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DISTRICT COURT, CITY AND COUNTY OF DENVER, COLORADO 1437 Bannock Street Denver, Colorado 80202 THE STATE OF COLORADO *ex rel.* CYNTHIA H. COFFMAN, ATTORNEY GENERAL, Plaintiff, v. PURDUE PHARMA L.P. and PURDUE PHARMA, INC., Defendants.	▲ **COURT USE ONLY** ▲
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COMPLAINT AND JURY DEMAND

TABLE OF CONTENTS

1. Plaintiff, the State of Colorado, upon relation of Cynthia H. Coffman, Attorney General for the State of Colorado, and acting in her *parens patriae* capacity, by and through undersigned counsel, states and alleges as follows:

INTRODUCTION

2. Colorado, along with the rest of the country, is in the midst of a public health crisis caused by prescription opioids. Purdue Pharma L.P. and Purdue Pharma, Inc. (collectively "Purdue"), maker of the blockbuster opioid painkiller OxyContin, originated and spearheaded a marketing campaign that led to the opioid epidemic.

3. Before Purdue started marketing opioids in the mid-1990s, there was scant scientific evidence on the effects of long-term opioid therapy. The medical community (*e.g.,* health care providers, educators, policymakers) believed opioids should be used sparingly and only in limited circumstances for acute, short-term pain, cancer-related pain, or end-of-life care.

4. Purdue implemented an unprecedented marketing strategy designed to drive up sales by deceiving the medical community and the public into believing that opioids were safe and effective to treat chronic, long-term pain. Purdue, which had been making opioids since the 1980s, knew that no reliable scientific or medical evidence existed to support this position.

5. Instead, Purdue seized on and manipulated unsubstantiated statements, and used what appeared to be independent doctors and third party organizations that Purdue paid and controlled, to spread the false and misleading message to prescribers and the public at large that chronic pain was a vastly undertreated condition that could be safely treated with opioids.

6. Purdue's strategy hinged on creating doubt around the prevailing wisdom that opioids, with their high potential for abuse, should be used sparingly, and Purdue seeded this doubt with promotional materials that appeared to be based on scientific evidence developed by reliable and independent third parties, but in reality were created and influenced by Purdue itself.

7. Beginning in the mid-to-late 1990s, Purdue deployed an army of sales representatives armed with these promotional materials to make in-person sales calls to health care providers in Colorado and nationwide.

8. Purdue trained its sales representatives to relax any aversion to prescription opioids using marketing materials promoting the expanded use of prescription opioids generally, and then to convert health care providers to prescribe Purdue's branded opioids. Once the health care providers began prescribing Purdue's branded drugs, the sales representatives focused on convincing them to increase the dosages and duration of patients' opioid treatment.

9. From the mid-1990s and continuing today, Purdue made the following misrepresentations to Colorado health care providers, patients, policymakers, and the public directly, and indirectly through surrogates:

- Purdue misrepresented the risk of addiction associated with opioids and the extent to which it could be managed;

- Purdue exaggerated the benefits of opioid treatment by overstating their efficacy at treating chronic non-cancer pain and improving patients' functionality and quality of life;

- Purdue manufactured a fake syndrome called "pseudoaddiction" (a purported condition which mimics addiction that is caused by the under treatment of pain, *i.e.,* not using a high enough dose of opioids to treat the pain) that Purdue concocted in order to counter claims that opioids could lead to abuse and addiction;

- Purdue deceptively advised health care professionals that they could manage and avoid addiction in their patients;

- Purdue misrepresented that OxyContin is effective for 12 hours, resulting in end-of-dose failure, which led doctors and patients to increase the frequency and dosages of OxyContin and enhanced the likelihood of addiction;

- Purdue misrepresented the increased risks posed by higher dosages of prescription opioids and pressured health care professionals by claiming that they were violating their Hippocratic Oath and failing their patients unless they treated pain symptoms with opioids;

- Purdue overstated the efficacy of abuse-deterrent formulations of opioids;

- Purdue misrepresented the severity of opioid withdrawal; and

- Purdue misrepresented the risks and benefits of opioids as compared to the risks and benefits associated with alternative pain treatments.

10. Through its misinformation campaign, Purdue successfully duped the medical community and the public into believing that opioids were safe and effective for treating chronic pain.

11. As a result, Purdue flooded Colorado and the nation with millions of prescription opioids, making an estimated $35 billion from the manufacturing and sale of OxyContin and Purdue's other opioid drugs.[1]

12. The impact of Purdue's misinformation campaign has devastated Colorado, and the State has borne much of the costs associated with treating individuals suffering from dependence or addiction and other opioid-related ailments, as well as the attendant costs to state health programs, child welfare, criminal justice, and other programs.

13. Most importantly, Purdue's deceptive marketing campaign resulted in thousands of deaths in Colorado. Colorado families have lost parents, children, and friends to this disastrous epidemic.

14. Purdue's conduct violated §§ 6-1-105(1)(b), (c), (e), (g), (h), and (u) of the Colorado Consumer Protection Act (CCPA), §§ 6-1-101, *et seq*., C.R.S. (2017). Purdue's conduct also created a public nuisance in Colorado, and its negligent and fraudulent conduct caused significant and severe harm to the State and its citizens.

15. The State of Colorado, by its Attorney General, Cynthia H. Coffman, brings this enforcement action to stop Purdue's deceptive conduct, enforce Colorado law, and hold Purdue responsible for remedying the harm its deceptive conduct has caused the State of Colorado and Colorado citizens.

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[1] Alex Morrell, *The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, Forbes (July 1, 2015, 10:17 AM), https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#4b8d2c5e75e0 (last visited Sept. 4, 2018).

PARTIES

16. The Plaintiff is the State of Colorado *ex. rel.* Cynthia H. Coffman, Attorney General (hereinafter "the State" or "Attorney General"). The Attorney General is authorized to commence this action pursuant to § 6-1-103 of the CCPA. The State, by and through the Attorney General, brings this action to address practices that violate the CCPA relating to the marketing and sale of opioid medications.

17. The Colorado Attorney General is also empowered to bring this action in her *parens patriae* capacity, as Colorado has a quasi-sovereign interest in the health and well-being—physically and economically—of its citizens, and has been directly and indirectly impacted by Purdue's conduct. The State of Colorado, as a legal entity, has suffered enormous losses as a direct and proximate result of Purdue's conduct described herein.

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

19. Defendant Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

20. Unless otherwise noted, all allegations contained herein are made against both Defendants. Purdue Pharma L.P. and Purdue Pharma, Inc. are hereinafter collectively referred to as "Purdue." At all relevant times, each Defendant acted jointly with every other named Defendant in committing all acts alleged herein.

21. Purdue transacts business in Colorado and nationwide and its campaign to promote the expanded use of all prescription opioids included the manufacturing, promoting, marketing, advertising, and selling its own specific prescription opioids including:

> Dilaudid (hydromorphone hydrochloride) is an opioid agonist currently indicated for "the management of pain severe enough to require an opioid

analgesic and for which alternative treatments are inadequate."[2] Dilaudid was approved by the Food and Drug Administration (FDA) in January 1984.[3] Prior to 2016, Dilaudid injection was indicated for the "management of pain where an opioid analgesic is appropriate."[4] Dilaudid is a Schedule II drug,[5] which indicates that it has a high potential for abuse.[6]

Dilaudid-HP (hydromorphone hydrochloride) is an opioid agonist currently indicated for the "use in opioid-tolerant patients who require higher doses of opioids for the management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate."[7] Dilaudid-HP was also approved by the FDA in January 1984.[8] Prior to 2016, Dilaudid-HP injection was indicated for "the management of moderate-to-severe pain in opioid-tolerant patients who require higher doses of opioids."[9] Dilaudid-HP has also previously been indicated "for the relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."[10] Dilaudid-HP is a Schedule II drug.[11]

MS Contin (morphine sulfate extended-release) is an opioid agonist tablet currently indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative

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[2] Highlights of Prescribing Information: DILAUDID (2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019891s024,019892s029lbl.pdf.
[3] *Id.*
[4] Highlights of Prescribing Information: DILAUDID (2011), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019034s021lbl.pdf.
[5] Highlights of Prescribing Information: DILAUDID (2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019891s024,019892s029lbl.pdf.
[6] The federal Controlled Substances Act and its implementing regulations identify drugs and other substances as "controlled substances," and classifies them into one of five schedules based in part on their potential for abuse, the degree of dependence they might cause, and their accepted medical use. *See generally* 21 U.S.C. §§ 801 *et seq*.; 21 C.F.R. §§ 1300-1399. Most prescription opioid painkillers are Schedule II controlled substances, meaning they have a high potential for abuse, which may lead to severe psychological or physical dependence. *See* 21 U.S.C. § 812(b)(2).
[7] Highlights of Prescribing Information: DLAUDID HP (2017), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019034s029lbl.pdf.
[8] *Id.*
[9] Highlights of Prescribing Information: DILAUDID HP (2011), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019034s021lbl.pdf.
[10] Dilaudid-HP Injection Label (2009), *available at*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/019034s018lbl.pdf.
[11] Highlights of Prescribing Information: DLAUDID HP (2017), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019034s029lbl.pdf.

treatment options are inadequate."[12] MS Contin was approved by the FDA in May 1987.[13] Prior to April 2014, MS Contin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."[14] MS Contin is a Schedule II drug.[15]

OxyContin (oxycodone hydrochloride extended-release) is an opioid agonist tablet currently indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[16] OxyContin is an extended-release oxycodone pill that purports to deliver the drug over 12 hours. OxyContin was approved by the FDA in 1995.[17] Prior to April 2014, OxyContin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."[18] OxyContin is Purdue's flagship product and the watershed branded opioid in the pharmaceutical opioid market in Colorado and throughout the country. OxyContin is a Schedule II drug.[19]

Ryzolt (tramadol HCI extended-release) is a centrally-acting synthetic opioid analgesic tablet indicated for the "management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their

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[12] Highlights of Prescribing Information: MS CONTIN (2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019516s049lbl.pdf.
[13] U.S. Food & Drug Admin., *FDA Approved Drug Products: MS Contin*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019516 (last visited Sept. 4, 2018).
[14] MS Contin Label (2010), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/019516s034lbl.pdf.
[15] Highlights of Prescribing Information: MS CONTIN (2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019516s049lbl.pdf.
[16] Highlights of Prescribing Information: OXYCONTIN (2015), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022272s027lbl.pdf.
[17] U.S. Food & Drug Admin., *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm (last visited Sept. 4, 2018).
[18] Highlights of Prescribing Information: OXYCONTIN (2010), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022272s006lbl.pdf.
[19] Highlights of Prescribing Information: OXYCONTIN (2015), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022272s027lbl.pdf.

pain for an extended period of time."[20] Ryzolt was approved by the FDA in December 2008.[21] Purdue discontinued the manufacture of Ryzolt in 2012.[22]

Butrans (buprenorphine) is an opioid partial agonist transdermal patch and currently indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[23] Butrans was approved by the FDA in June 2011.[24] Prior to April 2014, Butrans was indicated for "the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time."[25] Butrans is a Schedule III drug.[26]

Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) is a combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[27] Targiniq ER was approved by the FDA in July 2014[28] and is a Schedule II drug.[29]

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[20] Label: RYZOLT Label (2008), a*vailable at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021745s000lbl.pdf.
[21] U.S. Food & Drug Admin., *FDA Approved Drug Products: Ryzolt*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021745 (last visited Sept. 4, 2018).
[22] Magellan Medicaid Admin., *Long-Acting Narcotics Analgesics Therapeutic Class Review (TCR*) 3 (2014), *available at* https://healthandwelfare.idaho.gov/Portals/0/Medical/PrescriptionDrugs/LongActingNarcoticAnalgesics.pdf.
[23] Highlights of Prescribing Information: BUTRANS (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021306s015s019lbl.pdf.
[24] Center for Drug Evaluation and Research, *Approval Package: Butrans* (2010), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021306Orig1s000ApprovLtr.pdf.
[25] Highlights of Prescribing Information: BUTRANS (2010), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021306s000lbl.pdf.
[26] Highlights of Prescribing Information: BUTRANS (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021306s015s019lbl.pdf.
[27] Highlights of Prescribing Information: TARGINIQ ER (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205777lbl.pdf.
[28] U.S. Food & Drug Admin., *FDA Approved Drug Products: Targiniq,* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205777 (last visited Sept. 4, 2018).
[29] Highlights of Prescribing Information: TARGINIQ ER (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205777lbl.pdf.

Hysingla ER (hydrocodone bitrate) is an opioid agonist tablet indicated "for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[30] Hysingla ER was approved by the FDA in November 2014[31] and is a Schedule II drug.[32]

JURISDICTION AND VENUE

22. Pursuant to §§ 6-1-103, 110(1) and 112(1), C.R.S., this Court has jurisdiction to enter appropriate orders prior to and following an ultimate determination of liability under the CCPA. The Court also has jurisdiction to enter appropriate orders as requested here under Colorado's long-arm statute, § 13-1-124(b), C.R.S.

23. The behavior and the violations alleged herein occurred, in part, in the City and County of Denver. Therefore, venue is proper in Denver County, Colorado, pursuant to § 6-1-103, C.R.S., and Colo. R. Civ. P. 98 (2017).

PUBLIC INTEREST AND DUTY

24. Purdue owed a duty of care to the State of Colorado and its citizens, including but not limited to exercising reasonable care in the marketing and sale of opioids—a highly addictive controlled substance. Purdue knew or should have known that its conduct in aggressively and deceptively marketing and selling opioids created an unreasonable risk of harm to Colorado and its citizens.

25. Through the unlawful practices of its business, Purdue knowingly deceived, misled, and injured the State of Colorado, as well as Colorado prescribers, patients, policymakers, and citizens.

26. Although the FDA has approved the sale of opioids, Purdue's marketing of these drugs exceeded the labeled use and does not shield Purdue from

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[30] Highlights of Prescribing Information: HYSINGLA ER (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206627s000lbl.pdf.
[31] U.S. Food & Drug Admin., *FDA Approved Drug Products: Hysingla ER*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206627 (last visited Sept. 4, 2018).
[32] Highlights of Prescribing Information: HYSINGLA ER (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206627s000lbl.pdf.

liability for its deceptive marketing or the public nuisance created by its business model.

27. The State of Colorado has suffered financial and physical harm to its businesses and property due to the devastating effects of the opioid crisis which occurred as a direct and proximate result of Purdue's intentional, knowing, and reckless behavior. Purdue's dissemination of fraudulent and deceptive information related to the safety and efficacy of prescription opioids for treating chronic non-cancer pain directly and proximately caused the harm suffered by the State of Colorado.

28. Purdue's business practices severely negatively impacted the citizens of Colorado, both directly, and indirectly through the state agencies that serve the public.

29. These legal proceedings are in the public interest and are necessary to safeguard Colorado health care providers, patients, policymakers, and the citizens of Colorado, and to compensate those persons, including the State, harmed by Purdue's deceptive marketing campaign.

FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS

I. Background

A. Prescription opioids

30. Opioid drugs are comprised of natural, semi-synthetic, and synthetic chemicals that interact with opioid receptors on nerve cells in the body and brain, reducing the intensity of pain signals and feelings of pain.[33] There are several different opioid molecules, including morphine, hydrocodone, oxycodone, oxymorphone, hydromorphone, tapentadol, buprenorphine, and methadone.[34]

31. Opioids act as central nervous system depressants that attach to receptors in the brain, spinal cord, and gastrointestinal tract, and suppress function.[35] This results in the reduction of the intensity of pain signals that reach the brain, and is the reason why the primary clinical use of opioids is for pain relief,

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[33] John Williams, *Basic Opioid Pharmacology*, 1 Reviews in Pain 2, 2-3 (2008).
[34] *Id.*
[35] *Id.* at 3.

also known as analgesia.[36] In addition to reducing pain, opioids trigger chemical processes that create intense feelings of euphoria, making them highly susceptible to addiction and abuse.[37]

32. Prescription opioids come in two basic formulations: immediate release (IR) and extended release (ER).[38] IR opioids deliver the full dose quickly as the pill dissolves.[39] The market for IR opioids primarily consists of generic drugs. ER opioids are concentrated versions of the same active ingredients in IR opioids, but are contained in a time-release matrix that is supposed to release the drug over time.[40] OxyContin, for example, is oxycodone in a time-release matrix that Purdue claims delivers the drug over a 12-hour period. The ER opioid market has far more branded products, and has been historically dominated by Purdue.

B. Risks of prescription opioid treatment

33. Opioids place patients at significant risk of addiction, abuse, and overdose, all of which can lead to serious patient harm, including death. And, while opioids may be effective for alleviating pain in the short-term, clinical studies indicate that opioids are not effective for relieving chronic or long-lasting pain.[41] Patients are likely to see a decrease in function, and are at risk of increased pain sensitivity (known as hyperalgesia) when using opioids for a prolonged period: "Opioids may work acceptably well for a while, but over the long-term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[42] In 2016, the Centers for Disease Control and Prevention (CDC) issued guidelines, which confirmed that, "patients who do not

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[36] *Id.*
[37] *Id.*
[38] *See* Charles E. Argoff & Daniel I. Silvershein, *A Comparison of Long- and Short-Acting Opioids for the Treatment of Chronic Noncancer Pain: Tailoring Therapy to Meet Patient Needs*, 84 Mayo Clin. Proc. 602, 603 (2009).
[39] *Id.*
[40] *Id.*
[41] *See* Andrea Rubinstein, *Are we making pain patients worse*?, Sonoma Medicine, http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747 (last visited Sept. 4, 2018) (describing a common experience for patients on long-term opioid treatment).
[42] *See id.*

experience clinically meaningful pain relief in treatment (*i.e.*, in 1 month) are unlikely to experience pain relief with longer term use."[43]

34. The most common side effects of opioids can be divided into peripheral effects (constipation, urinary retention, hives, bronchospasm) and central effects (nausea, sedation, respiratory depression, hypotension, constriction of the pupil, cough suppression), all of which seriously affect their clinical utility and the patient's quality of life.[44] However, there are other severe consequences associated with prescription opioid use, including opioid dependence, opioid addiction (or opioid use disorder), and overdose. Respiratory depression is the primary mechanism by which opioids have killed thousands of Colorado citizens and hundreds of thousands of Americans. "[V]ictims of a fatal overdose usually die from respiratory depression – literally choking to death because they cannot get enough oxygen to feed the demands of the brain and other organ systems."[45]

35. All opioids, including those manufactured by Purdue, can easily lead to severe side effects, as well as dependence and addiction in long-term patients. Studies have found diagnosed dependence rates in primary care settings as high as 26%.[46] Among opioid users who received four prescriptions in a year, 41.3% meet the diagnostic criteria for lifetime opioid use disorder.[47]

36. Once a patient starts using opioids, it can be incredibly hard to stop. A 2017 CDC study determined that the probability of long-term opioid use rises most sharply after five days of opioid use, and surges again after one month of opioid use.[48] Patients who are initially prescribed one month of opioids have a 29.9%

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[43] Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity & Mortality Weekly Report 1, 13 (2016) (hereinafter "2016 CDC Guideline").
[44] Ream Al-Hasani & Michael R. Bruchas*, Molecular Mechanisms of Opioid Receptor-dependent Signaling and Behavior,* 115 Anesthesiology 1363, 1364 (2011).
[45] *See* Dina Fine Maron, *How Opioids Kill*, Scientific American (Jan. 8, 2018), https://www.scientificamerican.com/article/how-opioids-kill/ (last visited Sept. 4, 2018).
[46] 2016 CDC Guideline at 9-10.
[47] Joseph A. Boscarino, Stuart N. Hoffman, & John J. Han, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates*, 6 Substance Abuse & Rehabilitation 83, 88 (2015).
[48] Anuj Shah, Corey J. Hayes, & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66 Morbidity & Mortality Weekly Report 265, 267 (2017).

chance of continued opioid use one year later.[49] In one study, almost 60% of patients who used opioids for 90 days, which the CDC considers the minimum duration for "chronic pain,"[50] were still using opioids five years later.[51] Accordingly, the CDC's 2016 guidelines concluded that, "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[52]

37. While IR opioids also pose a risk of addiction, stopping opioid use is especially difficult for patients prescribed an ER opioid, like OxyContin. In requiring a new black-box warning on the labels of all IR opioids in March 2013, the FDA noted the "known serious risk [ ] of … addiction" which was present "even at recommended doses of all opioids."[53] The FDA further observed that ER opioids, like OxyContin, present "disproportionate safety concerns" as compared to IR opioids and that the data shows that the risk of misuse and abuse is greater for ER opioids than IR opioids.[54]

38. Moreover, for patients whose first opioid prescription is an ER opioid, like OxyContin, there is a 27.3% chance that they will be using opioids one year later, and a 20.5% chance that they will be using opioids three years later.[55]

39. High opioid dosages can also be associated with increased risks. A CDC clinical evidence review published in 2016 found that higher opioid dosages were associated with increased risks of motor vehicle injury, opioid use disorder, and overdose, and that the increased risk arises in a dose-dependent manner.[56] Another study from 2014 found that higher daily doses and possible opioid misuse were

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[49] *Id.*
[50] 2016 CDC Guideline at 1.
[51] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26 J. Gen. Internal. Med. 1450, 1456 (2011).
[52] 2016 CDC Guideline at 25. Purdue's business relies on this deadly reality. According to Purdue's internal documents, 87% of its OxyContin business and 82% of its Butrans business is driven by continuing prescriptions. PWG000062941; PWG000061454.
[53] Letter from Janet Woodcock, MD., Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013), *available at* http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.
[54] *Id.*
[55] Anuj Shah, Corey J. Hayes, & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66 Morbidity & Mortality Weekly Report 265, 266 (2017).
[56] 2016 CDC Guideline at 9-10, 19.

strong predictors of continued use and associated with risk of fractures, dependence, overdose, and death.[57]

40. Based on this information, in 2016 the CDC recommended that physicians carefully reassess increasing opioid doses beyond 50 morphine milligram equivalents (MMEs) and avoid exceeding 90 MMEs per day.[58] To put that in perspective, a single 60mg pill of oxycodone, the active ingredient in OxyContin, is 90 MME; a 40mg pill is 60 MME; and a single 30mg pill is 45 MME.[59] Since patients generally take 12-hour OxyContin twice a day, a prescription for a 30mg pill of OxyContin is already at the CDC's upper threshold.

41. The likelihood of developing an opioid use disorder increases threefold even for acute patients prescribed low-dose opioids.[60] For long-term patients who take a daily dose of more than 120 MMEs, or two 40mg oxycodone pills per day, the risk of developing an opioid use disorder is 122 times higher.[61]

42. Of the over 100 million OxyContin tablets sold by Purdue in Colorado from 2001 to 2017, almost 40% of them contained 40mg of oxycodone or more.[62]

C. Prescription opioids expose vulnerable populations to increased risks

43. The side effects and other consequences associated with opioid use carry even more severe risks for vulnerable populations, including the elderly, newborns, and veterans.

44. Opioids pose significant risks in older patients due to the decline in their ability to metabolize and excrete the drugs.[63] Older patients are particularly

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[57] Mark J. Edlund et al., *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-cancer Pain*, 30 Clin. J. Pain 557, 561-62 (2014).
[58] 2016 CDC Guideline at 16.
[59] *See* Centers for Disease Control and Prevention, *Calculating Total Daily Dose of Opioids for Safer Dosage* 2, *available at* https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.
[60] Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on Prescribing Opioids for Pain* 7, 34 (3d ed. 2015), *available at* http://www.agencymeddirectors.wa.gov/files/2015amdgopioidguideline.pdf.
[61] *Id.*
[62] PWG003984539. Hereinafter, documents beginning with the prefix "P", such as this document, were produced by Purdue.
[63] Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on*

prone to constipation (a common opioid side effect), are at an increased risk for falls and fractures, and have a higher risk of opioid-related adverse drug events.[64]

45. Nevertheless, Purdue routinely targeted elderly patients in Colorado for opioid prescriptions for ailments common to our elder population like osteoarthritis. As a result, since 2008 Coloradans over the age of 65 have consistently recorded more inpatient stays for opioid-related diagnoses than the national average.[65]

46. Increased opioid use also poses a danger to the unborn. Opioid use during pregnancy saw a three-to-four-fold increase nationwide between 2000 and 2009, with increased fetal, obstetrical, and neonatal abstinence syndrome (NAS) risk.[66] NAS may occur in up to 60-80% of infants exposed to opioids and has increased every year through 2013.[67] Of pregnant women enrolled in Medicaid from 2000 to 2007, 21.6% filled an opioid prescription during pregnancy.[68]

47. Additionally, opioids pose a risk for children and adolescents, even though most opioid use in this population is off-label (prescribed for reasons not indicated on the drug's FDA-approved label) because opioids are not approved for children.[69] Nonetheless, the 2016 CDC guideline found a significant increase in opioid prescribing for children and adolescents for chronic pain conditions like headaches and those resulting from sports injuries.[70] Use of prescription opioids before high school graduation is associated with a 33% increase in the risk of later opioid misuse, including the use of heroin later in life.[71]

Prescribing Opioids for Pain 49 (3d ed. 2015), *available at* http://www.agencymeddirectors.wa.gov/files/2015amdgopioidguideline.pdf.

[64] *Id.* at 47-49.

[65] Healthcare Cost and Utilization Project, *Opioid-Related Hospital Use*, https://www.hcup-us.ahrq.gov/faststats/OpioidUseServlet?radio-3=on&location1=CO&characteristic1=02&setting1=IP&location2=US&characteristic2=02&setting2=IP&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide (last visited Sept. 4, 2018).

[66] Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on Prescribing Opioids for Pain* 42 (3d ed. 2015), *available at* http://www.agencymeddirectors.wa.gov/files/2015amdgopioidguideline.pdf.

[67] *Id.* at 44.

[68] *Id.* at 43.

[69] *Id.* at 45.

[70] 2016 CDC Guideline at 3.

[71] *Id.*

48. Further, exposure to prescription and other opioids in the home can lead to hospitalizations and admissions to pediatric intensive care units (PICU) for children aged 1 to 17. The rate of pediatric hospitalization due to opioid poisoning increased significantly from 6.7 per 10,000 admissions in 2004 to 10.9 per 10,000 admissions in 2015, an increase of 63%.[72] One-third of those hospitalizations were of children under six years of age.[73] The rate of PICU admissions for opioid-related hospitalization increased significantly, from 24.9 per 10,000 admissions in 2004 to 35.9 per 10,000 admissions in 2015, an increase of 44%.[74]

49. For many veterans receiving certain anti-anxiety medications for PTSD and an opioid analgesic for pain, the results can be catastrophic. One study found that 27% of veterans who received opioid analgesics also received benzodiazepine, a commonly prescribed anti-anxiety medication used to treat PTSD.[75] In that study, half of the veterans' deaths from drug overdose occurred when the veterans were concurrently prescribed both medications.[76]

D. Prescription opioid use frequently leads to abuse, overdose, and death

50. One in 550 patients receiving opioid treatment die of opioid-related causes approximately 2.6 years after their first opioid prescription.[77] That number increases to 1 in 32 for patients receiving 200 MMEs per day.[78]

51. The risk of opioid overdose exists even in very low doses. When a patient takes between 20 and 49 MMEs, the risk of overdose doubles. When a patient takes 100 MMEs, the risk of overdose and death increases 9-fold.[79]

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[72] Jason M. Kane et al., *Opioid-Related Critical Care Resource Use in US Children's Hospitals*, 141 Pediatrics, April 2018, at 3.
[73] *Id.*
[74] *Id.*
[75] Taw Woo Park et al., *Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study*, BMJ 2015;350:h2698 at 1, *available at* https://www.bmj.com/content/bmj/350/bmj.h2698.full.pdf.
[76] *Id.*
[77] 2016 CDC Guideline at 2.
[78] *Id.*
[79] Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on Prescribing Opioids for Pain* 12 (3d ed. 2015), *available at* http://www.agencymeddirectors.wa.gov/files/2015amdgopioidguideline.pdf.

52. Between 1999 and 2016, more than 200,000 people died in the United States from overdoses related to prescription opioids.[80] As Dr. Thomas Friedan of the CDC explained, there is "no other medication routinely used for a nonfatal condition that kills patients so frequently."[81]

53. Opioid use is also associated with numerous non-fatal overdoses and other severe non-overdose side effects, including gastrointestinal impacts and bleeding, delayed recovery from injury, cognitive impacts, endocrine impacts, hyperalgesia, and increased risks of fracture, as well as hospitalization, tolerance, dependence, and addiction.[82]

II. Purdue knew of the risks associated with widespread and long-term opioid use, but nevertheless embarked upon a national misinformation campaign designed to increase its profits

A. Purdue's deceptive scheme begins

54. Prior to the mid-1990s, the generally accepted standards of medical practice dictated that health care providers only use opioids as a temporary treatment for acute, short-term pain, for cancer pain, or for end-of-life care.[83] The prevailing wisdom in the medical community was that opioids were not effective at relieving long-term pain, and that the significant risks associated with long-term opioid treatment outweighed any temporary and unproven benefits.[84]

55. Given the medical community's general aversion to prescription opioids at the time, Purdue knew that in order to increase the sales of Purdue's opioid drugs it would need to change the narrative about opioids as a general class of drugs.

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[80] Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data* (Aug. 1, 2017), https://www.cdc.gov/drugoverdose/data/overdose.html (last visited Sept. 4, 2018).
[81] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501, 1503 (2016).
[82] Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications* 2-6 (2014), *available at* https://www.colorado.gov/pacific/sites/default/files/Psycholigical%20and%20Physical%20Side%20Effects%20Teater%20NSC.pdf.
[83] *See* Russell K. Portenoy, *Opioid therapy for chronic nonmalignant pain*, 1 Pain Res. Manage. 17, 18 (1996).
[84] *Id.*

56. Purdue set out to undermine years of medical teachings about opioids with pseudoscience and cherry-picked experts who promoted Purdue's fraudulent and deceptive message that all prescription opioids were safe and effective treatments for chronic non-cancer pain.

i. *Purdue sponsored misleading "studies" to cast doubt upon well-established risks associated with prescribing opioids*

57. Beginning in the 1990's, Purdue began publishing misleading studies to promote the false perception that prescription opioids were effective long-term treatments for chronic pain conditions, and improve patients' functionality and quality of life.

58. One such study, titled *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*, was sponsored by Purdue and published in the Journal of Rheumatology in 1999.[85]

59. That study involved providing patients oxycodone for 30 days (not long-term), and then randomizing participants and providing a placebo, IR oxycodone with acetaminophen (*e.g.,* Percocet), or OxyContin.[86] Only 107 of 167 participants advanced to the second phase of the study, most withdrawing because they experienced adverse side effects (*e.g.,* nausea, vomiting, drowsiness, dizziness, or headaches) or because the opioid provided ineffective treatment.[87] The authors of the study acknowledged that the "results…should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition[s] such as OA [osteoarthritis]."[88] Yet they went on to conclude 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 [*sic*]."[89] Such a conclusion is not

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[85] Jacques R. Caldwell et al., *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 26 J. Rheumatology 862 (1999).
[86] *Id.* at 862.
[87] *Id.* at 864.
[88] *Id.* at 867.
[89] *Id.*

supported by the study itself because a substantial number of patients withdrew from the study, there was no reported data regarding addiction, and the study was not long-term.

60. Paradoxically, in that same year, Purdue published a different short-term study which concluded that it could not address the issues surrounding the long-term use of opioids for the treatment of chronic non-cancer pain because long-term studies were needed to assess the analgesic effects, psychological effects, effects on function and sleep quality, and safety of opioid analgesics in chronic use.[90]

61. Purdue continued to conduct similar studies, including one in 2003 entitled *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, misleadingly claiming that opioids are a safe and effective option for treating chronic pain.[91]

62. Despite the dearth of evidence supporting such assertions, Purdue continued promoting opioids generally, and its own drugs specifically, as effective for improving patients' functionality and quality of life:

- Purdue sponsored and drafted the content in the Federation of State Medical Board's (FSMB) 2007 *Responsible Opioid Prescribing*, which claimed that pain relief itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."[92] In fact, on the first page, *Responsible Opioid Prescribing* represents that some patients "rely on opioids for . . . improved function."[93] Purdue provided $900,000 for various FSMB initiatives related to opioids,[94] including $100,000 for the distribution of *Responsible Opioid Prescribing*[95] and $50,000 to fund Scott Fishman, M.D.'s, (a Purdue Key Opinion Leader, as described below) production of the book.

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[90] 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 Clinical J. Pain 179, 183 (1999).
[91] C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 Pain 71, 77 (2003).
[92] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 33 (Perry G. Fine et al. eds., 2007).
[93] *Id.* at 1.
[94] PTN000017380.
[95] PVT0060652.

- Purdue sponsored the American Pain Foundation's (APF) *Treatment Options: A Guide for People Living with Pain* (2007), which stated that opioids, when used properly, "give [pain patients] a quality of life we deserve."[96] The publication also notes that Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) (*e.g.*, aspirin and ibuprofen) have greater risks associated with long-term use, but neglected to disclose the same was true for opioid use.[97]

- Purdue sponsored APF's *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families* (2009), which taught veterans that opioid treatments "can go a long way toward improving your functioning in daily life."[98]

- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which incorrectly claimed that, "multiple clinical studies have shown that long-acting opioids in particular are effective in improving" "daily function," "psychological health," and "health-related quality of life for people with chronic pain."[99] The *Policymaker's Guide* implied that these studies presented claims of long-term improvement but, in fact, the sole reference for these claims noted the absence of long-term studies and actually stated, "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."[100]

63. Purdue sponsored a continuing medical education (CME) program entitled *Managing Patient's Opioid Use: Balancing the Need and the Risk* (2011), which made similarly unsubstantiated claims about improved functionality resulting from opioid treatment.[101] Lynn Webster, M.D., (one of Purdue's Key

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[96] American Pain Foundation, *Treatment Options: A Guide for People Living with Pain* 15 (Terry Altilio et al. eds., 2007).
[97] *Id.* at 8-15.
[98] Derek McGinnis & Stephen R. Braun, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families* 111 (2009).
[99] American Pain Foundation, *A Policymaker's Guide to Understanding Pain & Its Management* 29 (2011).
[100] Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174 Can. Med. Ass'n J. 1589, 1591 (2006), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/pdf/20060523s00017p1589.pdf.
[101] PWG000140004.

Opinion Leaders, as described below) presented the CME, claiming that opioid treatment for chronic non-cancer pain "can be associated with a number of benefits, including increased ability to work, improved function, and performing activities of daily living and improved quality of life."[102] The presentation also advised that prescribers should conduct "a benefit-to-harm evaluation that weighs the potential beneficial effects of chronic opioid therapy (ie, [*sic*] *decreased pain and improved function*) against the potential risks."[103] (Emphasis added.)

64. In 2014, almost two decades after Purdue's 1998 study on treating osteoarthritis with opioids, a similar internal Purdue literature review regarding the long-term efficacy of ER oxycodone (*e.g.*, OxyContin), suggested, in the words of Purdue's own employees, "that ERO [extended-release opioid] therapy did not lead to either substantial deterioration [in function] or further improved function."[104] In essence, Purdue admitted that opioids have little-to-no impact on a patient's function.

65. The same Purdue literature review found that more definitive data was still needed to establish "whether the potential benefits of long-term opioid therapy outweigh the serious risks associated with misuse and abuse."[105] All of the authors of that survey were full-time Purdue employees, including J. David Haddox, D.D.S., M.D. (a Purdue Key Opinion Leader and Senior Medical Director at the company), and yet Purdue continued to promote opioids as effective treatments for chronic non-cancer pain.

66. Purdue's persistent misrepresentations about the benefits of opioid therapy served its goal of masking the risks associated with opioids and influencing the prescribing habits of health care providers. A 2016 market study commissioned by Purdue found that some health care providers who prescribed opioids preferred ER opioids like OxyContin and Butrans to short-acting opioids because they preferred a "[s]teady state dose, so patients have fewer peaks and valleys for better pain control, improved function, and better quality of life."[106] That same study noted that health care providers who converted their patients directly from NSAIDs to ER opioids "speak to long-term goals of improving patient function and [quality of life] as reasons to prescribe [long-acting] opioids after NSAIDs," in contrast to those

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[102] PWG000139978.
[103] *Id.*
[104] PWG000224198.
[105] *Id.*
[106] PWG000072026.

health care providers who were reluctant to convert their patients to ER opioids because they wanted to "consider the long-term goal of getting patients off their opioid medications" and "[had] worries about weaning patients off [long-acting] opioids."[107]

67. Purdue's decades-long campaign to undermine the medical community's aversion to prescription opioids was a resounding success for Purdue but had deadly impacts for Colorado and the rest of the country. In 2012 alone, Purdue's OxyContin earned Purdue $2.8 billion.[108]

B. Purdue's deceptive scheme relied on seemingly non-biased marketing, educational materials, and medical professionals that were, in reality, sponsored by Purdue

i. *Purdue's deceptive unbranded marketing campaign*

68. While the FDA has general regulatory oversight responsibilities over the promotional activities related to Purdue's branded marketing of its specific opioid products, there are significant limitations to that regulatory scheme.

69. The FDA does not have oversight over unbranded marketing, meaning the promotional activity related to a class of drugs, *e.g.,* ER prescription opioids.[109] Notably, the FDA also does not monitor a drug company's in-person sales representatives.[110] The FDA also does not oversee unbranded CME programs or the materials distributed at those programs.[111]

70. Knowing that it could not successfully relax the medical community's skepticism about prescription opioids within the confines of the FDA's rules, Purdue exploited loopholes in the regulatory scheme by deploying a massive unbranded marketing campaign to convince the medical community that prescription opioids,

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[107] *Id.*
[108] Jenny Gold, Kaiser Health News, *Purdue Pharma promoted Oxycontin for years. Now, it is combating the opioid crisis*, PBS News Hour (Mar. 14, 2018, 11:22 AM), https://www.pbs.org/newshour/health/purdue-pharma-promoted-oxycontin-for-years-now-it-is-combating-the-opioid-crisis (last visited Sept. 4, 2018).
[109] Jesse R. Catlin & Cornelia (Connie) Pechmann, *An Investigation of Consumer and Doctor Regulatory Beliefs and Regulatory Knowledge About Pharmaceutical Drug Promotions*, 1 J. Ass'n of Consumer Research 392, 397-98 (2016).
[110] *Id.* at 396.
[111] *Id.*

as a class of drugs, were safe and effective treatments for chronic non-cancer pain. Even if this strategy indirectly benefitted its competitors, Purdue knew that in the end, if it successfully changed the narrative about opioids, it would benefit from the resulting increase in sales of its own branded opioids.

71. To avoid FDA scrutiny, Purdue developed its own national unbranded marketing campaigns, including one called *Partners Against Pain*, which ran from 1993 to 2016, and kept track of advertising metrics for these campaigns, evaluated the efficacy of Purdue's campaigns against those of competitors, and had its own marketing team create the unbranded materials used in these campaigns.

72. Purdue's marketing campaigns, including *Partners Against Pain*, targeted patients directly. For example, Purdue characterized "patient education material" and "Patient Savings Coupon Program" as part of its overall sales and marketing plan,[112] and hired celebrities like Naomi Judd and Jennifer Gray to help normalize the use of opioids and draw more attention to its branded drugs.[113]

73. Purdue's marketing strategy included funding third party organizations, known as Front Groups, to create and disseminate research, literature, and CME materials that promoted Purdue's misinformation about the safety and efficacy of opioid therapy. These Front Groups received significant monetary payments from Purdue, and much of the content in the research and materials they distributed was created, edited, and controlled by Purdue.

74. Purdue funded third party individuals to serve as "Key Opinion Leaders" (KOLs) in the industry. These individuals served on the Boards of Directors and in other leadership positions for the Front Groups. They also created and disseminated their own research and literature, and hosted CMEs that parroted Purdue's deceptive message about the safety and efficacy of opioids. Like the Front Groups, the KOLs received substantial monetary payments from Purdue, and their research and literature, as well as the content of the CMEs they presented, were heavily controlled by Purdue.

75. After Purdue laid the foundation for expanded opioid use through its Front Groups and KOLs, Purdue deployed an army of in-person sales representatives to visit prescribers in Colorado and throughout the country to

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[112] PWG000063001.
[113] PVT0054019.

promote the expanded use of opioids generally, and Purdue's branded opioids specifically.

ii. *Purdue-sponsored Front Groups*

76. Purdue's Front Groups, and the individuals leading them, disseminated written materials, like prescribing guidelines. They also hosted CMEs and other educational seminars, meant to persuade prescribers, patients, policymakers, and the general public that opioids were safe and effective for treating chronic non-cancer pain.

77. Purdue maintained control over the Front Groups by funding their operations and paying individuals who served on their respective Boards of Directors and in other leadership positions. By funding these Front Groups and the individuals leading them, Purdue was able to exert editorial control over the content of the materials distributed and seminars hosted by these groups.

78. From 2006 to 2016, Purdue provided more than $68 million in direct grants to its various Front Groups including:[114]

- $1.7 million to the American Academy of Family Physicians (AAFP);
- $1.1 million to the American Academy of Pain Management (AAPM);
- $700,000 to the American Academy of Pain Medicine (AAPMed);
- $300,000 to the American Academy of Physician Assistants (AAPA);
- $1 million to the American Osteopathic Association (AOA);
- $1.1 million to the American Pain Foundation (APF);
- $600,000 to the American Pain Society (APS);
- $2.4 million to the Center for Practical Bioethics (CPB);

[114] PWG000096255.

- $1.1 million to the National Association of Boards of Pharmacy (NABP);

- $4.5 million to the Patient Advocate Foundation (PAF);

- $400,000 to the American Society of Consultant Pharmacists (ASCP); and

- $200,000 to the US Pain Foundation (USPF).

79. Purdue funded many, if not all, of these grants to ensure that these seemingly credible and independent Front Groups supported Purdue's messaging about opioids. For example, APF received almost all of its funding from medical device and pharmaceutical companies, including Purdue.[115] In return, APF and other Front Groups disseminated unbranded publications, and conducted CMEs and other educational programs for health care providers, patients, policymakers, and the public that falsely promoted opioids as a safe and effective means of treating chronic non-cancer pain. As detailed below, Purdue largely controlled the content of those publications and CMEs.

80. In 2011, Purdue and APF entered into a "Master Consulting Services" agreement providing that Purdue would continue funding APF's operations in exchange for APF consulting services to promote Purdue's marketing initiatives.[116] Purdue provided "contacts" for each APF project, and APF provided periodic reporting on the progress of its projects, giving Purdue specific and regular access to the misrepresentations being made by APF about opioid use.[117]

81. Many of the Front Groups were led by Board members and other individuals who were paid by, or closely associated with, Purdue. For example, the AAPMed, whose leadership had significant ties to Purdue, issued a "consensus"

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[115] Charles Ornstein & Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011, 9:15 AM), https://www.propublica.org/article/the-champion-of-painkillers (last visited Sept. 4, 2018).
[116] PWG000048632.
[117] *See, e.g., id.*

statement in 1997 endorsing opioids to treat chronic pain, and claiming that the risk of opioid addiction was low.[118]

82. The chair of the committee issuing AAPMed's statement was Dr. Haddox,[119] who later became Purdue's Senior Medical Director. The sole consultant to the AAPMed committee was Russell Portenoy, M.D.,[120] one of Purdue's most prominent KOLs. AAPMed's corporate council included Purdue and other opioid manufacturers, and AAPMed's past presidents include Dr. Haddox (1998), Dr. Fishman (2005), Perry G. Fine, M.D. (2011), and Dr. Webster (2013), all of whom received significant financial payments from Purdue for promoting its deceptive messaging about opioids.[121]

83. In 2009, AAPMed and APS jointly issued treatment guidelines for opioid prescribing.[122] The authors of the treatment guidelines included Dr. Portenoy and Dr. Fine, as well as David A. Fishbain, M.D., another prominent Purdue KOL.[123] Fourteen of the twenty-one panel members behind AAPMed/APS's treatment guidelines received financial support from Purdue and other opioid manufacturers, all of whom were similarly financially motivated to promote increased opioid use.[124]

84. The AAPMed/APS treatment guidelines generally parroted Purdue's message about the safety and efficacy of opioids for treating chronic pain. But buried in the dense language of the guidelines is an acknowledgement that "[r]eliable evidence on methods to accurately assess the potential benefits of [chronic opioid therapy] is limited."[125] That is, Purdue knew it was overselling the benefits of opioids as an effective treatment for chronic pain.

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[118] American Academy of Pain Medicine & American Pain Society, *The Use of Opioids for the Treatment of Chronic Pain, A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clin. J. Pain 6, 7 (1997).
[119] *Id.* at 8.
[120] *Id.* at 8.
[121] *See* PTN000017361 (showing payments made by Purdue to Dr. Fishman, Dr. Fine, and Dr. Webster).
[122] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 J. of Pain 113 (2009).
[123] *Id.* at 113.
[124] *Id.* at 130.e1-130.e5.
[125] *Id.* at 116.

85. In the medical community, treatment guidelines generally have the effect of changing prescribing practices. Indeed, Purdue knew that treatment guidelines from seemingly independent associations could be especially influential over health care providers who were not experienced in prescribing opioids, like primary care physicians and family doctors, and thus would be more likely to rely upon what appeared to be credible and independent sources of information.

86. In fact, Purdue's sales call notes reflect that on August 5, 2013, a Colorado physician assistant informed a Purdue sales representative that he was willing to "change his treatment protocols because they are based on evidence and best practices set out by the American Pain Society."[126]

87. The 2009 treatment guidelines influenced not only prescribers, but also the scientific literature on opioids. They were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, and were widely disseminated on the internet and by other means.

88. One AAPMed/APS panel member, Joel Saper, M.D., Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel in 2008 because of his concerns that the guidelines were influenced by contributions made to AAPMed and APS and to committee members by opioid manufacturers, including Purdue.[127]

89. Purdue influenced the content of AAPMed/APS's 2009 guidelines through paid representatives on the panel, and was aware of the misinformation contained therein. When Purdue disseminated the 2009 guidelines, it failed to disclose material information including that there was limited reliable evidence on the benefits of opioid therapies, and the lack of evidence supporting claims of efficacy.

90. Purdue's influence over third party organizations also included trade organizations like the FSMB, of which the Colorado Medical Board is a member.

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[126] PCO000000002 Row: 108682 (08/05/2013).
[127] John Fauber, *Chronic Pain Fuels Boom in Opioids*, MedPage Today (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31254 (last visited Sept. 4, 2018).

91. In 2007, FSMB published *Responsible Opioid Prescribing: A Physician's Guide*,[128] and in 2012 FSMB published a second edition entitled *Responsible Opioid Prescribing: A Clinician's Guide*.[129]

92. While both editions of *Responsible Opioid Prescribing* were published by FSMB, the 2007 edition was written by Dr. Fishman, a Purdue KOL, and was heavily edited by Dr. Haddox,[130] who was the Senior Medical Director for Purdue at the time. Purdue also paid $100,000 for distribution.[131] A majority of the content and edits provided by Dr. Fishman and Dr. Haddox in the 2007 edition remained in the 2012 edition.[132]

93. FSMB knew that it had received funding from Purdue to distribute *Responsible Opioid Prescribing*. In fact, Purdue controlled the content and paid the authors of the publication. As a result, Purdue used both editions of *Responsible Opioid Prescribing* to put itself in a position to have tremendous influence over medical boards throughout the country. When the U.S. Senate Finance Committee asked FSMB in 2012 who, other than Dr. Fishman, contributed to the creation of both the 2007 and 2012 editions of *Responsible Opioid Prescribing*, nearly fifteen individuals were identified.[133] Dr. Haddox was notably absent from that list.[134]

94. The Front Groups also disseminated the same misleading information that Purdue was promoting directly. That misinformation had a profound impact on Colorado health care providers and their use of opioids to treat pain in Colorado patients.

iii. *Purdue-sponsored Key Opinion Leaders (KOLs)*

95. Purdue cultivated and financed KOLs to promote Purdue's message that opioids were safe and effective to treat chronic non-cancer pain.

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[128] Scott M. Fishman, *Responsible Opioid Prescribing A Physician's Guide* (Perry G. Fine et al. eds., 2007).
[129] Scott M. Fishman, *Responsible Opioid Prescribing A Clinician's Guide* (2d ed. 2012).
[130] PTN000019612.
[131] PVT0060652.
[132] *Compare* Scott M. Fishman, *Responsible Opioid Prescribing A Physician's Guide* (Perry G. Fine et al. eds., 2007) *with* Scott M. Fishman, *Responsible Opioid Prescribing A Clinician's Guide* (2d ed. 2012).
[133] Letter from Humayun J. Chaudry, President and CEO of the Federation of State Medical Boards, to Max Baucus, U.S. Senate (June 8, 2012).
[134] *Id.*

96. These KOLs were funded by Purdue and used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals. KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs, all of which advocated for long-term opioid therapy to treat chronic pain. As discussed above, KOLs also served on committees that developed treatment guidelines to encourage the use of opioids to treat chronic pain, and KOLs served on the Boards of the pro-opioid Front Groups that developed, selected, disseminated, and presented misleading materials and CMEs in Colorado and other states.

97. Purdue carefully vetted KOLs to ensure that they would stay on message and remain supportive of Purdue's unbranded marketing agenda. Purdue closely monitored the content of the KOLs' presentations, research materials, and CMEs. When a KOL published a "scientific" paper supporting Purdue's message about opioids, Purdue directed tremendous amounts of money and other resources into promoting that paper, and Purdue began widely citing the KOL's work in Purdue's marketing materials. Of course, in order to maintain the aura of legitimacy and independence, the KOLs and Purdue rarely, if ever, disclosed the levels to which the papers were financed and controlled by Purdue.

98. Because Purdue financed and controlled the content of the KOLs' presentations and other materials related to opioids, Purdue knew that the KOLs were overstating the benefits and efficacy of opioid treatment for chronic pain, and understating the risks associated with the drugs.

99. One of Purdue's most prominent KOLs was Dr. Portenoy who received significant funding from Purdue as early as 1997 for research and consulting work to promote opioids.[135]

100. In 1996, approximately one year before he began receiving payment from Purdue, Dr. Portenoy stated that opioid use was associated "with heightened pain and functional impairment, neuropsychological toxicity, prevarication about drug use, and poor treatment response."[136] Dr. Portenoy also stated that, "the

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[135] PTN000017361.

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

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."[137] (Emphasis added)

101. Dr. Portenoy also admitted in that same publication that, "controlled trials [of prescription opioid use] suggest favorable outcomes, but are very limited. The generalizability of these data are questionable due to the brief periods of treatment and follow-up."[138]

102. Nonetheless, Dr. Portenoy claimed that the lack of evidence supporting the efficacy of long-term opioid use should not stop doctors from prescribing opioids. Dr. Portenoy advocated for the increased use of opioids by noting that there was a lack of evidence:

> [T]hat nonmalignant pain generally, or any patient subgroup with nonmalignant pain (such as those with neuropathic pain, low back pain, headache, or idiopathic pain), are inherently unresponsive to opioids drugs. Consequently, therapy cannot be withheld based on the prior assumption that any particular pain or patient group will inevitably fail to benefit.[139]

103. Dr. Portenoy proposed what was, in effect, an uncontrolled experiment on the public with drugs he knew could have very serious consequences:

> 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.[140]

104. Purdue seized on Dr. Portenoy's opinions and mobilized its national marketing campaign to push opioids on primary care providers, nurse practitioners,

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[137] *Id.* at 208.
[138] *Id.* at 204.
[139] *Id.* at 206.
[140] *Id.* at 212.

physician assistants, and other prescribers – none of whom had the medical training, experience, or expertise of Dr. Portenoy, or the time to question Purdue's representations regarding the safety and efficacy of its opioid products.

105. Purdue hired additional health care providers like Dr. Portenoy to act as KOLs, and with the assistance of KOLs and Front Groups, Purdue set out to promote the *hypothesis* that opioids were a safe and effective treatment for chronic non-cancer pain as *fact*. Those KOLs included Dr. Webster, Dr. Fine, and Dr. Fishman, who were also affiliated with the Front Groups discussed above.[141]

106. Dr. Portenoy later admitted his deception. During an interview for the 2003 book *Pain Killer*, Dr. Portenoy was direct about his opioid work: "It was pseudoscience. I guess I'm going to have to always live with that one."[142]

107. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Dr. Portenoy admitted that his earlier work relied on evidence that was not "real":

> I gave so many lectures to primary care audiences in which the Porter and Jick article [in the *New England Journal of Medicine*, discussed below] was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*[143] (Emphasis added)

108. The letter Dr. Portenoy references, by Hershel Jick, M.D., and Jane Porter, was published in 1980 in the *New England Journal of Medicine* (NEJM) as a letter to the editor and asserted that incidences of addiction were "rare" for patients

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[141] PTN000017361.
[142] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 277 (2003).
[143] Excerpts of 2011 Interview of Russell Portenoy, 2:07-2:51, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?time_continue=2&v=DgyuBWN9D4w (last visited Sept. 4, 2018).

treated with opioids.[144] This statement was based only on a review of hospital records for hospitalized patients who were given opioids to treat *acute* pain.[145] Dr. Jick later explained to a journalist that he submitted his findings to the NEJM as a letter because the data was not robust enough to be published as a study.[146] While Purdue seized on the Jick/Porter letter, like they did Dr. Portenoy's statements, to promote its drugs as non-addictive, Dr. Jick later clarified that that was not what was suggested in the letter.[147]

109. Dr. Portenoy also admitted in a 2012 interview with the *The Wall Street Journal* that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[148] Despite these admissions, Purdue and its other KOLs continued their deceptive messaging about prescription opioids.

110. Around the same time that Dr. Portenoy's message about opioids began to unravel, Dr. Fine spoke at events and conducted CMEs in Colorado as a KOL for Purdue from 2003 to 2016, and continued to espouse the safety and efficacy of opioids.[149]

111. In the face of Dr. Portenoy's admissions, Dr. Fishman also gave presentations and lectures in Colorado as a KOL for Purdue from 2000-2010, similarly promoting opioids.[150]

112. Other Purdue KOLs visited Colorado. Micke Brown, B.S.N., R.N., a Purdue KOL and Director of Communications for APF, and Pamela Bennett, Purdue's Executive Director of Health Care Alliance Development, presented to Colorado prescribers during the Western Pain Society's 2009 Annual Clinical Meeting held in Englewood.[151]

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[144] Hershel Jick & Jane Porter, Letter to the Editor, *Addiction Rare in Patients Treated with Narcotics*, 302 N. Eng. J. Med. 123, 123 (1980).
[145] *Id.*
[146] Barry Meier, *Pain Killer: An Empire of Deceit and the Origin of America's Opioid Epidemic* 33 (2d ed. 2018).
[147] *Id.*
[148] Thomas Catan & Evan Perez*, A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, (Dec. 17, 2012, 11:36 AM), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (last visited Sept. 4, 2018).
[149] FIN000001.
[150] FISH000001.
[151] PWG000167890; PWG000167897.

113. During that meeting, Ms. Brown and Ms. Bennett gave three presentations entitled, *The Heart of Patient Advocacy: Bedside & Clinical Practice Settings*, *The Voice of Pain Advocacy: Influencing the Media*, and *Pain Advocacy in Action: Working the Frontlines of Policy*.[152] Although Ms. Bennett identified herself as a Purdue employee in the related PowerPoint presentation, Purdue's relationship with Ms. Brown was not similarly disclosed.[153]

114. To supplement the efforts of national KOLs, Purdue also employed Colorado KOLs to provide more trusted local sources of misinformation about opioids. Like the national KOLs, Purdue's Colorado-based KOLs serve in leadership positions for local third party pain organizations, like the Colorado Pain Society.[154]

115. Purdue made efforts in early 2014 to influence the Colorado Pain Society. Specifically, a Purdue sales representative was instructed to ask a Colorado prescriber about the Colorado Pain Society and find out "if there is any way the pharma reps can get involved."[155]

116. The Colorado Pain Society participated in a December 28, 2017 joint stakeholder's meeting at Colorado's Department of Regulatory Agencies (DORA) regarding new guidelines for prescribing opioids in Colorado. The Colorado Pain Society did not disclose during the meeting the affiliation between the organization's leadership and Purdue and other prescription opioid manufacturers.

117. At DORA's stakeholder's meeting, a representative for the Colorado Pain Society asserted that pain specialists are "unfairly [negatively] labeled" due to the high volume of opioids they prescribe.[156] The representative suggested that Colorado doctors should receive additional education on the treatment of pain and referred to the 2007 edition of *Responsible Opioid Prescribing*,[157] which, as discussed above, was published by FSMB but was drafted by Dr. Fishman and

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[152] PWG000167890.
[153] PWG000167897.
[154] PWG003799108; PWG003788106.
[155] PCO000000002 Row: 117251 (01/24/2014).
[156] The Division of Professions and Occupations, *Opioid Policy Stakeholder Meeting – December 28, 2017* at 13:00-13:40, YouTube (Dec. 28, 2017), https://www.youtube.com/watch?v=UEJW3o0-Dno&feature=youtu.be (last visited Sept. 4, 2018).
[157] *Id.* at 20:10-21:57.

heavily edited by Dr. Haddox from Purdue. Those relationships were not disclosed at the stakeholder's meeting.[158]

118. *Responsible Opioid Prescribing* contains much of the same misleading information about opioids detailed in this Complaint, including representations understating the risk of addiction associated with opioids, overstating the efficacy of opioids at improving function, and the deceptively-labeled concept of "pseudoaddiction," discussed in more detail below.[159]

119. By placing national and local KOLs in every available distribution channel for information in Colorado's medical community, Purdue and other opioid manufacturers effectively controlled all of the information Colorado health care providers received related to prescription opioids.

iv. *Purdue's army of sales representatives*

120. Purdue laid the groundwork for its unbranded marketing campaign with materials created and disseminated by Front Groups and KOLs, and Purdue weaponized that information through the deployment of thousands of sales representatives, called "detailers," around the country to visit prescribers in person and to facilitate speaking events hosted by local Purdue-paid health care providers. These detailers utilized and supplemented the misinformation spread by the Front Groups and KOLs to first relax prescribers' skepticism of opioids, then to convince them to convert their patients to Purdue's branded opioids, and then, finally, to increase the dosage of opioids being prescribed.

121. Russell Gasdia, a current Purdue executive and former Vice President for Sales and Marketing, testified in a 2014 deposition in another matter about Purdue's strategy to market opioids to health care providers in person. He explained "there is a process for any pharmaceutical product that is followed regardless of the product."[160] The process "usually starts with efficacy. A doctor wants to understand a products [*sic*] efficacy, will it work? Who is the patient that

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[158] *See id.* at 11:15-13:50.
[159] *See generally,* Scott M. Fishman, *Responsible Opioid Prescribing A Physician's Guide* (Perry G. Fine et al. eds., 2007); Scott M. Fishman, *Responsible Opioid Prescribing A Clinician's Guide* (2d ed. 2012).
[160] PWG003810464.

this is designed to be used for and what data or information do you have that can help me understand what its level of effectiveness will be?"[161]

122. Mr. Gasdia continued, "[t]he next important thing is how that product will be tolerated by [the] patient. Is this a product that will – what's the side effect profile? What kind of adverse events should I expect? That was the next major part of our promotional message."[162] Thus, "efficacy and side effects were the primary two things you had to demonstrate, an efficacious product with an acceptable side effect profile." [163]

123. Finally, Mr. Gasdia explained that "you try to provide a general sense of perspective for the physicians of how your drug compares to other products and categories, the efficacy, side effects, dosing schedule."[164]

124. Purdue's detailers specifically targeted primary care physicians, nurse practitioners, and physician assistants,[165] all of whom were less experienced with treating pain with opioids, and therefore likely to be more reliant on Purdue's promotional materials. Purdue also targeted prescribers who were already high volume opioid prescribers or those they believed could become high volume opioid prescribers–typically those who worked in "pain clinics."[166]

125. As the practice of medicine became more reliant on nurse practitioners and physician assistants, Purdue expanded its strategy from 2009 to 2015 to more intently target those prescribers. Purdue described nurse practitioners and physician assistants as "high value target[s], particularly due to impact on primary care."[167] Purdue wanted its sales representatives to be "deemed the preferred source for receiving promotional information" among this group of prescribers.[168]

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[161] *Id.*
[162] *Id.*
[163] *Id.*
[164] *Id.*
[165] *See, e.g.,* PWG000140164.
[166] *See, e.g.,* PWG003810929; PWG000154784.
[167] PWG000140164.
[168] PWG000435568.

126. In 2015, Purdue noted that nurse practitioners and physician assistants were responsible for over 800 million prescriptions per year, and represented the largest growth of prescribers—an 18% increase from 2014.[169]

127. Purdue's detailers reported on the visits to and conversations with Colorado health care providers in what are referred to as "call notes."

128. Purdue's detailer call notes were intended to "provide information of value for advancing sales calls," and were required to "accurately indicate who said what during the call."[170] Purdue's management and compliance department then reviewed and audited the call notes.[171]

129. Purdue's call notes indicate that, between 2006 and 2017, Purdue's Colorado detailers visited family medicine, internal medicine, and general practice physicians on more than 62,000 occasions.[172] During the same time, Purdue's sales representatives detailed nurse practitioners more than 13,000 times and physician assistants more than 23,000 times.[173]

130. Purdue trained its detailers to deliver company-approved messages, including materials created by Purdue's Front Groups, with the goal to increase opioid prescriptions generally and Purdue's drugs specifically. For example, one Purdue detailer recounted feedback they received from a Colorado prescriber about the messaging disseminated by AAPMed and APS: "[Colorado prescriber] shared a conversation he had last night with an individual who is an editor of the new guidelines coming from the AAPM[ed] and APS. The new guidelines are to show the use of opioids scientifically to be of significant benefit to patients in spite of potential for abuse. He feels this will be a significant movement in improving pain management."[174]

131. To ensure that its detailers delivered the desired message, Purdue directed and monitored its sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and by reviewing the

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[169] *Id.*
[170] PVT0006079.
[171] PWG003812775.
[172] PCO000000002.
[173] *Id.*
[174] PCO000000001 Row: 32 (11/07/2007).

detailers' call notes from each visit.[175] Purdue also required its detailers to use sales aides reviewed, approved, and supplied by Purdue and forbade detailers from using any materials that were not approved by Purdue's marketing and compliance departments.[176] Purdue ensured national consistency in its detailer's marketing by conducting national and regional sales trainings.[177]

132. Purdue knew that its detailing visits were effective at changing prescriber behavior. The effect of Purdue's detailing on prescriber behavior is well documented, including in a 2009 article correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling of in-person sales calls to prescribers.[178] In contrast, a 2017 study found that physicians ordered fewer brand-name medications and prescribed more cost-effective generic drugs if they worked in a hospital that restricted pharmaceutical sales representatives' access to prescribers.[179]

133. Detailers were trained how to handle prescribers' objections and concerns about converting patients from non-opioids or IR opioids to ER opioids, as well as concerns of prescribers who were skeptical about opioids all together. For example, when a Colorado prescriber expressed skepticism or concern about the risk of addiction associated with OxyContin, a Purdue sales representative gave "perspective" and "fair balance" "in the form that all opioids can be abused in the hands [of] those intent on abusing them."[180] (December 9, 2009)

134. When one Colorado prescriber stopped writing Butrans prescriptions because of abuse concerns, Purdue's sales representative "cleared the air and provided fair balance on Butrans stating that it is a [schedule III] opioid. It has become [the prescriber's] goal that he does not want to write for opioids or controlled substances. Having cleared the confusion the doc is now more willing to write for Butrans again."[181] (July 13, 2011). This downplayed the fact that Schedule III opioids are still addictive and prone to abuse.[182]

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[175] *See, e.g.*, PWG000346232; PTN000063163; PWG000191756.
[176] PWG003812775.
[177] *See, e.g.*, PWG000191756.
[178] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Public Health 221, 222-23 (2009).
[179] Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 JAMA 1785, 1793 (2017).
[180] PCO000000001 Row: 1343 (12/09/2009).
[181] PCO000000001 Row: 2893 (07/13/2011).
[182] 21 U.S.C. § 812(b)(3)(C).

135. Purdue also trained its detailers to convince prescribers to convert their patients from non-opioid pain treatments like NSAIDs, *e.g.*, aspirin, to ER opioids like oxycodone by overstating the efficacy of opioids, and also overstating the risks associated with NSAIDs as compared to opioids.

136. Even in the face of a national opioid epidemic, in order to gain additional market share Purdue commissioned a 2016 study to "[g]ain insight regarding what would make Prescribers who currently switch from an [*sic*] NSAID to an ERO [ER opioid] more likely to do so for a larger percentage of patients," and "[i]dentify what obstacles need overcome [*sic*] to make Prescribers more comfortable switching patients from NSAIDs to EROs."[183]

137. After they relaxed prescribers' skepticism about opioid treatment generally, Purdue trained its sales force to "[e]ffectively facilitate CONVERSIONS" (emphasis in original) to OxyContin and other Purdue branded drugs. One method used to facilitate these conversions was a 15-18 minute "Interactive Education Experience" with health care providers, in which the sales representative walked the prescriber through "5 brief patient-case vignettes highlighting the range of patients who may be appropriate for a conversion to OxyContin."[184] Three of these vignettes featured hypothetical patients with low back pain and two with osteoarthritis, *i.e.*, conditions involving chronic pain.[185]

138. Purdue sales representatives were trained to "wedge" themselves into a health care provider's prescribing decisions. As Mr. Gasdia explained in his deposition, for the promotion of Purdue's MS Contin:

> [H]ealthcare professionals [he] called on viewed [Purdue's detailers] as a resource, as people that understood the product, understood its utilization. Understood the prescribers, patient educational material, staff educational material.
>
> So [Purdue's detailers] were viewed as a resource. I don't know again specifically who or when someone might say,

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[183] PWG000072026.
[184] PWG000192795.
[185] *Id.*

> you are an expert. Certainly we were a resource and leaders in the market. And similar to other products that are leaders in market that have been involved with – you start to get viewed as a resource. And *someone they can look to for the information they need to make prescribing decisions.*[186] (Emphasis added.)

139. One training, provided at a 2012 national sales meeting, instructed detailers that "[m]ost doctors follow a stepwise approach when treating pain patients… [top sales representatives] figure out how to wedge Butrans into the appropriate clinical decision points … once their success [*sic*] with one or two patients they further drive that wedge in and ask that doctor to commit to using it in as many appropriate patients as possible."[187]

140. After Purdue's detailers effectively convinced prescribers to convert to Purdue's branded opioids, they were trained to convince prescribers to increase the dosages of the opioids being prescribed. For example, Purdue trained its detailers that "[o]nce a [health care provider] identifies an appropriate patient, Representatives should then transition to the S.T.A.R.T. Principles to help ensure the [health care provider] initiates and converts to an appropriate analgesic dose."[188] The "S.T.A.R.T." principles were one method by which Purdue's sales representatives were trained to insert themselves into the prescriber's decision-making process by "assess[ing] patients for initiation, conversion, and titration of OxyContin," presumably outside the presence of the patient.[189] "S.T.A.R.T." stands for "Supplement with IR analgesic, Titrate every 1-2 days, Adjust dose 25-50%, Reassess pain, Tailor dose."[190]

141. Using these strategies, Purdue disseminated misinformation that overstated the efficacy of its opioids, minimized or concealed the serious risks and side effects associated with opioid use, and misrepresented the ease with which those risks could be managed.

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[186] PWG003810464.
[187] PWG000191810.
[188] PWG000197618.
[189] PWG000199388.
[190] PWG000357055.

III. Purdue deployed its Front Groups, KOLs, and its own sales force to spread its false gospel about opioids for the purpose of increasing opioid use and Purdue's profits

A. Purdue misrepresented the risk of opioid addiction and how that risk could be managed

142. Purdue misled Colorado health care providers and the public at large about the consequences of taking prescription opioids, especially the risk of addiction.

143. From the launch of OxyContin, Purdue knew that it would have to overcome decades of skepticism and wariness in the medical community about the risks of addiction associated with opioids. Purdue had not conducted any studies to prove that its drugs were not addictive and Purdue knew that no independent data existed to support its claims. So, Purdue latched onto Dr. Jick's and Ms. Porter's 1980 one-paragraph letter to the editor of NEJM, which Purdue then used directly, and through its KOLs and Front Groups, to make misrepresentations about the addictiveness of opioids.

144. Relying on Dr. Jick's letter, Purdue began inundating the medical community with misleading claims that opioids were not addictive. For example, in its 1998 promotional video, *I Got My Life Back*, Purdue claimed that "[i]n fact, the rate of addiction amongst pain patients who are treated by doctors is much less than 1%."[191]

145. APF's *Exit Wounds*, which was sponsored by Purdue and targeted veterans, claimed that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."[192]

146. *Exit Wounds*, which also appeared on Purdue's website, www.inthefaceofpain.com, contained numerous other misrepresentations about the risk of addiction associated with opioids, including as an example:

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[191] Our Amazing World, *Purdue Pharma OxyContin Commercial*, YouTube (Sept. 22, 2016), https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited Sept. 4, 2018).
[192] Derek McGinnis & Stephen R. Braun, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families* 107 (2009).

> For a number of reasons, healthcare providers may be afraid to prescribe [opioids], and patients may be afraid to take them. At the core of this wariness is the fear of addiction, so I want to tackle this issue head-on.[193]
>
> If your body adjusts to a drug or medication, it may become less effective over time. This is called tolerance. This is simply a psychological process that doesn't occur for all people or with all medications. Many people with persistent pain, for example, *don't* develop tolerance and stay on the same dose of opioids for a long time. . . .[194]
>
> Opioid medications can, however, be abused or used as recreational drugs, and some people who use these drugs this way *will* become addicted. . . .[195]
>
> Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications. When used correctly, opioid pain medications *increase* a person's level of functioning; conversely, when a drug is used by somebody who is addicted, his or her function *decreases*.[196]

147. Contrary to the above representation, a great number of people who take prescription opioids do become tolerant and require ever-increasing dosages to receive the same analgesic effect.[197] Indeed, Purdue's OxyContin business relies on continuous use of the drug[198] and its sales representatives are trained to convince prescribers to increase the dosages being prescribed to patients.[199]

148. While it is true that people who abuse or misuse opioids may be become addicted, the same is also true for many people who use opioids as

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[193] *Id.* at 106.
[194] *Id.*
[195] *Id.* at 107.
[196] *Id.*
[197] Jane C. Ballantyne & Jianren Mao, *Opioid Therapy for Chronic Pain*, 349 N Engl. J. Med. 1943, 1945-46 (2003).
[198] PWG000062941; PWG000061454.
[199] *See, e.g.,* PWG000197619; PWG000199388; PWG000357055.

prescribed. Additionally, as discussed above, even the appropriate use of opioids does not guarantee increased functionality. The reality is that opioids, even when used as prescribed, are much more addictive than Purdue represented.

149. Purdue trained its detailers to parrot the message understating the risk of addiction to Colorado prescribers:

- After visiting a Colorado health care provider that prescribed OxyContin for post-operation pain, a Purdue detailer reported that the health care provider "says many [patients] have fear of getting addicted if they go on [OxyContin]. I told him that if [patients] are fearful of addiction they will probably be good when taking [OxyContin] and convince them you would not prescribe any product that would lead to major problems."[200] (March 31, 2010)

- Other call notes indicate that a Purdue detailer went over "addiction in clinical issues to show how rare it occurs in pain [patients] to alleviate concerns" of a Colorado prescriber.[201] (August 2, 2006)

150. In an effort to further convince Colorado health care providers that opioids were not addictive, Purdue's detailers also tried to distinguish between the technical definitions of opioid addiction and dependence.

- One detailer spoke with Colorado health care providers regarding the "[difference] [between] [physical dependence], tolerance, and addiction. Showed defining key terms in pain [management] tear off sheets encouraged to use [with] patients shared [patient prescribing information] for use [with patients] and their families to help educate."[202] (February 18, 2009)

- Another detailer reported "[reviewing] definitions … [health care provider] agreed some [patients] may have an addiction, but rare."[203] (July 8, 2008)

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[200] PCO000000002 Row: 42504 (03/31/2010).
[201] PCO000000002 Row: 3337 (08/03/2006).
[202] PCO000000002 Row: 23464 (02/18/2009).
[203] PCO000000002 Row: 15645 (07/08/2008).

- Another sales representative "talked to [a Colorado pharmacist] about 'confusion in her mind of physical dependence and addiction'…."[204] (January 8, 2009)

151. In fact, the alleged distinction between opioid addiction and dependence is one without a substantive difference. Whether a patient is tolerant, dependent, or addicted to opioids, the result is the same – the patient will require higher or more frequent dosages of the drug and, therefore, be at greater risk of overdose and death. To draw this distinction for the purposes of suggesting that opioids are safe is misleading, and has had deadly consequences in Colorado and nationwide.

152. Just as Purdue grew more successful in expanding the use of opioids, evidence exposing the falsity of Purdue's claims began to mount. Even a Purdue-funded study in 1999 found that 13% of patients who used OxyContin to treat headaches became addicted to the drug.[205] As discussed above in Section I, evidence-based, peer-reviewed studies indicate that the addiction rates are much higher.

B. Purdue promoted a fake condition called "pseudoaddiction"

153. To counter findings of the evidence-based, peer-reviewed studies showing that its drugs are addictive, Purdue engaged in a campaign to convince health care providers that their patients were actually just in need of higher doses of opioids—a condition Purdue called "pseudoaddiction."

154. Purdue began assuring doctors that everything they had learned in their training about opioid addiction was wrong, and that patients do not become addicted to opioids, but instead suffer from "pseudoaddiction," because "opioids are frequently prescribed in doses that are inadequate."[206]

155. By convincing prescribers that their patients were not suffering from opioid addiction, but rather "pseudoaddiction," Purdue was not only able to

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[204] PCO000000002 Row: 22158 (01/08/2009).
[205] Lawrence Robbins & Halleh Akbarnia, *Headache Relief Long-acting opioids can help alleviate the pain associated with severe, refractory chronic daily headaches*, Practical Pain Management (May 16, 2011), https://www.practicalpainmanagement.com/pain/headache/headacherelief (last visited Sept. 4, 2018).
[206] PTN000006070.

undermine common medical knowledge through its KOLs, Front Groups, and detailers, but also to increase its profits by urging doctors to increase the dosage of opioids being prescribed to patients in order to prevent "pseudoaddiction" from occurring.

- One Purdue detailer "discussed pseudoaddiction [with a Colorado prescriber] using the [American Pain Society's] booklet … [the health care provider] said he didn't really have a remedy of sorting these patients out from true addicts other than just gut feeling."[207] (May 2, 2006)

- Another detailer "briefly went over the [American Pain Society's] definition of pseudoaddiction [with a Colorado prescriber]. He admitted that he has a hard time identifying these patients."[208] (May 23, 2006)

156. The reason Colorado prescribers, and those around the country, had a difficult time distinguishing between patients who were truly addicted to opioids, and those suffering from "pseudoaddiction," was because the term had no basis in medical science, having been concocted by Dr. Haddox,[209] a Purdue executive and KOL. Nevertheless, Purdue, and many of its Front Groups, KOLs, and detailers, heavily promoted the fake science behind this false condition in an effort to deceive health care providers into second-guessing their education, training, and experience, and into prescribing more opioids.

157. A 2008 Purdue pamphlet, *Clinical Issues in Opioid Prescribing*, urged doctors to look for symptoms of "pseudoaddiction":

> [Pseudoaddiction is a] term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug-seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can

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[207] PCO000000002 Row: 1803 (05/02/2006).
[208] PCO000000002 Row: 2166 (05/23/2006).
[209] *See* David E. Weissman & J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36 Pain 363 (1989).

be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.[210]

158. In another pamphlet, *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substances Prescribing Practices* (2008), Purdue warned prescribers: "Fact[ ] About Addiction: 'Misunderstanding of addiction and mislabeling of patients as addicts results in unnecessary withholding of opioid medications.'"[211] And in its 2009 *Opioid Clinical Management Guide*, Purdue told prescribers that the patients who faced the greatest risk of opioid addiction were those who received *too little* of the drug: "The primary risk factor for misuse is uncontrolled or inadequately treated pain."[212]

159. In 2011, Purdue issued a second edition of *Providing Relief, Preventing Abuse*, which continued to urge doctors to increase dosages to address "pseudoaddiction": "The term pseudoaddiction has emerged in the literature to describe the inaccurate interpretation of [drug-seeking] behaviors in patients who have pain that has not been effectively treated."[213] Purdue's revised publication failed to disclose that none of the "literature" was based on scientific or medical evidence supporting the concept of "pseudoaddiction," and instead all came from Purdue or its Front Groups and KOLs.[214]

160. The 2012 version of the Purdue-sponsored book, *Responsible Opioid Prescribing*, which was referenced in the December 2017 DORA stakeholder's meeting, also suggested that patients who exhibit signs of addiction were instead "receiving an inadequate dose," and urged prescribers to raise the dosages of opioids in order to combat these behaviors.[215] Purdue failed to disclose the increased risk of addiction and overdose associated with higher doses of opioids.

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[210] Partners Against Pain, *Clinical Issues in Opioid Prescribing: Considerations for the practitioner in the use of opioids in managing moderate to severe pain* 2 (2008).
[211] Purdue Pharma L.P., *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substances Prescribing Practices* 6 (2008).
[212] The C.A.R.E.S. Alliance, *Opioid Clinical Management Guide: A Prescriber's Resource for Responsible Prescribing and Use* 5 (2009).
[213] Purdue Pharma L.P., *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substances Prescribing Practices* 9 (2d ed. 2011).
[214] *See generally id.*
[215] Scott M. Fishman, *Responsible Opioid Prescribing A Clinician's Guide* 92 (2d ed. 2012).

161. This false "pseudoaddiction" concept continues to be disseminated to Colorado prescribers, patients, policymakers, and the general public, including at the DORA stakeholder meeting in December 2017 referenced above.

162. Purdue knew its campaign to push "pseudoaddiction" was deceptive. KOLs and other individuals on Purdue's payroll even admitted that they used the concept of "pseudoaddiction" to describe "behaviors that are clearly characterized as drug abuse."[216] Purdue's misrepresentations and deceptive campaign about "pseudoaddiction" shows its total disregard for the increased risk of addiction caused by its actions. Instead of helping prescribers identify patients addicted to Purdue's opioids and in need of help, Purdue recklessly pushed for higher dosages to increase its sales and profits.

C. Purdue pressured prescribers by claiming that they were failing their patients if they did not prescribe opioids to relieve pain

163. In order to combat the reliable evidence exposing Purdue's deception about the efficacy of opioids and the risks associated with the drugs, Purdue sought to turn the tables on the medical community, convincing prescribers that they were in fact *failing* their patients by not treating pain with opioids. For example:

- From 2008 to 2015, Purdue's website, *In the Face of Pain*, claimed that pain care policies are at odds with best medical practices and encouraged patients to be persistent in finding doctors who will treat their pain with opioids.[217] Consistent with their general marketing strategy, that website provided testimonials from several dozen "advocates" supporting Purdue's message.[218]

- Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which downplayed the risk of addiction by only giving a few extreme examples when patients misuse prescription opioids.[219] The *Guide* also reinforced Purdue's warnings to the medical community that "under-use [of opioids] has been responsible for much unnecessary suffering" and claimed that

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[216] RP_011700.
[217] PVT0034554.
[218] *Id.*
[219] *See generally* American Pain Foundation*, Treatment Options: A Guide for People Living with Pain* (Terry Altilio et al. eds., 2007).

"[d]espite the great benefits of opioids, they are often underused," emphasizing that "[r]estricting access to the most effective medication for treating pain is not the solution to drug abuse or addiction."[220]

- APF's Purdue-sponsored *A Policymaker's Guide to Understanding Pain & Its Management* (2011) incorrectly claimed that less than 1% of children prescribed opioids would become addicted.[221] Again parroting Purdue's warnings to health care providers, the *Policymaker's Guide* also claimed that "too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include … misconceptions about opioid addiction."[222]

- A Purdue sales representative recalled that one Colorado prescriber was "concerned [that] patients who start on oxyconitn [*sic*] never get off of it."[223] In response, the sales representative "discussed how most patients have been undertreated and may have neuronal plasticity."[224] (February 6, 2006)

164. In response to one Colorado prescriber's decision to stop treating chronic pain patients, a Purdue sales representative's call notes reflect that she was "not trying to make [the Colorado health care provider] a pain provider [ ] it's just that pain is one of main reasons patients come to [health care providers]."[225] When the Colorado prescriber maintained that she would not take any new pain patients, the sales representative attempted to exert peer pressure, writing, "what are you going to do when current patient develops pain condition? … let me show you what some of your peers are doing."[226] (June 27, 2013)

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[220] *Id.* at 11-12, 15.
[221] American Pain Foundation, *A Policymaker's Guide to Understanding Pain & Its Management* 40 (2011)
[222] *Id.* at 6.
[223] PCO000000002 Row: 414 (02/06/2006).
[224] *Id.*
[225] PCO000000002 Row: 106992 (06/27/2013).
[226] PCO000000002 Row: 106992 (06/27/2013).

D. Purdue falsely claimed that addiction risks could be easily managed

165. Recognizing that evidence was mounting against opioids and that it would be difficult to convince prescribers to ignore the risks of addiction, Purdue set out to convince the more skeptical health care providers that they could effectively manage those risks, and even prevent addiction. To do this, Purdue and its Front Groups provided addiction management "tools" that were themselves deceptive.

166. For example, Purdue claimed that, by subjectively screening patients, medical professionals could effectively mitigate the risks of addiction:

- The *Treatment Options* guide, published by APF with Purdue's funding, falsely suggested that "opioid agreements" between patients and prescribers would "ensure that you take the opioid as prescribed."[227]

- Purdue's detailers provided Colorado prescribers a *Partners Against Pain* "Pain Management Kit" that contained several "drug abuse screening tools."[228] Those screening tools included the "Opioid Risk Tool," which is a five question, one-minute screening tool that relied on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease."[229]

167. Efforts to convince Colorado prescribers that they could manage the risk of addiction were central to Purdue's mission of increasing opioid prescriptions. Like many of Purdue's other representations about opioids, these efforts lacked any evidentiary support.

168. Contrary to Purdue's representations, the evidence shows that methods for preventing abuse and addiction among high-risk patients do not work in practice. For example, a 2014 Evidence Report by the Agency for Health Care Research and Quality "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" and identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment

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[227] American Pain Foundation, *Treatment Options: A Guide for People Living with Pain* 15 (Terry Altilio et al. eds., 2007).
[228] Partners Against Pain, *Pain Management Kit* 61 (2008).
[229] *Id.*

instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[230]

169. Despite this evidence, Purdue's detailers continued to mislead Colorado prescribers about their ability to manage the risks of addiction. Call notes to Colorado prescribers show that Purdue targeted health care providers who prescribed opioids to the very patients who are most predisposed to addiction and for whom Purdue's addiction management methods do not work.

170. For example, a Colorado prescriber informed a Purdue sales representative that "she tries not to treat chronic pain because her patient population is high risk … her patients tend to want lots of pain meds and it is never enough to satisfy their pain[.]"[231] Even after the prescriber admitted that "she is not fully equipped to handle treatment of chronic pain," the sales representative reported that he "bridged [the] conversation to OxyContin, [and] closed on [pursuing] Percocet patients around the clock, and patients taking hydrocodone 5mg q6h for Butrans."[232] (September 18, 2014)

E. Purdue misrepresented that OxyContin is effective for 12 hours

171. Purdue represented that its flagship drug, OxyContin, delivered 12 hours of "steady pain relief." In reality, OxyContin does not last 12 hours for most patients. This means that patients who take the drug require more opioids and face increased risk of addiction and abuse because when a patient is inadequately dosed, they begin to experience distressing psychological and physical withdrawal symptoms, which feeds their craving for higher and higher doses.

172. In order to satisfy the cravings caused by OxyContin, patients may take their next dose ahead of schedule or resort to a rescue dose of another opioid, thereby increasing the number and potency of opioids they are consuming and putting them at an increased risk of overdose.

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[230] Agency for Healthcare Research and Quality, *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain* 1, 21 (2014).
[231] PCO000000002 Row: 129368 (09/18/2014).
[232] *Id.*

173. Since its inception in the mid-1990s, OxyContin has been approved by the FDA for twice-daily "Q12" dosing. Purdue sought approval from the FDA for OxyContin's 12-hour dosing rather than 8-hour dosing, and made the 12-hour claim central to its marketing campaign. Purdue acknowledged in two letters to the FDA in 2003 and 2004, that the reason "Purdue has always trained its sales force to promote q12h dosing only" and has not sought approval for a more frequent dosing label, *e.g.*, every 8 hours, is because "[t]he 12 hour dosing schedule represents a significant competitive advantage of OxyContin over other products."[233]

174. Purdue promoted OxyContin as providing continuous, around-the-clock pain relief with the convenience of not having to wake up to take a third or fourth pill. In its advertising, Purdue claimed that OxyContin provides "Consistent Plasma Levels Over 12 Hours" and included a chart depicting plasma levels on a logarithmic scale.[234] The chart concealed the decline in OxyContin's effectiveness over 12 hours by manipulating the Y-axis to make 10mg appear to be half of 100mg.[235] This deception made the absorption rate of OxyContin appear steadier than it really is.

175. According to its own research during the development of OxyContin, Purdue knew that the drug wears off in under 6 hours in a quarter of patients and in under 10 hours in more than half of patients.[236] In 2008, the FDA found that a "substantial number" of chronic pain patients taking OxyContin experience "end-of-dose failure" with little or no pain relief at the end of the dosing period.[237]

176. In a 2013 public hearing held by the FDA, David Egliman, M.D., M.P.H., a Brown University professor and expert in "OxyContin litigation" testified about the efficacy of the Q12 dosing:

> Now, why did we get to a Q12 dose? It wasn't because of the data on efficacy of the drug. It was because Purdue Pharma needed something to distinguish its drug from

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[233] PWG000269777; PWG001165463.
[234] *See* Jeffrey Fudin et al., *OxyContin was submitted and justifiably approved by the agency as a 12-hour dosage form*, 9 J. Pain Res. 609, 610 fig.1 (2016).
[235] *Id.*
[236] PWG001048786.
[237] Letter from Janet Woodcock, MD., Dir., Center for Drug Eval. and Research, to Connecticut Attorney General Richard Blumenthal (Sept. 9, 2008), *available at https://www.scribd.com/document/328752805/Blumenthal-Cp-Woodcock*.

> other short-acting narcotics, and this became the main marketing device to increase profits. On the other hand, the data showed something else. As you can see, at 10 milligrams, the OxyContin product release was effective for less than six hours in at least 25 percent of patients. And the 20 and 30 milligram dose were effective for less than 10 hours in at least 50 percent of patients. Other Purdue studies, all of them in fact, allowed rescue or short-acting [OxyContin] to cover patients who had pain breakthrough before 12 hours. However, this does not—and this information is omitted from the label.[238]

177. In spite of this evidence and other anecdotal experiences reported by prescribers about the effectiveness of Purdue's product, Purdue continued to emphasize 12-hour dosing to prescribers, including those in Colorado:

- In the call notes from a Purdue sales call, a Colorado prescriber told the detailer "that he saw himself accelerating doses more with OxyContin vs Avinza and had good luck with Avinza, but he said he was also worrying about dose dumping with OxyContin and it is not lasting a full 12 hours. Discussed [prescribing] with 7am and 7pm vs bid [twice a day] and he agreed. Showed him levels in [prescribing information] showing no dose dump and lasting full 12 hours."[239] (February 10, 2009)

- Call notes from a Colorado sales representative's supervisor offering praise: "[y]ou addressed the importance of keeping the dosing at q12h dosing 7 and 7 or 8 and 8 etc. When he hears a patient say that OxyContin isn't lasting for 12 [hours] does he increase the frequency or does she increase the q12h dose?"[240] (January 25, 2010)

- Another Colorado prescriber "[s]tated that he almost without exception has to write OxyContin [three times a day] because it

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[238] FDA Center for Drug Evaluation and Research Public Hearing: Impact of Approved Drug labeling on Chronic Opioid Therapy, Testimony of David Egilman at 90:22-91:11, (Feb. 8, 2013), *available at* http://www.tvworldwide.com/events/fda/130207/UCM342713.pdf.
[239] PCO000000001 Row: 656 (02/09/2009).
[240] PCO000000001 Row: 1415 (01/25/2010).

doesn't last for 12 hours. He said he has the patients at the dose he feels they should be on. Was pretty firm about this."[241] (July 29, 2013)

178. As can be seen in the January 2010 call note above, for those patients who did not experience 12 hours of pain relief from OxyContin, Purdue's proposed "solution" was to increase the dosage of the opioid, rather than the frequency of the same dosage. And, as described in more detail below, instead of relinquishing its "competitive advantage" by admitting the true effective duration of OxyContin, Purdue knowingly put Colorado patients at an increased risk of addiction, overdose, and death by pushing ever higher dosages of its products.

F. Purdue misrepresented the efficacy of, and risks associated with, increased dosages

179. To increase its profits, Purdue pushed health care providers to increase the dosages of the opioids they were prescribing to patients. Purdue trained its detailers to reassure prescribers that there was no ceiling on the amount of OxyContin a patient could be prescribed.

180. Purdue emphasized to its sales representatives that increasing patients' dosages ("titration") was key to making a sale. They provided a guide entitled *Initiation, Conversion, and Titration Discussion with Appropriate Selling Tools* to help the sales force "practice verbalizing the titration message" to get patients on higher doses of opioids.[242]

181. Purdue monitored the pace at which prescribers titrated up their patients' opioids, and pushed its detailers to lobby Colorado doctors for further increases in dosage, regardless of whether it was appropriate for the patient.

- A Purdue sales representative recorded in his call notes that he had been "[c]oached on getting in a strong OxyContin presentation with focus on titration."[243] (January 3, 2012)

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[241] PCO000000002 Row: 108265 (07/29/2013).
[242] PWG000197618.
[243] PCO000000001 Row: 3538 (01/03/2012).

- Other call notes reflect that a Purdue detailer had been instructed to use Purdue's clinical studies to convince a physician of her "probable need for titration [of Butrans] from the 5 mcg to the 10 mcg" immediately following the initial dose.[244] (May 17, 2012)

182. Purdue's strategy relied heavily on the in-person sales calls when it came to increasing dosages. An internal analysis "found that there is greater loss in the 60mg and 80mg strengths (compared to other strengths) when we don't make primary sales calls."[245] Purdue's business plan emphasized that, "OxyContin is promotionally sensitive, specifically with the higher doses, and recent research findings reinforce the value of sales calls."[246]

183. Purdue convinced prescribers to increase dosages by promising that, "[o]pioid dose was not a risk factor for opioid overdose,"[247] directly contrary to Purdue's own internal admissions that "it is very likely" that there is a "dose-related overdose risk in [chronic non-cancer pain] patients on [chronic opioid therapy]."[248]

184. Purdue continued to push doctors to increase dosages because higher doses meant higher profits. While Purdue generally ignored the correlation between its drugs and the harm they caused, it very carefully monitored the correlation between even a small decrease in dosage and a decrease in revenues. According to a Purdue marketing presentation, "[a] small shift of roughly 15K prescriptions from 20mg or 15mg down to 10mg has a $2MM impact."[249]

185. Purdue's trainings on titration resonated with its Colorado detailers:

- Notes from a visit with a Colorado prescriber include the instruction "[k]eep teaching titration and get her over fear of dosing too high."[250] (January 18, 2006)

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[244] PCO000000001 Row: 4078 (05/17/2012).
[245] PWG000197618.
[246] PWG000062654.
[247] PWG000131801.
[248] PWG000226020.
[249] PWG000062583.
[250] PCO000000002 Row: 144 (01/18/2006).

- Another instruction reads, "[k]eep discussing the titration process and break through meds goals as I grow business."[251] (September 18, 2015)

- One sales representative notes that he "[c]overed titration with [Colorado health care provider], and brought up his reluctance to titrate to the 20mcg. He agreed he will do so now…I bridged to Hysingla ER and also covered initiation and titration. I got him to agree to do with both [initiation and titration]."[252] (April 6, 2016)

- One sales representative wrote in his call notes that "I noticed [Colorado health care provider] was not titrating beyond the 40mg strength. I went over titration with support of approved clinical trials. He agreed to utilize other strengths such as the 60mg and 80mg if he needs to titrate to effect."[253] (September 2, 2016)

186. Colorado prescribers relied upon Purdue's deceptive representations, and began to prescribe patients higher and higher doses of OxyContin:

- A Purdue detailer noted that a Colorado health care provider "normally doesn't go above 80mg…feels like if a patient hasn't responded by that dose they aren't going to respond…Reminded her that [OxyContin] doesn't have a ceiling dose and that as long as a patient is increasing function [OxyContin] can still provide relief at higher doses."[254] (December 13, 2006) During a subsequent sales call, the same prescriber described being "freaked out" by a referral patient who was on a dose of 480mg of OxyContin every 12 hours.[255] In response, Purdue's sales representative "[d]iscussed lacke [*sic*] of ceiling dose and end organ damage with OxyContin."[256] According to Purdue's internal records tracking OxyContin prescriptions, this prescriber rarely prescribed high dosages of OxyContin before being called on by Purdue–only 17 prescriptions for over 60mg of

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[251] PCO000000002 Row: 150668 (09/18/2015).
[252] PCO000000002 Row: 15986 (04/06/2016).
[253] PCO000000002 Row: 167051 (09/02/2016).
[254] PCO000000002 Row: 5712 (12/13/2006).
[255] PCO000000002 Row: 8205 (05/16/2007).
[256] *Id.*

OxyContin over 5 years.[257] After the sales visits described above, the prescriber began to increase her high dosage OxyContin prescriptions from 17 prescriptions in 2007 to a high of 102 prescriptions in 2010.[258] During that time, Purdue detailed the prescriber 108 times, more than twice a month on average.[259]

- A Purdue detailer also recalled discussing "[the health care provider's] OxyContin ceiling dose…said he know [*sic*] there isn't a ceiling dose [with] OxyContin but he usually starts looking of [*sic*] other options above 80mg q12°h ... said he has gone above this, but he usually finds the [patient's] pain isn't opioid responsive if they aren't getting relief [at] that level…discussed function as a key indicator…said he agrees…if he sees functional improvement he will [continue] to titrate if indicated."[260] (November 21, 2007)

- Some Purdue call notes indicate that Purdue's detailers would begin their conversations by asking Colorado prescribers whether they had an "arbitrary" dosing ceiling for OxyContin.[261]

187. Purdue convinced Colorado health care providers to increase patients' dosages, especially when prescribers began growing skeptical of Purdue's drugs:

- When a Colorado physician indicated that she normally would not prescribe more than 80mg of OxyContin because patients should respond to such a dose, Purdue's detailer "[r]eminded her that OxyContin doesn't have a ceiling dose and that as long as a patient is increasing function OxyContin can still provide relief at higher doses."[262] (December 13, 2006)

- When another Colorado prescriber indicated that her patients did not want Butrans, Purdue's detailer "went over the potential need to titrate up as was seen in clinical trials" and "[a]sked her if she

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[257] *See* PWG003984533; PCO000000002.
[258] *Id.*
[259] PCO000000002.
[260] *Id.* at Row: 11558 (11/21/2007).
[261] *See, e.g., id.* at Row: 90180 (08/10/2012).
[262] *Id.* at Row: 5712 (12/13/2006).

would be willing to do this before going away from Butrans."[263] (September 10, 2012)

- When a Colorado physician assistant reported that she did not prescribe Butrans because it had failed to control pain in some patients, Purdue's detailer asked her "if she would be willing to titrate up as well as give breakthrough medication if necessary."[264] (June 21, 2012)

188. In 2017, only after public scrutiny of opioid misuse was at a fever pitch, Purdue's Colorado call notes finally begin reflecting a shift toward pressuring prescribers to lower patients' dosages and taking them off opioids all together.[265]

G. Purdue misrepresented the efficacy of abuse-deterrent formulations of opioids

189. Facts refuting Purdue's addiction management claims come from Purdue itself. In 2010, Purdue introduced a reformulation of OxyContin that it claimed was abuse-deterrent and discontinued marketing its original formulation. The result of this action by Purdue meant that other opioid manufacturers could petition the FDA to make generic versions of Purdue's original OxyContin formulation. Before approving an Abbreviated New Drug Application (ANDA) for a generic formulation of OxyContin, the FDA was asked to determine whether the original OxyContin was voluntarily withdrawn from the market for "safety or effectiveness reasons."[266]

190. Sensing the threat generic OxyContin posed to Purdue's market dominance and bottom line, Purdue abruptly changed messaging on the addictiveness of its product. On July 13, 2012, Purdue submitted a citizen's petition to the FDA arguing that the original OxyContin formulation was prone to abuse.[267] Thus, according to Purdue itself, if generic OxyContin were allowed, "abuse of

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[263] *Id.* at Row: 92010 (09/10/2012).
[264] *Id.* at Row: 87289 (06/21/2012).
[265] *See generally id.*
[266] *See* 21 C.F.R. § 314.161 (2017).
[267] Purdue Pharma L.P., *Citizen Petition to the Food and Drug Admin.* (July 13, 2012), *available at* https://www.regulations.gov/document?D=FDA-2012-P-0760-0001.

extended release oxycodone could return to the levels experienced prior to the introduction of reformulated [abuse-deterrent] OxyContin."[268]

191. In order to protect its "competitive advantage," Purdue also argued that granting market access to generic OxyContin would exacerbate the public health crisis caused by prescription opioids–a crisis ignited by Purdue's original formulation of the drug.[269] Purdue revealed what it had known all along–opioids, and OxyContin in particular, posed significant risks to the public that far outweighed any benefits promised by Purdue.

192. By blocking approval of ANDAs for generic versions of Purdue's original OxyContin formulation, Purdue protected its market position for the release of its new allegedly abuse-deterrent drug. For reasons described below, the new formulation was not the effective "abuse-deterrent" that Purdue promised it was.

193. The 2010 reformulation introduced what Purdue called an "abuse-deterrent" formulation of its ER opioids. Specifically, Purdue's ER opioids are contained in a timed-release matrix that releases the drug over time. But if that timed-release formulation can be defeated, by crushing the pill for example, a person can get the fully concentrated dose all at once. Purdue claimed that its abuse-deterrent formulations would make it harder to crush, dissolve, or otherwise defeat the timed-release formulation.[270]

194. According to Purdue's website in 2016, abuse-deterrent formulations "are designed to provide pain relief when taken as directed while also deterring abuse by snorting and injection," and are "intended to help deter the abuse, misuse, and diversion of these prescription pain medications, while ensuring that patients in pain continue to have appropriate access to these important therapies."[271]

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[268] *Id.* at 44.
[269] *Id.* at 46.
[270] Highlights of Prescribing Information: OXYCONTIN, § 9.2 (2015), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022272s027lbl.pdf.
[271] Internet Archive Way Back Machine, Purdue Pharma L.P., *Opioids With Abuse-Deterrent Properties*, https://web.archive.org/web/20160204145228/http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last visited Sept. 4, 2018).

195. Because Purdue was the first opioid manufacturer to create an FDA-approved abuse-deterrent formula, and because of the public health crisis created by Purdue's original OxyContin, the abuse-deterrent formulation is prominently featured in Purdue's more recent marketing efforts. A 2015 marketing plan emphasized "digital tactics to increase HCP (health care professional) awareness of the ADPs (abuse-deterrent properties) of OxyContin" and proposed to "expand the HCP base" and "deliver [opioids with abuse-deterrent properties] rationale and brand specific messages."[272]

196. Like Purdue's misrepresentations about the 12-hour duration of OxyContin, Purdue sought to use its abuse-deterrent formulations to distinguish its drugs and gain an upper hand in the opioid market. In response to an objection from UnitedHealthcare that OxyContin "is still addictive in pain patients, and our patients primarily abuse orally," Purdue claimed that "addiction and abuse diagnoses in patients dispensed OxyContin [is] lower than or similar to other opioids in commercially insured and Medicaid patients," and that "OxyContin deters oral abuse in the community."[273]

197. Purdue's claims about its abuse-deterrent formulations have not held up to scientific scrutiny. There is no evidence that orally administered opioids, regardless of any abuse-deterrent features, are any less addictive–making Purdue's abuse-deterrent formulations no less risky than the originals. There are no evidence-based, peer-reviewed studies that support Purdue's claims that its abuse-deterrent formulation of OxyContin is less addictive or risky than the original formulation.[274]

198. The 2016 CDC guidelines found no evidence that abuse-deterrent formulations are an effective risk mitigation strategy.[275] Instead, the 2016 guidelines state that another study found that they might be associated with increased use of other opioids, including heroin.[276]

199. Purdue has succeeded in its efforts to promote misinformation about the efficacy of its abuse-deterrent formulations. A 2016 survey revealed that 46% of physicians erroneously believed that abuse-deterrent formulations were less

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[272] PWG000435617.
[273] PWG000062741.
[274] 2016 CDC Guideline at 21-22.
[275] *Id.*
[276] *Id.* at 14.

addictive than non-abuse-deterrent formulations.[277] In reality, both formulations are equally addictive.[278]

200. In response to a 2016 article critical of its abuse-deterrent marketing, Purdue admitted that "products with abuse-deterrent properties address [abuse] through certain routes, but they only make abuse more difficult, not impossible, and they provide no deterrence against swallowing the intact tablet."[279]

201. Nevertheless, as recently as April 2018, Dr. Webster, a one-time Purdue KOL, was still touting the benefits of abuse-deterrent opioids in Colorado.[280]

H. Purdue misrepresented the severity of opioid withdrawal

202. Purdue claimed that patients' opioid dependence could be managed by tapering the dosage being prescribed and misrepresented the severe symptoms associated with such tapering, including pain associated with opioid withdrawal.

203. For example, Purdue's 2010 *Training Guide for Health Care Providers* claimed that patients who were physically dependent on OxyContin and other opioids, but who had not developed an "addiction disorder", "[c]an generally discontinue their medicine with mild to no withdrawal syndrome once their symptoms are gone by gradually tapering the dosage according to their doctors orders."[281] Purdue's call notes, however, reveal that withdrawal syndrome from OxyContin and other opioids was a real and ongoing problem:

- A Colorado health care provider reported to a Purdue sales representative that "[h]e feels that his patients stay on ER opioids

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[277] Catherine S. Hwang et al., *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32 Clinical J. Pain 279, 281 (2016).
[278] *See* 2016 CDC Guideline at 11, 21-22 (noting that no study has evaluated the effectiveness of abuse-deterrent formulations for improving outcomes related to overdose, addiction, abuse, or misuse, and that abuse deterrent technologies do not prevent oral abuse—the most common route of administration—and can still be abused by non-oral routes).
[279] PWG000439823.
[280] Lynn R. Webster, Power Point Presentation, *The Role of ADFs in Curbing Opioid Abuse*, *available at* https://webcache.googleusercontent.com/search?q=cache:tB0-zJbrKxoJ:https://coloradopainsociety.org/wp-content/uploads/2018/04/Dr.-Webster-The-Role-of-ADFs-in-Curbing-Opioid-Abuse-Colorado.ppt+&cd=1&hl=en&ct=clnk&gl=us.
[281] PTN000000596.

and that he has a hard time getting them tapered off when it's time."[282] (February 1, 2013)

- When asked if he encountered any difficulties using Butrans, a Colorado physician indicated that he found "patients tend to go through more withdrawal due to the hyperalgesia that Butrans has an association with."[283] (March 7, 2013)

- A Colorado family medicine practitioner informed a Purdue sales representative that a patient was "suffering from withdrawals … trying to titrate themselves off of OxyContin."[284] (April 16, 2013)

204. Paradoxically, the withdrawal symptoms often associated with prescription opioid treatment include physical pain.[285] Withdrawal symptoms manifest when a patient develops a tolerance to opioids and becomes physically dependent on them.[286] Tolerance occurs when the patient no longer experiences the intended analgesic effect of the drug at a given dose, and physical dependence occurs when a patient develops an altered physiological state and exhibits withdrawal symptoms when opioids are not present in his or her system.[287] Tolerance begins after the first dose of opioids, while physical dependence begins after 5-7 days of opioid use and is clinically noticeable as early as 14-21 days after the first dose.[288] As the patient grows tolerant, they require increased dosages to deliver the same level of pain relief.[289] Additionally, as a patient becomes physically dependent they are at a greater risk for addiction because they may begin to

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[282] PCO000000002 Row: 99010 (02/01/2013).
[283] PCO000000002 Row: 100796 (03/07/2013).
[284] PCO000000002 Row: 103067 (04/16/2013).
[285] Donald Teater, *The Psychological and Physical Side Effects of Pain Medications*, Nat'l Safety Council, at 4, *available at* http://safety.nsc.org/sideeffects.
[286] *Id.*; Thomas Kosten & Tony George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 Sci. Practice Perspectives 13, 14-15 (2002).
[287] Ramsin Benyamin et al., *Opioid Complications and Side Effects*, 11 Pain Physician J., S105, S106 (2008).
[288] Patrick Rothwell, Mark Thomas, & Jonathan Gewirtz, *Protracted Manifestations of Acute Dependence After a Single Morphine Exposure*, 4 Psychopharmacology 991, 992 (2014); Kanwaljeet J.S. Anand et al., *Tolerance and Withdrawal from Prolonged Opioid Use in Critically Ill Children*, 5 Pediatrics e1208, e1210 (2010); B-J. Collett, *Opioid tolerance: the clinical perspective*, 81 British J. of Anaesthesia 58, 62 (1998).
[289] Ramsin Benyamin et al., *Opioid Complications and Side Effects*, 11 Pain Physician J., S105, S106 (2008).

experience "dysphoria (pain, agitation, malaise) and other withdrawal symptoms, which can lead to a cycle of relapse to drug use."[290] This cycle of withdrawal can lead to addiction because "repeated exposure to opioid drugs includes the brain mechanisms of dependence, which leads to daily drug use to avert the symptoms of drug withdrawal."[291] Higher and repeated dosages also increase the withdrawal pain that patients experience when they decrease or stop using prescription opioids.[292] The severity of withdrawal pain increases for patients who use opioids long-term and at a higher dose, which makes it more difficult for them to stop using opioids and more likely that they will develop an addiction and be at a greater risk of overdose.[293]

205. Purdue's representations ignored the severe symptoms associated with opioid withdrawal, including physical pain, which can be difficult to manage and often causes people to seek more opioids. Because many patients become dependent on opioids after only 5-7 days but are generally prescribed opioids (including OxyContin) for a minimum of 30 days to treat chronic pain, managing withdrawal symptoms is significantly more difficult than Purdue represents.

I. Purdue disparaged alternative pain treatments with deceptive information

206. In its efforts to the corner the market for pain treatment, Purdue overstated the benefits of its own drugs while understating the associated risks, and Purdue deliberately undermined the medical community's trust in opioid alternatives, like over-the-counter acetaminophen or NSAIDs.

207. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which parroted Purdue's claim that some opioids have "no ceiling dose as there is with the NSAIDs" and therefore are more appropriate for treatment of pain. In fact, higher doses of opioids pose a greater risk of dependence, addiction, overdose, and death.[294]

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[290] Thomas Kosten & Tony George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 Sci. Practice Perspectives 13, 15-16 (2002).
[291] *Id.* at 15.
[292] *Id.*
[293] *Id.*
[294] American Pain Foundation, *Treatment Options: A Guide for People Living with Pain* 12 (Terry Altilio et al. eds., 2007).

208. *Treatment Options* (2007) attributed 10,000 to 20,000 annual deaths to NSAID overdose,[295] when the true figure was closer to 3,200 per year.[296] Additionally, it failed to disclose the more than 12,000 prescription opioid-related deaths nationwide in 2006,[297] including 123 that year from natural or semi-synthetic opioid analgesics in Colorado alone.[298] The publication also warned that the risks associated with NSAIDs increase if "taken for more than a period of months," but failed to disclose the severe risks associated with long-term opioid use.[299]

209. APF's Purdue-sponsored *Exit Wounds*, which targeted veterans, also exaggerated the side effects of opioid alternatives like NSAIDs (*e.g.*, stomach ulcers and gastrointestinal bleeding) while understating the significantly more serious side effects associated with opioids (*e.g.*, nausea and vomiting, constipation, and mental clouding).[300] *Exit Wounds* failed all together to disclose the most dangerous consequences of opioid use—addiction, overdose, and death.[301] *Exit Wounds* also omitted warnings about the fatal interaction between opioids and anti-anxiety medicines called benzodiazepines,[302] which are commonly prescribed to veterans, and failed to acknowledge that NSAIDs, unlike opioids, are considered safe to take for pain while using benzodiazepines.[303]

210. As late as 2016, Purdue continued to target NSAID patients for conversion to opioids. At Purdue's 2016 National Sales Meeting, the "Take the

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[295] *Id.* at 10.
[296] Robert E. Tarone et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates From Recent Epidemiologic Studies*, 11 American J. Therapeutics 17, 21 (2004).
[297] Grant Baldwin, PowerPoint, *Health Burden of Prescription Drug and Heroin Overdoses* (July 1, 2015), *available at* https://www.fda.gov/downloads/drugs/newsevents/ucm454826.pdf.
[298] Colorado Dep't of Public Health & Env't, *Vital Statistics Program*, *Drug poisoning/overdose deaths by sex, manner of death, and involvement of specific drug types: Colorado residents, 1999-2017*, https://colorado.gov/pacific/cdphe/vital-statistics-program (last visited Sept.4, 2018).
[299] American Pain Foundation, *Treatment Options: A Guide for People Living with Pain* 10 (Terry Altilio et al. eds., 2007).
[300] Derek McGinnis & Stephen R. Braun, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families* 103-11 (2009).
[301] *See generally id.*
[302] *See generally id.*
[303] *See, e.g.,* Valium Medication Guide, Food and Drug Admin. 7-8 (2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/013263s094lbl.pdf#page=14 (noting that the "concomitant use of benzodiazepines and opioids increases the risk of respiratory depression" but not including any such warning regarding concomitant use of benzodiazepines and NSAIDS).

Lead" presentation identified "NSAIDs [as a] key opportunity for growth" for Butrans.[304] The presenter then set a goal for detailers: 10% of Butrans prescriptions should be conversions from NSAIDs.[305]

211. Purdue's sales representatives would frequently discuss the ceiling dose for NSAIDs and acetaminophen with Colorado prescribers, positioning opioids as a safer alternative without a ceiling dose:

- One Purdue sales representative explained this approach with a Colorado prescriber, stating that he "discussed [the prescriber's] [acetaminophen] ceiling for patients. Said he tries to keep it as low as possible. Usually doesn't go above 3000mg/day. Reminded him that by going to oxycontin when indicated can help reduce overall [acetaminophen] levels."[306] (October 10, 2006)

- Another Purdue sales representative described similar interactions with other Colorado prescribers, stating that he "discussed [acetaminophen] ceiling with Dr. [K] and Dr. [B]. Both agreed that they try and keep it between 2500-3000mg per day. Reminded both of them that by switching to OxyContin when indicated can help redue [*sic*] overall [acetaminophen] usage. Both agreed and said they usally [*sic*] go to a long acting before [acetaminophen] levels break 3000mg/day."[307] (October 5, 2006)

- In the follow up notes for a January 5, 2009 visit to one Colorado prescriber, the Purdue detailer reminded herself to "[p]ush him on combo use and ceiling doses due to Tylenol."[308]

- During another visit, the Purdue detailer "used up front close to get [the prescriber] to agree that there is no ceiling dose with OxyContin. Used [APS's osteoarthritis] book as evidence. She agreed with that in theory, but she said she usually doesn't go above a few hundred milligrams."[309] (February 12, 2007)

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[304] PWG000210548.
[305] *Id.*
[306] PCO000000002 Row: 4650 (10/10/2006).
[307] PCO000000002 Row: 4547 (10/05/2006).
[308] PCO000000002 Row: 21937 (01/05/2009).
[309] PCO000000002 Row: 6515 (02/12/2007).

212. Purdue's representations about the efficacy and safety of opioids as compared to alternative pain treatments lack any reliable scientific support. Purdue had no evidence for its position that opioids generally, or its drugs specifically, were more effective or safer than any other drugs or alternative pain treatments. Purdue's own 2013 "Guidelines on Product Promotion" admits repeatedly that "[w]e have no drugs with clinical studies that satisfy this standard."[310]

213. Purdue's deceptive campaign against NSAIDs and other opioid alternatives worked to draw prescribers away from safer pain treatments. For example, a study of 7.8 million doctor visits between 2000 and 2010 found that while prescriptions for NSAIDs and acetaminophen fell from 38% to 29%, opioid prescriptions increased from 11.3% to 19.6%.[311]

J. Purdue knowingly and intentionally continued its false and deceptive campaign for the last 25 years

214. Actual evidence-based, peer-reviewed studies about opioid therapy have laid bare the falsity of Purdue's claims about opioids generally and Purdue's branded drugs specifically. Contrary to Purdue's misrepresentations, prescription opioids are not effective for treating chronic non-cancer pain, and those who take opioids face severe risks like addiction, overdose, and death. Nonetheless, Purdue's misinformation campaign, as detailed above, and the immense harm Purdue has caused throughout the country, continues today.

215. A 2012 study in the "Journal of Pain," which followed 68,000 women over three years, found that patients who received opioid treatment were less likely to have improvement in pain, and had worsened function.[312]

216. In its 2016 published *Guideline for Prescribing Opioids for Chronic Pain* (finding no evidence supporting the proposition that opioids are effective for relieving pain or improving function or quality of life), the CDC notes that "patients who do not experience clinically meaningful pain relief in treatment (*i.e.* in 1 month)

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[310] PWG000008024.
[311] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000–2010*, 51 Med. Care 870, 870 (2013).
[312] Jennifer Brennan Braden et al., *Predictors of Change in Pain and Physical Functioning Among Post-Menopausal Women with Recurrent Pain Conditions in the Women's Health Initiative Observational Cohort*, 13 J. Pain 64, 69 (2012).

are unlikely to experience pain relief with longer-term use."[313] The Guideline also defines "chronic pain" as "pain that lasts [more than] 3 months or past the time of normal tissue healing."[314]

217. As Thomas Frieden, M.D., M.P.H., the Director of the CDC from 2011 to 2017, and Debra Houry, M.D., M.P.H., the Director of the National Center for Injury Prevention and Control, explained in 2016: "[T]he science of opioids for chronic pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh unproven and transient benefits."[315]

218. The evidence from real world opioid use similarly reflects a lack of efficacy. According to the 2017 CDC report, "[s]ales of prescription opioids in the U.S. nearly quadrupled from 1999 to 2014, but there has not been an overall change in the amount of pain Americans report."[316]

219. Preliminary analysis of state worker's compensation claims in Colorado suggest that claims in which an opioid was prescribed greatly increased both the duration and cost of such claims. That was especially true as the total number of opioid prescriptions in a particular claim increased.

220. Yet, in the face of contrary evidence and a mounting national opioid epidemic, Purdue, with the assistance of its surrogates, continued to promote opioids for a purpose that was proven to be ineffective.

IV. Purdue's false and deceptive campaign tremendously influenced Colorado health care providers' prescribing practices

221. Purdue's decades-long misinformation campaign played out in Colorado, as it has throughout the country, with dire consequences.

222. Purdue's unbranded marketing campaign, facilitated by Purdue's detailers, Front Groups, and KOLs, effectively relaxed Colorado prescribers' skepticism about prescribing opioids and expanded their use throughout this State.

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[313] 2016 CDC Guideline at 13.
[314] *Id.* at 19.
[315] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501, 1503 (2016).
[316] Centers for Disease Control and Prevention, *Prescribing Data* (Aug. 30, 2017, https://www.cdc.gov/drugoverdose/data/prescribing.html (last visited Sept. 4, 2018).

223. Purdue's detailers used unbranded CME materials related to opioids to gain access to new prescribers and convince them to prescribe opioids:

- One sales representative detailing a Colorado prescriber for OxyContin wrote: "followed up with our discussion last time on him having fears that many of his patients might be [drug] seekers. Brought in the updated CME catalog and pointed out 2 different courses that might be helpful in practicing pain management in his practice and help him identify proper patients for opioid therapy. Also discussed some of the products in the FACETS catalog that might help him in documentation. He said that he thought this resource could be helpful to him. I asked him if I could follow up with him in a few weeks to see if the courses were helpful to him and he said yes."[317] (February 22, 2010)

- Another sales representative wrote that a Colorado prescriber "is frustrated by treating pain and is by no means an expert. He feels comfortable treating a patient for a month or 2 and if the pain persists he likes to refer them to a specialist. He has a typical family medicine practice. Since he has not been in the practice long he does not know the specific break up. He has not done any of the CME work yet but plans on it."[318] (March 11, 2010)

- Another sales representative noted that "[prescriber] does not like pain patient [*sic*] they think they are a pain. He will typically refer his chronic pain patients out for a consult…. He thinks CME work might be helpful. He is not completely comfortable treating pain."[319] (May 12, 2010)

224. Call notes illustrate that in Colorado Purdue deployed its strategy of targeting prescribers who were less experienced using opioids, as well as targeting practitioners who were more likely to be high volume opioid prescribers, like pain clinicians:

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[317] PCO000000002 Row: 40448 (02/22/2010).
[318] PCO000000002 Row: 41442 (03/11/2010).
[319] PCO000000002 Row: 44690 (05/12/2010).

- One training call note states "[Colorado prescriber] is a new PA to practice. He is interested in learning more about pain management and you did a great job in providing him resources like [Partners Against Pain]. He looking [*sic*] for your guidance on pain management."[320] (January 31, 2011)

- Another training call note reads "[f]ollow up with an RN from the dinner program last evening. Planned on closing her for action to get the provider she works for to get back to [prescribing] Butrans based on the information the RN learned at the dinner. Call went fantastic – before you could close, the RN said she wants to get with the provider since they need to be using more Butrans. I would go one step further and start to help her identify patient types that they will commit to using in so next time you can close for action in a specific patient. Nice work getting a key player in the [prescribing] process in this office to get more EDUCATION on Butrans!"[321] (Emphasis in original) (October 11, 2012)

- Another call note indicates a health care provider's willingness to change prescribing practices in response to Purdue's unbranded marketing materials: "he said he will [*sic*] to change his treatment protocols because they are based on evidence and best practices set out by the American Pain Society."[322]

- One Colorado physician assistant "[s]tated that he almost without exception has to write OxyContin [three times a day] because it doesn't last for 12 hours. He said he has the patients at the dose he feels they should be on. Was pretty firm about this." The Purdue sales representative challenged him nonetheless on the appropriate dosing: "discussed titrating to next higher OxyContin dose and reducing dosing schedule to q12h as per the [full prescribing information]."[323]

- And, as one Colorado family medicine practitioner told a Purdue sales representative, "she just has never been comfortable

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[320] PCO000000001 Row: 2303 (01/31/2011).
[321] PCO000000001 Row: 4686 (10/11/2012).
[322] PCO000000002 Row: 108682 (08/05/2013).
[323] PCO000000002 Row: 108265 (07/29/2013).

> [prescribing] long acting opioids because she doesn't feel she got enough training." The sales representative responded: "I told her she wasn't alone as I hear similar statements from area [health care providers] … I told her I felt well qualified to help her."[324] (July 2, 2015)

225. Purdue designed its sales and marketing practices to overcome prescribers' traditional apprehension about using opioids and to convince them to increase both the volume and the dosage of opioids. Colorado prescribers were relentlessly detailed by Purdue's sales representatives for extended periods of time, significantly increasing the number of prescriptions they wrote, resulting in more opioid use in Colorado and, in some cases, death.

A. Dr. O.C., M.D. and Ms. A.G., R.N., A.N.P.[325]

226. Dr. O.C., M.D., was a family practitioner in Fort Collins, Colorado and Ms. A.G., R.N., A.N.P., was his nurse practitioner beginning in 2006. Despite having no specialized education, training, or experience in pain management, Dr. O.C. ran a "Pain Treatment Center" in Fort Collins.

227. Purdue's detailers visited Dr. O.C. over 340 times from January 2006 to February 2016, or almost three times every month.[326] They also visited Ms. A.G. specifically over 315 times from May 2006 to January 2016, also almost three times every month.[327]

228. Purdue's call notes with Dr. O.C. note that he generally used OxyContin as his first choice for long-acting opioid pain medication. On January 3, 2008, a Purdue detailer noted that when discussing the success Dr. O.C. had with prescribing OxyContin he asked Dr. O.C. to "use OxyContin for as many [patients] as he can when it fits [the] indication."[328]

229. According to Purdue's records, Dr. O.C. was the top OxyContin prescriber in Colorado, writing over 19,000 prescriptions for OxyContin alone from

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[324] PCO000000002 Row: 146748 (02/07/2015).
[325] While the individuals highlighted in Sections IV(A)-(C) were all subject to public disciplinary or criminal proceedings, their identities have not been disclosed here.
[326] PCO000000002.
[327] *Id.*
[328] *Id.* at Row: 12185 (01/03/2008).

January 1998 to October 2016.[329] That amounted to almost 1.7 million pills of OxyContin, about 70% of which were 40mg or stronger and about 34% of which were 80mg of the drug.[330]

230. According to public records, the Colorado Medical Board disciplined Dr. O.C. in April 2013 for failure to properly treat and monitor a patient to whom he was prescribing opioids. Specifically, Dr. O.C. failed to recognize signs of drug abuse and benzodiazepine addiction. Purdue detailed Dr. O.C. almost 120 times after that 2013 disciplinary action, or almost 3.5 times every month, which was a higher sales rate visit than before his 2013 disciplinary action.[331]

231. On one of those post-disciplinary sales calls, on June 3, 2014, during which Purdue's detailer wanted to determine what Dr. O.C.'s "biggest problem with long acting opioids" was, Dr. O.C. told the detailer that he "had trouble with the perception from new patient's [*sic*] families that the patient will become a drug addict."[332] In response, Purdue's detailer coached Dr. O.C. on "how he talks to families about addiction."[333]

232. Dr. O.C. surrendered his medical license in October 2016 following another investigation by the Colorado Medical Board for his treatment of one patient from 2007 through 2014. Dr. O.C. prescribed opioids to that patient in doses up to 870 MMEs per day. Upon information and belief, many of those prescriptions were for OxyContin.

233. Ms. A.G. was also one of the top OxyContin prescribers in Colorado, writing almost 12,000 prescriptions for OxyContin from January 2004 to December 2016, according to Purdue's records.[334] That amounted to over 900,000 OxyContin pills, almost 50% of which were 40mg or stronger and almost 10% of which were 80mg.[335]

234. In 2006, Purdue detailers tried to get Ms. A.G. to "do [a] better assessment to idnetify [*sic*] real pain patients, and not worry so much about abuse

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[329] PWG003984533.
[330] PWG003984539.
[331] PCO000000002.
[332] *Id.* at Row: 123661 (06/03/2014).
[333] *Id.*
[334] PWG003984533.
[335] PWG003984539.

and diversion."[336] When Ms. A.G. first started working for Dr. O.C., Ms. A.G. expressed concerns to Purdue's detailers about patients abusing OxyContin, to which she was advised that "[Dr. O.C.] uses OxyContin the most" and that she should "ask him why he feels comfortable using [it] for most [patients]."[337]

235. Only a few months later in 2006, Purdue's detailer noted that Ms. A.G. reported things were going well with regard to her patients on OxyContin and that "she seems to be surprised because she had been trained that OxyContin leads to abuse."[338]

236. Although Purdue's internal records show that Ms. A.G. wrote more and more prescriptions for OxyContin,[339] Purdue was not satisfied, and its detailers continued to push Ms. A.G. to prescribe OxyContin to more of her patients, utilizing the drug "sooner in the process."[340]

237. According to public records, the Colorado Board of Nursing Examiners disciplined Ms. A.G. in September 2016 for negligently or willfully practicing nursing in a substandard manner related to her treatment of a patient suffering from fibromyalgia and chronic back pain with opioids.

238. Ms. A.G.'s license was voluntarily surrendered in February 2017 after the Board found that she had willfully disregarded generally accepted nursing standards and because Ms. A.G. had a disability that made her dependent on opioids herself, making her unable to practice nursing with the reasonable skill necessary such that her patients were not endangered.

B. Dr. D.H., M.D.

239. Dr. D.H., M.D., was a primary care physician associated with several chiropractic and physical therapy clinics in Aurora, Denver, and Thornton, Colorado. Dr. D.H. did not have any specialization or certification in pain management and had not completed any medical residency that would have been applicable in the field of pain management.

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[336] PCO000000002 Row: 153 (01/19/2006).
[337] *Id.* at Row: 2019 (05/15/2006).
[338] *Id.* at Row: 3014 (07/17/2006).
[339] PWG003984533; PWG003984539.
[340] PCO000000002 Row: 18277 (10/01/2008).

240. Purdue began detailing Dr. D.H. in November 2008.[341] Dr. D.H. was immediately responsive to Purdue's promotions and on December 15, 2008, said "he would love to use OxyContin" but that he was concerned about his patients' ability to afford the drug.[342] Only a couple of weeks later, on January 9, 2009, Purdue's detailer visited Dr. D.H. again to discuss savings cards and Dr. D.H. "agreed to switch his patients who fit the criteria."[343]

241. Recognizing Dr. D.H.'s receptiveness to expanding his use of oxycodone generally and OxyContin specifically, Purdue's detailers returned on February 10, 2009. During that visit, the sales representative recognized a "need to get [Dr. D.H.] to think intermittant vs. persistant [*sic*] with OxyContin."[344] As early as this visit, the Purdue sales representative noted that Dr. D.H. "does worry about some [patients] abusing the meds."[345]

242. By July 2009, "[Dr. D.H.] said [he was] done with Vicoden [*sic*] and Percocet" and that he was "comfortable using both Ryzolt and OxyContin."[346] After several more visits, on February 3, 2010, Dr. D.H. discussed a patient with the Purdue sales representative that was on an "extremely high dose of OxyContin."[347]

243. After several more detailing visits, on June 4, 2010, Dr. D.H. told the Purdue sales representative that he was writing more and more OxyContin prescriptions and expressed a concern that too many patients were coming to him who were being treated for chronic pain with short-acting opioids like Percocet. Dr. D.H. thought it was inappropriate to prescribe a short-acting opioid, like Percocet, that the patient had to take 4-10 times per day.[348]

244. One of Dr. D.H.'s patients ("E.B.") died from opioid toxicity on June 14, 2011 after receiving 900 30mg oxycodone tablets from Dr. D.H.'s physician assistant one month prior. E.B. first visited Dr. D.H. in December 2010 complaining of pain from a fall 9 years earlier, and Dr. D.H. prescribed 60 80mg OxyContin tablets and 180 30mg OxyContin tablets. On January 25, 2011, E.B.

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[341] PCO000000002.
[342] *Id.* at Row: 21392 (12/15/2008).
[343] *Id.* at Row: 22194 (01/09/2009).
[344] *Id.* at Row: 23078 (02/09/2009).
[345] *Id.*
[346] *Id.* at Row: 30122 (07/16/2009).
[347] *Id.* at Row: 39581 (02/03/2010).
[348] *Id.* at Row: 45921 (06/04/2010).

complained that he was using almost double the prescribed dose and had run out early. Dr. D.H. then prescribed E.B. 180 oxycodone 30mg tablets and 60 OxyContin 80mg tablets. Two weeks later, after E.B. complained that OxyContin upset his stomach and that he was still experiencing chronic pain, Dr. D.H. prescribed E.B. 180 oxycodone 30mg tablets and 60 Opana 30mg tablets, an oxycodone drug manufactured by one of Purdue's competitors.

245. When E.B. returned a few weeks later, on March 15, 2011, complaining about the cost of Opana, Dr. D.H. prescribed 120 40mg OxyContin tablets and 180 30mg oxycodone tablets. Less than a month later, on April 8, 2011, E.B. returned to Dr. D.H. complaining of chronic pain and was prescribed 180 40mg OxyContin tablets and increased the other oxycodone prescription to 600 30mg tablets.

246. Purdue's call notes from a June 13, 2011 visit to Dr. D.H., the day before E.B. died from opioid toxicity, are as follows:

> [Dr. D.H.'s] first questions were about OxyContin. He asked if we knew of patients on real high doses of OxyContin. Per the OxyContin [Full Prescriber Information] says that there is no ceiling dose as long as the patient can tolerate the side effects. He then asked about Butrans. He said that he has not used it yet. He asked his new [Physician Assistant] if she had used it [ ]. She had not heard of it. I showed him the 4 patches and let him know that it was a months [*sic*] [prescription]. He then asked about the cost of Butrans. We let him know the cash price per local pharmacies. I also talked about the managed care coverage. He said that he currently did not see managed care but with the addition of [his new Physician Assistant] he was going to start. They were using many of the Partners in Pain literature. They wanted to make sure they are seeing the right patient. He identified a couple of patients that he and [his new Physician Assistant] thought of. He was thinking of patients that were on a [*sic*] opioid already. So we let him know that it takes 3 days to reach steady state.[349]

[349] PCO000000002 Row: 64598 (06/13/2011).

247. Dr. D.H. pled guilty to one count of "dispensing and distributing oxycodone outside the usual course of professional practice and for a purpose other than a legitimate medical purpose" in 2017 and was sentenced to 96 months in federal prison. On December 14, 2017, Dr. D.H. agreed to permanently relinquish his license with the Colorado Medical Board.

248. In the two years prior to E.B.'s first prescription in December of 2010, Purdue sales representatives called on Dr. D.H. 69 times, averaging almost three times per month.[350]

249. Dr. D.H. routinely wrote prescriptions for more than 300 oxycodone tablets each month and was referred to as the "Candy Man" by some patients who were later identified as members of a conspiracy to distribute prescription opioid tablets to others. From March 2010 to September 2011, Dr. D.H. wrote prescriptions for almost 44,000 oxycodone tablets.

C. Dr. K.C., D.O.

250. Dr. K.C., D.O., was an Osteopath who operated a pain clinic in Wheat Ridge, Colorado.

251. Purdue's sales representatives began detailing Dr. K.C. on January 26, 2006, with the goal of making him a high OxyContin prescriber. After almost 30 sales visits from Purdue detailers over 18 months, on May 10, 2007, Dr. K.C. agreed that "going to [OxyContin] makes sense" but he expressed concerns "about doing this because of [ ] abuse and diversion."[351]

252. After more than 30 additional visits over the course of the next 18 months, on October 1, 2008, Purdue's sales representative met with Dr. K.C. to discuss "where he is using OxyContin and with good success."[352] During that same visit, Dr. K.C. said that he "lik[ed] using [OxyContin] because it is covered and inexpensive when he uses [Purdue's] coupons."[353]

253. On April 6, 2010, after 19 more sales visits, a Purdue sales representative asked Dr. K.C. about an alleged forged prescription reported to

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[350] PCO000000002.
[351] PCO000000002 Row: 8104 (05/10/2007).
[352] *Id.* at Row: 18287 (10/01/2008).
[353] *Id.*

Purdue by a pharmacy in Littleton. The sales representative "urged [Dr. K.C.] to enroll in [the Prescription Drug Management Program]. [Dr. K.C.] said he has it on his laptop, and fires anyone that is [doctor] shopping. [I] also gave him the [Partners Against Pain] disc and went over pain contracts and urine screens. He said he follows the rules to a T." Despite recognizing these red flags, the sales representative made sure not to leave that meeting with Dr. K.C. without "[leaving] more savings cards."[354]

254. About a month later, on May 13, 2010, Purdue's sales representative returned to Dr. K.C.'s office reporting "concerns form [*sic*] local pharmacy's [*sic*] that his patients may not be legitimate. [Dr. K.C.] [s]aid he is doing all the right things such as urine testing and opioid contracts. He has had some dealings in the past with stolen [prescription] pads. I left the MED ED resource catalog for him to pull out ideas on how to protect his practice." When the sales representative left Dr. K.C.'s office, they "notice[d] most patients were young and particularly healthy looking."[355] The May 13 visit was Purdue's last to Dr. K.C.'s office.[356] Upon information and belief, Purdue never reported any of these red flags about Dr. K.C.'s practice to state or federal law enforcement in Colorado.

255. One of Dr. K.C.'s patients taking Purdue's opioids died approximately three and a half months later.

256. Between January 26, 2006 and May 13, 2010, Purdue visited Dr. K.C.'s office 95 times, nearly twice a month.[357]

257. During that time, around April 1, 2009, Dr. K.C. came under investigation for the illegal distribution of oxycodone. That investigation ultimately found that Dr. K.C. "intentionally distributed and dispensed oxycodone … outside the scope of professional practice and not for legitimate medical purposes." As the investigation came to a close, Dr. K.C. prescribed oxycodone to a patient on September 2, 2010, and that patient died the next day from "aspiration of gastric contents associated with oxycodone toxicity." While Dr. K.C. was not charged with the death of this particular patient, the prescription that Dr. K.C. wrote was found at the scene of the patient's death and it was determined that "[Dr. K.C.'s] prescription helped contribute to the death of [the patient]."

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[354] *Id.* at Row: 42855 (04/06/2010).
[355] *Id.* at Row: 44767 (05/13/2010).
[356] *See generally, id.*
[357] *See generally, id.*

258. Dr. K.C.'s medical license was revoked on January 12, 2012. He pled guilty to illegal distribution of oxycodone on May 23, 2013 and was sentenced to 48 months in federal prison.

259. Upon information and belief, Purdue rarely, if ever, reports suspicious opioid prescribers to federal or state authorities in Colorado, including the individuals identified above.

V. Purdue's false and deceptive campaign has and continues to cause significant harm to the State of Colorado and its citizens

260. Purdue's deceptive conduct, as alleged in this Complaint, which occurred in the course of Purdue's business, vocation, or occupation, has had a significant public impact on the health and well-being of the State of Colorado. Colorado has suffered an injury in fact to the health and well-being of its citizens, as well as to the financial condition of the State, which has borne a majority of the costs to mitigate the impact of the opioid epidemic caused by Purdue, and will continue to do so for years to come.

261. In 2006, more than 2.9 million opioid prescriptions were written in Colorado, a rate of approximately 62.2 prescriptions dispensed per 100 persons.[358] Approximately 15,000 of those were prescriptions for OxyContin alone, which equates to about 1.3 million OxyContin tablets.[359]

262. Opioid prescribing in Colorado peaked in 2012 at nearly 3.9 million prescriptions, a rate of 73.5 prescription per 100 residents.[360] Approximately 123,000 of those were for OxyContin prescriptions alone, which equates to approximately 8.3 million OxyContin tablets distributed in Colorado that year.[361]

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[358] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2006* (July 31, 2017), https://www.cdc.gov/drugoverdose/maps/rxstate2006.html (last visited Sept. 4, 2018).
[359] PWG003984533; PWG003984539.
[360] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2012* (July 31, 2017), https://www.cdc.gov/drugoverdose/maps/rxstate2012.html (last visited Sept. 4, 2018).
[361] PWG003984533; PWG003984539.

263. From 2006 to 2012, opioid prescriptions in Colorado increased by about 30%.[362] OxyContin prescriptions in Colorado during the same time increased by approximately 700%, and the number of OxyContin tablets distributed in Colorado during that time increased by approximately 500%.[363]

264. Prescriptions for opioids have declined in the last couple of years, dropping to approximately 3.3 million prescriptions in 2016, a rate of 59.8 prescriptions per 100 residents.[364] For most years, this translated to an opioid prescription for two out of every three Coloradans.

265. In Colorado, there were nearly 3,000 overdose deaths between 1999 and 2017 related to natural or semi-synthetic opioids, and a total of 4,287 deaths (excluding heroin) if synthetic opioids are included.[365] During this period, opioid-related overdose deaths in Colorado (excluding heroin) increased more than 409%.[366] And, despite a decline in the total number of opioid prescriptions in Colorado since 2013, the 372 deaths in 2017 was an increase of 26% in just the last four years.[367]

266. Overdose deaths in Colorado over the last two years would have been even worse had the Attorney General not facilitated the supply of naloxone ("Narcan") to law enforcement agencies and other first responders across the State. Naloxone, which is sold under the brand name Narcan, is a medication used to block the effects of opioid overdose. When administered to an overdosing person, naloxone can reverse the effects of the overdose, revive the individual, and

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[362] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2006* (July 31, 2017), https://www.cdc.gov/drugoverdose/maps/rxstate2006.html (last visited Sept. 4, 2018); United States Census Bureau, *County Intercensal Datasets: 2000-2010* (Dec. 2, 2016), https://www.census.gov/data/datasets/time-series/demo/popest/intercensal-2000-2010-counties.html, (last visited Sept. 4, 2018); Center for Disease Control and Prevention, *U.S. Prescribing Rates, 2012* (July 31, 2017), https://www.cdc.gov/drugoverdose/maps/rxstate2012.html (last visited Sept. 4, 2018); United States Census Bureau (Mar. 23, 2017), https://www2.census.gov/programs-surveys/popest/datasets/2010-2016/counties/totals/ (last visited Sept. 4, 2018).
[363] PWG003984533; PWG003984539.
[364] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2016* (July 31, 2017), https://www.cdc.gov/drugoverdose/maps/rxstate2016.html (last visited Sept. 4, 2018).
[365] Colorado Dep't of Public Health & Env't, *Vital Statistics Program*, *Drug poisoning/overdose deaths by sex, manner of death, and involvement of specific drug types: Colorado residents, 1999-2017*, https://colorado.gov/pacific/cdphe/vital-statistics-program (last visited Sept. 4, 2018).
[366] *Id.*
[367] *Id.*

potentially prevent death. Since mid-2016, there have been more than 400 overdose reversals in Colorado using naloxone.[368]

267. Between 2012 and 2014, the rate of opioid-related non-fatal overdose emergency department visits in Colorado was at the rate of 15.2 visits per 100,000 Coloradans, and opioid-related hospitalizations for an overdose were at the rate of 18.6 per 100,000 Coloradans.[369] Overall hospitalizations in Colorado from an opioid-related adverse event ranged from as low as 123 in-patient stays per 100,000 Coloradans in 2008 to a high of 251 in-patient stays per 100,000 Coloradans in 2016.[370]

268. Colorado has seen a steady increase in the number of its citizens seeking treatment for an opioid use disorder. From 2006 to 2016, Colorado saw the number of patients being treated at an Opioid Treatment Program (OTP) facility grow from 1,328 in 2006 to nearly 2,400 in 2016.[371] Over the last five years, as Colorado almost doubled the number of OTP facilities in response to the opioid crisis, those numbers are now well in excess of 5,000[372]—with most facilities having long waiting periods to serve new patients.

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[368] Interim Committee Opioid and Other Substance Use Disorder Committee, Testimony of Attorney General Cynthia Coffman at 38:00-38:30 (July 20, 2018), *available at* http://coloradoga.granicus.com/MediaPlayer.php?view_id=96&clip_id=12914.

[369] Colorado Dep't of Public Health and Env't, *Colorado Prescription Drug Profile* 5-6 (July 2017), *available at* https://www.colorado.gov/pacific/sites/default/files/PW_ISVP_Colorado%20Rx%20Drug%20Data%20Profile.pdf.

[370] Healthcare Cost and Utilization Project, *HCUP Fast States - Opioid-Related Hospital Use* (June 26, 2018), https://www.hcup-us.ahrq.gov/faststats/OpioidUseServlet?radio-3=on&location1=CO&characteristic1=01&setting1=IP&location2=US&characteristic2=01&setting2=IP&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide (last visited Sept. 4, 2018).

[371] Substance Abuse and Mental Health Services Admin., *State Profile – Colorado (2006), National Survey of Substance Abuse Treatment Services (N-SSATS)*, *available at* https://wwwdasis.samhsa.gov/dasis2/nssats/n2006_st_profiles.pdf; Substance Abuse and Mental Health Services Admin., *United States and Other Jurisdictions National Survey of Substance Abuse Treatment Services (N-SSATS): 2016 State Profile -- Colorado*, *available at* https://wwwdasis.samhsa.gov/dasis2/nssats/n2016_st_profiles.pdf.

[372] Colorado Dep't of Human Services Office of Behavioral Health, Medication-Assisted Treatment Expansion in Colorado 8 (July 20, 2018), *available at http://leg.colorado.gov/sites/default/files/images/mat_slide_deck_for_interim_study_comiittee_july_20_2018_final_.pdf*.

269. Many rural communities throughout Colorado have no OTP facilities and few, if any, practitioners providing medication-assisted treatment on an out-patient basis.[373] Thus, as a result of Purdue's conduct, there is significant need for dramatically expanded OTP and outpatient services.

270. The impact of Purdue's conduct has also been felt by some of Colorado's most vulnerable communities. In Colorado, the incidence of neonatal abstinence syndrome per every 1,000 hospital births increased from 0.4 in 1999 to 3.6 in 2014– an increase of more than 160%.[374] Additionally, opioid-related hospitalizations for patients in Colorado 65 years of age and older increased from a rate of 275 per 100,000 Coloradans in 2008 to 503 per 100,000 Coloradans population in Q3 2016— an 83% increase in just eight years.[375]

271. Additional impacts in Colorado caused by Purdue's conduct include increased incidences of child abuse and neglect as well as criminal behavior, including drug-seeking behavior resulting in assaults, burglaries, and thefts related to opioid use.

272. The State of Colorado has been harmed by Purdue's conduct and is expending its resources to address the opioid epidemic created by Purdue, and will continue to do so. State programs impacted by Purdue's conduct include, but are not limited to:

- Health care services for the poor and nearly poor, including substance and opioid use disorder treatment and medication-assisted treatment;

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[373] Substance Abuse and Mental Health Services Admin., *Buprenorphine Treatment Practitioner Locator*, https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator?distance%5Bpostal_code%5D=&distance%5Bsearch_distance%5D=10&distance%5Bsearch_units%5D=mile&field_bup_physician_city_value=&field_bup_physician_us_state_value=CO&=Apply (last visited Sept. 4, 2018).

[374] Sarah C. Haight et al., *Opioid Use Disorder at Delivery Hospitals—United States, 1999*-2014, 67 Morbidity & Mortality Weekly Report 845, 847 (2018).

[375] Healthcare Cost and Utilization Project, *Opioid-Related Hospital Use* (June 26, 2018), https://www.hcup-us.ahrq.gov/faststats/OpioidUseServlet?radio-3=on&location1=CO&characteristic1=02&setting1=IP&location2=US&characteristic2=01&setting2=IP&expansionInfoState=hide&dataTablesState=show&definitionsState=hide&exportState=hide (last visited Sept. 4, 2018).

- State workers compensation benefits;
- Criminal justice system, including law enforcement, criminal prosecutions, probation, community corrections, imprisonment, and parole;
- College/university health facilities;
- Provision of naloxone to first responders across Colorado;
- Adult protective services;
- Child welfare services, including prosecution of dependency and neglect proceedings and foster care;
- Youth Corrections;
- Adult Corrections;
- Lost Productivity/Lost Tax Revenue;
- Work/Food/Employment Assistance; and
- Early childhood development.

273. The injuries and damages suffered by the State of Colorado and its citizens were foreseeable by Purdue.

274. Purdue's conduct was the proximate cause of the injuries and damages suffered by the State of Colorado and its citizens.

FIRST CLAIM FOR RELIEF

(Violation of Section 6-1-105(1)(e) of the Colorado Consumer Protection Act: False representation as to the characteristics, ingredients, uses, benefits, alterations, or quantities of goods or services)

275. Plaintiff incorporates herein by reference all of the allegations contained in this Complaint.

276. Through the above-described conduct in the course of Purdue's business, occupation, or vocation, Purdue knowingly made false representations as to the characteristics, uses, benefits, and quantities of opioids generally, and its opioid drugs specifically, by claiming, among other things, that opioids were effective for treating chronic non-cancer pain, that they were not addictive, and that they administered pain relief for 12 hours, all in violation of the CCPA, § 6-1-105(1)(e), C.R.S.

277. In order to convince the medical community and the public at large to expand their use of opioids, Purdue deployed its Front Groups, KOLs, and detailers to spread Purdue's false and deceptive message that opioids are safe and effective methods of treating pain.

278. Purdue misrepresented nearly all of the essential characteristics of opioids, as well as specific uses, benefits, and quantities of opioids generally, and Purdue's drugs in particular. Those misrepresentations include:

- Opioids are effective at treating chronic non-cancer pain and improving function and quality of life;
- Opioids are more effective in higher doses, and higher doses do not pose an increased risk to patients;
- Opioids are not addictive, and to the extent that they are, patients' addiction can be easily managed with higher doses of opioids;
- Opioid withdrawals are not severe, and are easy to manage;
- Opioids are more effective and less risky than opioid alternative treatments, like NSAIDs; and

- Abuse-deterrent opioid formulations are effective at reducing opioid misuse.

279. Purdue knowingly and intentionally engaged in unlawful deceptive trade practices and knowingly made false representations as to the characteristics, uses, benefits, and quantities of opioids generally and its opioid drugs specifically in order to expand the use of opioids in Colorado and reap the corresponding profits.

280. The harm caused by Purdue's deception has been catastrophic in Colorado and throughout the country. Hundreds of thousands of people have died from opioid overdoses or suffered other serious consequences associated with prescription opioids, including from OxyContin and Purdue's other drugs, without any meaningful decrease in chronic pain.

SECOND CLAIM FOR RELIEF

(Section 6-1-105(1)(u), C.R.S. of the Colorado Consumer Protection Act: Fails to disclose material information concerning goods or services)

281. Plaintiff incorporates herein by reference all of the allegations contained in this Complaint.

282. Through the above-described conduct in the course of its business, occupation, or vocation, Purdue knowingly failed to disclose material information about opioids generally, and Purdue's drugs specifically–information that Purdue has known since the launch of OxyContin in the 1990s–with the intent to induce health care providers to prescribe more opioids, patients to pay for and consume more opioids, and third party payors, including the State of Colorado, to pay for more opioid prescriptions, in violation of the CCPA, § 6-1-105(1)(u), C.R.S.

283. From the time that Purdue launched its flagship opioid, OxyContin, Purdue knew that none of the representations it made, directly or indirectly, about the safety and efficacy of opioid treatment were based on reliable scientific evidence. Yet Purdue advanced its false messaging about opioids through Front Groups and KOLs in order to give its promotional scheme the appearance of reliability and substantiation. Purdue's sales force, armed with the seemingly reliable information about opioids and Purdue's products, further misled Colorado prescribers and patients, as well as policymakers and the general public.

284. Purdue failed to disclose that its representations about the efficacy of opioids, including that they were beneficial for treating chronic non-cancer pain, that OxyContin lasted for 12 hours, and that higher doses could mitigate the risk of dependence and addiction, were not based on any reliable scientific evidence. Purdue further failed to disclose that the Front Groups and KOLs it used to disseminate its misinformation campaign were paid and controlled by Purdue. Prescribers, patients, and other members of the public relied on the representations Purdue made to them without having knowledge of this material information.

285. Purdue knowingly engaged in unlawful deceptive trade practices by failing to disclose that its representations about the safety and efficacy of opioids, and its drugs specifically, were not supported by reliable scientific evidence. Purdue also failed to disclose that it funded and directed the content of the information provided to the public by Purdue's Front Groups and KOLs with the intent to influence Colorado prescribers, consumers, and the general public.

286. The harm caused by Purdue's deception has been catastrophic in Colorado and throughout the country. Hundreds of thousands of people have died from opioid overdoses or suffered other serious consequences associated with prescription opioids, including from OxyContin and Purdue's other drugs, without any meaningful decrease in chronic pain.

THIRD CLAIM FOR RELIEF

(Section 6-1-105(1)(g), C.R.S. of the Colorado Consumer Protection Act: Represents that goods or services are of a particular standard, quality, or grade if he knows or should know that they are of another)

287. Plaintiff incorporates herein by reference all of the allegations contained in this Complaint.

288. Through the above-described conduct in the course of their business, occupation, or vocation, Purdue represented that its goods were of a particular standard and quality, knowing that those representations were exaggerated, understated, or simply false, all in violation of the CCPA, § 6-1-105(1)(g), C.R.S.

289. Purdue knowingly and intentionally sought to convince prescribers, patients, and the public that opioids are a safe and effective means of treating chronic non-cancer pain. Through its Front Groups, KOLs, and sales representatives, Purdue sought to convince health care providers that opioids

generally, and its drugs in particular, were effective at treating chronic non-cancer pain. Purdue had no reliable evidence to support this representation. Purdue also knew that since OxyContin's inception, evidence-based, peer-reviewed studies proved otherwise.

290. Purdue also made more specific misrepresentations about the efficacy of some of the particular elements of its drugs, including but not limited to, that OxyContin would last for 12 hours, and that its new abuse-deterrent formulations would discourage opioid misuse.

291. Purdue also claimed that the limited benefits of opioids outweighed the risks by downplaying the severe consequences associated with opioid use, namely addiction, overdose, and death. However, as multiple public health experts have found, and as Purdue's own internal documents support, opioid treatment can have serious consequences, including dependence, addiction, overdose, and death. Contrary to Purdue's representations, these risks far outweigh the limited benefits of prescription opioid treatment.

292. When the evidence laid bare the falsity of Purdue's claims about the addictiveness of opioids, Purdue manufactured a false health condition, known as "pseudoaddiction," to convince Colorado prescribers that opioids were safer than the evidence suggested. Purdue also misrepresented the ease with which opioid addiction could be managed, including by promoting the efficacy of abuse-deterrent formulations of OxyContin that was not based in reality.

293. Purdue knowingly and intentionally engaged in unlawful deceptive trade practices. Purdue represented that opioids generally, and its drugs in particular, were of a particular standard and quality–that they were safe and effective methods of treating pain–without any evidence to support its claims. And when reliable evidence undermined its claims, Purdue persisted with its deceptive scheme in order to increase its profits.

294. The harm caused by Purdue's deception has been catastrophic in Colorado and throughout the country. Hundreds of thousands of people have died from opioid overdoses or suffered other serious consequences associated with prescription opioids, including from OxyContin and Purdue's other drugs, without any meaningful decrease in chronic pain.

295. The harm caused by Purdue's deception has been catastrophic in Colorado and throughout the country. Hundreds of thousands of people have died

from opioid overdoses or suffered other serious consequences associated with prescription opioids, including from OxyContin and Purdue's other drugs, without any meaningful decrease in chronic pain.

FOURTH CLAIM FOR RELIEF

(Section 6-1-105(1)(b), C.R.S. of the Colorado Consumer Protection Act: False representation as to the source, sponsorship, approval, or certification of goods or services)

296. Plaintiff incorporates herein by reference all of the allegations contained in this Complaint.

297. Through the above-described conduct in the course of its business, occupation, or vocation, Purdue knowingly made false representations as to the sources of information being disseminated to Colorado prescribers and patients claiming that opioids were effective for the long-term treatment of chronic non-cancer pain and were not addictive, or otherwise safe, all in violation of the CCPA, § 6-1-105(1)(b), C.R.S.

298. Purdue's Front Groups and KOLs presented themselves as reliable independent sources of information about the safety and efficacy of opioids generally, and Purdue's drugs specifically. Purdue's Front Groups and KOLs were held out to Colorado prescribers, patients, policymakers, and the general public as independent and reliable experts about opioids, but in reality they were nothing more than paid mouthpieces for Purdue.

299. The Front Groups and KOLs represented that they had reliable, fact-based evidence about the efficacy and safety of opioids. In reality, they had no reliable evidence supporting their claims that opioids were effective for the treatment of chronic non-cancer pain, or that the benefits of opioid treatment outweighed the risks.

300. Purdue knowingly and intentionally engaged in unlawful deceptive trade practices. Purdue deceived prescribers and patients as to the reliability and independence of the sources of information supporting their claims that opioids were safe and effective treatments for chronic non-cancer pain.

301. The harm caused by Purdue's deception has been catastrophic in Colorado and throughout the country. Hundreds of thousands of people have died

from opioid overdoses or suffered other serious consequences associated with prescription opioids, including from OxyContin and Purdue's other drugs, without any meaningful decrease in chronic pain.

FIFTH CLAIM FOR RELIEF

(Section 6-1-105(1)(c), C.R.S. of the Colorado Consumer Protection Act: False representation as to affiliation, connection, or association with or certification by another)

302. Plaintiff incorporates herein by reference all of the allegations contained in this Complaint.

303. Through the above-described conduct in the course of their business, occupation, or vocation, Purdue knowingly made false representations as to its affiliation, connection, or association with Front Groups and KOLs, and the information being disseminated by them claiming that opioids were effective at treating chronic non-cancer pain and were not addictive, or otherwise safe for long-term use, all in violation of the CCPA, § 6-1-105(1)(c), C.R.S.

304. Purdue's Front Groups and KOLs presented themselves as independent and reliable sources of information about the safety and efficacy of opioids for treatment of chronic non-cancer pain. The Front Groups and KOLs were integral to Purdue's strategy to convince health care providers, patients, and the public that the medical community's long-held suspicions about opioids were wrong. The Front Groups and KOLs disseminated written materials, hosted CMEs, and conducted speaking programs parroting Purdue's false and deceptive messaging that opioids were effective for treating chronic non-cancer pain, were safe for public consumption, and any risks were far outweighed by the benefits.

305. In reality, Purdue paid millions of dollars in grants and personal payments to the Front Groups and KOLs so that they would push Purdue's campaign to expand opioid use in Colorado and throughout the country, and increase Purdue's profits. The content of the materials, speeches, and CMEs published and promoted by the Front Groups and KOLs were sponsored by Purdue and only released to the public after being reviewed and approved by Purdue.

306. Purdue knowingly and intentionally engaged in unlawful deceptive trade practices. Purdue did not disclose its affiliation, connection, or association with the Front Groups or KOLs because such a revelation would undermine

Purdue's portrayal of the Front Groups and KOLs as independent and reliable sources of information for prescribers, patients, policymakers, and the general public.

307. The harm caused by Purdue's deception has been catastrophic in Colorado and throughout the country. Hundreds of thousands of people have died from opioid overdoses or suffered other serious consequences associated with prescription opioids, including from OxyContin and Purdue's other drugs, without any meaningful decrease in chronic pain.

SIXTH CLAIM FOR RELIEF

(Section 6-1-105(1)(h), C.R.S. of the Colorado Consumer Protection Act: Disparages the goods, services, or business of another by false or misleading representation of fact)

308. Plaintiff incorporates herein by reference all of the allegations contained in this Complaint.

309. Through the above-described conduct in the course of their business, occupation, or vocation, Purdue knowingly and intentionally disparaged the goods or services of another by falsely representing the risks and benefits of opioid-alternative treatments and misrepresenting the superiority of opioids as compared to those alternative treatments, all in violation of the CCPA, § 6-1-105(1)(h), C.R.S.

310. Seeking to protect and expand its dominance of the pain treatment market, Purdue set out to undermine its biggest non-opioid competitors, *e.g.*, over-the-counter pain pills and prescription NSAIDs. Purdue deployed their marketing machine, consisting of Front Groups, KOLs, and detailers, to promote false declarations about NSAIDs, including that NSAIDs caused 10,000-20,000 deaths annually when the actual number was dramatically lower.

311. Purdue also sought to undermine the market position of opioid alternatives by presenting false comparisons between opioids and non-opioid pain treatments. Purdue falsely claimed that opioids have no ceiling dose, as compared to NSAIDs, when all reliable evidence is to the contrary. And, conspicuously absent from the representations about NSAID-related death rates, was the fact that the death rate associated with opioids was significantly higher than the death rate associated with NSAIDs and other opioid-alternative pain treatments.

312. Purdue knowingly and intentionally engaged in unlawful deceptive trade practices. Purdue disparaged opioid-alternative treatments by making false claims about the alternative products and services and misleading statements about the benefits and risks of opioids as compared to opioid alternatives. Purdue's strategy was effective as it resulted in a decreased market share for opioid alternatives and an increased market share for Purdue.

313. The harm caused by Purdue's deception has been catastrophic in Colorado and throughout the country. Hundreds of thousands of people have died from opioid overdoses or suffered other serious consequences associated with prescription opioids, including from OxyContin and Purdue's other drugs, without any meaningful decrease in chronic pain.

SEVENTH CLAIM FOR RELIEF

(Public Nuisance)

314. Plaintiff incorporates herein by reference all of the allegations contained in this Complaint.

315. By engaging in the conduct described in this Complaint, Purdue created or was a substantial participant in creating and maintaining a public nuisance of addiction, illness, and death that significantly interferes with the public health, safety, and welfare. This nuisance has caused injury to the State of Colorado and killed thousands of its citizens.

316. Specifically, Purdue engaged in a campaign of deceptive marketing that facilitated the sale and distribution of opioids generally and Purdue's drugs specifically, leading directly to an epidemic of opioid addiction, illness, and death, which resulted in substantial public injuries to the State of Colorado.

317. The public nuisance created by Purdue's actions and omissions is substantial and unreasonable; it has caused harm and continues to cause significant harm to the State of Colorado and its citizens. The harm inflicted outweighs any potentially offsetting benefit.

318. Purdue knew or should have known that its deceptive and aggressive branded and unbranded promotion of opioid use would create an ongoing public nuisance.

319. The health, safety, and welfare of the citizens of Colorado, including those who use, have used, or will use opioids, as well as those affected by opioid use, is a matter of great public interest to the State.

320. Stemming the flow of prescription opioids, and abating the nuisance caused by the improper use, sale, and distribution of opioids, will save lives, prevent injuries, and make Colorado a safer place to live.

321. The State has had to use public funds to reimburse opioid prescriptions covered by the State of Colorado's employee and retiree health plans, and the State's Workers' Compensation Program. Due to Purdue's deceptive and illegal conduct in promoting opioids to treat chronic non-cancer pain, the State reimbursed opioid prescriptions for chronic non-cancer pain.

322. The State has suffered and continues to suffer injuries from a public health crisis of opioid addiction, overdose, injury, and death that Purdue knowingly created and perpetuated. As a result, the State has borne the financial costs to manage the impacts of that crisis, including but not limited to:

- Costs expended to provide health care services to treat those suffering from ailments associated with opioid use, including the provision of pharmaceutical drugs, mental health services, and other means of treating those suffering from opioid use disorder; and

- Public service costs expended to manage the harm caused by the opioid epidemic, including increased criminal justice costs, foster care costs, first responder costs, as well as youth services and elder care costs.

EIGHTH CLAIM FOR RELIEF

(Negligence)

323. Plaintiff incorporates herein by reference all of the allegations contained in this Complaint.

324. Purdue owed a duty of care to the State of Colorado and its citizens, including, but not limited to, the exercise of reasonable care in the marketing and sale of highly addictive opioids.

325. Purdue knew or should have known that its affirmative conduct in falsely, deceptively, and aggressively marketing and selling opioids generally and Purdue's drugs specifically created an unreasonable risk of harm to the State and its citizens. Knowing that severe consequences were associated with prescription opioid treatment, including addiction, overdose, and death, Purdue not only breached its duty of care, but acted with reckless indifference, implementing an aggressive branded and unbranded marketing scheme designed to deceive doctors and patients, as well as policymakers and the general public, in order to increase the use and dosages of prescription opioids generally as well as Purdue's own drugs.

326. Purdue's conduct was the cause in fact and proximate cause of increased opioid prescribing in Colorado along with the inevitable and foreseeable consequences and public harms associated with increased opioid use, including addiction, overdose, and death of Colorado citizens. The State of Colorado has suffered financial and physical harm to its business and property due to the devastating effects of the opioid crisis caused by the intentional, knowing, and reckless behavior of Purdue.

327. As a sophisticated pharmaceutical company, Purdue was aware of the FDA rules and regulations governing its conduct and marketing practices. Purdue took advantage of gaps in the federal regulatory scheme, and knowingly and deliberately tailored its marketing activities, both branded and unbranded, to avoid government oversight.

328. Purdue was aware from its internal sales data, adverse reports, publicly available studies and reports, and other sources that its deceptive marketing was expanding the use of opioids for treating chronic non-cancer pain and causing public harm.

329. The State of Colorado has used public funds to reimburse opioid prescriptions covered by the State's employee and retiree health plans, and the State's Workers' Compensation Program. Due to Purdue's negligence in promoting opioids to treat chronic non-cancer pain, the State reimbursed opioid prescriptions for chronic non-cancer pain that otherwise would not have been written or reimbursed.

330. Further, the State has suffered and continues to suffer from a public health crisis of opioid addiction, overdose, injury, and death that Purdue knowingly helped create and perpetuate. As a result, the State has borne the financial costs to manage the impacts of that crisis, including but not limited to:

- Costs expended to provide health care services to treat those suffering from ailments associated with opioid use, including the provision of pharmaceutical drugs, mental health services, and other means of treating those suffering from opioid use disorder; and

- Public service costs expended to manage the harm caused by the opioid epidemic, including increased criminal justice costs, foster care costs, first responder costs, as well as youth services and elder care costs.

NINTH CLAIM FOR RELIEF

(Fraudulent Misrepresentation)

331. Plaintiff incorporates herein all of the allegations contained in this Complaint.

332. Purdue knowingly and intentionally made material misrepresentations regarding opioids generally and Purdue's drugs specifically with the intent to induce Colorado health care providers to rely on Purdue's misrepresentations and prescribe more opioids, patients to pay for and consume more opioids, and third party payors, including the State of Colorado, to pay for more opioid prescriptions.

333. From the time that it launched its flagship opioid, OxyContin, Purdue knew that none of the representations it made about the safety and efficacy of opioid treatment were based on any reliable scientific evidence. Yet, Purdue advanced its deceptive and misleading messaging about opioids through Front

Groups and KOLs in order to give the guise of reliability and substantiation. Purdue's sales force, armed with seemingly reliable information about opioids and Purdue's products, further misled Colorado prescribers, patients, and the public.

334. Purdue's misrepresentations about the efficacy of opioids and its aggressive misinformation campaign about the known dangers of opioids, such as addiction, abuse, misuse, diversion, and overdose, were undertaken with the specific intent that health care providers, citizens, and the State of Colorado would rely on this false information and increase the use of opioids.

335. The State has suffered and continues to suffer from a public health crisis of opioid addiction, overdose, injury, and death that Purdue knowingly helped create and perpetuate. As a result, the State has borne the financial costs to manage the impacts of that crisis, including but not limited to:

- Costs expended to provide health care services to treat those suffering from ailments associated with opioid use, including the provision of pharmaceutical drugs, mental health services, and other means of treating those suffering from opioid use disorder; and

- Public service costs expended to manage the harm caused by the opioid epidemic, including increased criminal justice costs, foster care costs, first responder costs, as well as youth services and elder care costs.

TENTH CLAIM FOR RELIEF

(Fraudulent Concealment)

336. Plaintiff incorporates herein all of the allegations contained in this Complaint.

337. Purdue knowingly and intentionally concealed material facts regarding opioids generally and its drugs specifically with the intent to induce Colorado health care providers to rely on Purdue's misrepresentations and prescribe more opioids, patients to pay for and consume more opioids, and third party payors, including the State of Colorado, to pay for more opioid prescriptions.

338. Based on the known dangers associated with opioid treatment, including addiction, abuse, misuse, diversion, and overdose, as well as the lack of scientific evidence to substantiate the efficacy of opioids for treating chronic non-cancer pain, Purdue had a duty to disclose material information about the addictive and potentially deadly nature of opioid drugs.

339. From the time that Purdue launched its flagship opioid, OxyContin, Purdue intentionally and knowingly concealed material information regarding the lack of reliable scientific evidence about the safety and efficacy of opioid treatment. Purdue used Front Groups and KOLs to advance its false and deceptive messaging about opioids in order to give the guise of reliability and substantiation. Purdue's sales force, armed with seemingly reliable information about opioids and Purdue's products, further concealed the dangers associated with opioids with the intent to mislead Colorado health care providers, patients, and the public.

340. Purdue intentionally and knowingly concealed material information about the efficacy of opioids. Purdue's failure to disclose material facts about the known dangers of opioids, such as addiction, abuse, misuse, diversion, and overdose, was undertaken with the specific intent that health care providers, citizens, and the State would rely on this false information and prescribe, pay for, and use more opioids.

341. The State has suffered and continues to suffer from a public health crisis of opioid addiction, overdose, injury, and death that Purdue knowingly helped create and perpetuate. As a result, the State has borne the financial costs to manage the impacts of that crisis, including but not limited to:

- Costs expended to provide health care services to treat those suffering from ailments associated with opioid use, including the provision of pharmaceutical drugs, mental health services, and other means of treating those suffering from opioid use disorder; and

- Public service costs expended to manage the harm caused by the opioid epidemic, including increased criminal justice costs, foster care costs, first responder costs, as well as youth services and elder care costs.

RELIEF REQUESTED

WHEREFORE, the State of Colorado requests that this Court enter judgments and orders against Defendants, jointly and severally, for all claims alleged herein as follows:

A. An Order declaring Purdue's above-described conduct to be in violation of the CCPA, §§ 6-1-105(1)(b), (c), (e), (g), (h), and (u).

B. An Order permanently enjoining Purdue, its officers, directors, successors, assigns, agents, employees, and anyone in active concert or participation with Purdue with notice of such injunctive orders, from engaging in any deceptive trade practices as defined in and proscribed by the CCPA and as set forth in this Complaint.

C. Orders necessary to prevent Purdue's continued or future deceptive trade practices.

D. A Judgment in an amount to be determined at trial for restitution, and/or disgorgement, or such orders as may be necessary to completely compensate or restore to the original position of any person injured by means of Purdue's deceptive practices, pursuant to § 6-1-110(1) of the CCPA.

E. An Order requiring Purdue to forfeit and pay to the General Fund of the State of Colorado, civil penalties pursuant to §§ 6-1-112(1)(a) and 6-1-112(1)(c) of the CCPA.

F. An Order requiring Purdue to pay the costs and expenses of this action incurred by the Attorney General, including, but not limited to, Plaintiff's attorneys fees, pursuant to § 6-1-113(4) of the CCPA.

G. An Order requiring Purdue to abate the public nuisance alleged herein and a Judgment for all damages, including economic and non-economic, caused by Purdue's deceptive, negligent, and fraudulent conduct.

H. An Award of pre-judgment and post-judgment interest.

I. Any such further Orders or other relief as the Court may deem just and proper.

JURY DEMAND

THE STATE OF COLORADO DEMANDS A JURY ON ALL ISSUES SO TRIABLE.

Dated this 6th day of September, 2018.

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