 100 residents.<sup>20</sup> The county with the next highest prescribing rate was Sevier, with 113 prescriptions per 100 residents. By comparison, the rates in Salt Lake and Tooele Counties were 70.5 and 70.3 prescriptions per 100 residents, respectively.

16. One result is that the economic impacts of the opioid epidemic seen nation and state – wide, are even more pronounced in some of the communities least equipped to address them. Carbon County ranks 11th in the nation for the highest per-capita opioid costs, coming in at a staggering \$6,365.<sup>21</sup>

17. Utah prescribers have changed their prescribing behaviors because of Purdue’s actions. Utah prescribers prescribe more opioids for their patients than they otherwise would.

18. Utah ranked 7<sup>th</sup> in the United States for prescription drug poisoning deaths from 2013-2015, “which have outpaced deaths due to firearms, falls, and motor vehicle crashes.”<sup>22</sup>

19. The State and its agencies have been damaged by Purdue’s actions. These damages include the costs of (a) medical care, therapeutic and prescription drugs, and other treatments for patients suffering from opioid-related addiction, overdoses, or disease, or from medical conditions exacerbated by opioid abuse; (b) treatment of infants born with opioid-related addiction or medical conditions; (c) law enforcement and public safety measures necessitated by the opioid crisis; (d) opioid-related counseling and rehabilitation services; (e) welfare for

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<sup>20</sup> Centers for Disease Control and Prevention, U.S. County Prescribing Rates (2016), <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html>.

<sup>21</sup> Alex Brill & Scott Ganz, *The Geographic variation in the Cost of the Opioid Crisis*, American Enterprise Institute 5 (Mar. 2018)

<sup>22</sup> Utah Department of Health, *Prescription Drug Overdoses*, <http://health.utah.gov/vipp/topics/prescription-drug-overdoses/>.

children whose parents suffer from opioid-related disease or incapacitation; (f) expenditures under Medicaid for purchases of prescription opioids for non-medical, illegitimate, or other improper purposes; and (g) emergency room care. These costs continue to mount.

20. Utah has also suffered substantial damages relating to the lost productivity of Utah citizens and Utah businesses, and lower tax revenue for the State. Damages suffered by Utah citizens include costs of unnecessary opioid prescriptions for chronic pain treatment, out-of-pocket expenditures for medical care, and treatments related to opioids.

21. To remedy Purdue's misconduct, the State brings this action for (a) violations of Utah's Consumer Sales Practices Act; (b) nuisance; (c) negligence; (d) unjust enrichment; and (e) fraud.

22. The State seeks (a) a cease-and-desist order; (b) compensatory damages for the increased costs to Utah's healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenue; (c) civil penalties under various provisions of the Utah Code; (d) disgorgement of all amounts unjustly obtained by Purdue; (e) restitution of all expenditures by the State and state agencies resulting from Purdue's conduct; (f) an order of this Court that Purdue abate the nuisance it has created; (g) punitive damages; (h) attorneys' fees and costs; and (i) such further relief as justice may require.



## Parties

### **The State of Utah**

23. The State of Utah brings this action on its own and on behalf of its state agencies. The Attorney General is statutorily authorized to initiate and maintain this action and does so pursuant to Utah Code § 67-5-1(2).

### **Purdue**

24. Defendant Purdue Pharma L.P. (together with Purdue Pharma Inc. and The Purdue Frederick Company, “Purdue”) is a limited partnership organized and existing under the laws of the State of Delaware with its principal place of business located in Stamford, Connecticut. During all relevant times, Purdue Pharma L.P. has manufactured substantial amounts of prescription opioids that have been, and continue to be, distributed and sold in Utah. Purdue Pharma L.P. has engaged in consensual commercial dealings with Utah and its citizens and has purposefully availed itself of the advantages of conducting business with and within Utah.

25. Defendant Purdue Pharma Inc. (together with Purdue Pharma L.P. and The Purdue Frederick Company, “Purdue”) is a corporation organized and existing under the laws of New York State with its principal place of business located in Stamford, Connecticut. During all relevant times, Purdue Pharma Inc. has manufactured substantial amounts of prescription opioids that have been, and continue to be, distributed and sold in Utah. Purdue Pharma Inc. has engaged in consensual commercial dealings with Utah and its citizens and has purposefully availed itself of the advantages of conducting business with and within Utah.

26. Defendant, The Purdue Frederick Company (together with Purdue Pharma L.P. and Purdue Pharma Inc., “Purdue”) is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located in Stamford, Connecticut. During all relevant times, The Purdue Frederick Company has manufactured substantial amounts of prescription opioids that have been, and continue to be, distributed and sold in Utah. The Purdue Frederick Company has engaged in consensual commercial dealings with Utah and its citizens and has purposefully availed itself of the advantages of conducting business with and within Utah.

27. As discussed further below, Purdue has made misstatements or omitted information regarding the risks of using prescription opioids to treat chronic pain, in violation of its legal obligations.

### **Jurisdiction and Venue**

28. This Court has subject matter jurisdiction over this matter pursuant to Utah Code § 78A-5-102(1).

29. The Attorney General has authority to bring this action pursuant to Utah Code § 67-5-1(2), 76-1-806, and 13-11-17(1).

30. This Court has personal jurisdiction over Purdue because each Defendant entity is, or was during the relevant time period, licensed to do business in Utah; is transacting or has transacted business in Utah; or has other significant contacts with Utah. Each Defendant has sufficient contacts with Utah to give rise to the current action, has continuous and systematic contacts with Utah, or has consented either explicitly or implicitly to the jurisdiction of this Court.

31. Venue is proper in Carbon County because none of the defendants resides in the State of Utah, and the plaintiff, the State of Utah, here designates Carbon County to commence and try the action. Utah Code § 78B-3-307(3). And, some part of the cause of action arose in Carbon County. Utah Code § 78B-3-307(1). To the extent the State seeks any relief properly considered a fine or penalty, venue is proper in Carbon County because the cause, or some part of the cause, arose in Carbon County. Utah Code § 78B-3-302(2).

### **Factual Background**

#### **1. Prescription opioids are dangerous.**

32. Prescription opioids are powerful pain-reducing medications that include non-synthetic, partially-synthetic, and fully-synthetic derivatives of the opium poppy. While these drugs can have benefits when used properly, and under appropriate medical supervision, they also pose serious risks. In particular, government agencies have warned that opioids present “substantially increase[d]” risk when used to treat chronic pain and “can cause serious harm, including addiction, overdose and death” when “misused or abused.”<sup>23</sup>

33. Given these risks, the marketing, distribution, and sale of prescription opioids are heavily regulated under Utah and federal law. Utah’s Pharmacy Practice Act, Utah Code § 58-17b-101, *et seq.*, Utah’s Controlled Substances Act, Utah Code § 58-37-1, *et seq.*, and numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances provide strict controls and requirements throughout the opioid distribution chain. These provisions of Utah law also incorporate and reference federal law regarding the marketing,

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<sup>23</sup> *Opioid Medications*, Food and Drug Admin., <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm>.

distribution, and sale of prescription opioids, including the Federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321, *et seq.*

34. As discussed below, despite the dangers of prescription opioids, Purdue wrongfully marketed them through misleading statements that minimized the risk of these drugs and failed to disclose accurately the true magnitude of those risks. Purdue's actions created an inflated market for prescription opioids, which in turn led to massive diversion of these drugs from legitimate to illegitimate channels. As a result of Purdue's wrongful acts, Utah and its citizens suffered injuries and damages.

## **2. Purdue has legal duties to accurately disclose the risks of opioids.**

35. Purdue has a legal obligation under Utah statutory and common law to exercise reasonable care in the marketing, promotion, and sale of opioids. Purdue knew, or should have known that its misleading and aggressive marketing efforts created an unreasonable risk of harm.

36. Under Utah law, those acting under a pharmacy license, such as Purdue, engage in unprofessional conduct by "misbranding or adulteration of any drug or device or the sale, distribution, or dispensing of any outdated, misbranded, or adulterated drug or device." Utah Code § 58-17b-502(3). The referenced chapter defines a misbranded drug or device as a drug or device misbranded under 21 U.S.C. Sec. 352 (2003). Utah Code § 58-17b-102(38).

37. The Federal Food, Drug, and Cosmetic Act defines misbranding to include misleading advertising. *See* 21 U.S.C. § 302(n). It further defines misleading advertising to include both "representations made or suggested by statement, word, design, device, or any combination thereof," and:

The extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may

result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

38. Purdue also has a common law duty to make a full and fair disclosure as to the matters about which it chooses to speak.

### **3. Purdue violated its duties.**

#### **3.1. Purdue made misleading statements about the risks of prescribing opioids to treat chronic pain and failed to state accurately the magnitude of those risks.**

39. In the mid-1990s, at about the time Purdue introduced its drug OxyContin to the marketplace, 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.<sup>24</sup>

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

40. The medical community knew that published reports associated opioid use “with heightened pain and functional impairment, neuropsychological toxicity, prevarication about

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<sup>24</sup> Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt, 247 (1994).

drug use, and poor treatment response.”<sup>25</sup> 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.”<sup>26</sup>

41. 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.”<sup>27</sup>

42. Dr. Portenoy claimed that the lack of evidence should not deter doctors from prescribing opioids, arguing there was a lack of data that non-malignant pain generally, or any patient subgroup with non-malignant pain (such as those with neuropathic pain, low back pain, headache, or idiopathic pain), are inherently unresponsive to opioid drugs. Consequently, he believed, therapy could not be withheld based on the *a priori* assumption that any particular pain or patient group will inevitably fail to benefit.<sup>28</sup>

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<sup>25</sup> Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A Review of the Critical Issues*, 11 J. Pain & Symptom Mgmt. 203, 206 (1996)

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

43. 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.<sup>29</sup>

44. Purdue seized on Dr. Portenoy's work. 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.

45. 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" 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. 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 Utahns who have suffered as a result, untrue.

46. Purdue has made statements through websites, promotional materials, conferences, guidelines for doctors, and other vehicles that suggested that the risk of opioid

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<sup>29</sup> *Id.*

addiction when used for chronic pain was low — statements directly contrary to established scientific evidence.

47. Purdue’s marketing claims also differ from the safety warnings that Purdue must place on many of its opioid products. In fact, Purdue has been repeatedly fined or otherwise sanctioned for its misleading statements in marketing opioids.

### **3.2. Purdue seeded the science of opioid efficacy and risk with flawed and biased research.**

48. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific support for its marketing claims by sponsoring studies that were methodologically flawed, and biased, and which drew inappropriate conclusions from prior evidence. It then published studies with favorable outcomes and suppressed the problematic ones. The result was a body of literature whose primary purpose was to promote the use of opioids for chronic pain but which was passed off as legitimate scientific research. Subsequent studies then cited—and continue to cite—this research to insidious effect: the body of evidence on which physicians rely to prescribe opioids now fully incorporates Purdue’s skewed science.

49. For example, Purdue-sponsored studies, and Purdue marketing materials that cited them, regularly made claims that the risk of psychological dependence or addiction is low absent a history of substance abuse.

50. One such study, published in the journal *Pain* in 2003 and widely referenced since (with nearly 600 citations in Google Scholar),<sup>30</sup> ignored previous **Purdue-commissioned** research showing addiction rates between 8% and 13%—far higher than Purdue acknowledged

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<sup>30</sup> C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 *Pain* 71 (2003).



was possible in its mainstream marketing. Purdue relegated those earlier studies to less-prominent headache journals, where it knew they would be less widely read.<sup>31</sup>

51. Instead, to support the claim that OxyContin rarely was addictive, the *Pain* article reached back to a 1980 letter to the editor—not an article, but a letter—in the *New England Journal of Medicine*.

52. That letter, the “Porter-Jick Letter,” appeared as follows:<sup>32</sup>

**ADDICTION RARE IN PATIENTS TREATED  
WITH NARCOTICS**

*To the Editor:* Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients<sup>1</sup> who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,<sup>2</sup> Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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Surveillance Program

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53. The Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. The Porter-Jick Letter notes that the review found almost no references to signs of addiction, though there is no indication that staff were instructed to assess or document signs of addiction. And because the opioids were

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<sup>31</sup> Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) *Headache Quarterly* 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 *Headache Quarterly* 305 (1999).

<sup>32</sup> J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New England Journal of Medicine* 123 (1980).

administered in a hospital, there was no risk of patients taking more or higher doses than were prescribed.

54. The Porter-Jick Letter has become a mainstay in scientific literature, with more than 1,000 citations in Google Scholar. Purdue, for example, has cited it in support of Purdue’s patently false marketing claim that “less than 1%” of opioid patients become addicted, most prominently in its 1998 “I Got My Life Back” video. Yet Purdue failed to disclose either the nature of the citation (a letter, not a study) or any of its serious limitations. Dr. Jick later complained that drug companies “pushing out new pain drugs” had misused the Letter—citing it to conclude that their opioids were not addictive, even though “that’s not in any shape or form what we suggested in our letter.”<sup>33</sup> In June 2017, the *New England Journal of Medicine*, citing a new analysis of the Porter-Jick Letter’s citation history, added this editor’s note to its online version of the Letter: “For reasons of public health, readers should be aware that this letter has been ‘heavily and uncritically cited’ as evidence that addiction is rare with opioid therapy.”

55. Purdue published other research supporting chronic opioid therapy that was just as flawed as the 2003 *Pain* article. One such Purdue-sponsored study, which featured two Purdue-employed authors and appeared in the *Journal of Rheumatology* in 1999, misleadingly suggested that OxyContin was safe and effective as a long-term treatment for osteoarthritis.<sup>34</sup> Patients were given OxyContin only for 30 days, only 106 of the 167 patients continued the

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<sup>33</sup> National Public Radio, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis*, (June 16, 2017), <http://www.npr.org/sections/healthshots/2017/06/16/533060031/>.

<sup>34</sup> 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*, 26:4 *Journal of Rheumatology* 862-868 (1999).

study after their appropriate dose was determined, and most who left did so due to ineffective pain control or side effects from the drug. While acknowledging the short-term nature of the trial, the authors still drew the unsupported conclusion 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 managing patients with opioids longterm.”

56. Another Purdue-authored study, published in the *Clinical Journal of Pain* in 1999, misleadingly implied that OxyContin was safe and effective as a long-term treatment of back pain.<sup>35</sup> This study, too, had a high dropout rate and, though it concerned a chronic condition, it followed patients on OxyContin only between four and seven days. The study was not set up to consider long-term risks, including the risk of addiction, but blithely concluded that “common opioid side effects can be expected to become less problematic for the patient as therapy continues.”

### **3.3. Purdue worked with professional associations to create treatment guidelines that overstated the benefits and understated the risks of opioids.**

57. Treatment guidelines were particularly important to Purdue in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Treatment guidelines not only directly inform doctors’ prescribing practices, but also are cited throughout the scientific literature and referenced by third-party payors in determining whether they should

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<sup>35</sup> Martin E. Hale et al., *Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain*, 15(3) *Clinical Journal of Pain* 179-183 (Sept. 1999).

cover prescriptions. Purdue financed and collaborated with two groups, in particular, on guidelines that have been, and continue to be, broadly influential in Utah and nationwide.

### **3.3.1. AAPM/APS Guidelines**

58. The American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) each received substantial funding from Purdue.

59. In 1997, AAPM and APS issued a consensus statement, “The Use of Opioids for the Treatment of Chronic Pain,” that endorsed using opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was, at the time, a paid speaker for Purdue and later became a senior executive for the company. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011. The statement was taken down from AAPM’s website only after a doctor complained, though it lingers on elsewhere on the internet.

60. AAPM and APS also issued a 2001 set of recommendations, titled “Definitions Related to the Use of Opioids for the Treatment of Pain,” that advanced the unsubstantiated concept of “pseudoaddiction.” The term, coined by Dr. Haddox in a 1989 journal article, reflects the idea that signs of addiction may actually be the manifestation of undertreated pain and will resolve once the pain is effectively treated—i.e., with more or higher doses of opioids.<sup>36</sup> The 2001 AAPM/APS recommendations claimed “clock-watch[ing],” “drug seeking,” and “[e]ven such behaviors as illicit drug use and deception can occur in the patient’s efforts to obtain [pain] relief.”

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<sup>36</sup> David E. Weismann & J. David Haddox, *Opioid Pseudoaddiction—an Iatrogenic Syndrome*, 36 *Pain* 363-366 (1989).

61. The 2016 CDC Guideline rejects the concept of pseudoaddiction, explaining that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use” and that physicians should “reassess[] pain and function within 1 month” to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”<sup>37</sup>

62. In 2009, AAPM and APS issued comprehensive opioid prescribing guidelines (“2009 AAPM/APS Guidelines”), drafted by a 21-member panel, that promoted opioids as “safe and effective” for treating chronic pain. The panel made what it termed “strong recommendations” despite “low quality evidence,” and concluded that the risk of addiction is manageable for patients, even patients with a prior history of drug abuse.

63. Six of the panel members, including Dr. Portenoy, received financial backing from Purdue, and another eight received funding from other opioid manufacturers. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions that drug companies, including Purdue, made to the sponsoring organizations and committee members.

64. The 2009 AAPM/APS Guidelines were reprinted in the *Journal of Pain*, were distributed by Purdue sales representatives to prescribers, and have been relied upon by Utah prescribers in their practices. The guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific

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<sup>37</sup> 2016 CDC Guideline at 13, 25.

evidence on opioids. According to Google Scholar, the guidelines have now been cited nearly 1,700 times in academic literature.

### **3.3.2. FSMB Guidelines**

65. The Federation of State Medical Boards (“FSMB”) is an association of the various state medical boards in the United States. The FSMB has financed opioid- and pain-specific programs through grants from pharmaceutical manufacturers, including more than \$800,000 from Purdue between 2001 and 2008.

66. In 1998, the FSMB developed its Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“FSMB Guidelines”), which the FSMB acknowledged were produced “in collaboration with” pharmaceutical companies and allied groups such as the APS.<sup>38</sup> The FSMB Guidelines described opioids as “essential” for treatment of chronic pain, including as a first-line option; failed to mention risks of respiratory depression and overdose; addressed addiction only to define the term as separate from physical dependence; and state that an “inadequate understanding” of addiction can lead to “inadequate pain control.”

67. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from them, *Responsible Opioid Prescribing*, repeated the 1998 version’s claims. The book also claimed that opioids would improve patients’ function and endorsed the dangerous, now-discredited concept of pseudoaddiction, suggesting that signs of addiction may actually reflect undertreated pain that should be addressed with more opioids.

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<sup>38</sup> FSMB, *Position of the FSMB in Support of Adoption of Pain Management Guidelines*, (1998), [https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/1998\\_grpol\\_Pain\\_Management\\_Guidelines.pdf](https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/1998_grpol_Pain_Management_Guidelines.pdf).

68. *Responsible Opioid Prescribing* was sponsored by Purdue, among other opioid manufacturers, and Purdue had editorial input into its contents.

69. Through at least 2015, the FSMB website described the book as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationwide through state medical boards and non-profit organizations.

70. “A Policymaker’s Guide to Understanding Pain & Its Management,” an October 2011 American Pain Foundation pamphlet “made possible by support from Purdue Pharma LP,” asserted that “[l]ess than 1 percent of children treated with opioids become addicted” and that pain was generally “undertreated” due to “misconceptions about opioid addiction.”<sup>39</sup> Similarly, “Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain,” a February 2009 article funded by the American Pain Society and written by several authors with financial ties to Purdue, promoted opioids as “safe and effective” for chronic pain treatment and indicated that the risk of addiction was manageable for all patients regardless of past drug abuse history.<sup>40</sup> Likewise, in 2002 testimony to the Senate, the American Pain Foundation claimed that addiction is rare, limited to certain extreme cases, and “no additional legislation is needed to attack the diversion and abuse of all opioid pain medications.”<sup>41</sup>

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<sup>39</sup> *A Policymaker’s Guide to Understanding Pain & Its Management*, Am. Pain Found. 6 (Oct. 2011), <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

<sup>40</sup> Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 *The J. of Pain* 113 (Feb. 2009), <http://dx.doi.org/10.1016/j.jpain.2008.10.008>.

<sup>41</sup> *Testimony by the American Pain Foundation: Senate Health, Education, Labor and Pensions Committee Hearing to Examine the Effects of the Painkiller OxyContin, Focusing on Risks and Benefits*, 2 (Feb. 12, 2002) (statement of John D. Giglio, Executive Director American Pain Foundation).

71. Purdue produced and provided directly to doctors and patients marketing materials that made similar misstatements. Purdue issued marketing materials, starting in 1996, stating that “addiction to opioids legitimately used in the management of pain is very rare.”<sup>42</sup>

72. Purdue trained salesmen to minimize the risk of addiction when discussing opioids with doctors. For instance, Purdue salesmen were instructed to tell doctors that opioids’ addiction risk was “less than one percent.”<sup>43</sup>

73. Purdue sponsored training sessions where doctors were given similar misleading information regarding the risks of opioid addiction. For example, Purdue sponsored training sessions in the late 1990s and early 2000s where opioid addiction was described as “exquisitely rare.”<sup>44</sup>

74. All of these statements were contrary to scientific facts. The CDC has directly contradicted Purdue’s representations that opioid addiction is rare when opioids are used properly. The CDC has stated that there is “extensive evidence” of the possible harms of opioids, including opioid use disorder, overdose, motor vehicle injury, and stated that “[o]pioid pain medication use presents serious risks” including addiction; and highlighted that using opioids to treat chronic pain “substantially increases” the risk of addiction.<sup>45</sup> A 2016 CDC guideline

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<sup>42</sup> Drug Label for Oxycodone Hydrochloride 5mg Capsule, <https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=4106>.

<sup>43</sup> U.S. Gov’t Accountability Office, GAO-04-110, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* 22 (Dec. 2003), <https://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/content-detail.html>.

<sup>44</sup> Barry Meier, *Pain Killer: A “wonder” drug’s trail of addiction and death* 190 (2003).

<sup>45</sup> Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 *Morbidity and Mortality Weekly Report* 1 (2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.



discusses studies that found that as many as 26% of long-term users of opioids experience problems with addiction or dependence.<sup>46</sup>

75. Moreover, in August 2016, the U.S. Surgeon General published an open letter to physicians nationwide, worrying that “heavy marketing to doctors” had led many to be “taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.”<sup>47</sup> This letter also noted the “devastating” results that followed from this misinformation.<sup>48</sup>

76. Findings by the Food and Drug Administration (“FDA”) similarly belie Purdue’s assertions that opioids are safe for treating chronic pain. These findings show that (1) “most opioid drugs have ‘high potential for abuse’”; (2) treatment of chronic pain with opioids poses “known serious risks,” including “addiction, abuse, and misuse ... overdose and death” even when used “at recommended doses”; and (3) opioids should be used only “in patients for whom alternative treatment options” have failed.<sup>49</sup> And several published clinical studies finding double-digit rates of prescription drug abuse in chronic pain patients controvert Purdue’s claims that addiction rates are only one percent.<sup>50</sup>

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<sup>46</sup> *Id.*

<sup>47</sup> Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), <https://perma.cc/VW95-CUYC>.

<sup>48</sup> *Id.*

<sup>49</sup> Food and Drug Admin., Letter from Janet Woodcock, M.D., Dir. of Center for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), [http://www.supportprop.org/wp-content/uploads/2014/12/FDA\\_CDOR\\_Response\\_to\\_Physicians\\_for\\_Responsible\\_Opioid\\_Prescribing\\_Partial\\_Petition\\_Approval\\_and\\_Denial.pdf](http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDOR_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf).

<sup>50</sup> Caleb J. Banta-Green et al., *Opioid Use Behaviors, Mental Health and Pain— Development of a Typology of Chronic Pain Patients*, 104 *Drug and Alcohol Dependence* 34 (Sept. 2009), <http://dx.doi.org/10.1016/j.drugalcdep.2009.03.021>; Joseph A. Boscarino et al., *Risk Factors for Drug Dependence Among Out-Patients on Opioid Therapy in a Large US Health-Care System*, 105 *Addiction* 1776 (Oct. 2010), <http://dx.doi.org/10.1111/j.1360-0443.2010.03052.x>; Jette Højsted et al., *Classification and Identification of Opioid*

77. Similarly, a prominent neuropharmacologist at the Washington University School of Medicine in St. Louis, Missouri, Dr. Theodore Cicero, remarked in 2016 that Purdue’s OxyContin dosing is “the perfect recipe for addiction” due to its encouragement of psychological and physical withdrawal symptoms.<sup>51</sup>

78. As recently as June 2017, the New England Journal of Medicine published an analysis finding that Purdue’s introduction of OxyContin into the marketplace coincided with a significant increase in misleading dissemination of the claim that addiction to opioids is rare. Moreover, the authors of the June 2017 analysis concluded that “[w]e believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy.”<sup>52</sup>

### **3.4. Purdue falsely claimed that there was no risk in increasing opioid dosages to treat chronic pain.**

79. Purdue also falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk. Guidelines edited and sponsored by Purdue and another opioid manufacturer, Endo<sup>53</sup>—namely “Treatment Options: A Guide for People Living with Pain” (2006) and “A Policymaker’s Guide to Understanding Pain & Its Management” (2011)—

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*Addiction in Chronic Pain Patients*, 14 *European J. of Pain* 1014 (Nov. 2010), <http://dx.doi.org/10.1016/j.ejpain.2010.04.006>.

<sup>51</sup> Harriet Ryan, “You Want a Description of Hell?” *OxyContin’s 12-Hour Problem*,” *Los Angeles Times*, May 5, 2016, <http://www.latimes.com/projects/oxycontin-part1/>.

<sup>52</sup> Pamela T. M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 *New England J. of Med.* 2194 (June 1, 2017), <http://www.doi.org/10.1056/NEJMc1700150>.

<sup>53</sup> Am. Pain Found., *Annual Report* (2010), <https://www.documentcloud.org/documents/277604-apf-2010-annual-report>.

claim that (a) some patients “need” a larger opioid dose, regardless of the dose prescribed; (b) opioids have “no ceiling dose” and are therefore the most appropriate treatment for severe pain; and (c) dosage escalations, even unlimited ones, are “sometimes necessary.”<sup>54</sup>

80. As recently as June 2015, Purdue’s “In the Face of Pain” website was promoting the notion that if a patient’s doctor does not prescribe what, in the patient’s view, is a sufficient dosage of opioids, the patient should find another doctor who will. Also in 2015, Purdue presented a paper at the College on the Problems of Drug Dependence, challenging the correlation between opioid dosage and overdose.<sup>55</sup> And in 2016, Purdue’s Dr. Haddox falsely claimed that evidence does not show that Purdue’s opioids are being abused in large numbers.

81. Purdue made these statements despite strong contrary scientific evidence. The FDA has stated that the available data “suggest a relationship between increasing opioid dose and risk of certain adverse events.”<sup>56</sup> The CDC has stated that there is “an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages,” and has

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<sup>54</sup> Am. Pain Found., *Treatment Options: A guide for people living with pain* (2006), <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>; Am. Pain Found., *A Policymaker’s Guide to Understanding Pain & Its Management* (Oct. 2011), <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

<sup>55</sup> A. DeVeugh-Geiss et al., *Is Opioid Dose a Strong Predictor of the Risk of Opioid Overdose?: Important confounding factors that change the dose-overdose relationship*, CPDD 76th Annual Scientific Meeting Program (June 2014), <http://cpdd.org/wp-content/uploads/2016/07/2014CPDDprogrambook.pdf>.

<sup>56</sup> Food and Drug Admin., Letter from Janet Woodcock, M.D., Dir. of Center for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), [http://www.supportprop.org/wp-content/uploads/2014/12/FDA\\_CDERR\\_Response\\_to\\_Physicians\\_for\\_Responsible\\_Opioid\\_Prescribing\\_Partial\\_Petition\\_Approval\\_and\\_Denial.pdf](http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDERR_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf).

specifically recommended that doctors “avoid increasing doses” above 90 morphine milligram equivalents (“MME”) per day.<sup>57</sup>

82. Nonetheless, Purdue misrepresented the effects of escalating dosages to further its relentless pursuit of corporate profit. The ability to escalate dosages was critical to Purdue’s efforts to market opioids for chronic pain treatment because doctors would otherwise abandon treatment when patients built up tolerance and no longer obtained pain relief. And for at least some products, escalation of dosage was key: of the seven available OxyContin tablet strengths, the three strongest—40 milligrams (120 MME), 60 milligrams (180 MME), and 80 milligrams (240 MME)—all exceed the CDC limit by 2.5 to 5.3 times, even taken twice per day as directed.

### **3.5. Purdue’s misleading statements were designed for maximum effect and targeted to specific audiences.**

83. Purdue disseminated these misstatements to doctors through a wide array of sources, each designed to maximize impact and each targeted to a specific receptive audience.

84. Purdue often delivered its misstatements through “key opinion leaders”—doctors in the field of pain management who were heavily funded by Purdue. Purdue frequently used opinion leaders to deliver its message because it knew that doctors often place great confidence in seemingly independent peers.

85. One notable opinion leader was Dr. Russell Portenoy, who held himself out as an unbiased expert on opioids but received substantial funding from Purdue. Dr. Portenoy gave, in

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<sup>57</sup>Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

his words, “innumerable” lectures and media appearances promoting opioids.<sup>58</sup> During these appearances, he routinely downplayed the dangers of opioids. In 2010, he said on Good Morning America that “[a]ddiction, when treating pain, is distinctly uncommon” and that “most doctors can feel very assured that that person is not going to become addicted.” He also regularly repeated—including in a 1986 paper published in the journal of the American Pain Society, a 1996 paper written on behalf of the American Pain Society and the American Academy of Pain, and numerous lectures—the unsubstantiated claim that the addiction risk posed by opioids was lower than one percent.<sup>59</sup> Dr. Portenoy later conceded that some of his statements were misleading. In December 2012, he was quoted as saying, “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did.”<sup>60</sup>

86. Between 2001 and 2010, Purdue’s “In the Face of Pain” website similarly presented the statements of opinion leaders who were portrayed as independent experts, including Dr. Portenoy and other doctors associated with the American Pain Foundation. The website not only failed to disclose that Purdue had paid many of these opinion leaders for other

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<sup>58</sup> Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

<sup>59</sup> Russell Portenoy, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25 Pain 171 (May 1986), <https://www.ncbi.nlm.nih.gov/pubmed/2873550>; Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A review of the critical issues*, 11 J. of Pain and Symptom Mgmt. 203 (Apr. 1996), [http://dx.doi.org/10.1016/0885-3924\(95\)00187-5](http://dx.doi.org/10.1016/0885-3924(95)00187-5); Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain*, 1 Pain Research and Mgmt. 17 (1996), <http://downloads.hindawi.com/journals/prm/1996/409012.pdf>.

<sup>60</sup> Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

work, but also did not identify Purdue’s involvement beyond a small copyright notice at the bottom of the website.<sup>61</sup>

87. Purdue also often disseminated its misstatements through industry groups that presented themselves to the public as independent patient advocacy organizations, but whose content and funding came largely from Purdue. These groups included the American Pain Foundation, the American Pain Society, and the American Academy of Pain Medicine. Much like the opinion leaders, these industry groups allowed Purdue to present its misstatements as if they came from unbiased experts.

88. These groups published many of the misleading “guidelines” described above, based on content and funding provided by Purdue, including: (1) “Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain” (2009);<sup>62</sup> (2) “A Policymaker’s Guide to Understanding Pain & Its Management” (2011);<sup>63</sup> and (3) “Treatment Options: A Guide for People Living with Pain” (2006).<sup>64</sup> In 2007, the American Pain Society repeated, at a Senate Judiciary Committee hearing, Purdue’s misstatements that addiction was a “rare problem” for

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<sup>61</sup> Advocacy Voices, In the Face of Pain (archived Nov. 7, 2010), <https://web.archive.org/web/20101107090355/http://www.inthefaceofpain.com:80/search.aspx?cat=4#7>.

<sup>62</sup> Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 *The J. of Pain* 113 (Feb. 2009), <http://dx.doi.org/10.1016/j.jpain.2008.10.008>.

<sup>63</sup> Am. Pain Found., *A Policymaker’s Guide to Understanding Pain & Its Management* (Oct. 2011), <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

<sup>64</sup> Am. Pain Found., *Treatment Options: A guide for people living with pain* (2006), <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

patients using opioids for chronic pain and that there was “no causal effect ... between the marketing of [a particular opioid] and the abuse and diversion of the drug.”<sup>65</sup>

89. Purdue also conducted conferences, training sessions, and educational programs for doctors, often with all expenses paid at resort destinations. These events were useful to Purdue because studies show that such events influence the attending practitioners’ prescribing habits and views towards a drug.<sup>66</sup>

90. From 1996 to 2001, Purdue conducted more than 40 pain management and speaker training sessions at resorts to recruit and train physicians, nurses, and pharmacists as speakers on behalf of Purdue.<sup>67</sup> Purdue trained more than 5,000 people at these all-expenses-paid events.<sup>68</sup> In addition, the DEA has estimated that Purdue funded over 20,000 opioid pain-related educational programs between 1996 and July 2002 through direct sponsorship or financial grants.<sup>69</sup>

91. Purdue also used direct salesmen to market opioids. These salesmen often received the majority of their compensation based on individual sales figures, ensuring that they

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<sup>65</sup> *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Hearing Before the S. Comm. on Judiciary*, 110th Cong. 1 (2007) (Statement of James Campbell, M.D.).

<sup>66</sup> Ray Moynihan, *Doctors’ Education: The invisible influence of drug company sponsorship*, 336 *The BMJ* 416 (Feb. 23, 2008), <http://dx.doi.org/10.1136/bmj.39496.430336.DB>; A.C. Anand, *Professional Conferences, Unprofessional Conduct*, 67 *Medical J. Armed Forces India* 2 (Jan. 2011), [http://dx.doi.org/10.1016/S0377-1237\(11\)80002-X](http://dx.doi.org/10.1016/S0377-1237(11)80002-X); David McFadden et al., *The Devil Is in the Details: The pharmaceutical industry’s use of gifts to physicians as marketing strategy*, 140 *J. of Surgical Research* 1 (2007), <http://dx.doi.org/10.1016/j.jss.2006.10.010> .

<sup>67</sup> U.S. Go’t Accountability Office, *Prescription Drugs: OxyContin abuse and diversion and efforts to address the problem* 22 (Dec. 2003), <https://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/content-detail.html>.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.* at 23.

were strongly motivated to present their audiences with misleading information minimizing the risks of opioids.<sup>70</sup>

92. Purdue not only issued misstatements through channels thought to be the most productive, but also targeted marketing to doctors who would be most receptive to the misstatements.

93. Purdue specifically targeted its marketing to primary care physicians, who are generally less aware of the medical literature regarding the dangers of treating chronic pain with opioids. One longtime Purdue collaborator speaking to an FDA advisory panel on January 30, 2002 acknowledged this fact, stating that “[g]eneralists are adopting [opioid] therapy without adequate knowledge of pain management principles.”<sup>71</sup> On information and belief, Purdue also directly targeted susceptible patients like veterans and the elderly.

94. Purdue developed methods to specifically target physicians who were already prescribing higher-than-average numbers of opioids. Purdue created a database to identify physicians with large numbers of chronic-pain patients (which also showed which physicians were simply the most frequent prescribers of opioids). This database has given Purdue extensive knowledge of where and how its drugs are being used across the country, including in Utah, and has allowed Purdue to target doctors already susceptible to its message.<sup>72</sup>

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<sup>70</sup> *Id.* at 22.

<sup>71</sup> Food and Drug Admin., Anesthetic and Life Support Drugs Advisory Comm., Tr. of Meeting 119 (Jan. 30, 2002), <http://wayback.archive-it.org/7993/20170404083838/https://www.fda.gov/ohrms/dockets/ac/02/transcripts/3820t1.pdf>.

<sup>72</sup> Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial triumph, public health tragedy*, 99 Am. J. of Public Health 221, 222 (Feb. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf>.



### 3.6. Purdue knew or should have known that its statements were misleading.

95. The problems engendered by the deceptive and unfair marketing of opioids were specifically known by Purdue. Purdue was aware that its statements were misleading not only because it knew these statements were contrary to established fact, but also because it was fined and otherwise sanctioned by various government entities for its misleading marketing.

96. Purdue has been aware that its long-acting opioids are susceptible to misuse, diversion into illicit channels, and abuse since the late 1990's.<sup>73</sup>

97. In 2007, Purdue settled federal allegations that it had introduced misbranded drugs into interstate commerce. The settlement included over \$700 million in payments to the United States and guilty pleas by three of Purdue's former executive officers.<sup>74</sup> Purdue acknowledged that "some employees made, or told other employees to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the FDA-approved prescribing information for OxyContin and the express warning it contained about risks associated with the medicine."<sup>75</sup>

98. On August 20, 2015, New York State concluded a multiyear investigation of Purdue and settled claims against the company related to its marketing and sales practices. Specifically, the agreement required Purdue to ensure that its sales representatives flag doctors

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<sup>73</sup> Barry Meyer, *Origins of an Epidemic: Purdue Pharma Knew its Opioids Were Widely Abused*, New York Times, (May 29, 2018), <https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html>.

<sup>74</sup> *Id.*; Plea Agreement at 4, *United States of America v. The Purdue Frederick Co., Inc.*, Case No. 1:07-cr-00029-JPJ (W.D. Va. May 10, 2017), <http://i.bnet.com/blogs/purdue-agreed-facts.pdf>.

<sup>75</sup> Shannon Henson, *Purdue, Employees to Pay \$700M in OxyContin Case*, LAW360, (May 10, 2007, 12:00 AM), <https://www.law360.com/illinois/articles/24509/purdue-employees-to-pay-700m-in-oxycontin-case>.

and other professionals who were improperly prescribing and/or diverting opioids, stop calling and/or marketing to doctors on the company’s “no-call list,” and provide information to health care providers about FDA-approved training programs regarding the appropriate prescription of opioids. The agreement also required Purdue to cease marketing representations on its website “www.inthefaceofpain.com” implying that the website was neutral or unbiased, and to disclose the financial relationships Purdue’s purported neutral experts have with the company.<sup>76</sup>

99. In August 2017, Purdue settled, for over \$20 million, claims by numerous Canadian plaintiffs that the company failed to warn about the dangers of OxyContin, including its addictive properties.<sup>77</sup>

100. Purdue has also represented to the public that it is taking steps to curb the opioid epidemic, rather than creating it.

101. As recently as November 2017, Purdue stated on its website that “...too often these medications [opioids] are diverted, misused, and abused. Teenagers, in particular, are vulnerable to prescription drug abuse, which has become a national epidemic.”<sup>78</sup> In response to

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<sup>76</sup> Press Release, N.Y. State Office of the Attorney General, A.G. Schneiderman Announces Settlement With Purdue Pharma That Ensures Responsible And Transparent Marketing Of Prescription Opioid Drugs By The Manufacturer (August 20, 2015), <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent>.

<sup>77</sup> Will Davidson LLP, *Purdue Pharma Agrees to OxyContin Settlement, but Is it Fair?*, Lexology (Aug. 22, 2017), <https://www.lexology.com/library/detail.aspx?g=d53ee1ee-44cb-4ef5-b916-e570a385b568>.

<sup>78</sup> Purdue Pharma, *Combating Opioid Abuse*, <http://webcache.googleusercontent.com/search?q=cache:yQnPIZfguWAJ:www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/combating-opioid-abuse/+&cd=1&hl=en&ct=clnk&gl=us>.

the misuse of opioids, Purdue said that “Corporations have a responsibility to address this issue, and Purdue has dedicated vast resources for helping to prevent drug abuse...”<sup>79</sup>

102. Purdue also stated in November 2017 that it is “committed to being part of the solution to prescription drug abuse” and that it “offers an array of programs focused on education, prevention, and deterrence and through partnerships with (1) healthcare professionals, (2) families and communities, and law enforcement and government” to combat the “widespread abuse of opioid prescription pain medications [that] can lead to tragic consequences, including addiction, overdose, and death.”<sup>80</sup>

103. Also in November 2017, Purdue discussed the opioid epidemic and its response to it, stating that “The nation is experiencing a public health crisis involving licit and illicit opioids. Purdue endorses the following policies that support a comprehensive approach to reducing addiction, abuse, diversion, and overdose related to opioids.”<sup>81</sup> The policies employed by Purdue include limiting the duration of a patient’s first opioid prescription; use of prescription drug monitoring programs; requiring demonstrated competence for opioid prescribing; and expanding the use of naloxone, an opioid reversal agent, among other things.<sup>82</sup>

104. However, on information and belief, these representations are untrue. For example, notwithstanding its public statements of corporate responsibility, Purdue has failed to

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<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> Purdue Pharma, *Public Policies to Address the Opioid Crisis*, <http://www.purduepharma.com/about/purdue-pharma-public-policy/>.

<sup>82</sup> *Id.*

report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its “constructive role in the fight against opioid abuse” and “strong record of coordination with law enforcement.”<sup>83</sup>

105. Additionally, since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. According to Purdue, physicians could be added to this database based on observed indicators of illicit prescribing, such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing volume. Purdue has said publicly that “[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company’s interaction with the prescriber or pharmacist and initiate an investigation.”<sup>84</sup>

106. Yet, according to a 2016 investigation by the *Los Angeles Times*, Purdue failed to cut off these providers’ opioid supply at the pharmacy level and failed to report these providers to state medical boards or law enforcement — meaning Purdue continued to generate sales revenue from their prescriptions.<sup>85</sup>

107. The *Times*’ investigation also found that “for more than a decade, Purdue collected extensive evidence suggesting illegal trafficking of OxyContin” and yet consistently

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<sup>83</sup> Purdue Pharma L.P., *Setting the Record Straight on OxyContin’s FDA-Approved Label* (May 5, 2016), <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontin-fda-approved-label/>; Purdue Pharma L.P., *Setting the Record Straight on Our Anti-Diversion Programs* (July 11, 2016), <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/>.

<sup>84</sup> *Id.*

<sup>85</sup> See Harriet Ryan et al., *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

failed to report suspicious dispensing or to stop supplies to the pharmacy.<sup>86</sup> Despite its knowledge of illicit prescribing, Purdue did not report its suspicions, for example, until years after law enforcement shut down a Los Angeles clinic that Purdue’s district manager described internally as “an organized drug ring” and that had prescribed more than 1.1 million OxyContin tablets.<sup>87</sup>

### **3.7. Purdue’s conduct violated its duties.**

108. Purdue has continued to promote, directly and indirectly, deceptive marketing messages that misrepresent, and fail to include material facts about, the dangers of opioid usage in Utah, despite actual or constructive knowledge that the opioids were ultimately being consumed by Utah citizens for unsafe and non-medical purposes.

109. Purdue has negligently or recklessly failed to control adequately the content and distribution of marketing materials and sales efforts regarding opioids. A reasonably prudent manufacturer of opioids would have anticipated the dangers of widely advertising and distributing dangerous opioid products and protected against it. A reasonably prudent manufacturer could have (a) ensured physicians were judicious in considering when to prescribe opioids; (b) carefully worded its marketing materials to ensure the risks of opioids were clearly communicated; (c) conducted and publicized scientific studies testing the risks of opioid products; (d) taken greater care in hiring, training, and supervising employees responsible for marketing and selling opioid products; (e) investigated demographic or epidemiological data

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<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

concerning the increasing demand for narcotic painkillers in Utah and the linkage of that demand with Purdue's marketing efforts; and (f) followed applicable statutes, regulations, professional standards, and guidance, as Purdue agreed to do when settling prior actions.

110. On information and belief, Purdue failed to take any of these steps to prevent its misrepresentations and omissions from contributing to the opioid epidemic.

#### **4. Purdue's misconduct has injured and does injure Utah and its citizens.**

111. Purdue had the ability and the duty to prevent misleading marketing and opioid diversion, which both presented known or foreseeable dangers of serious injury. But it failed to do so, resulting in substantial injury to the State of Utah and its citizens.

112. Purdue's marketing campaign has resulted in a significant increase in opioid usage: between 1999 and 2016 the number of opioids prescribed nationwide quadrupled.<sup>88</sup> Nationally, the number of people who take prescription opioids for non-medical purposes is now greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.<sup>89</sup>

113. Every year, millions of Americans misuse and abuse opioid pain relievers in ways that can lead to addiction, overdose, and death. Data from the CDC suggest that over 2.6 million Americans are opioid-dependent and over 16.5 million Americans use prescription opioids for non-medical purposes.

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<sup>88</sup> Li Hui Chen et al., *Drug-Poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat'l Ctr. for Health Statistics Data Brief (Sept. 2014), <https://www.cdc.gov/nchs/data/databriefs/db166.pdf>; Rose A. Rudd, et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015*, 65 Morbidity and Mortality Weekly Report 1445 (Dec. 30, 2016), <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.html>.

<sup>89</sup> Substance Abuse and Mental Health Servs. Admin., *Results from the 2009 National Survey on Drug Use and Health*, NSDUH Series H-38A, HHS Publication No. SMA 10-4586 Findings (2010).

114. In Utah, data indicates that over 80,000 of the opioid prescriptions dispensed in 2014 were used by individuals for non-medical purposes.<sup>90</sup> Similarly, Utah Department of Health data shows that in the past few years, Utah has seen annual number of opioid prescriptions dispensed almost equivalent to the population, meaning one prescription for every resident,<sup>91</sup> which is far more than is medically necessary.

115. This growth in non-medical demand, addiction, and diversion has led to serious harm in Utah and across the nation. The increase in opioid usage has led to levels of addiction that, according to the U.S. Surgeon General, have “devastated” communities across America.<sup>92</sup> Princeton University economist Alan Krueger found that opioids may be responsible for roughly 20% of the national decline in workforce participation by prime-age men and 25% of the drop by women.<sup>93</sup> In 2011, the CDC reported that overdose deaths from prescription opioids had reached “epidemic levels.”<sup>94</sup> That year, 16,917 people died from a prescription opioid-related overdose, an increase of more than 20% over the previous three years.<sup>95</sup> Since then, the national death toll

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<sup>90</sup> *Opioid Prescribing Practices in Utah: 2002-2015*, Utah Department of Health: Violence & Injury Prevention Program 4,7 (April 2016), <https://www.health.utah.gov/vipp/pdf/RxDrugs/PrescribingPracticeInUtah.pdf>.

<sup>91</sup> *Id.* at 11. In 2014 there were 2,678,995 opioid prescriptions dispensed and the population was 2,942,902. *Id.*

<sup>92</sup> Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), <https://perma.cc/VW95-CUYC>.

<sup>93</sup> Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, Brookings Papers on Econ. Activity Conference Draft (Aug. 26, 2017).

<sup>94</sup> Press Release, CDC, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), [https://www.cdc.gov/media/releases/2011/p1101\\_flu\\_pain\\_killer\\_overdose.html](https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html).

<sup>95</sup> Li Hui Chen et al., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat'l Ctr. for Health Statistics Data Brief (Sept. 2014), <https://www.cdc.gov/nchs/data/databriefs/db166.pdf>.

has continued to rise. In 2014, 18,893 people died from a prescription opioid-related overdose.<sup>96</sup> In 2015, that number increased again to 22,598.<sup>97</sup> As discussed above, overdose deaths in the United States involving prescription opioids have quadrupled since 1999. Utah alone has seen a 26.7% increase from just 2010-2014.<sup>98</sup> And data shows that over 1,000 Utah residents died from prescription opioid overdoses from 2011–2014.<sup>99</sup>

116. It was reasonably foreseeable to Purdue that its deceptive and aggressive marketing of opioids in and around Utah would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

117. It was reasonably foreseeable to Purdue that when at-risk users gained access to opioids based on deceptive and false marketing, tragic, preventable injuries would result, including abuse, addiction, overdoses, and death. It was also reasonably foreseeable that many of these injuries would be suffered by Utah citizens, and that the costs of these injuries would be shouldered by the State and state agencies.

118. Purdue knew or should have known that its continuing efforts to employ deceptive and unfair marketing, despite being previously sanctioned by government agencies for such actions, would contribute to the opioid epidemic in Utah, and would create access to

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<sup>96</sup>Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths— United States, 2010–2015*, 65 *Morbidity and Mortality Weekly Report* 1445 (Dec. 30, 2016), <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

<sup>97</sup>*Id.*

<sup>98</sup>*Opioid Prescribing Practices in Utah: 2002-2015*, Utah Department of Health: Violence & Injury Prevention Program 5 (April 2016), <https://www.health.utah.gov/vipp/pdf/RxDrugs/PrescribingPracticeInUtah.pdf>.

<sup>99</sup> *Id.*



opioids by at-risk and unauthorized users, which, in turn, would perpetuate the cycle of abuse, addiction, demand, and illegal transactions.

119. Purdue knew or should have known that a substantial amount of the opioids dispensed in and around Utah were being dispensed as a result of its deceptive and unfair marketing. It was foreseeable that the increased number of prescriptions for opioids resulting from Purdue's deceptive and unfair marketing would cause harm to individual pharmacy customers, third-parties, and Utah.

120. Purdue made substantial profits over the years based on the deceptive and unfair marketing of opioids in Utah. Purdue's conduct has foreseeably caused injuries to the citizens of Utah and financial damages to Utah. Purdue knew that Utah would be unjustly forced to bear the costs of these injuries and damages.

121. Purdue's deceptive and unfair marketing of prescription opioids to Utah citizens showed a reckless disregard for the safety of Utah and its citizens. its conduct poses a continuing threat to the health, safety, and welfare of Utah and its citizens.

#### **4.1. Purdue's misconduct has damaged Utah and its citizens.**

122. Purdue's misleading marketing and failure to prevent opioid diversion in and around Utah has contributed to a range of social problems, including violence and delinquency. Adverse social outcomes include child neglect, family dysfunction, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, more and more of Utah's resources and those of its counties and municipalities are devoted to addiction-related problems. Meanwhile, the prescription opioid crisis diminishes

Utah's available workforce, decreases productivity, increases poverty, and consequently requires greater State and local expenditures.

123. Prescription opioid abuse costs the State approximately \$238 million in healthcare costs, not to mention additional social services and education expenses.<sup>100</sup> And, it adds an estimated \$169 per capita in costs to Utah's healthcare system, loss in productivity, and criminal justice costs.<sup>101</sup> Mortality costs brings the total to approximately \$1,827 per Utahn.<sup>102</sup>

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<sup>100</sup> Matric Global Advisors, *Health Care Costs from Opioid Abuse: A state-by-state analysis*, 5 (2015), [http://drugfree.org/wp-content/uploads/2015/04/Matrix\\_OpioidAbuse\\_040415.pdf](http://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf) (prescription opioid abuse costs the citizens and State of Utah approximately \$238 million in healthcare costs each year); Kohei Hasegawa et al., *Epidemiology of Emergency Department Visits for Opioid Overdose: A population-based study*, 89 *Mayo Clinic Proceedings* 462, 465, 467 (2014) (there are about two times as many opioid overdoses in Emergency Departments among publicly-insured individuals than among individuals with private insurance and publicly-insured individuals are approximately twice as likely to have a second visit to the Emergency Departments for opioid overdose as are privately-insured individuals); The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets*, 27 (May 2009), <http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets> (State governments spend 27% of the amount they spend on healthcare to fund the social services related to substance abuse.); The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets*, 27 (May 2009), <http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets> (State governments spend 77% of the amount they spend on healthcare on the K–12 education expenses associated with substance abuse.).

<sup>101</sup> Alex Brill & Scott Ganz, *The Geographic variation in the Cost of the Opioid Crisis*, American Enterprise Institute 5 (Mar. 2018); Howard Birnbaum et al., *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, 12 *Pain Med.* 657, 661 (2011); Scott Strassels, *Economic Burden of Prescription Opioid Misuse and Abuse*, 15 *J. of Managed Care & Specialty Pharmacy* 556 (2009); Ryan Hansen et al., *Economic Costs of Nonmedical Use of Prescription Opioids*, 27 *The Clinical J. of Pain* 194 (2011) (All studies estimate that the lost productivity costs are *at least* as large as the healthcare costs resulting from opioid abuse, and possibly as large as ten times annual healthcare costs.).

<sup>102</sup> *Id.* at 8. Carbon County ranks 11th in the nation for the highest per-capita opioid costs, coming in at a staggering \$6,365.

**Count I: Violation of the Utah Consumer Sales Practices Act**

124. Utah realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

125. The Utah Consumer Sales Practices Act (“CSPA”) prohibits, in connection with a consumer transaction, unfair, deceptive or unconscionable consumer sales practices that mislead consumers about the nature of the product they are receiving. Utah Code § 13-11-1, *et seq.*

126. This Cause of Action is brought in the public interest under the Utah Consumer Sales Practices Act, Utah Code § 13-11-17(1). Utah seeks to:

- a. obtain a declaratory judgment that Purdue has violated that CSPA;
- b. enjoin Purdue, in accordance with the principles of equity, from violations of the CSPA, because Purdue has violated, is violating, or is otherwise likely to violate the CSPA;
- c. recover, for each violation, actual damages or obtain other relief on behalf of complaining consumers;
- d. impose a fine, in an amount determined after considering the factors in Utah Code § 13-11-17(6); and
- e. recover attorney’s fees, courts costs, and costs of investigation.

127. In marketing and selling prescription opioids, Purdue has persistently committed deceptive acts or practices, in violation of the CSPA. Utah Code § 13-11-1, *et seq.*

128. Purdue has knowingly or intentionally indicated that the opioids it manufactured had sponsorship, approval, performance characteristics, accessories, uses, or benefits they did not have. Purdue knowingly or intentionally omitted or concealed material facts and failed to correct

prior misrepresentations and omissions about the risks and benefits of opioids. Purdue's omissions rendered even its seemingly truthful statements about opioids deceptive.

129. Purdue violated the CSPA by knowingly or intentionally indicating that opioids had sponsorship, approval, performance characteristics, uses, or benefits, when they did not, in violation of Utah Code § 13-11-4(2)(a).

130. Purdue violated the CSPA by knowingly or intentionally indicating that opioids were of a particular standard, quality, grade, style, or model, when they were not, in violation of Utah Code § 13-11-4(2)(b).

131. Purdue violated the CSPA by knowingly or intentionally indicating that opioids had been supplied in accordance with Purdue's previous representations, when they had not, in violation of Utah Code § 13-11-4(2)(e).

132. By manufacturing and selling opioids in the manner described above, Purdue has also committed unconscionable acts or practices. Utah Code § 13-11-5. Specifically, Purdue has ignored state and federal laws that prohibit misbranding drugs, has violated its statutory duties to Utah and Utah citizens, has misused its position of trust in the community, and has preyed on Utah's most vulnerable residents.

133. Purdue has marketed drugs through misstatements and omissions of facts regarding the safety of those drugs. And it has failed adequately to guard against misstatements and omissions concerning opioids.

134. Each instance where Purdue misrepresented material facts or suppressed, concealed, or omitted any material fact regarding the prescription opioids it manufactured or sold constitutes a violation of the CSPA.

## Count II: Nuisance

135. Utah realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

136. The Attorney General is authorized to bring suit on behalf of the State and its citizens to abate a public nuisance. Utah Code § 76-10-806.

137. Purdue has caused, is causing, and will continue to cause a public nuisance, in that it has committed offenses against the order and economy of the State by unlawfully marketing prescription opioids through misleading statements in ways that facilitate the sale, distribution, and dispensing of such drugs from premises in and around Utah to unauthorized users in Utah—including children, people at risk of overdose or suicide, and criminals.

138. Purdue has also omitted to perform duties with respect to the sale, distribution, and dispensing of opioids.

139. Purdue's activities have unreasonably interfered, are interfering, and will interfere with the common rights of the general public:

- a. to be free from reasonable apprehension of danger to person and property to be free from the spread of disease within the community, including the disease of addiction and other diseases associated with widespread illegal opioid use;
- b. to be free from the negative health and safety effects of widespread illegal drug sales on premises in and around Utah;
- c. to be free from blights on the community created by areas of illegal drug use and opioid sales;

- d. to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and foster a secondary market of illegal transactions; and
- e. to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

140. Purdue's interference with these public rights has been, is, and will continue to be unreasonable and objectionable because it:

- a. has harmed and will continue to harm the public health and public peace of Utah;
- b. has harmed and will continue to harm Utah neighborhoods and communities by increasing crime, and thereby interfering with the rights of the community at large
- c. is proscribed by Utah and Federal statutes;
- d. is of a continuing nature, and has produced long-lasting effects; and
- e. is known to Purdue that its conduct has a significant effect upon the public rights of Utah citizens and the State.

141. The nuisance has undermined, is undermining, and will continue to undermine Utah citizens' public health, quality of life, and safety. It has resulted in increased crime and property damage within Utah. It has resulted in high rates of addiction, overdoses, and dysfunction within Utah families and entire communities.

142. Public resources have been, are being, and will be consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources which could be used to benefit the Utah public at large.

143. As a direct and proximate result of the nuisance, Utah citizens have been injured in their ability to enjoy rights common to the public.

144. As a direct and proximate result of the nuisance, Utah and its counties and municipalities have sustained economic harm by spending substantial sums trying to alleviate the societal harms caused by Purdue's nuisance-causing activity, including costs to the healthcare, criminal justice, social services, welfare, and education systems.

145. The State seeks all remedies available for itself and its citizens caused by Purdue, including injunctive relief, abatement, consequential and incidental damages, costs and any other damages or remedies to which it may be entitled in law or equity.

### **Count III: Negligence**

146. Utah realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

147. Purdue owes a duty to Utah to conform its behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

148. Purdue's conduct has fallen below the reasonable standard of care. Its negligent acts have included:

- a. marketing opioids with misleading statements resulting in oversupply in and around Utah of highly addictive prescription opioids;

- b. enhancing the risk of harm from prescription opioids by marketing those drugs with misleading statements and omissions;
- c. inviting criminal activity into Utah by marketing opioids in violation of Utah and Federal laws;
- d. failing to adhere to all applicable law and regulations pertaining to the marketing of prescription opioids;
- e. failing to train or investigate its employees properly; and
- f. failing to provide adequate safeguards against misleading marketing, even after being sanctioned by state and federal authorities.

149. Purdue had a responsibility to exercise reasonable care in marketing prescription opioids.

150. Purdue marketed opioids using misleading statements and omissions knowing that (a) there was a substantial likelihood this marketing would lead to sales illicit and non-medical purposes; and (b) opioids are an inherently dangerous product when used for chronic pain and non-medical purposes.

151. Purdue was negligent or reckless in not acquiring or not utilizing special knowledge and special skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such distinctive and significant dangers.

152. Purdue breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in marketing and introducing into commerce dangerous controlled substances.



153. Purdue was also negligent or reckless in voluntarily undertaking duties to the State that it breached. Purdue, through its affirmative statements regarding protecting consumers, undertook duties to take all reasonable precautions to avoid misleading marketing statements.

154. Purdue's conduct was the cause-in-fact and proximate cause of injuries and damages to the State and its citizens, including but not limited to the following: increased costs for healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenues.

155. Utah is without fault, and its injuries would not have happened in the ordinary course of events if Purdue had used due care commensurate to the dangers involved in the marketing of controlled substances.

#### **Count IV: Unjust Enrichment**

156. Utah realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

157. Utah has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Purdue's misleading statements.

158. The estimated \$238 million in annual health care costs to Utah from opioid abuse have added to Purdue's wealth. The expenditures by Utah have helped sustain Purdue's businesses.

159. In this way, Utah has conferred a benefit on Purdue, by paying for what may be called its externalities—the costs of the harm caused by Purdue's misleading statements and omissions.

160. Utah has also expended substantial amounts of money paying for purchases by unauthorized users of prescription opioids illegally marketed by Purdue. In this way, the State has conferred a benefit upon Purdue.

161. Purdue made substantial profits while fueling the prescription opioid epidemic in Utah.

162. Purdue continues to receive considerable profits from the sale of controlled substances in Utah.

163. Purdue is aware of these obvious benefits, and retention of these benefits is unjust.

164. Purdue has been unjustly enriched by these benefits.

165. It would be inequitable to allow Purdue to retain these benefits.

#### **Count V: Fraud**

166. Utah realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

167. Purdue, itself and acting through third-party agents, fraudulently, intentionally, willfully, or recklessly made misrepresentations and omissions of facts material to Utah and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

168. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, Purdue has engaged in misrepresentations and knowing omissions of material fact.

169. Purdue's statements about opioids generally and its opioids in particular were false.

170. Further, Purdue's omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead when taken in the context of the surrounding circumstances.

171. Purdue fraudulently, intentionally, willfully, or recklessly made these misrepresentations and omissions, which were reasonably calculated to deceive and in fact did deceive Utah and its residents.

172. Purdue intended that Utah and its residents would rely on its misrepresentations and omissions.

173. Utah and its residents reasonably relied on Purdue's misrepresentations and omissions.

174. As a direct and proximate result of Purdue's misrepresentations and omissions of material fact, Utah suffered actual pecuniary damage.

## **Prayer for Relief**

**WHEREFORE**, Plaintiff, State of Utah, prays that this Court enter judgment in its favor against Purdue and:

### **On Count I (Violation of the Consumer Sales Practices Act):**

Issue a declaratory judgment that Purdue has violated the CSPA;

Enter an order that directs Purdue to cease and desist its unlawful conduct, i.e., cease and desist violating the Utah Consumer Sales Practices Act, in connection with the marketing, manufacture, and sale of prescription opioids;

Enter an order providing relief for complaining consumers as contemplated by Utah Code § 13-11-17(1)(c);

Assess a fine against Purdue, in an amount determined after considering the factors in Utah Code § 13-11-17(6);

Award Utah such additional relief as may be necessary to remedy Purdue's CSPA violations; and

Award Utah the costs of bringing this action, reasonable attorney's fees, court costs, and investigative costs, and such other and additional relief as the Court may determine to be just and proper.

### **On Count II (Nuisance):**

Order Purdue to pay the expenses Utah, its counties and municipalities have incurred or will incur in the future to abate fully the nuisance it has caused; and

Order such further relief as justice and equity may require

**On Count III (Negligence):**

Award Utah compensatory damages for the increased costs to Utah’s healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenue due to Purdue’s negligence; and

Order such further relief as justice and equity may require.

**On Count IV (Unjust Enrichment):**

Award Utah restitution of its costs caused by Purdue’s actions, including the costs of addressing Purdue’s externalities and the costs of prescription opioids paid for by the State;

Disgorge Purdue of all amounts it has unjustly obtained; and

Order such further relief as justice and equity may require.

**On Count V (Fraud):**

Award Utah restitution of its costs caused by Purdue’s actions, including the costs of addressing Purdue’s externalities and the costs of prescription opioids paid for by the State;

Disgorge Purdue of all amounts it has unjustly obtained;

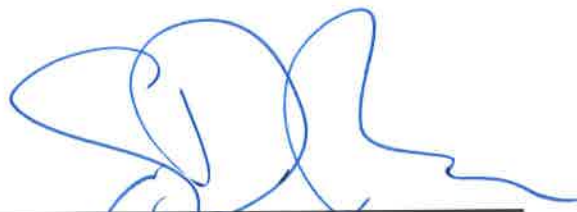
Award punitive damages against Purdue; and

Order such further relief as justice and equity may require.

**REQUEST FOR JURY TRIAL**

Utah respectfully requests that all issues presented by its above Complaint be tried by a jury, with the exception of those issues that, by law, must be tried before the Court.

Dated this 31<sup>st</sup> day of May 2018.



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SEAN D. REYES  
UTAH ATTORNEY GENERAL  
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