DISTRICT COURT, CITY AND COUNTY OF DENVER, COLORADO 1437 Bannock Street Denver, Colorado 80202	DATE FILED: July 1, 2019 10:04 AM FILING ID: D657658E49C82 CASE NUMBER: 2018CV33300
THE STATE OF COLORADO *ex rel.* PHILIP J. WEISER, ATTORNEY GENERAL, Plaintiff, v. PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.; RHODES PHARMACEUTICALS, L.P.; MNP CONSULTING LIMITED; and RICHARD SACKLER; MORTIMER D.A. SACKLER; JONATHAN SACKLER; KATHE SACKLER; ILENE SACKLER LEFCOURT; BEVERLY SACKLER; THERESA SACKLER; DAVID SACKLER; RUSSELL GASDIA; MARK TIMNEY; CRAIG LANDAU; and JAMES DAVID HADDOX, individually, Defendants.	▲ **COURT USE ONLY** ▲
PHILIP J. WEISER, Attorney General ERIC R. OLSON, 36414* Solicitor General LESLIE A. EATON, 17791* *Acting* Deputy Attorney General JAN M. ZAVISLAN, 11636* Senior Counsel MEGAN PARIS RUNDLET, 27474* Assistant Solicitor General JOHN FEENEY-COYLE, 44970* Assistant Attorney General 1300 Broadway, 7th Floor Denver, CO 80203 Phone: (720) 508-6000 John.Feeney-Coyle@coag.gov *Counsel of Record	Case No. 18CV33300 Courtroom 275
FIRST AMENDED COMPLAINT AND JURY DEMAND	

TABLE OF CONTENTS

1. Plaintiff, the State of Colorado, upon relation of Philip J. Weiser, Attorney General for the State of Colorado, and acting in his *parens patriae* capacity, by and through undersigned counsel, alleges the following First Amended Complaint against Defendants.

DEFENDANTS CREATED THE OPIOID EPIDEMIC

2. The State of Colorado and its citizens are suffering the ravages of the opioid epidemic. The root cause of the opioid epidemic is a blizzard of prescription opioids Defendants unleashed on the medical community and the public.

3. At the epicenter of the opioid epidemic are Defendants Purdue Pharma, L.P. and Purdue Pharma, Inc. (collectively, "Purdue"), the manufacturer of the blockbuster opioid painkiller, OxyContin. OxyContin is 50% stronger than morphine.

4. Purdue and the individual Defendants originated, spearheaded, directed, and/or sanctioned a widespread multifaceted deceptive and reckless campaign to market and sell opioids.

5. When Purdue launched OxyContin in the winter of 1996, the company's executives proclaimed it was time to "Awaken the Sleeping Giant!"[1] One of Purdue's owners, Richard Sackler, ominously predicted, "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition." The blizzard will "be so deep, dense and white that you will never see their White Flag."[2]

6. Purdue and the individual Defendants knew that the success of OxyContin hinged on overcoming the prevailing wisdom in the medical community that opioids should rarely be prescribed because of the high risk of addiction and overdose. Defendants seeded doubt in the medical community with promotional materials that appeared to be based upon scientific evidence developed by reliable and independent third parties but, in reality, were created, sponsored, and influenced by Purdue and the individual Defendants.

7. Purdue and the individual Defendants seized upon and manipulated unsubstantiated "studies," and used what appeared to be independent "experts" and

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[1] PKY180280954.
[2] PKY180280951-52, 58.

third party organizations – all paid and controlled by Purdue – to spread false and misleading messages to prescribers and to the public at large that chronic pain is a vastly undertreated condition that can be safely and effectively treated with opioids.

8. For example, just two years after OxyContin's launch, the Sackler Defendants directed and/or sanctioned the release of Purdue's promotional video, *I Got My Life Back*, which over the course of several years was mailed to thousands of health care providers around the country, including in Colorado, and appeared on Purdue's website, www.partnersagainstpain.com.[3] *I Got My Life Back* featured seven patients who claimed that OxyContin improved their lives. The video also featured a Purdue-paid "expert" who falsely claimed that "[i]n fact, the rate of addiction amongst pain patients who are treated [with opioids] by doctors is much less than 1%."[4] Following the release of *I Got My Life Back*, at least two of the seven featured patients died as active opioid abusers, and a third patient became addicted to OxyContin before quitting the drug for fear of overdose. The Purdue-paid "expert" later admitted that his claim about the low rate of opioid addiction was not based on any long-term studies and that he went too far in suggesting otherwise.[5]

9. Purdue's captive third party organizations and independent "experts," like the one featured in *I Got My Life Back*, were key components of Defendants' deceptive marketing campaign.

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[3] PDD9521403504.
[4] Our Amazing World, *Purdue Pharma OxyContin Commercial*, YouTube (Sept. 22, 2016), https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited June 26, 2019); PDD9521403001.
[5] John Fauber and Ellen Gabler, *What happened to the poster children of OxyContin?*, MILWAUKEE JOURNAL SENTINEL (Sept. 8, 2012), http://archive.jsonline.com/watchdog/watchdogreports/what-happened-to-the-poster-children-of-oxycontin-r65r0lo-169056206.html/?abc=S3DgxOpm (last visited June 26, 2019).

10. Another key component of Defendants' deceptive marketing campaign was Purdue's army of sales representatives. Armed with Purdue's deceptive promotional materials, a massive sales force made millions of in-person sales calls on health care providers in Colorado and nationwide. As directed and/or sanctioned by the individual Defendants, Purdue's sales force was trained to support the launch of OxyContin by:

> [C]onvincing health care professionals to start with OxyContin as soon as patients with moderate to severe pain require opioid therapy for more than a few days. [OxyContin] is also the one to stay with by [increasing] the dose, thereby eliminating or delaying the need for other long-acting products. This strategy more than doubles the market potential for OxyContin…[6]

11. Purdue and the individual Defendants trained sales representatives to: (a) relax prescriber aversion to prescription opioids using unbranded marketing materials promoting the expanded use of prescription opioids; (b) convert prescribers to Purdue's branded opioids; (c) convince prescribers to increase (titrate up) opioid dosages and the duration of opioid treatment; and then when Purdue lost the patents for its branded opioids, (d) convince prescribers and pharmacies to prescribe or fill prescriptions for Defendant Rhodes Pharmaceuticals's generic opioids.

12. Defendants deceived Colorado health care providers, patients, policymakers, and the public about the safety and efficacy of prescription opioids. Defendants' material misrepresentations in Colorado about opioids include:

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

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

- Conjuring up a deceptive syndrome called "pseudoaddiction" (a purported condition which mimics addiction that is caused by the under treatment of

[6] PKY180280954.

pain, *i.e.,* not using enough opioids) in order to counter claims that opioids could lead to abuse and addiction;

- Deceptively advising health care professionals that they could manage and avoid addiction in their patients;

- Misrepresenting the effective treatment duration of its opioids and the risks associated with end-of-dose failure;

- Misrepresenting the efficacy of, and risks associated with, increased dosages and longer durations of opioid treatment, including a failure to disclose the corresponding increased risks of addiction, overdose, and death;

- Overstating the efficacy of abuse-deterrent formulations of opioids;

- Downplaying the severity of opioid withdrawal; and

- Downplaying the risks and overstating the benefits of opioids as compared to alternative pain treatments.

13. Defendants' deceptive and reckless marketing campaign successfully duped the medical community and the public into believing that opioids were safe and effective for treating chronic pain with low risk of addiction.

14. Defendants' blizzard of opioids blanketed Colorado and the nation with innumerous opioid pills, earning billions of dollars from the sale of OxyContin and Purdue's other opioid drugs.[7] Defendant Rhodes Pharmaceuticals further blanketed Colorado with millions more generic prescription opioids.

15. Defendants' deceptive and reckless marketing campaign has devastated Colorado. When Defendants became aware of the devastation their campaign wrought on Colorado, not only did they do nothing to stop it, they pushed forward on their quest for greater corporate profits and larger personal fortunes.

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[7] 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 June 26, 2019).

16. When Defendants realized that they were going to be held responsible for creating and continuing the country's opioid epidemic, they conspired to drain Purdue of billions of dollars and other assets rather than taking any action to remediate the crisis they created.

17. The State paid for millions of opioid prescriptions and has borne much of the costs to treat opioid addiction and remediate the devastating public impacts caused by Defendants' deceptive and reckless conduct. The State's employee health insurance and workers compensation programs, health programs, child welfare, criminal justice, and other programs have incurred massive costs as a result of the opioid epidemic.

18. Most tragically, Defendants' deceptive and reckless opioid campaign resulted in widespread opioid addiction, overdoses, and thousands of deaths in Colorado. While Defendants reaped billions in corporate and personal profits, Colorado families have lost parents, children, and friends to this disastrous opioid epidemic.

19. Attorney General, Philip J. Weiser, brings this enforcement action on behalf of the State of Colorado to stop Defendants' deceptive and reckless conduct, to enforce Colorado law, and to hold all Defendants jointly and severally responsible for remedying the harm they have caused Colorado and its citizens.

PARTIES

20. Plaintiff is the State of Colorado *ex. rel.* Philip J. Weiser, Attorney General (hereinafter "the State" or "Attorney General").

21. The Attorney General is authorized to bring this action in his *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 Defendants' misconduct. The State of Colorado, as a legal entity, has suffered enormous damages and losses as a direct and proximate result of Defendants' misconduct described herein.

22. The Attorney General is authorized to bring this action against Defendants for violations of the Colorado Consumer Protection Act ("CCPA") pursuant to § 6-1-103, C.R.S. (2019).

23. The Colorado Attorney General is authorized to bring this action against Defendants for violations of the Colorado Organized Crime Control Act ("COCCA") pursuant to § 18-17-106(5), C.R.S. (2019).

22. As a "creditor" under § 38-8-102(5), C.R.S., of the Colorado Uniform Fraudulent Transfer Act ("CUFTA"), the State of Colorado *ex rel.* the Attorney General, is authorized to bring this action seeking relief under CUFTA, § 38-8-108, C.R.S. (2019).

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

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

25. Purdue Pharma L.P and Purdue Pharma, Inc. are referred to collectively as "Purdue." Unless otherwise noted, all allegations herein asserted against Purdue are directed to Purdue Pharma L.P. and Purdue Pharma, Inc.

26. At all relevant times, Defendant members of the Sackler family owned, directed, and controlled Purdue. Since the launch of OxyContin in 1996, Defendant members of the Sackler family directed Purdue's conduct directly and since at least 2003, Defendant members of the Sackler family directed Purdue's conduct directly and/or indirectly through the company's Executive Committee.[8]

27. From 2003 through at least 2018, Purdue's Executive Committee has been the primary decision-making body at the company, always acting under the direction and control of the Sacklers.[9] For example, according to the Charter for Purdue's 2015 Executive Committee:

> *Under the direction of the Board*, the Executive Committee is the primary governance and decision-making body at Purdue. The Executive Committee sets overall product, organizational direction, and strategy (including identifying new therapeutic areas to enter, product development and acquisition opportunities to

[8] #92782.1.
[9] PPLPC037000075129.

> pursue and significant changes to business processes), and oversees processes to manage critical events. This committee focuses on providing high level direction on key day-to-day operational issues. Regularly reviews and provides input on the decisions and direction being recommended/taken by a specified group of subsidiary committees[.][10] (emphasis added)

28. Purdue's various CEOs always served as the Chair of the Executive Committee, including Defendants Mark Timney and Craig Landau.[11] Russell Gasdia served on Purdue's Executive Committee for several years before leaving the company at the end of 2014.[12] Craig Landau served on the Executive Committee for several years before taking charge of Purdue Canada in 2013, and then returned to Chair the Executive Committee when he became President and CEO of Purdue in 2017.[13]

29. All of the non-Sackler individual Defendants were executives at Purdue and, with the exception of Defendant James David Haddox, all served on Purdue's Executive Committee during their tenure with the company. As executives and/or members of Purdue's Executive Committee, all of the non-Sackler individual Defendants carried out the Sackler Defendants' directives that Purdue engage in a years-long deceptive and reckless marketing campaign in Colorado and around the country. The Defendant Sackler family members were and are the ultimate intended beneficiaries of virtually all of Purdue's profits. The individual Sackler Defendants are living Sackler family members who served on the Board of Directors and/or as officers of Purdue.

30. Purdue, as directed by the individual Defendants, transacts business in Colorado and nationwide. Purdue specifically targeted its deceptive and reckless opioid business at Colorado prescribers, patients, and the public to increase sales of opioids in Colorado. Purdue's Colorado and nationwide opioid sales resulted in

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[10] PPLPC016000243953.
[11] #92782.1; PDD8901816720; PDD8901159365; PPLPC012000189634; PPLPC037000075085; PPLPC037000075729; PPLPC037000076751; PPLPC034000480964; PPLPC012000307270; PPLPC012000372090; PPLPC018000679680; PPLPC019000705550; PPLPC019000733182; PPLPC012000405266; PPLPC015000151585; PPLPC037000148253; PPLPC037000194404; PPLPC016000243953.
[12] PDD8901816720; PPLPC012000189634; PPLPC037000075085; PPLPC034000480964; PPLPC012000307270; PPLPC012000372090; PPLPC012000405266; PPLPC037000148253.
[13] PDD8901816720; PPLPC012000189634; PPLPC037000075085; PPLPC034000480964; PPLPC012000307270; PPLPC012000372090; PPLPC012000405266; PPLPC016000316640-644.

immense profits for Purdue, and funded the personal fortunes of the Sackler Defendants.

31. Purdue and the individual Defendants promoted the expanded use of all prescription opioids generally, and Purdue's specific branded 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."[14] Dilaudid was approved by the Food and Drug Administration (FDA) in January 1984.[15] Prior to 2016, Dilaudid injection was indicated for the "management of pain where an opioid analgesic is appropriate."[16] Dilaudid is a Schedule II drug,[17] which indicates that it has a high potential for abuse.[18]
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> 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."[19] Dilaudid-HP was also approved by the FDA in January 1984.[20] 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."[21] Dilaudid-HP has also previously been indicated "for the relief of moderate-to-severe pain

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[14] Highlights of Prescribing Information: DILAUDID (2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019891s024,019892s029lbl.pdf.
[15] *Id.*
[16] Highlights of Prescribing Information: DILAUDID (2011), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019034s021lbl.pdf.
[17] Highlights of Prescribing Information: DILAUDID (2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019891s024,019892s029lbl.pdf.
[18] 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).
[19] Highlights of Prescribing Information: DLAUDID HP (2017), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019034s029lbl.pdf.
[20] *Id.*
[21] Highlights of Prescribing Information: DILAUDID HP (2011), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019034s021lbl.pdf.

in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."[22] Dilaudid-HP is a Schedule II drug.[23]

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 treatment options are inadequate."[24] MS Contin was approved by the FDA in May 1987.[25] 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."[26] MS Contin is a Schedule II drug.[27]

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."[28] OxyContin is an extended release oxycodone pill that purports to deliver the drug over 12 hours. OxyContin was approved by the FDA in 1995.[29] 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."[30] OxyContin is Purdue's flagship product and the

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[22] Dilaudid-HP Injection Label (2009), *available at*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/019034s018lbl.pdf.
[23] Highlights of Prescribing Information: DLAUDID HP (2017), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019034s029lbl.pdf.
[24] Highlights of Prescribing Information: MS CONTIN (2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019516s049lbl.pdf.
[25] 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 June 26, 2019).
[26] MS Contin Label (2010), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/019516s034lbl.pdf.
[27] Highlights of Prescribing Information: MS CONTIN (2016), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019516s049lbl.pdf.
[28] Highlights of Prescribing Information: OXYCONTIN (2015), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022272s027lbl.pdf.
[29] 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 June 26, 2019).
[30] Highlights of Prescribing Information: OXYCONTIN (2010), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022272s006lbl.pdf.

watershed branded opioid in the pharmaceutical opioid market in Colorado and throughout the country. OxyContin is a Schedule II drug.[31]

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 pain for an extended period of time."[32] Ryzolt was approved by the FDA in December 2008.[33] Purdue discontinued the manufacture of Ryzolt in 2012.[34]

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."[35] Butrans was approved by the FDA in June 2011.[36] Prior to April 2014, Butrans was indicated for the "the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time."[37] Butrans is a Schedule III drug,[38] which indicates that abuse of the drug "may lead to moderate or low physical dependence or high psychological dependence."[39]

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

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[31] Highlights of Prescribing Information: OXYCONTIN (2015), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022272s027lbl.pdf.
[32] Label: RYZOLT (2008), a*vailable at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021745s000lbl.pdf.
[33] 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 June 26, 2019).
[34] Magellan Medicaid Admin., *Long-Acting Narcotics Analgesics Therapeutic Class Review (TCR*) at 3 (2014), *available at* https://healthandwelfare.idaho.gov/Portals/0/Medical/PrescriptionDrugs/LongActingNarcoticAnalgesics.pdf.
[35] Highlights of Prescribing Information: BUTRANS (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021306s015s019lbl.pdf.
[36] Center for Drug Evaluation and Research, *Approval Package: Butrans* (2010), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021306Orig1s000ApprovLtr.pdf.
[37] Highlights of Prescribing Information: BUTRANS (2010), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021306s000lbl.pdf.
[38] Highlights of Prescribing Information: BUTRANS (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021306s015s019lbl.pdf.
[39] 21 U.S.C. § 812(b)(3)(C).

daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[40] Targiniq ER was approved by the FDA in July 2014[41] and is a Schedule II drug.[42]

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."[43] Hysingla ER was approved by the FDA in November 2014[44] and is a Schedule II drug.[45]

32. Defendant Rhodes Pharmaceuticals, L.P. ("Rhodes") is a Delaware limited partnership, with headquarters located in Coventry, Rhode Island. Rhodes and its affiliates, like Rhodes Technologies, Inc., is owned by Coventry Technologies, L.P. which directs profits from the sale of Rhodes's generic opioids to trusts owned and operated for the benefit of the Sackler Defendants.

33. Rhodes was formed by the Sackler family in or around 2007 to manufacture and sell generic equivalents of Purdue's branded opioids.

34. When Purdue's patents for its branded prescription opioids expired, Rhodes became the primary vehicle through which the Sackler Defendants continued to profit from the sale of generic opioids. Purdue's deceptive unbranded promotion of all prescription opioids, together with its promotion of generics as a safe substitution for Purdue's branded opioids, fueled the generic prescription opioid market. Rhodes became a major player and is now one of the largest manufacturers of generic opioids in the United States.

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[40] Highlights of Prescribing Information: TARGINIQ ER (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205777lbl.pdf.
[41] 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 June 26, 2019).
[42] Highlights of Prescribing Information: TARGINIQ ER (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205777lbl.pdf.
[43] Highlights of Prescribing Information: HYSINGLA ER (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206627s000lbl.pdf.
[44] 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 June 26, 2019).
[45] Highlights of Prescribing Information: HYSINGLA ER (2014), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206627s000lbl.pdf.

35. Rhodes manufactures, promotes, distributes, and/or sells generic equivalents of Purdue's branded prescription opioids nationally, including in Colorado. Rhodes's generic prescription opioids include oxycodone, morphine sulfate, hydrocodone, hydromorphone, and buphrenorphine. Rhodes also manufacturers Purdue's branded morphine drug, MS Contin.

36. Defendant MNP Consulting Limited ("MNP Consulting") is a Delaware corporation. MNP refers to "Mundipharma-Napp-Purdue." The shares of MNP Consulting are held by two trusts owned by and operated for the benefit of the Sackler Defendants: the MDS Family Jersey Trust and the RSS Family U.S. Trust. MNP Consulting's Board of Directors includes Defendants Richard Sackler, Mortimer D.A. Sackler, Jonathan Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, and David Sackler. As the Board of Directors for MNP Consulting, the Sackler Defendants exercised control over their global network of pharmaceutical companies, including Purdue and Rhodes, and their conduct in Colorado.

37. Defendant Richard Sackler is a resident of New York, Florida, and Texas. He served on Purdue's Board of Directors from the 1990s until at least 2018, and was President of Purdue from 1999 to 2003. Richard Sackler directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado.

38. Defendant Mortimer D.A. Sackler is a resident of New York. He served on Purdue's Board of Directors from the 1990s until at least 2018, and was a Vice President of Purdue until 2007. Mortimer Sackler directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado. Mortimer Sackler's now-deceased father (also named Mortimer) was also intimately involved in Purdue's business activities until his death. Unless otherwise noted, all references herein to "Mortimer Sackler" relate to Mortimer D.A. Sackler, not his father.

39. Defendant Jonathan Sackler is a resident of Connecticut. He served on Purdue's Board of Directors from the 1990s until at least 2018, and was a Senior Vice President of Purdue until 2007. Jonathan Sackler directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado.

40. Defendant Kathe Sackler is a resident of Connecticut and New York. She served on Purdue's Board of Directors from the 1990s until at least 2018, and

was a Senior Vice President of Purdue until 2007. Kathe Sackler directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado.

41. Defendant Ilene Sackler Lefcourt is a resident of New York. She served on Purdue's Board of Directors from the 1990s until at least 2018. Ilene Sackler Lefcourt directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado. Unless otherwise noted, references to "Ilene Sackler" herein are related to Ilene Sackler Lefcourt.

42. Defendant Beverly Sackler is a resident of Connecticut. She served on Purdue's Board of Directors from the 1990s until at least 2017. Beverly Sackler directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado.

43. Defendant Theresa Sackler is a resident of New York and the United Kingdom. She served on Purdue's Board of Directors from the 1990s until at least 2018. Theresa Sackler directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado.

44. Defendant David Sackler is a resident of New York. He served on Purdue's Board of Directors from 2012 until at least 2018. David Sackler directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado.

45. Defendant Russell Gasdia is a resident of Connecticut and Massachusetts. He began working at Purdue as a hospital sales representative in 1985 and served various managerial roles within the sales and marketing departments at Purdue throughout the 1990s and early 2000s. He was Vice President of Sales and Marketing from 2008 until July 2014 and served on Purdue's Executive Committee from at least 2007 through 2013. In 2014, he became Purdue's Head of Strategic Initiatives before leaving the company at the end of 2014. At the direction of the Board, Russell Gasdia directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado.

46. Defendant Mark Timney is a resident of Connecticut. He was President and CEO of Purdue from 2014 until June of 2017. During his time as President and CEO, Mark Timney also served as the Chair of Purdue's Executive Committee. At the direction of the Board, Mark Timney directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado.

47. Defendant Craig Landau is a resident of Connecticut. He joined Purdue in 2000 as Executive Medical Director and served in that and other leadership roles at Purdue until he became President and CEO of Purdue Canada in September 2013. Craig Landau returned to the United States to become President and CEO of Purdue in June 2017. Craig Landau was a member of Purdue's Executive Committee, as well as its OxyContin Messaging Committee before leaving for Purdue Canada. While Craig Landau was leading Purdue Canada, he continued to participate in reports to Purdue's Board of Directors and in Defendants' marketing campaign in the United States. When he returned to the United States to be President and CEO of Purdue in 2017, he became the Chair of Purdue's Executive Committee. At the direction of the Board, Craig Landau directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado.

48. Defendant James David Haddox ("David Haddox") is a resident of Connecticut and Florida. David Haddox has worked for Purdue since at least the early 2000s in several management, officer, and/or director roles at Purdue, including Senior Medical Director and Vice President for Risk Management and Health Policy. David Haddox was also a paid Key Opinion Leader for Purdue. In 2001, David Haddox was designated by the Sacklers to be Purdue's "Primary Spokesperson," a role he continued to serve until 2018. At the direction of the Sacklers and Purdue's Executive Committee, David Haddox directed and controlled Purdue's business activities, including Purdue's deceptive and reckless marketing and sale of OxyContin and other opioids in Colorado. As Purdue's "Primary Spokesperson," David Haddox was also intimately involved in lobbying activity in Colorado related to opioids generally and to opioids manufactured and sold by Purdue and/or Rhodes.

49. Unless otherwise noted, all of the allegations herein referencing the "Sacklers," the "Sackler family," the "Sackler Defendants, the "Board of Directors," and/or the "Board" for conduct from the 1995 to 2012 are alleged against Defendants Richard, Mortimer, Jonathan, Kathe, Ilene, Beverly, and Theresa

Sackler. David Sackler joined Purdue's Board of Directors in 2012, and unless otherwise noted, all allegations referencing conduct and activities in and after 2012 against the "Sacklers," the "Sackler family," the "Sackler Defendants, the "Board of Directors," and/or the "Board" are also alleged against David Sackler.

50. Each Defendant acted jointly and in concert with each other named Defendant in committing all acts alleged herein.

JURISDICTION AND VENUE

51. 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 has jurisdiction to enter appropriate orders under COCCA, § 18-17-106, C.R.S., and under CUFTA, §38-8-108, C.R.S. The Court also has jurisdiction under Colorado's long-arm statute, § 13-1-124(b), C.R.S.

52. The conduct 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 (2019).

PUBLIC INTEREST AND DUTY

53. Defendants 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. Defendants knew or should have known that their reckless and deceptive marketing and sale of opioids created an unreasonable risk of harm to Colorado and its citizens. Defendants had a duty to monitor and report any suspicious opioid prescribers, pharmacies, or opioid orders in Colorado to the appropriate authorities. Despite having knowledge about suspicious activities in Colorado related to their opioids, Defendants rarely, if ever, reported any suspicious prescribers, pharmacies, or orders to the authorities. In the rare instance in which they did report suspicious activity, Defendants only did so after learning that such activities were already under investigation by law enforcement or regulatory authorities. Defendants knew or should have known that their failure to monitor and report suspicious activity to the appropriate authorities, and failure to mitigate any of the harm caused by their misconduct, created an unreasonable risk of harm to Colorado and its citizens.

54. Through the unlawful and reckless practices of their business, Defendants knowingly and intentionally deceived, misled, and injured the State of Colorado, as well as Colorado prescribers, patients, policymakers, and citizens.

55. Defendants' deceptive and reckless marketing and sale of OxyContin and other prescription opioids resulted in thousands of overdoses and deaths in Colorado and thousands, if not millions, of cases of opioid addiction.

56. The State is not bringing this action to enforce requirements imposed on Defendants by the U.S. Food, Drug, and Cosmetic Act, or its implementing regulations. Defendants' deceptive marketing of opioids exceeded the FDA labeled use of their opioid drugs. FDA labels cannot shield Defendants from liability for their deceptive marketing and reckless sale of prescription opioids, or the public nuisance created by their conduct.

57. The State is not bringing this action to enforce requirements imposed on Defendants by the U.S. Controlled Substance Act, or its implementing regulations, to monitor and report suspicious activities related to its opioids, but points to the relevant federal statutes and/or regulations as evidence of Defendants' common law duties to monitor and report suspicious opioid prescribers, pharmacies, and orders.

58. The State of Colorado has suffered financial and physical harm to its businesses and property as a result of the opioid crisis caused by Defendants' intentional, knowing, and reckless behavior. Defendants' dissemination of fraudulent and deceptive information about 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. Defendants' reckless failure to monitor and report suspicious activity related to their opioids, and failure to mitigate harm caused by their conduct, also directly and proximately caused the harm suffered by the State of Colorado.

59. From 1995 to present, the Sacklers, in pursuit of a joint common interest with the other Defendants, conspired to defraud the people of Colorado and reap huge profits from that fraud, by deceptively and recklessly selling opioids in Colorado and fraudulently transferring the proceeds from those sales to themselves. In furtherance of this conspiracy and course of action, the Sacklers and the other Defendants engaged in the unlawful conduct alleged herein, directed at patients and prescribers in Colorado, and further conspired to and directed Purdue to fraudulently divest itself of its assets, including proceeds from opioid sales in

Colorado, in order to deprive the State and its citizens of any meaningful source of compensation for such wrongdoing.

60. 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 the State for harm and losses caused by Defendants' deceptive and reckless marketing and sale of prescription opioids.

FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS

I. DEFENDANTS' PRESCRIPTION OPIOIDS CAUSED AN EPIDEMIC OF ADDICTION, OVERDOSE, AND DEATH

A. Opioids Reprogram the Brain and the Body

61. 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.[46] There are several different opioid molecules, including morphine, hydrocodone, oxycodone, oxymorphone, hydromorphone, tapentadol, buprenorphine, and methadone.[47]

62. Opioids act as central nervous system depressants that attach to receptors in the brain, spinal cord, and gastrointestinal tract, and suppress function.[48] 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, also known as analgesia.[49] In addition to reducing pain, opioids trigger chemical processes that create intense feelings of euphoria, making them highly susceptible to addiction and abuse.[50]

63. Prescription opioids come in two basic formulations: immediate release ("IR") and extended release ("ER").[51] IR opioids deliver the full dose quickly as the

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[46] John Williams, *Basic Opioid Pharmacology*, 1 Reviews in Pain 2, 2-3 (2008).
[47] *Id.*
[48] *Id.* at 3.
[49] *Id.*
[50] *Id.*
[51] *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).

pill dissolves.[52] 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.[53] 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 is dominated by Purdue and has far more branded products than the IR opioid market.

B. Defendants Misrepresented the Efficacy of Prescription Opioids for Treating Long-Term Chronic Pain, and Defendants Failed to Disclose the Serious Risks and Side Effects

64. Opioids expose patients to significant risk of dependence, addiction, abuse, and overdose, all of which can lead to serious patient harm, including death. Although opioids may be effective for alleviating pain in the short-term, clinical studies indicate that opioids are not similarly effective for relieving chronic or long-lasting pain.[54] 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."[55]

65. In 2016, the Centers for Disease Control and Prevention ("CDC") issued guidelines confirming that, "patients who do not experience clinically meaningful pain relief in treatment (*i.e.*, in 1 month) are unlikely to experience pain relief with longer term use."[56]

66. 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

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[52] *Id.*
[53] *Id.*
[54] *See* Andrea Rubinstein, *Are we making pain patients worse*?, Sonoma Medicine (Sept. 2009) (describing a common experience for patients on long-term opioid treatment).
[55] *See id.*
[56] 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").

patient's quality of life.[57] Severe consequences associated with prescription opioid use include opioid dependence, opioid addiction (or opioid use disorder), and overdose.

67. Respiratory depression is the primary mechanism by which opioids cause death. 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."[58]

68. Opioids, including those manufactured by Purdue and Rhodes, can cause 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%.[59] Among opioid users who received four prescriptions in a year, 41.3% meet the diagnostic criteria for lifetime opioid use disorder.[60]

69. 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.[61] Patients who are initially prescribed one month of opioids have a 29.9% chance of continued opioid use one year later.[62] In one study, almost 60% of patients who used opioids for 90 days, which the CDC considers the minimum duration for "chronic pain,"[63] were still using opioids five years later.[64] Accordingly,

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[57] Ream Al-Hasani & Michael R. Bruchas*, Molecular Mechanisms of Opioid Receptor-dependent Signaling and Behavior,* 115 Anesthesiology 1363, 1364 (2011).
[58] *See* Dina Fine Maron, *How Opioids Kill*, Scientific American (Jan. 8, 2018), https://www.scientificamerican.com/article/how-opioids-kill/ (last visited June 26, 2019).
[59] 2016 CDC Guideline at 9-10.
[60] 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).
[61] 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).
[62] *Id.*
[63] 2016 CDC Guideline at 1.
[64] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26 J. Gen. Internal. Med. 1450, 1456 (2011).

the CDC's 2016 guidelines concluded that, "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[65]

70. Many patients face significant withdrawal symptoms that feed their opioid dependence and addiction after receiving five prescriptions in a year. Purdue nevertheless distributed opioid savings cards for the specific purpose of driving increased dosage and duration of prescriptions. In 2008, Russel Gasdia reported back to Richard, Mortimer, Jonathan, and Kathe Sackler that 27% of Purdue's opioid savings cards were used by patients for at least five prescriptions of Purdue's opioids.[66]

71. Ceasing 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."[67] The FDA stated 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.[68]

72. Patients whose first opioid prescription is an ER opioid, like OxyContin, have 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.[69]

73. A 2014 study found that higher daily doses and possible opioid misuse were strong predictors of continued use and associated with risk of fractures, dependence, overdose, and death.[70] A 2016 CDC clinical evidence review also

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[65] 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.
[66] PPLPC012000186395.
[67] 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.
[68] *Id.*
[69] 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).
[70] 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).

concluded that higher opioid dosages are associated with increased risks of motor vehicle injury, opioid use disorder, and overdose.[71]

74. Based on this information, the CDC recommended that physicians carefully reassess increasing opioid doses beyond 50 morphine milligram equivalents (MMEs) and avoid exceeding 90 MMEs per day.[72] Put 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.[73] 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.

75. 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.[74] The likelihood of developing an opioid use disorder increases threefold for acute patients prescribed low-dose opioids.[75] 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.[76]

C. Opioid Risks Are Even Higher for Vulnerable Populations

76. The side effects and other consequences associated with opioid use carry even more severe risks for vulnerable populations, including older adults, newborns, and veterans.

77. Opioids pose significant risks in older patients due to their reduced ability to metabolize and excrete the drugs.[77] Older patients are particularly prone

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[71] 2016 CDC Guideline at 9-10, 19.
[72] 2016 CDC Guideline at 16.
[73] *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.
[74] PWG003984539.
[75] Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on Prescribing Opioids for Pain* 7, 34 (3rd ed. 2015), *available at* http://www.agencymeddirectors.wa.gov/files/2015amdgopioidguideline.pdf.
[76] *Id.*
[77] Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on Prescribing Opioids for Pain* 49 (3rd ed. 2015), *available at* http://www.agencymeddirectors.wa.gov/files/2015amdgopioidguideline.pdf.

to constipation (a common opioid side effect), are at increased risk for falls and fractures, and have a higher risk of opioid-related adverse drug events.[78]

78. Nevertheless, in May 2011, Russell Gasdia reported back to Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler that Purdue specifically targeted Butrans "for specific patient types," which in Colorado meant the elderly.[79] Purdue routinely targeted older patients in Colorado for opioid prescriptions for common ailments like osteoarthritis. Following through on this directive from the Sacklers and Russell Gasdia, Purdue sales representatives urged Colorado health care providers to prescribe opioids to the elderly at least 160 times in 2011 alone.[80] Since 2008, Coloradans over the age of 65 have consistently recorded more inpatient stays for opioid-related diagnoses than the national average.[81]

79. At the direction of Purdue's former CEO, John Stewart, and Russell Gasdia, working in close coordination with the Sacklers, Purdue's sales force continued to push Butrans on Colorado's elderly into 2013.[82] In an effort to boost sales, members of Purdue's Executive Committee, including Mark Timney, reported back to the Sacklers that a key Purdue strategy for Q3 2013 was to pressure health care providers to prescribe OxyContin to the elderly on Medicare.[83]

80. Opioid use is extremely dangerous to the unborn. Opioid use during pregnancy increased three-to-four-fold nationwide between 2000 and 2009, with increased fetal, obstetrical, and neonatal abstinence syndrome (NAS) risk.[84] NAS can occur in up to 60-80% of infants exposed to opioids, and incidents of NAS increased every year at least through 2013.[85] Of pregnant women enrolled in Medicaid from 2000 to 2007, 21.6% filled an opioid prescription during pregnancy.[86]

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[78] *Id.* at 47-49.
[79] PPLPC012000326017.
[80] PCO000000001-2.
[81] 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 June 26, 2019).
[82] PPLPC012000451664; PPLPC012000451665; PPLPC002000186925.
[83] PPLPC002000186925.
[84] Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on Prescribing Opioids for Pain* 42 (3rd ed. 2015), *available at* http://www.agencymeddirectors.wa.gov/files/2015amdgopioidguideline.pdf.
[85] *Id.* at 44.
[86] *Id.* at 43.

81. Opioid use by children and adolescents is high risk. 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.[87] But, that did not stop Craig Landau and the Sacklers from adopting as part of Purdue's 2011 goals and objectives a push to get FDA approval for the sale of OxyContin to children.[88]

82. The 2016 CDC guideline found a significant increase in opioid prescribing for children and adolescents for chronic pain conditions like headaches, and acute pain resulting from sports injuries.[89] 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.[90]

83. Children exposed to prescription and other opioids in the home are at risk of serious injury often requiring hospitalization. The rate of pediatric hospitalization due to opioid poisoning increased 63% from 2014 to 2015.[91] One-third of those hospitalizations were children under six years of age.[92] The rate of pediatric intensive care unit admissions for opioid poisoning increased 44% from 2014 to 2015.[93]

84. For veterans who receive an anti-anxiety prescription to treat PTSD along with an opioid prescriptions 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.[94] That study showed that half of the veteran deaths from drug overdose occurred when a veteran was concurrently prescribed both medications.[95]

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[87] *Id.* at 45.
[88] PPLPC013000286366; PPLPC013000286367.
[89] 2016 CDC Guideline at 3.
[90] *Id.*
[91] Jason M. Kane et al., *Opioid-Related Critical Care Resource Use in US Children's Hospitals*, 141 Pediatrics, April 2018, at 3.
[92] *Id.*
[93] *Id.*
[94] 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.
[95] *Id.*

D. Prescription Opioid Use Leads to Addiction, Abuse, Overdose, and Death

85. One in 550 patients receiving opioid treatment dies of opioid-related causes approximately 2.6 years after their first opioid prescription.[96] That number increases to 1 in 32 for patients receiving 200 MMEs per day.[97]

86. There is risk of opioid overdose even at low doses. When a patient takes between 20 and 49 MMEs, the risk of overdose doubles, and for patients taking 100 MMEs, the risk of overdose and death increases nine-fold.[98]

87. Between 1999 and 2016, more than 200,000 people died in the United States from overdoses related to prescription opioids.[99] As Dr. Thomas Friedan of the CDC explained, there is "no other medication routinely used for nonfatal condition that kills patients so frequently."[100]

88. 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.[101]

II. DEFENDANTS DESIGN AND DEPLOY THEIR MISINFORMATION CAMPAIGN

89. Prior to the mid-1990s, generally accepted standards of medical practice dictated that health care providers only use opioids as a temporary

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[96] 2016 CDC Guideline at 2.
[97] *Id.*
[98] Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on Prescribing Opioids for Pain* 12 (3rd ed. 2015), *available at* http://www.agencymeddirectors.wa.gov/files/2015amdgopioidguideline.pdf.
[99] Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data* (Aug. 1, 2017), https://www.cdc.gov/drugoverdose/data/overdose.html (last visited June 26, 2019).
[100] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501, 1503 (2016).
[101] 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.

treatment for acute, short-term pain, for cancer pain, or for end-of-life care.[102] The prevailing wisdom 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.[103]

90. Given the general aversion to prescription opioids, Purdue and the Sacklers knew that, in order to increase the sales of Purdue's opioid drugs, they would need to change the narrative about opioids as a general class of drugs.

91. Purdue and the Sacklers set out to undermine years of medical teachings about opioids with Purdue-created pseudoscience and with cherry-picked experts who promoted the fraudulent and deceptive message that prescription opioids were safe and effective treatments for chronic non-cancer pain.[104]

A. Defendants Used an Unbranded Marketing Campaign to Spread Their Deceptive Messages About Opioids Free from Regulatory Oversight

92. A key component of Defendants' misinformation campaign was avoiding federal oversight of their promotional activities.

93. The FDA's general regulatory oversight over Purdue's marketing of opioid products has significant limitations. While the FDA can regulate promotional activities marketing branded drugs, the FDA does not have regulatory oversight over unbranded marketing, meaning the promotion of an entire class of drugs, *e.g.,* ER prescription opioids generally.[105]

94. The FDA does not monitor a drug company's in-person sales representatives.[106] The FDA does not oversee unbranded continuing medical education ("CME") programs or materials distributed at such CME programs.[107]

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[102] *See* Russell K. Portenoy, *Opioid therapy for chronic nonmalignant pain*, 1 Pain Res. Manage. 17, 18 (1996).
[103] *Id.*
[104] PDD1701857738; PPLPC045000003850.
[105] 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).
[106] *Id.* at 396.
[107] *Id.*

95. Purdue and the Sacklers knew that the traditional aversion to prescribing opioids could not be overcome within the confines of FDA rules. So they devised a massive misinformation campaign to exploit loopholes in the FDA's regulatory scheme.

96. Instead of focusing on Purdue's branded opioid drugs, the promotion of which was subject to FDA scrutiny, Purdue and the Sacklers deployed a massive unbranded marketing campaign to convince the medical community that prescription opioids, as a general class of drugs, were safer and more effective treatments for chronic non-cancer pain than the evidence suggested. Even if this unbranded strategy indirectly benefited their competitors, Purdue and the Sacklers knew that in the end, changing the narrative about opioids would redound to their great benefit by increasing sales or Purdue's opioid drugs.

97. Purdue's own marketing team created the unbranded materials used in these campaigns, including *Partners Against Pain*, which ran from 1993 to 2016. Purdue and the Sacklers kept close track of advertising metrics for its unbranded campaigns, evaluated their efficacy against competitors' campaigns, and even directed the marketing team to hire specific employees to execute the unbranded campaign.

98. Purdue's unbranded marketing campaign targeted health care providers and directly targeted patients. In 2009, the Sacklers directed Purdue's executives, including Craig Landau and David Haddox, to hire a Director of ePromotion responsible for both branded and unbranded electronic marketing, including *Partners Against Pain*, directed at health care providers in Colorado and around the country.[108] Purdue also marketed directly to patients with its "patient education material" and "Patient Savings Coupon Programs."[109] Purdue hired celebrities like Naomi Judd and Jennifer Gray to help normalize the use of opioids and draw more attention to its branded drugs.[110]

B. Defendants Sponsored Misleading "Studies" to Cast Doubt Upon Well-Established Risks Associated With Prescribing Opioids

99. Beginning in the mid-to-late 1990's, Purdue and the Sacklers began disseminating misleading and incomplete studies claiming that prescription opioids were effective long-term treatments for chronic pain conditions. These "studies"

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[108] PPLPC012000221936.
[109] PWG000063001.
[110] PVT0054019.

were specifically intended to relax the medical community's traditional aversion to using opioids to treat pain outside of cancer and end-of-life care.

100. Purdue and the Sacklers knew there was no reliable scientific evidence to support Purdue's messaging.

101. Purdue and the Sacklers also ignored Purdue's own experts' warnings about the dangers of opioids. Soon after the 1996 release of OxyContin, Dr. Robert Kaiko, the inventor of OxyContin, advised Richard, Mortimer, Kathe, and Jonathan Sackler that Purdue did not "have a sufficiently strong case to argue that OxyContin has minimal/or no abuse liability … oxycodone containing products are still among the most abused opioids in the U.S."[111]

102. OxyContin is and has always been multitudes more potent than morphine. Purdue and the individual Defendants have all known for years that OxyContin is far stronger and more dangerous than morphine, but nevertheless seeded and fostered the dangerous misconception that OxyContin was weaker. A 1997 report Purdue staff sent to Richard Sackler discussed the dangerous misconception Purdue's marketing was promoting to prescribers – that OxyContin was weaker than MS Contin (morphine). Not wanting to risk the profit limitations that could result from telling the truth, Richard Sackler's singular response to this report was, "I think that you have this issue wellin [*sic*] hand."[112]

103. Purdue and the Sacklers also concocted a deceptive marketing message that opioids can improve quality of life, again with no scientific evidence to support these claims. Seeking to "broaden [Purdue's] perspectives of opportunities for intervention," in 1998, Richard Sackler directed Purdue's executives to review a number of "papers" on "Lifestyle Drugs." The goal was to characterize opioids to the public as "Performance Enhancing Agents," and draw positive comparisons between opioids, like MS Contin and OxyContin, and other "Lifestyle Drugs" like Viagra. Thus, Purdue and the Sacklers embarked on a misinformation campaign intended to convince the health care community, without any basis in the truth, that opioids like OxyContin provided more than merely "therapeutic" value, they also delivered "enhance[d] personal performance."[113]

104. In 1999, Purdue sponsored a study published in the Journal of Rheumatology titled, *Treatment of Osteoarthritis Pain with Controlled Release*

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[111] PDD1706195889-893.
[112] PDD8801141848; PDD1508224773; PDD1701801141.
[113] PDD1701546497.

Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: a Double Blind, Randomized, Multicenter, Placebo Controlled Trial.[114] The study involved providing a small number of 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.[115] Only 107 of 167 study participants advanced to the second phase of the study – patients withdrew from the study because they experienced adverse side effects (*e.g.,* nausea, vomiting, drowsiness, dizziness, or headaches) or because the opioid provided ineffective treatment.[116] The study expressly admits that the "results…should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition[s] such as [osteoarthritis],"[117] but nevertheless claimed 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 long term."[118]

105. The 1999 study on its face did not support its claims. The study was based upon a very small number of patients, it was not long term (only 30 days), many patients withdrew from the study before the second phase, and there was no reported data regarding addiction. Nevertheless, Purdue and the Sacklers used the 1999 study to support their claims that opioid treatment is safe and effective for treatment of osteoarthritis pain.

106. Purdue and the Sacklers knew the 1999 short-term opioid use study did not support their misleading claims that opioid treatment was safe and effective for treating long term chronic pain. In the same year (1999) Purdue and the Sacklers received another short-term study specifically concluding that a short-term study could not address the efficacy of long-term opioid use for treating chronic non-cancer pain. Instead, long-term studies are necessary to assess the analgesic effects, psychological effects, effects on function and sleep quality, and safety of opioid analgesics in chronic use.[119]

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[114] 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).
[115] *Id.* at 862.
[116] *Id.* at 864.
[117] *Id.* at 867.
[118] *Id.*
[119] 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).

107. Purdue continued to conduct similar "studies," including one in 2003 titled, *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, that misleadingly claimed that opioids are a safe and effective option for treating chronic pain.[120]

108. Despite a dearth of evidence, Purdue and the Sacklers began and continued to promote opioids generally, and Purdue's branded opioids specifically, as effective for improving 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."[121] On the first page, *Responsible Opioid Prescribing* states that some patients "rely on opioids for . . . improved function."[122] Purdue provided $900,000 for various FSMB initiatives related to opioids,[123] including $100,000 for the distribution of *Responsible Opioid Prescribing,*[124] and $50,000 to fund Scott Fishman, M.D.'s, (a Purdue Key Opinion Leader, as described below) production of the book.

- 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."[125] The publication also states that Nonsteroidal Anti-Inflammatory Drugs ("NSAIDs") (*e.g.*, aspirin and ibuprofen) have greater risks associated with long-term use, but failed to disclose the same is true for opioid use.[126]

- Purdue sponsored APF's *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families* (2009), which

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[120] 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).
[121] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 33 (Perry G. Fine et al. eds., 2007).
[122] *Id.* at 1.
[123] PTN000017380.
[124] PVT0060652; PWG000184869.
[125] American Pain Foundation, *Treatment Options: A Guide for People Living with Pain* 15 (Terry Altilio et al. eds., 2007).
[126] *Id.* at 8-15.

advised veterans that opioid treatments "can go a long way toward improving your functioning in daily life."[127]

- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which falsely claims 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."[128]

109. In 2011, Purdue sponsored a CME program titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, which repeated unsubstantiated claims about improved functionality resulting from opioid treatment.[129] Lynn Webster, M.D. (one of Purdue's Key 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."[130] The presentation directed prescribers to conduct "a benefit-to-harm evaluation that included consideration of the potential beneficial effects of chronic opioid therapy (*ie decreased pain and improved function*) against the potential risks."[131] (Emphasis added.)

110. In 2014, a Purdue internal literature review of the long-term efficacy of ER oxycodone (*e.g.*, OxyContin), admits, in the words of Purdue's own employees, "that [extended-release opioid] therapy did not lead to either substantial deterioration [in function] or further improved function."[132]

111. The same Purdue internal literature review of OxyContin, states that definitive data is needed to establish "whether the potential benefits of long-term opioid therapy outweigh the serious risks associated with misuse and abuse."[133] All of the authors of that survey were full-time Purdue employees, and included David Haddox.

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[127] Derek McGinnis & Stephen R. Braun, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families* 111 (2009).
[128] American Pain Foundation, *A Policymaker's Guide to Understanding Pain & Its Management* 29 (2011).
[129] PWG000140004.
[130] PWG000139978.
[131] *Id.*
[132] PWG000224198.
[133] *Id.*

112. With full knowledge that there was no scientific evidence to support their claims about the safety and efficacy of opioids, Purdue and the Sacklers continued their widespread deceptive marketing campaign making these claims.

113. Persistent misrepresentations by Purdue and the Sacklers about the "quality of life" benefits of opioid therapy succeeded in influencing the prescribing habits of health care providers. A 2016 market study commissioned by Purdue stated that some health care providers preferred ER opioids like OxyContin and Butrans to short-acting opioids because ER opioids provide a "[s]teady state dose, so patients have fewer peaks and valleys for better pain control, improved function, and better quality of life."[134]

114. The same 2016 Purdue-sponsored study reports that health care providers who converted their patients directly from NSAIDs to ER opioids mentioned "long-term goals of improving patient function and [quality of life] as reasons to prescribe [long-acting] opioids after NSAIDs." In contrast, health care providers who were reluctant to convert their patients to ER opioids said they should "consider the long-term goal of getting patients off their opioid medications," and "[had] worries about weaning patients off [long-acting] opioids."[135]

115. The decades-long deceptive misinformation campaign designed by Purdue and the Sacklers, and executed by the other individual Defendants, for the specific purpose of altering the medical community's aversion to prescription opioids was a resounding success. In 2012 alone, Purdue's OxyContin earned $2.8 billion.[136]

116. Purdue and the Sacklers' success, and the massive profits they earned from the sale of opioids, came at a grim cost to Colorado and the rest of the nation, including a widespread epidemic of addiction, overdose, and hundreds of thousands of deaths.

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[134] PWG000072026.

[135] *Id.*

[136] 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 June 26, 2019).

C. Defendants Deployed Front Groups, Key Opinion Leaders, and a Massive Sales Force to Spread Their False Gospel About Opioids

1. Purdue-sponsored Front Groups spread Defendants' false and misleading message that opioids were safe and effective for chronic long-term pain

117. The marketing strategy designed by Purdue and the Sacklers included funding seemingly independent 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. The Front Groups received significant monetary payments from Purdue, and much of the content in the research and materials distributed by Front Groups was actually created, edited, and controlled by Purdue.

118. In April 2001, Richard Sackler clearly articulated Purdue's intentions with regard to the Front Groups in an email chain that included former Purdue executive Michael Friedman and David Haddox: "Our goal is to bind [the American Pain Society and American Pain Foundation] more closely to us than heretofore, but also to align them with our expanded mission and to see that the fate of our product(s) are inextricably bound up with the trajectory of the pain movement."[137]

119. Purdue maintained control over the Front Groups by funding operations and paying individuals who served on their Boards of Directors or in other leadership positions. By funding the 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.

120. Members of Purdue's Executive Committee and other Purdue staff regularly reported back to the Sacklers and other individual Defendants on the grants or other funds administered by Purdue to the Front Groups and tracked the effectiveness of these payments.

121. From 2006 to 2016, Purdue provided more than $68 million in direct grants to national Front Groups including:[138]

- $1.7 million to the American Academy of Family Physicians (AAFP);

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[137] PPLPC045000004929.
[138] PWG000096255.

- $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);
- $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).

122. Purdue and the Sacklers were willing to fund these grants to ensure that seemingly independent and credible 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.[139] 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 deceptively promoting opioids as a safe and effective means of treating chronic non-cancer pain. Purdue controlled the content of APF's publications and CMEs.

123. In 2011, Purdue and APF entered into a "Master Consulting Services" agreement providing that Purdue would continue funding APFs operations in exchange for APF consulting services to promote Purdue's marketing initiatives.[140]

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[139] 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 June 26, 2019).
[140] PWG000048632.

Purdue provided employee "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 APF made about opioid use.[141]

124. Board members and other individuals leading the Front Groups were paid by or were closely associated with Purdue. AAPMed, whose leadership had significant ties to Purdue, issued a "consensus" statement in 1997 endorsing opioids to treat chronic pain, and claiming that the risk of opioid addiction was low.[142]

125. David Haddox was the Chair of the AAPMed Committee issuing the 1997 consensus statement.[143] David Haddox is a long-time Purdue employee and was the company's "primary spokesperson" from at least 2001 until 2018. David Haddox also served as Purdue's Senior Medical Director for several years.

126. AAPMed's sole consultant was Russell Portenoy, M.D.,[144] one of Purdue's most prominent Key Opinion Leaders. AAPMed's corporate council included Purdue and other opioid manufacturers. AAPMed's past Presidents include David Haddox (1998), Dr. Fishman (2005), Perry G. Fine, M.D. (2011), and Dr. Webster (2013), all of whom worked for Purdue or received significant financial payments from Purdue for promoting Purdue's deceptive messaging about opioids.[145]

127. In 2009, AAPM and APS jointly issued treatment guidelines for opioid prescribing.[146] The authors of the treatment guidelines included Dr. Portenoy and Dr. Fine, as well as David A. Fishbain, M.D., another prominent Purdue Key Opinion Leader.[147] Fourteen out of the twenty-one panel members behind AAPM/APS's treatment guidelines received financial support from Purdue and other opioid manufacturers.[148]

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[141] *See, e.g., id.*
[142] 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).
[143] *Id.* at 8.
[144] *Id.* at 8.
[145] *See* PTN000017361 (showing payments made by Purdue to Dr. Fishman, Dr. Fine, and Dr. Webster).
[146] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 J. of Pain 113 (2009).
[147] *Id.* at 113.
[148] *Id.* at 130.e1-130.e5.

128. The AAPM/APS treatment guidelines generally parroted Purdue's message about the safety and efficacy of opioids for treating chronic pain.

129. Notably, buried in the dense language of the guidelines is an admission that "[r]eliable evidence on methods to accurately assess the potential benefits of [chronic opioid therapy] is limited."[149] Thus, Purdue and the Sacklers, and their Front Groups and Key opinion Leaders knew they were overselling the benefits of opioids as an effective treatment for chronic pain.

130. In the medical community, treatment guidelines generally have the effect of changing prescribing practices. Purdue and the Sacklers knew that treatment guidelines from seemingly independent associations could be especially influential over health care providers who were not experienced opioid prescribers – such as primary care physicians and family doctors. Purdue and the Sacklers knew that health care providers who lacked experience prescribing opioids would be more likely to rely upon what appeared to be credible and independent sources of information about opioids.

131. Health care providers told Purdue sales representatives that they were influenced by treatment guidelines issued by purportedly independent associations. By way of example, Purdue's sales call notes show that on August 5, 2013, a Colorado physician's assistant said he was willing to "change his treatment protocols because they are based on evidence and best practices set out by the American Pain Society."[150]

132. The 2009 AAPM/APS treatment guidelines also had a significant impact on the scientific literature about opioids. The treatment guidelines 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.

133. One AAPM/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 monetary contributions made to AAPM and APS and to committee members by opioid manufacturers, including Purdue.[151]

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[149] *Id.* at 116.
[150] PCO000000002 Row: 108682 (08/05/2013).
[151] John Fauber, *Chronic Pain Fuels Boom in Opioids*, MedPage Today (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31254 (last visited June 26, 2019).

134. Purdue influenced the content of AAPM/APS's 2009 treatment guidelines with Purdue-paid representatives on the panel, and Purdue was aware of the misinformation contained in those guidelines. Nevertheless, Purdue disseminated the 2009 treatment guidelines without disclosing its funding, and Purdue failed to disclose that there was limited reliable evidence supporting its claims about the efficacy and benefits of opioid therapy.

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

136. In 2007, FSMB published *Responsible Opioid Prescribing: A Physician's Guide*,[152] and in 2012 FSMB published a second edition titled, *Responsible Opioid Prescribing: A Clinician's Guide*.[153]

137. While both editions of *Responsible Opioid Prescribing* were published by FSMB, the 2007 edition was actually written by Dr. Fishman, a Purdue Key Opinion Leader, and was heavily edited by David Haddox.[154] Purdue also paid $100,000 for distribution.[155]

138. The majority of the content and edits provided by Dr. Fishman and David Haddox in the 2007 edition of *Responsible Opioid Prescribing* remained in the 2012 edition.[156]

139. Purdue used both editions of *Responsible Opioid Prescribing* to put itself in a position to have tremendous influence over medical boards throughout the country.

140. Purdue also provided grants and other funding to organizations in Colorado. Members of Purdue's Executive Committee, including Mark Timney, Craig Landau, and Russell Gasdia, and other Purdue staff, including David Haddox, tracked those payments and reported them directly back to the Sacklers. For example, in early 2009, Kathe Sackler requested and received from members of

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[152] Scott M Fishman, *Responsible Opioid Prescribing A Physician's Guide* (Perry G. Fine et al. eds., 2007).
[153] Scott M Fishman, *Responsible Opioid Prescribing A Clinician's Guide* (2d ed. 2012).
[154] PTN000019612.
[155] PVT0060652.
[156] *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).

Purdue's Executive Committee and other staff, Purdue's "Philanthropy/Indirect Non-brand report" on grant funds expended in 2008, and grant funds budgeted for 2009. That report included grants of tens of thousands of dollars to organizations in Colorado, including the Colorado State Board of Pharmacy and the Western Pain Society.[157]

141. Purdue provided grants and/or other funding to other Colorado organizations including:[158]

- $30,000 in 2008 to Denver-based Pharmacy Choice for the CMEs, "The Pharmacist's Role in Pain Management: A Legal Perspective" and "Understanding Pain and the Community Pharmacist's Role in its Management";[159]

- $669,929 in 2009 to the Littleton-based Global Education Group for the CMEs, "The Pain Paradox: Providing Effective Relief While Mitigating Risk (2nd and 3rd Editions)" and "The Challenge of Managing Pain While Mitigating Risk IDEAL (Interactive Digitally Enhanced Atmosphere for Learning) [CME] Longitudinal Curriculum";[160]

- $155,000 in 2010 again to the Global Education Group for the CMEs, "Pain Educators Forum," "IDEAL Clinicians' Forum: The Challenge of Managing Pain While Mitigating Risk," and "PAINWeekEND Regional Conference Series";[161]

- $441,448 in 2011 again to the Global Education Group for the CMEs, "Clinicians' Forum: IDEAL Pain Management and Risk Mitigation – A Practical Approach," "Identifying and Managing Chronic Low Back Pain," "Pain Educators FORUM at PAINWeek 2011," "PAIN EDUCATORS IN PRACTICE: Optimizing Pain Management in the 20-Minute Visit – An IDEAL Live CME/CE Learning Center Activity at PAINWeek 2011," and PAIN EDUCATORS IN PRACTICE: Optimizing Pain Management in the

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[157] PPLPC012000213086; PPLPC012000213088.
[158] PPLP003477188.
[159] *Id.*, lines 69-70.
[160] *Id.*, lines 213, 234, 287.
[161] *Id.*, lines 383, 444, 495.

20-Minute Visit – An IDEAL Live CME/CE Learning Center Activity at AAPM 2012";[162]

- $50,000 in 2012 again to the Global Education Group for the CME, "Pain Educators Forum at PAINWeek 2012;[163]

- $150,000 in 2013 to the Englewood-based Postgraduate Institute for Medicine for the CME, "The Chronic Pain Continuing Mission: Providing Relief While Minimizing Risk: An IDEAL Live Clinical Encounter CME Activity";[164]

- $125,000 in 2013 again to the Global Education Group for the CME, "Pain Educator Forum at PAINWeek 2013";[165] and

- $105,000 in 2014 again to the Global Education Group for the CME, "Pain Educators Forum at PAINWeek 2014."[166]

142. In March 2014, Colorado's Department of Regulatory Agencies ("DORA"), in collaboration with the Nurse-Physician Advisory Task Force for Colorado Healthcare, issued a draft Policy for Prescribing and Dispensing Opioids. Purdue was concerned that DORA's policy deviated from the FSMB guidelines and wondered internally why Colorado did not simply endorse the FSMB guidelines and drafted talking points for the Task Force to use to endorse the FSMB guidelines.[167]

143. Purdue also had significant concerns that DORA's Policy conflicted with the FSMB. DORA's Policy truthfully linked high-dosage opioids and extended opioid treatment to adverse events: "High opioid doses >120[MME] per day is a dosage that Boards agree is more likely dangerous for the average adult (changes for unintended death are higher). . . ."[168] To counter DORA's position on the dangers of high dosage opioids, David Haddox prepared a response criticizing the CDC's studies underlying DORA's Policy, and urged Purdue's Colorado lobbyists to push for revisions to DORA's Policy that would minimize the dangers of high-dosage

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[162] *Id.*, lines 568, 608, 609, 668.
[163] *Id.*, line 776.
[164] *Id.*, line 854.
[165] *Id.*, line 950.
[166] *Id.*, line 1017.
[167] PPLPC01700052234; PPLPC023000661847.
[168] PPLPC01700052234.

opioids: "I would like to have the 120mg language removed, based on what we know about how those numbers are derived and the fallacies inherent in them . . . ."[169]

144. Purdue and the Sacklers used their Front Groups and other organizations to influence federal and state legislation and regulations related to pain treatment and opioids, including in Colorado. One of Purdue's most notable partners in this effort was the Pain Care Forum ("PCF"). PCF is a coalition of opioid manufacturers, distributors, trade groups, and Front Groups. PCF was co-founded by Purdue's Washington D.C. lobbyist and the Executive Director of APF.[170] From 2015 to 2018, the PCF and/or its members paid close to $1 million per year for lobbying efforts in Colorado, not including political contributions, related to pain and opioid use.

145. Through the PCF, Purdue sought to combat state and federal legislation, regulations, and policies that it perceived to be harmful to its pro-opioid agenda and bottom line. For example, in 2010 the Patient Protection and Affordable Care Act ("ACA") directed the U.S. Department of Health and Human Services to engage the Institute of Medicine ("IOM") to produce a study on pain in America.[171] David Haddox and other Purdue staff reported in 2011 to members of Purdue's Executive Committee, including John Stewart and Russell Gasdia, that the IOM report was "the result of the legislation enacted and advocated by the [PCF]" and Purdue Front Group members of the PCF, including AAPM.[172] David Haddox and other Purdue staff also stated that the PCF and Purdue Front Group members influenced what topics the IOM would study and ensured that the IOM's final report issued favorable findings, including on topics like the undertreatment of pain.[173] Once the report was published, the PCF and several Purdue Front Groups, including the CPB, embarked on a nationwide project, known as the PAAINS Project ("Pain Action Alliance to Implement a National Strategy"), to publicize the results of IOM's biased studies.[174]

146. The PCF, in coordination with Purdue Front Groups like AAPM, also worked tirelessly from 2009 to 2012 to help Purdue and the rest of the opioid industry dilute the FDA's REMS Rulemaking, and in 2013 to ensure the FDA

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[169] PPLPC017000522695-700.
[170] PWG000165268.
[171] PPLP004023237.
[172] PTN17821.
[173] PPLPC17000324520, 522.
[174] PPLP004023237.

rejected most of the 2013 class-wide opioid label change requests submitted by Physicians for Responsible Opioid Prescribing.[175]

147. In 2015, when Purdue and the Sacklers felt threatened by the impending release of the CDC's Opioid Prescribing Guidelines, David Haddox and some of Purdue's lobbying partners crafted strategies, which Purdue shared with PCF and its members, to fight back against the CDC. The strategies included efforts to "address CDC and their uneven treatment of the opioid problem, the misleading or partial data driving the prescription opioid 'epidemic'" and "to articulate in affirmative language what the CDC should be doing to help keep patients who need opioids safe."[176]

i. Defendants' use of the Denver-based Research, Abuse, Diversion, and Addiction-Related Surveillance ("RADARS") system

148. Defendants relied on PCF and Purdue's Front Group members of PCF to influence opioid-related legislation, rulemaking, and policies in Colorado. One of the PCF's most influential members in Colorado is the Research Abuse, Diversion and Addiction-Related Surveillance ("RADARS") system, which is now housed in the Denver Health and Hospital Authority.

149. RADARS originated as an internal Purdue program in 2001 in response DEA and FDA concerns that Purdue lacked any program to monitor growing incidents of OxyContin abuse and diversion.[177] When RADARS was implemented, the Sacklers directly tapped the individuals who would serve on RADARS's Board of Directors.[178] Five out of the original thirteen members of RADARS's Board remain on the current 8-person Scientific Advisory Board at RADARS, including Richard Dart, the current Executive Director of RADARS.[179] David Haddox also represented Purdue at RADARS's Board meetings from the program's inception in 2001 until 2018, even after the program was transferred to the Denver Health and Hospital Authority.

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[175] PWG004290063, 0065; PPLP4409973; PPLP4410319.
[176] PPLP003892225.
[177] PDD8013007919.
[178] PPLPC031000070547.
[179] *About the Scientific Advisory Board,* RADARS System, https://www.radars.org/what-is-the-radars-system/about-the-scientific-advisory-board.html (last visited June 26, 2019).

150. The Sacklers received regular reports on RADARS's tracking of opioid abuse, diversion, and overdoses. For example, in October 2004, the Sacklers received a report that RADARS was "defining areas of the country where prescription opioid abuse [is] a problem."[180]

151. By 2005, Purdue and the Sacklers grew weary of the financial burdens RADARS's monitoring put on their bottom line.[181] To alleviate those pressures, the Sacklers directed David Haddox to find a potential buyer for RADARS.[182] When David Haddox proposed that the Sacklers donate RADARS to the Denver Health and Hospital Authority, Richard Sackler countered with a proposal to have the program valued by an investment banker so that the Sacklers could profit from its sale:

> Does it matter if we can sell [RADARS] for $30M? It seems to me that we aren't so wealthy that we can forego substantial profits especially when we are going to run a considerable tax loss and will be op [*sic*] profit break even according to plan. But if we can sell, what would we have to do to make our Advisors and Denver comfortable?"[183]

152. The Sacklers ultimately directed Purdue's then President and CEO, Michael Friedman, to execute a sale contract for RADARS with the Denver Health and Hospital Authority in November 2005.[184] Purdue sold RADARS to the Denver Health and Hospital Authority for $100 and $10 million worth of annual subscriptions so that Purdue could continue receiving RADARS reports on opioid abuse, diversion, and overdoses.[185] Since the sale of RADARS to the Denver Health and Hospital Authority, RADARS has produced numerous state and national studies and other reports about opioid use and misuse.[186] RADARS's data and studies are relied upon by national pharmaceutical and other health care companies who pay upwards of $1 million per year for a RADARS subscription.[187]

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[180] #133927.1.
[181] PPLPC054000016688.
[182] *Id.*
[183] *Id.*
[184] PPLPC051000036081.
[185] *Id.*
[186] PURDUE PHARMA, https://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/ (last visited June 26, 2019); PPLPC051000036081.
[187] PPLPC051000077322.

153. Since Purdue transferred RADARS to the Denver Health and Hospital Authority in 2005, the two organizations have maintained a unique and mutually beneficial relationship. Purdue has received millions of dollars' worth of RADARS subscription data and studies at no cost. Purdue's executives also received personal subscriptions to RADARS. For example, even while Craig Landau was President and CEO of Purdue Canada, he used his RADARS subscription to receive reports on opioid abuse and diversion to his Purdue (US) email.[188]

154. In November 2009, as a member of the Executive Committee, Craig Landau, at the direction of the Sacklers, entered into a Master Consultant Services Agreement on behalf of Purdue with the Denver Health and Hospital Authority to have RADARS's Executive Director, Richard Dart, provide consulting services to Purdue.[189] While that Agreement terminated in 2011, Richard Dart and Purdue, via the Denver Health and Hospital Authority, often amended and supplemented the Agreement with Statements of Work in order to continue providing reporting, consulting, lobbying, and advocacy services to Defendants through at least 2018. Like the original Agreement executed by Craig Landau, the supplemental Statements of Work with Richard Dart and the Denver Health and Hospital Authority were always executed by members of Purdue's Executive Committee at the direction of the Sacklers.[190]

155. From 2008 to 2012, Purdue gave the Denver Health and Hospital Authority thousands of dollars for their "Night Shine Gala," and Purdue paid RADARS representatives, including Richard Dart, hundreds of thousands of dollars through at least 2016.[191]

156. Through at least 2018, Purdue and all of the individual Defendants continued to use RADARS and its hand-picked Board members to further their opioid business and increase their corporate and personal fortunes.

157. In September 2015, ten years after RADARS was transferred to the Denver Health and Hospital Authority, Purdue and Rhodes made a "Rating Agency Presentation" seeking "corporate and facility ratings" in order to secure financing for their business.[192] Mark Timney and other Purdue and Rhodes executives led the

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[188] PPLPC039001122365.
[189] PWG003929104.
[190] PWG003939923.
[191] PPLP003477188, line 1666; *see e.g., Dollars for Docs: How Industry Dollars Reach Your Doctors*, PROPUBLICA, https://projects.propublica.org/docdollars/doctors/pid/204780 (last visited June 26, 2019).
[192] PPLPC030000962915.

presentation and touted RADARS studies supporting their deceptive abuse-deterrent opioid formulations.[193] The presentation also identified Mark Timney, as well as Richard, Mortimer, Jonathan, Kathe, Beverly, Theresa, Ilene, and David Sackler, as members of the combined companies' "Performance-Oriented Management Team and Board" above the tag-line, "[f]amily legacy has resulted in stable board composition."[194]

158. In February 2018, RADARS and Richard Dart issued a coordinated response with Purdue to counter a citizens' petition to the FDA seeking the removal of ultra high dosage opioids from the market.[195]

159. As set out in more detail below, Purdue and the individual Defendants also directed RADARS and its Board members to advocate for Purdue's abuse-deterrent opioids and lobby for opioid-friendly legislation and regulations in Colorado and other state legislatures around the country.

2. Purdue-sponsored Key Opinion Leaders promote Defendants' misleading messages about opioids

160. Purdue and the Sacklers cultivated and financed individuals to serve as "Key Opinion Leaders" to promote Purdue's misleading message that opioids are safe and effective to treat chronic non-cancer pain. Key Opinion Leaders were 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 by independent medical professionals. But, in reality, Key Opinion Leaders were not independent because they received substantial monetary payments from, and were controlled by, Purdue.

161. Purdue's Key Opinion Leaders served on Boards and in other leadership positions for pro-opioid Front Groups that developed, selected, disseminated, and presented misleading materials and CMEs in Colorado and other states. Key Opinion Leaders also served on committees that developed treatment guidelines to encourage the use of opioids to treat chronic pain.

162. Key Opinion Leaders created and disseminated what was purported to be their own research and literature, and hosted CMEs. Key Opinion Leaders

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[193] *Id.*
[194] *Id.*
[195] PPLPC036000267754; PPLPC033000042633.

wrote, consulted, edited, and lent their names to books and articles, and Key Opinion Leaders gave speeches and CMEs, all advocating for long-term opioid therapy to treat chronic pain. Purdue and the individual Defendants heavily controlled Key Opinion Leader research and literature, as well as the content of the CMEs presented by Key Opinion Leaders.

163. Purdue and the individual Defendants carefully vetted Key Opinion Leaders to ensure that they would stay on message and remain supportive of Purdue's opioid marketing agenda. Russell Gasdia also regularly reported back to the Sacklers on the progress of Purdue's Key Opinion Leader program. For example, after a July 2010 Board meeting, the Sacklers demanded "more information on the strategy/tactics with respect to [Key Opinion Leaders], how they are identified, how do we plan to interact with them, how do we see them helping build appropriate utilization of Butrans – and any other relevant information that will/could influence prescribing of the product."[196]

164. Russell Gasdia also contracted with Key Opinion Leaders in Colorado on behalf of Purdue. For example, in June 2012 Russell Gasdia entered into an agreement with a Colorado Key Opinion Leader for 150 annual hours of services through June 2017. As was common for such agreements, the Colorado Key Opinion Leader was required to "obtain the express prior written consent of [Purdue] prior to any publication or presentation of reports, study results or other documentation generated" pursuant to the agreement.[197]

165. When a Key Opinion Leader published a "scientific" paper supporting Purdue's message about opioids, Purdue directed tremendous amounts of money and other resources into promoting the paper. Purdue would also widely cite the Key Opinion Leader's paper in its marketing materials. Of course, in order to maintain the aura of legitimacy and independence, the Key Opinion Leader and Purdue rarely, if ever, disclosed the levels to which the papers were financed and controlled by Purdue.

166. Purdue and the Sacklers knew that the Key Opinion Leaders were overstating the benefits and efficacy of opioid treatment for chronic pain and understating the risks associated with opioids. Because Purdue financed Key Opinion Leader presentations and other materials about opioids, the Sacklers closely monitored the content of the Key Opinion Leaders' Purdue-sponsored

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[196] PPLPC012000283165.
[197] PPLP003378690.

messaging and received reports on "compliance issues" occurring in the Key Opinion Leader program.[198]

167. One of Purdue's most prominent Key Opinion Leaders was Dr. Portenoy, who received significant funding from Purdue as early as 1997 for research and consulting work to promote opioids.[199]

168. In 1996, the year OxyContin was launched (approximately one year before Dr. Portenoy began receiving payment from Purdue), Dr. Portenoy published a comment that opioid use was associated "with heightened pain and functional impairment, neuropsychological toxicity, prevarication about drug use, and poor treatment response."[200]

169. In the same publication, Dr. Portenoy stated, "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."[201] Dr. Portenoy also warned, "the problematic nature of opioid therapy in some patients *is unquestionable*, and the potential adverse impact of all possible outcomes related to treatment, including physical dependence, deserves to be addressed."[202] (Emphasis added). Nonetheless, Dr. Portenoy commented that the lack of evidence supporting the efficacy of long-term opioid use should not stop doctors from prescribing opioids.[203]

170. 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

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[198] PPLPC0002000181049, 073-074.
[199] PTN000017361.
[200] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A Review of the Critical Issues*, 11 J. Pain & Symptom Mgmt. 203, 206 (1996).
[201] *Id.* at 204.
[202] *Id.* at 208.
[203] *Id.* at 206.

> record of pain, side effects, functional status, and drug-related behaviors must be ongoing and explicit.[204]

171. Purdue and the Sacklers seized on the untested opinions published by Dr. Portenoy to mobilize Purdue's national marketing campaign and to push opioids on primary care providers, nurse practitioners, physician assistants, and other prescribers – none of whom had the medical training, experience, or expertise of Dr. Portenoy.

172. Purdue hired additional health care providers to act as Key Opinion Leaders and, with the assistance of Front Groups, Purdue set out to promote as *fact* Dr. Portenoy's *hypothesis* that opioids were a safe and effective treatment for chronic non-cancer pain.

173. 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."[205]

174. 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 [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.*[206] (Emphasis added)

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[204] *Id.* at 212.
[205] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 277 (2003).
[206] 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 June 26, 2019).

175. The "Porter and Jick article" referenced by Dr. Portenoy as a "piece of data" was a 1980 letter to the editor of the *New England Journal of Medicine* ("NEJM") stating that incidences of opioid addiction were "rare."[207] That statement was based only on a review of hospital records for patients who were given opioids to treat *acute* pain, not long-term pain.[208] 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.[209]

176. While Purdue seized on the Jick/Porter letter, just as it seized on Dr. Portenoy's untested opinions, to promote its false message that opioids are non-addictive, Dr. Jick made it clear that Purdue's interpretation was not what was intended or presented in his letter.[210]

177. 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."[211]

178. Undeterred by the damning admissions of Dr. Portenoy and the clarification made by Dr. Jick, Purdue and its Front Groups and Key Opinion Leaders continued their deceptive messaging about prescription opioids.

179. When studies began surfacing in and around 2011 questioning the safety and efficacy of opioids, Defendants turned to Purdue Key Opinion Leaders to combat growing skepticism. In a 2011 email, Craig Landau and another Executive Committee member acknowledged that because Dr. Portenoy's stance on opioids had "shifted," they now needed to "interview … select [Key Opinion Leaders] from [Purdue's] portfolio Advisory Board (already contracted and accessible)" to aide Purdue's counter-messaging about the efficacy of ER opioids.[212]

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[207] Hershel Jick & Jane Porter, Letter to the Editor, *Addiction Rare in Patients Treated with Narcotics*, 302 N. Eng. J. Med. 123, 123 (1980).
[208] *Id.*
[209] Barry Meier, *Pain Killer: An Empire of Deceit and the Origin of America's Opioid Epidemic* 33 (2d ed. 2018).
[210] *Id.*
[211] 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 June 26, 2019).
[212] PTN000022181.

180. As a result, at 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 Key Opinion Leader for Purdue from 2003 to 2016, continuing to deceptively espouse the safety and efficacy of opioids.[213]

181. Dr. Fishman also gave presentations and lectures in Colorado as a Key Opinion Leader for Purdue from 2000-2010, similarly promoting opioids.[214]

182. Other Purdue Key Opinion Leaders visited Colorado. Micke Brown, B.S.N., R.N., a Purdue Key Opinion Leader 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.[215]

183. 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*.[216] Although Ms. Bennett identified herself as a Purdue employee in the related PowerPoint presentation, Purdue's relationship with Ms. Brown was not disclosed.[217]

184. To supplement the efforts of national Key Opinion Leaders, Purdue employed Colorado Key Opinion Leaders to provide more what they hoped would be perceived as trusted local sources of misinformation about opioids. Like the national Key Opinion Leaders, Purdue's Colorado-based Key Opinion Leaders served in leadership positions for local third party pain organizations, like the Colorado Pain Society ("CPS").[218]

185. Purdue made efforts in early 2014 to influence CPS. Specifically, a Purdue sales representative was directed to ask a Colorado prescriber about CPS and find out "if there is any way the pharma reps can get involved."[219]

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[213] FIN000001.
[214] FISH000001.
[215] PWG000167890; PWG000167897.
[216] PWG000167890.
[217] PWG000167897.
[218] PWG003799108; PWG003788106.
[219] PCO000000002 Row: 117251 (01/24/2014).

186. CPS participated in a December 28, 2017 joint stakeholder's meeting at DORA regarding new guidelines for prescribing opioids in Colorado. CPS did not disclose during the meeting the affiliation between the organization's leadership and Purdue and other opioid manufacturers.

187. At DORA's 2017 stakeholder's meeting, a representative for the CPS asserted that pain specialists are "unfairly [negatively] labeled" due to the high volume of opioids they prescribe.[220] The CPS representative suggested that Colorado doctors should receive additional education on the treatment of pain and recommended the 2007 edition of *Responsible Opioid Prescribing*,[221] which, as discussed above, was published by FSMB, but was actually drafted by Purdue Key Opinion Leader Dr. Fishman and heavily edited by David Haddox. Purdue's substantial involvement was not disclosed.[222]

188. The edition of *Responsible Opioid Prescribing* promoted by CPS at the DORA's stakeholder's meeting contains much of the same misleading information about opioids detailed herein, 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."[223]

189. By placing national and local Key Opinion Leaders in every available distribution channel for information about opioids in Colorado's medical community, Defendants effectively controlled all of the information Colorado health care providers received related to prescription opioids.

3. Defendants deployed Purdue's army of sales representatives to increase Purdue's profits by widely spreading false and misleading information about opioids

190. Purdue and the Sacklers laid the groundwork for their unbranded marketing campaign with false and misleading materials created and disseminated by Front Groups and Key Opinion Leaders. Purdue then weaponized that misinformation by deploying thousands of sales representatives, also called

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[220] 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 June 26, 2019).
[221] *Id.* at 20:10-21:57.
[222] *See id.* at 11:15-13:50.
[223] *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).

"detailers," to convey its false and deceptive messaging in personal visits to prescribers.

191. The Purdue detailers utilized and supplemented the misinformation spread by the Front Groups and Key Opinion Leaders to relax prescribers' skepticism of opioids, convinced prescribers to convert their patients to Purdue's branded opioids, and then convinced prescribers to increase the dosage and duration of patients' opioid treatment. When Purdue lost patents for its branded opioids, those same sales representatives were used to convince prescribers and pharmacies to write and fill prescriptions for Rhodes's generic opioids.

192. Regarding Purdue's sales force, the U.S. General Accounting Office ("GAO"), in conjunction with the DEA, the FDA, and Purdue itself, reported to Congress in December 2003:

> Purdue significantly increased its sales force to market and promote OxyContin to physicians and other health care practitioners. In 1996, Purdue began promoting OxyContin with a sales force of approximately 300 representatives in its Prescription Sales Division. Through a 1996 copromotion agreement, Abbott Laboratories provided at least another 300 representatives, doubling the total OxyContin sales force. By 2000, Purdue had more than doubled its own internal sales force to 671. The expanded sales force included sales representatives from the Hospital Specialty Division, which was created in 2000 to increase promotional visits on physicians located in hospitals.[224]

193. In the same report, the GAO detailed 2002 DEA data showing "that OxyContin abuse and diversion problems had spread into larger areas of the initial 8 states, as well as parts of 15 other states," including Colorado.[225] The GAO report included a letter from the DEA's Chief Inspector stating in part:

> The DEA has previously stated that [Purdue's] aggressive methods, calculated fueling of demand and the grasp for major market share very much exacerbated OxyContin's widespread abuse and diversion. While Purdue

[224] PKY183266843.
[225] *Id.*

> highlights its funding of pain-related educational programs and websites and its partnership with various organizations, the fact remains that Purdue's efforts – which may be viewed as self-serving public relations damage control – would not have been necessary had Purdue not initially marketed its product aggressively and excessively.[226]

194. Purdue incentivized its sales force to increase OxyContin and other opioid prescriptions. An October 2008 report back to the Sacklers from members of Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, described Purdue's "Toppers Club sales contest," awarding bonuses to sales representatives for increasing ER opioid prescriptions. Notably, the same report to the Sacklers included Purdue's own surveillance data showing "a *wide geographic dispersion* of abuse and diversion cases involving OxyContin in the U.S.," including in Colorado, caused by "availability of the product" and "prescribing practices."[227] Yet, the Sacklers and Purdue's Executive Committee showed no concern about the role prescription-based incentive programs like "Toppers Club" played in influencing prescribing practices and increasing the availability of opioids.

195. Purdue's sales force specifically targeted prescribers less experienced in treating pain with opioids such as primary care physicians, nurse practitioners, and physician assistants.[228] Purdue and the Sacklers believed these less experienced prescribers were likely to be more reliant on Purdue's promotional materials. Purdue and the Sacklers also targeted prescribers who were already high-volume opioid prescribers, and prescribers they believed could become high-volume opioid prescribers–typically those who worked in "pain clinics."[229]

196. In 2011, when "40 and 80mg tablet prescriptions had decreased significantly," Purdue's Executive Committee, including Craig Landau and Russell Gasdia, reported back to the Sacklers that Purdue would rely on sales visits and paid physician spokespersons to maintain demand for the high-dosage opioids.[230] Towards those ends, Russell Gasdia sent a report back to Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler, and to David Haddox, detailing Purdue's strategy to increase high dosage prescriptions, which included, "[i]mproving physician 'targeting' to ensure representatives are calling on the highest potential

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[226] PKY183266880.
[227] PDD9316101020-029.
[228] *See, e.g.,* PWG000140164.
[229] *See, e.g.,* PWG003810929; PWG000154784.
[230] PPLPC012000327303; PPLP004406102-123.

physicians," and "[i]ncreasing call frequency on a select 'super core' of physicians." The Executive Committee also reported "seeing a direct correlation between call activity and results."[231] As directed and/or sanctioned by the individual Defendants, for the "Super Core" of "Very High Potential" opioid prescribers, Purdue's sales force made visits *every week*.[232]

197. As of Q1 2013, Purdue targeted 363 "Super Core" and 1,152 "Core" health care providers in Colorado as most likely to be high opioid prescribers. Over the previous 6 months, Purdue's sales force visited the "Core" and "Super Core" prescribers in Colorado almost 6,000 times, resulting in over 4,200 Butrans prescriptions alone.[233]

198. In July 2013, Executive Committee members, including John Stewart, Russell Gasdia, and Craig Landau and other Purdue staff, reported back to Richard, Mortimer, Kathe, Jonathan, Theresa, and David Sackler that OxyContin sales had declined and identified the reason for the decline as *insufficient volume* of sales visits. To reverse this trend, Purdue's Executive Committee and staff recommended increasing the number of sales representatives, and told the Sacklers that the international consulting firm, McKinsey & Company ("McKinsey"), would be studying how to get more doctors prescribing OxyContin.[234]

199. In July 2013, the Sacklers met to discuss one of McKinsey's reports, *Identifying Granular Growth Opportunities for OxyContin: First Board Update*. That report urged Purdue and the Sacklers to demand more in person sales visits from the sales force – increasing their annual quota from 1,400 visits per year to 1,700. The report also advised the Sacklers and other individual Defendants to exert more control over the sales force's target list to focus on prescribers who provide the biggest payoff, and advised Purdue and the Sacklers to collect "prescriber level milligram dosing data" in order to identify high dosage prescribers.[235]

200. During the following month, the Sacklers met again to discuss a follow-up report from McKinsey with recommendations for further increasing opioid sales. McKinsey's follow-up report urged Purdue and the Sacklers to direct sales visits to

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[231] PPLPC012000326017.
[232] PPLP004406102-123.
[233] PPLPC012000326017; PPLPC015000141319.
[234] PPLPC012000431148; PPLPC012000431309.
[235] PPLP004409871.

the most prolific opioid prescribers, noting that these high-volume prescribers write "25 times as many OxyContin scripts" as the lower-volume prescribers.[236]

201. In December 2013, Executive Committee members, including John Stewart and Russell Gasdia, and other Purdue staff reported back to Richard Sackler that Butrans sales were increasing due to the increased targeting of "Core" and "Super Core" prescribers.[237] In early 2014, Purdue's Executive Committee, including Mark Timney and Russell Gasdia, reported back to the Sacklers and David Haddox that the sales force's bonus pay was tied to the number of visits they made to "high value" prescribers.[238]

202. As the practice of medicine became more reliant on nurse practitioners and physician assistants, from 2009 to 2015, Defendants expanded their strategy to more intently target those prescribers. Purdue staff, including members of Purdue's Executive Committee, described nurse practitioners and physician assistants as "high value target[s], particularly due to impact on primary care."[239] Purdue wanted its sales force to be "deemed the preferred source for receiving promotional information" for this group of prescribers.[240] According to one of Purdue's Q1 2013 reports, of the over 1,500 "Core" or "Super Core" prescribers in Colorado, 321 (22%) were nurse practitioners or physician assistants. In Q3 and Q4 2012, Purdue's sales representatives visited those Colorado nurse practitioners and physician assistants almost 1,200 times, which resulted in over 950 Butrans prescriptions alone.[241]

203. By 2015, Purdue and the individuals Defendants had data showing that nurse practitioners and physician assistants were responsible for over 800 million opioid prescriptions per year, representing the largest growth of prescribers—an 18% increase from 2014.[242] For their 2016 Budget, Purdue's Executive Committee, including Mark Timney and Craig Landau, and other Purdue staff reported back to the Sacklers that Purdue's budget priority for that year was to "Focus on Growing Customers" by "[t]arget[ing] [nurse practitioners]/[physician assistants], the only growing segment in the overall [ER Opioid] market."[243]

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[236] PPLP004409892.
[237] PPLPC012000454676.
[238] PPLPC020000756513.
[239] PWG000140164.
[240] PWG000435568.
[241] PPLPC015000141319.
[242] *Id.*
[243] PPLPC011000069975, 69977, 70000.

204. At all relevant times, Purdue's sales force reported on their visits to and conversations with Colorado health care providers in "call notes." 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."[244] Purdue management and Purdue's compliance department reviewed and audited the call notes.[245]

205. Purdue call notes indicate that, between 2006 and 2017, Purdue's Colorado sales force visited family medicine, internal medicine, and general practice physicians on more than 62,000 occasions.[246] During the same time period, Purdue sales representatives detailed nurse practitioners more than 13,000 times, and detailed physician assistants more than 23,000 times.[247]

206. Purdue trained its sales force to deliver company-approved messages, including materials created by Purdue's Front Groups, with the goal to increase opioid prescriptions generally, and prescriptions for Purdue's opioid drugs specifically. One Purdue detailer in 2007 recounted feedback received from a Colorado prescriber about the messaging disseminated by AAPM 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 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."[248]

207. To ensure that Purdue detailers delivered the desired messaging, Purdue and the individual Defendants trained, directed, and monitored detailers utilizing detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and by reviewing the call notes from each visit.[249] Purdue required its sales force to use sales aides reviewed, approved, and supplied by Purdue. Sale representatives were prohibited from using any materials not approved by Purdue's marketing and compliance departments.[250] Purdue ensured marketing consistency by conducting national and regional sales trainings.[251]

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[244] PVT0006079.
[245] PWG003812775.
[173] PCO000000002.
[174] *Id.*
[248] PCO000000001 Row: 32 (11/07/2007).
[249] *See, e.g.*, PWG000346232; PTN000063163; PWG000191756.
[250] PWG003812775.
[251] *See, e.g.*, PWG000191756.

208. Defendants knew that Purdue's sales 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 the doubling of Purdue's sales force, and the trebling of the number of in-person sales calls to prescribers.[252]

209. Purdue's sales force was trained how to handle prescribers' objections and concerns about converting patients from non-opioids or IR opioids to ER opioids, and concerns from prescribers who were skeptical about opioids in general. In 2009, when a Colorado prescriber expressed skepticism or concern about the risk of addiction associated with OxyContin, a Purdue sales representative reported that the prescriber was given "perspective" and "fair balance" by emphasizing to the prescriber "all opioids can be abused in the hands [of] those intent on abusing them."[253]

210. When one Colorado prescriber stopped writing Butrans prescriptions due to 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."[254] (July 13, 2011). This "fair balance" information provided to the prescriber ignored the fact that Schedule III opioids are still addictive and prone to abuse.[255]

211. 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. Detailers were directed to overstate the efficacy of opioids, and misrepresent risks associated with NSAIDs.

212. Even when faced with the knowledge that overprescription of opioids had created a national opioid epidemic, Purdue and the individual Defendants continued efforts to gain 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 [ER opioid] more likely to do so for a larger percentage of

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[252] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Public Health 221, 222-23 (2009).
[253] PCO000000001 Row: 1343 (12/09/2009).
[254] PCO000000001 Row: 2893 (07/13/2011).
[255] 21 U.S.C. § 812(b)(3)(C).

patients," and "[i]dentify what obstacles need overcome [*sic*] to make Prescribers more comfortable switching patients from NSAIDs to [ER opioids]."[256]

213. Once Purdue's detailers relaxed prescriber skepticism about opioid treatment generally, they were trained to "[e]ffectively facilitate CONVERSIONS" (emphasis in original) to OxyContin and other Purdue branded drugs. One method used to make conversions was a 15-18 minute "Interactive Education Experience" that Purdue sales representatives walked prescribers through. It consisted of "5 brief patient-case vignettes highlighting the range of patients who may be appropriate for a conversion to OxyContin."[257] Three of these vignettes featured hypothetical patients with low back pain, and two featured hypothetical patients with osteoarthritis – all conditions presenting chronic non-cancer pain.[258]

214. Purdue sales representatives were trained to "wedge" themselves into a health care provider's prescribing decisions. As Russell Gasdia explained:

> 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.*[259] (Emphasis added.)

215. Purdue's sales 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."[260]

216. Once a Purdue detailer convinced a prescriber to convert to prescribing Purdue's branded opioids, their training directed them to next work on convincing prescribers to increase dosages. Detailers were instructed, "[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

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[256] PWG000072026.
[257] PWG000192795.
[258] *Id.*
[259] PWG003810464.
[260] PWG000191810.

converts to an appropriate analgesic dose."[261] The "S.T.A.R.T." principles are a method for Purdue detailers to insert themselves into the prescriber's decision-making process by "assess[ing] patients for initiation, conversion, and titration of OxyContin . . . ."[262] Presumably this was done outside the presence of the patient. "S.T.A.R.T." stands for "Supplement with IR analgesic, Titrate every 1-2 days, Adjust dose 25-50%, Reassess pain, Tailor dose."[263]

217. Purdue's sales force, charged with implementing Purdue and the individual Defendants' sales strategies, misrepresented the efficacy of 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.

218. For decades, Defendants sought to increase opioid prescriptions in Colorado and throughout the United States using aggressive and deceptive sales tactics. At the direction and under the control of the individual Defendants, Purdue's deceptive messaging strategies succeeded in flooding Colorado's market with a blizzard of prescription opioids. The success of Purdue's deceptive marketing campaign lined Purdue and Rhodes's corporate pockets and the individual Defendants' personal pockets, and created the opioid epidemic ruining hundreds of thousands of lives in Colorado and throughout the country.

III. DEFENDANTS' DEADLY MISREPRESENTATIONS

A. Defendants Misrepresented the Risk of Opioid Addiction

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

220. OxyContin was launched in 1996. Purdue's marketing campaign claimed that opioid treatment was effective for treatment of chronic long term pain, and the risk of addiction was minimal.

221. Purdue had not conducted any studies to prove that its drugs were not addictive, and Purdue knew no independent data existed to support their claims.

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[261] PWG000197618.
[262] PWG000199388.
[263] PWG000357055.

222. Purdue and the Sacklers ignored 1997 warnings from Dr. Kaiko (the inventor of OxyContin) that, "oxycodone containing products are still among the most abused opioids in the U.S. … [i]f OxyContin is uncontrolled … it is highly likely that it will eventually be abused."[264]

223. A Purdue-funded study in 1999 found that 13% of patients who used OxyContin to treat headaches became addicted to the drug.[265]

224. Without any scientific basis, and intentionally disregarding strong warnings to the contrary, Purdue and the Sacklers devised and launched a widespread multifaceted marketing campaign grounded upon deceptive representations that opioid treatment was effective for chronic long term pain, and the risk of addiction was minimal.

225. Purdue began inundating the medical community with misleading claims that opioids were not addictive. In its 1998 promotional video, *I Got My Life Back*, Purdue falsely claimed that "[i]n fact, the rate of addiction amongst pain patients who are treated by doctors is much less than 1%."[266] Purdue mailed *I Got My Life Back* to thousands of health care providers around the country, including in Colorado, and the video was available on Purdue's website, www.partnersagainstpain.com.[267]

226. Shortly after the launch of OxyContin, Purdue and the Sacklers learned that Purdue's marketing led doctors to believe that OxyContin was not as potent as morphine. No one at Purdue sought to correct this dangerous misconception because the truth would mean fewer OxyContin prescriptions and less profit for Purdue and the Sacklers.[268]

227. Purdue's misinformation campaign about opioid addiction was the basis for 2007 criminal guilty pleas and civil admissions of liability by Purdue and its top executives – these plea agreements and civil admissions were approved by the Sacklers.

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[264] PDD1706195889-893.
[265] 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 June 26, 2019).
[266] Our Amazing World*, Purdue Pharma OxyContin Commercial*, YouTube (Sept. 22, 2016), https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited June 26, 2019); PDD9521403001.
[267] PDD9521403504.
[268] PDD8801141848; PDD1508224773; PDD1701801141.

228. In August 2007, recently-convicted Purdue executive and Executive Committee member, Howard Udell, emailed Richard, Mortimer, Kathe, Jonathan, Ilene, and Theresa Sackler, as well as David Haddox: "Over the last week there have been numerous news stories across the nation reporting on the Associated Press's analysis of DEA data showing very large increases in the use of opioids analgesics (particularly OxyContin) between the years 1997 and 2005. Many of these articles have suggested that this increase is a negative development suggesting overpromotion and increasing abuse and diversion of these products."[269]

229. In the wake of the 2007 criminal guilty pleas and civil admissions, Purdue and the Sacklers could have sought to promote the truth about opioids and opioid addiction. But, the allure of profits and personal fortunes proved too great.

230. Reports of opioid abuse and diversion were not imagined by prosecutors or by the media. In October 2008, Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, and other Purdue staff advised the Sacklers that Purdue's opioid abuse data showed a "wide geographic dispersion" of abuse and diversion of OxyContin "throughout the United States," including in Colorado. The Executive Committee and staff also reported that "availability of the product" and "prescribing practices" were key factors driving abuse and diversion of OxyContin. Instead of taking any corrective action, Purdue and the Sacklers doubled down on their aggressive and deceptive promotional scheme.[270]

231. APF's 2009 *Exit Wounds*, was sponsored by Purdue and targeted veterans. It was posted on Purdue's website, www.inthefaceofpain.com. *Exit Wounds* 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."[271]

232. *Exit Wounds* contained numerous other misrepresentations about the risk of opioid addiction:

> For a number of reasons, healthcare providers may be afraid to prescribe [opioids], and patients may be afraid to

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[269] PPLPC012000153272.
[270] PDD9316101020, 025, 029.
[271] Derek McGinnis & Stephen R. Braun, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families* 107 (2009).

> take them. At the core of this wariness is the fear of addiction, so I want to tackle this issue head-on.[272]
>
> 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. . . .[273] (emphasis in original)
>
> Opioid medications can, however, be abused or used as recreational drugs, and some people who use these drugs this way *will* become addicted. . . .[274]
>
> 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*.[275]

233. Contrary to these statements, the truth is that almost every person who takes prescription opioids becomes tolerant, and many require ever-increasing dosages to receive the same analgesic effect over time.[276] Indeed, Purdue and the Sacklers' OxyContin business relies on continuous use of the drug.[277]

234. Opioid addiction is not limited to people who abuse or misuse opioids. In reality, many people who use opioids as prescribed become addicted. Purdue and the individual Defendants were well aware that opioids are highly addictive even when used as prescribed. Purdue tracked opioid abuse, including the means by which people began abusing opioids (orally, snorting, injecting). In February 2011, members of Purdue's Executive Committee, including John Stewart and Craig

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[272] *Id.* at 106.
[273] *Id.*
[274] *Id.* at 107.
[275] *Id.*
[276] Jane C. Ballantyne & Jianren Mao, *Opioid Therapy for Chronic Pain*, 349 N Engl. J. Med. 1943, 1945-46 (2003).
[277] PWG000062941; PWG000061454.

Landau, and other staff reported back to the Sacklers that 83% of patients in substance abuse treatment centers began using and abusing opioids by swallowing the pills, 16% began abusing opioids by snorting, and 1% by injecting).[278] In that same report, the Executive Committee and staff also reported that "[Purdue] can now examine abuse outcomes on an unprecedented level of detail," by tracking "OxyContin exposure calls to Poison Centers by zip code."[279] The Executive Committee and staff showed the Sacklers a map that included OxyContin exposure calls to Poison Centers throughout Colorado.[280]

235. As directed and/or sanctioned by the individual Defendants, Purdue trained its detailers to understate the risk of addiction to prescribers, including Colorado prescribers:

- After visiting a Colorado health care provider who 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."[281] (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.[282] (August 2, 2006)

236. To convince Colorado health care providers that opioids were not addictive, Purdue's sales force was also trained to talk about the technical definitions of opioid dependence and opioid addiction:

- 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]

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[278] PDD8901468036-038, 100, 108-109.
[279] PDD8901468108-09.
[280] *Id.*
[281] PCO000000002 Row: 42504 (03/31/2010).
[282] PCO000000002 Row: 3337 (08/03/2006).

for use [with patients] and their families to help educate."[283] (February 18, 2009)

- A detailer reported "[reviewing] definitions" … [health care provider] agreed some [patients] may have an addiction, but rare."[284] (July 8, 2008)

- A sales representative "talked to [a Colorado pharmacist] about 'confusion in her mind of physical dependence and addiction'…."[285] (January 8, 2009)

237. The distinction between opioid dependence and opioid addiction touted by Purdue is a distinction without a substantive difference. Whether a patient is tolerant, dependent, or addicted to opioids, the result is the same – the patient will require higher and/or more frequent dosages of the drug and, therefore, be at greater risk of addiction, overdose, and death. Purdue's misrepresentation about the differences between opioid dependence and opioid addiction is not just misleading – it had deadly consequences in Colorado and nationwide.

238. Purdue and the Sacklers were well aware of the growing opioid epidemic ravaging Colorado and the rest of the country. On a quarterly basis from at least 2007 to 2017, members of Purdue's Executive Committee, including John Stewart, Russell Gasdia, Mark Timney, and Craig Landau, as well as David Haddox and other Purdue staff, provided the Sacklers "Reports of Concern" and other reports on adverse events, internal compliance violations, and concerning issues related to the Purdue's opioid drugs. For example, Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, and Purdue staff reported back to the Sacklers that in 2007 and 2008 alone, Purdue received over 4,400 "Reports of Concern" about abuse and diversion of Purdue's opioids. Purdue's Executive Committee and staff also reported back that of the thousands of reports submitted to Purdue's compliance hotline during the same time period, only 562 follow-up investigations were conducted.[286]

239. Purdue's Executive Committee, including John Stewart, Russell Gasdia, Mark Timney, and Craig Landau, as well as David Haddox and other staff, presented regular reports back to the Sacklers containing detailed information on specific "Reports of Concern" and adverse events, including the date reported, a

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[283] PCO000000002 Row: 23464 (02/18/2009).
[284] PCO000000002 Row: 15645 (07/08/2008).
[285] PCO000000002 Row: 22158 (01/08/2009).
[286] PWG000300836; PPLPC012000157459; PDD8901733995; PDD8901724450; PPLP004367317; PDD9316101027.

description of the incident, and how Purdue and/or Rhodes staff responded. Not surprisingly, Defendants rarely, if ever, reported these "Reports of Concern" or any other suspicious activity to the FDA, the DEA, or any other federal, state, or local authorities.

240. Purdue and the individual Defendants were well aware of the growing pressure the opioid epidemic was putting on their bottom line. In 2017, members of Purdue's Executive Committee, including Mark Timney and Craig Landau, and staff recommended to the Sacklers that "Purdue Needs a New Approach" – one which was less misleading: "A New Narrative: Appropriate Use."[287]

241. In that same 2017 report, the Executive Committee and staff also recommended that the Sacklers create a family foundation to help solve the opioid epidemic. The Sacklers flatly rejected the proposed "New Narrative" and charitable remediation foundation. Instead, the Sacklers directed a plan to increase opioid sales by requiring Purdue's sales force to visit prescribers in Colorado and throughout the country over 1 million times in 2018 – almost double the number of sales visits made in 2010 during OxyContin's heyday.[288]

B. Defendants Concocted a Deceptive Condition Called "Pseudoaddiction," and Used it to Sell More Opioids

242. To counter findings of the evidence-based, peer-reviewed studies showing that opioids are addictive, Purdue and the individual Defendants conjured and promoted a condition called "pseudoaddiction." Defendants misrepresented to health care providers that patients who showed signs of addiction were not really addicted, but rather presenting signs of "pseudoaddiction," and needed *more* opioids. More opioids meant higher profits for Purdue, and a larger fortune for the Sacklers.

243. As directed and/or sanctioned by the individual Defendants, Purdue told health care providers that everything they had learned in their training about opioid addiction was wrong. They told prescribers that patients showing signs of addiction were not becoming addicted to opioids, but instead were suffering from

[287] PPLPC011000151189.
[288] *Id.*

"pseudoaddiction," because "opioids are frequently prescribed in doses that are inadequate."[289]

244. While some patients exhibiting signs of addiction may simply need more appropriate dosing, the reality is that the vast majority of patients who exhibit signs of opioid addiction are, unsurprisingly, in fact addicted.

245. By convincing prescribers that their patients were presenting signs of "pseudoaddiction," Purdue and the individual Defendants, through their Key Opinion Leaders, Front Groups, and sales force, were able to undermine common medical knowledge, and increase Purdue's profits by urging prescribers to increase opioid dosages 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."[290] (May 2, 2006)

- Another detailer "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."[291] (May 23, 2006)

246. Prescribers had a difficult time distinguishing between patients who were truly addicted to opioids, and those suffering from "pseudoaddiction," because the term has no basis in medical science. It was concocted by David Haddox.[292] Nevertheless, Purdue and the individual Defendants, through Front Groups, Key Opinion Leaders, and detailers, heavily promoted fake science behind this deceptive condition in an effort to cause health care providers to second-guess their education, training, and experience, and prescribe more opioids.

247. In a July 2007 Board report, Purdue's Executive Committee, including John Stewart, Russell Gasdia, Craig Landau, and other Purdue staff reported back to the Sacklers that Purdue distributed by mail more than 12,000 pro-opioid publications in Colorado and throughout the country during the first half of 2007. The single most-distributed publication was volume #1 of Purdue's *Focused and*

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[289] PTN000006070.
[290] PCO000000002 Row: 1803 (05/02/2006).
[291] PCO000000002 Row: 2166 (05/23/2006).
[292] *See* David E. Weissman & J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36 Pain 363 (1989).

Customized Education Topic Selections in Pain Management ("FACETS").[293] FACETS not only falsely represented that physical dependence on opioids is not dangerous, but instead actually improves patients' "quality of life" – it also misrepresented that patients who showed signs of addiction were likely suffering from "pseudoaddiction."[294]

248. In the same 2007 Board report, Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, and staff also reported back to the Sacklers that another publication called *Complexities in Caring for People in Pain*, was also distributed by mail to prescribers in Colorado and throughout the country. That publication also promoted "pseudoaddiction."[295]

249. 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 be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.[296]

250. Another 2008 Purdue pamphlet, *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substances Prescribing Practices* (2008), warned prescribers: "Fact[ ] About Addiction: 'Misunderstanding of addiction and mislabeling of patients as addicts results in unnecessary withholding of opioid medications.'"[297]

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[293] PWG000300818.
[294] PTN000004691-693.
[295] PWG000300818; PTN000005318.
[296] 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).
[297] Purdue Pharma L.P., *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substances Prescribing Practices* 6 (2008).

251. Purdue's 2009 pamphlet, *Opioid Clinical Management Guide*, told prescribers that the patients faced the greatest risk of opioid addiction if they received *too little* of the drug: "The primary risk factor for misuse is uncontrolled or inadequately treated pain."[298]

252. In 2011, Purdue issued a second edition of *Providing Relief, Preventing Abuse*, which again urged prescribers to increase dosage to address "pseudoaddiction." The pamphlet states, "[t]he 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."[299]

253. The 2012 version of the Purdue-sponsored book, *Responsible Opioid Prescribing*, told prescribers 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.[300]

254. Purdue's materials on "pseudoaddiction" failed to disclose that the condition was actually conjured by David Haddox in the late 1980's and published as a four-page Case Note after he reviewed the case of a single teenage patient suffering from cancer-related pain, not chronic non-cancer pain.[301] There is little-to-no unbiased "literature" or other scientific or medical evidence supporting "pseudoaddiction" as the widespread condition Purdue claimed was affecting patients receiving opioid treatment to treat chronic pain.

255. Defendants never disclosed the increased risk of addiction associated with higher doses of opioids when recommending higher doses of opioids to combat "pseudoaddiction."

256. Purdue's "pseudoaddiction" condition continues to be disseminated to Colorado prescribers, patients, policymakers, and the public, including at the DORA stakeholder meeting as recently as December 2017.

257. Defendants knew their messaging on "pseudoaddiction" was deceptive and was really intended to push higher doses of opioids, and correspondingly, more

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[298] The C.A.R.E.S. Alliance, *Opioid Clinical Management Guide: A Prescriber's Resource for Responsible Prescribing and Use* 5 (2009).
[299] Purdue Pharma L.P., *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substances Prescribing Practices* 9 (2d ed. 2011).
[300] Scott M Fishman, *Responsible Opioid Prescribing A Clinician's Guide* 92 (2d ed. 2012).
[301] PPLPC018000641529.

sales. Key Opinion Leaders and other individuals on Purdue's payroll have admitted that they used the concept of "pseudoaddiction" to describe "behaviors that are clearly characterized as drug abuse."[302] Defendants' misrepresentations and deceptive marketing campaign featuring "pseudoaddiction" is shocking evidence of Defendants' knowing and total disregard for increased risks of opioid addiction, overdose, and death.

C. Defendants Accused Prescribers of Failing Their Patients by Not Prescribing Opioids to Relieve Pain

258. In order to drive sales, Defendants sought to turn the tables on the medical community's aversion to prescribing opioid drugs by telling 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.[303] The website also posted testimonials from "advocates" supporting Purdue's messaging.[304]

- 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 that occurred when patients misused prescription opioids.[305] The *Guide* reinforced Purdue's warnings to the medical community that "under-use [of opioids] has been responsible for much unnecessary suffering."[306]

- APF's Purdue-sponsored *A Policymaker's Guide to Understanding Pain & Its Management* (2011) falsely claimed that less than 1% of children prescribed opioids would become addicted.[307] The *Policymaker's Guide* also claimed that "too many Americans are not getting the pain care they

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[302] RP_011700.
[303] PVT0034554.
[304] *Id.*
[305] *See generally* American Pain Foundation, *Treatment Options: A Guide for People Living with Pain* (Terry Altilio et al. eds., 2007).
[306] *Id.* at 11-12, 15.
[307] American Pain Foundation, *A Policymaker's Guide to Understanding Pain & Its Management* 40 (2011).

need and deserve. Some common reasons for difficulty in obtaining adequate care include … misconceptions about opioid addiction."[308]

- A Purdue sales representative recalled that one Colorado prescriber was "concerned [that] patients who start on oxyconitn [*sic*] never get off of it."[309] In response, the sales representative "discussed how most patients have been undertreated and may have neuronal plasticity."[310] (February 6, 2006)

259. In 2011 and 2012, John Stewart, then President and CEO of Purdue and Chair of the Executive Committee, delivered a series of speeches entitled, *Providing Relief, Preventing Abuse*, asserting that pain is undertreated and that patients are to blame for addiction, overdose, and death because of abuse.[311] Purdue's 2012 "Business Strategy," drafted and presented to the Sacklers by members of the Executive Committee, including Russell Gasdia and Craig Landau, included "[i]ncreas[ing] awareness of the extent of untreated pain" as a major message for Purdue's "Mid-term to Long-term: 2014-2020" strategy.[312]

260. Following through on Defendants' 2014-2020 strategy, Purdue's Colorado sales force began increasing their pressure on Colorado prescribers by accusing them of not properly treating patients' pain with opioids. For example, in response to a Colorado prescriber's decision to stop treating chronic pain patients, a Purdue sales representative pressured the prescriber asking, "what are you going to do when current patient develops pain condition? … let me show you what some of your peers are doing."[313] (June 27, 2013)

D. Defendants Falsely Claimed That Opioid Addiction Risks Could Be Easily Managed

261. Purdue and the individual Defendants set out to convince health care providers that they could effectively manage the risk of addiction, and even prevent it. To do this, Purdue and its Front Groups and Key Opinion Leaders distributed addiction management "tools" to prescribers that were themselves deceptive.

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[308] *Id.* at 6.
[309] PCO000000002 Row: 414 (02/06/2006).
[310] *Id.*
[311] PWG000217342-343.
[312] PWG000164127, 129, 149.
[313] PCO000000002 Row: 106992 (06/27/2013).

262. Purdue claimed that a prescriber could conduct a subjective patient screening to effectively mitigate the risks of addiction:

- The *Treatment Options* guide, published by APF with Purdue's funding, falsely stated that "opioid agreements" between patients and prescribers "ensure that [the patient] take the opioid as prescribed."[314]

- Purdue's detailers provided Colorado prescribers a *Partners Against Pain* "Pain Management Kit" with purported "drug abuse screening tools."[315] The "Opioid Risk Tool" included in the Kit is nothing more than a five question, one-minute, discussion between prescriber and patient that relies entirely on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease."[316]

263. In September 2010, Russell Gasdia reported back to the Sacklers and David Haddox that 82% of OxyContin prescriptions written were for patients who were already taking the drug.[317] This data underscored the need for Defendants to convince prescribers that the risk of addiction could be managed in order to drive increased sales.

264. Contrary to Purdue's representations that opioid addiction can be managed, the evidence shows that Purdue's recommended methods for preventing abuse and addiction among high-risk patients do not work.

265. 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 instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring

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[314] American Pain Foundation, *Treatment Options: A Guide for People Living with Pain* 15 (Terry Altilio et al. eds., 2007).
[315] Partners Against Pain, *Pain Management Kit* 61 (2008).
[316] *Id.*
[317] PPLPC012000290691.

intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[318]

266. Call notes documenting visits to Colorado prescribers also showed Purdue and the individual Defendants that their recommended addiction management methods do not work. 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[.]"[319] Even after the prescriber admitted that "she is not fully equipped to handle treatment of chronic pain," the sales representative "bridged [the] conversation to OxyContin, [and] closed on [pursuing] Percocet patients around the clock, and patients taking hydrocodone 5mg q6h for Butrans."[320] (September 18, 2014)

E. Defendants Misrepresented the Effective Duration of Purdue's Opioids and the Risks Associated With End-of-Dose Failure

267. Purdue and the individual Defendants misrepresented that their 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. If a patient is inadequately dosed, the patient can experience distressing psychological and physical withdrawal symptoms, which feeds cravings for higher and higher doses, which in turn increases the risk of addiction, overdose, and death.

268. In response to withdrawal symptoms and cravings prior to the expiration of the 12 hour period, 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 addiction and overdose.

269. Since its launch in 1996, 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

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

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."[321]

270. 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.[322] 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.[323] This deception makes the absorption rate of OxyContin appear steadier than it really is.

271. While OxyContin may last 12 hours for some patients, according to Purdue's own research during the development of OxyContin, OxyContin wears off in under 6 hours for quarter of patients, and in under 10 hours in more than half of patients.[324] 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.[325]

272. 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 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

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[321] PWG000269777; PWG001165463.
[322] *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).
[323] *Id.*
[324] PWG001048786.
[325] 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*.

> 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.[326]

273. In the face of empirical and anecdotal evidence that OxyContin did not provide 12 hours of pain relief, Purdue continued to tout 12-hour dosing to prescribers, including those in Colorado:

- Purdue sales call note report that 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."[327] (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?"[328] (January 25, 2010)

- Another Colorado prescriber "[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."[329] (July 29, 2013)

274. For patients who did not experience 12 hours of pain relief from OxyContin, Purdue's proposed "solution" was to increase the dosage of the opioid, (which was more profitable for Purdue) rather than increasing the frequency of the same dosage.

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[326] 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.
[327] PCO000000001 Row: 656 (02/09/2009).
[328] PCO000000001 Row: 1415 (01/25/2010).
[329] PCO000000002 Row: 108265 (07/29/2013).

275. Rather than give up the "competitive advantage" provided by 12-hour dosing by admitting that the true effective duration of OxyContin was shorter, Purdue and the individual Defendants knowingly put Colorado patients at an increased risk of addiction, overdose, and death by pushing ever higher dosages of its products.

276. In May 2016, a "Weekly Executive Summary" prepared by Purdue's Colorado Government Affairs staff relayed a Colorado Key Opinion Leader's concerns about the effective duration of OxyContin:

> My concern is that of consistency in analgesia from OxyContin. The [prescribing information] does not in my mind reflect clinical practice. The original study remains in the [prescribing information] now nearly 2 decades later. It is a very weak study: 133 patients, 2 week duration, 2 dosing levels only with the lower level adjudicated as ineffective and a fixed 12 hour interval. After all these years, is this the best we can do??[330]

277. The misrepresentations about the effective duration of Purdue opioids were not limited to OxyContin. For example, Purdue was not legally allowed to say that Butrans was effective for 7 days because the data did not support such a statement. Nonetheless, in a July 2010 Board meeting, Russell Gasdia and other members of Purdue's Executive Committee and staff were criticized by the Sacklers for not including in Purdue's marketing materials representations that Butrans was effective for 7 days.[331]

278. In the same July 2010 Board meeting, the Sacklers asked Russell Gasdia, Craig Landau, and other members of Purdue's Executive Committee if Purdue's sales force could sell more Butrans by remaining silent about a failed clinical trial using Butrans to treat osteoarthritis: "What can be said in response to a prescriber who asks directly or indirectly…'[C]an [Butrans] be prescribed for my patient with [osteoarthritis]?' In responding are we required to specifically mention the failed trial in [osteoarthritis], and is there an adequate mechanism for describing or managing the conversations concerning the failed trials?"[332]

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[330] PPLPC031001442512-14.
[331] PPLPC012000283167.
[332] *Id.*

F. Defendants Misrepresented the Efficacy of, and Risks Associated With, Increased Dosages and Longer Durations of Opioid Treatment

279. As the opioid market grew more competitive, Defendants explored other strategies to increase Purdue's profits and their personal fortunes. Acting on recommendations from McKinsey, Defendants began pushing health care providers to increase the doses of opioids and to increase the duration of patients' opioid treatment. As directed and/or sanctioned by the individual Defendants, Purdue trained detailers to reassure prescribers by misrepresenting that there was no ceiling on the amount of opioids a patient could be prescribed. In reality, the ceiling doses for opioids are imposed by adverse reactions caused by increased doses, including overdose, respiratory depression, and other serious adverse events.

280. As directed and/or sanctioned by the individual Defendants, Purdue trained detailers to pressure prescribers to "titrate up," or increase, the doses of opioids and the duration of patients' treatment. Purdue also started distributing savings cards to prescribers and patients. The savings cards were intended to offset increased expenses for patients to take more expensive high-dose opioid for longer periods of time. Purdue and the individual Defendants closely tracked redemption rates and increased revenue resulting from Purdue's savings card program.

281. Purdue's opioid savings card program was a powerful tactic for increasing doses and keeping patients on the drugs for longer. In August 2009, Russell Gasdia reported back to Richard, Mortimer, Kathe, and Jonathan Sackler that 160,000 patients used the savings cards, more than doubling the results reported to the Sacklers the year before.[333] Purdue's 2012 10-year plan included data showing that the savings cards meant "more patients remain on OxyContin after 90 days."[334] A Purdue internal analysis also showed that the savings cards had the highest "return on investment" in the entire "OxyContin Marketing Mix." Purdue earned $4.28 in revenues for every $1 the savings cards offered to patients.[335]

282. Approximately 60% of patients who use opioids for 90 days continue to use opioids five years later, which is why the CDC concluded that, "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[336]

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[333] PPLPC012000235543 *compare to* PPLPC012000186394.
[334] PWG000164240.
[335] PWG000414917.
[336] *See supra* ¶ 69.

Purdue and the individual Defendants were well aware of this frightening statistic and, nevertheless, directed and/or sanctioned the distribution of Purdue savings cards to increase doses and duration of therapy. Defendants never disclosed to prescribers or patients the severe risks associated with doing so.

283. As directed and/or sanctioned by the individual Defendants, Purdue emphasized to its sales force that increasing patient doses was key to making a sale. Detailers were given a guide entitled *Initiation, Conversion, and Titration Discussion with Appropriate Selling Tools* to help them "practice verbalizing the [increased] titration message" to get patients on higher doses of opioids.[337]

284. Purdue and the individual Defendants monitored the pace at which prescribers titrated up their patients' opioids. They pressured the Purdue sales force to lobby Colorado prescribers 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."[338] (January 3, 2012)

- Other call notes state 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.[339] (May 17, 2012)

285. The strategy to increase opioid dosages relied heavily on in-person sales calls with prescribers. A Purdue 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."[340] 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."[341]

286. As directed and/or sanctioned by the individual Defendants, Purdue convinced prescribers to increase dosages by falsely promising that, "[o]pioid dose

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[337] PWG000197618.
[338] PCO000000001 Row: 3538 (01/03/2012).
[339] PCO000000001 Row: 4078 (05/17/2012).
[340] PWG000197618.
[341] PWG000062654.

was not a risk factor for opioid overdose."[342] This misrepresentation was 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]."[343]

287. As directed and/or sanctioned by the individual Defendants, Purdue continued to push prescribers to increase dosages because higher doses meant higher profits. While Defendants ignored the correlation between sales of its opioid drugs and the harm they caused, they very carefully monitored the correlation between even a small decrease in dosages and decreases in revenues: "A small shift of roughly 15K prescriptions from 20mg or 15mg down to 10mg has a $2MM impact."[344]

288. 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."[345] (January 18, 2006)

- A detailer noting another instruction from Purdue, "[k]eep discussing the titration process and break through meds goals as I grow business."[346] (September 18, 2015)

- One sales representative noted 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]."[347] (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

[342] PWG000131801.
[343] PWG000226020.
[344] PWG000062583.
[345] PCO000000002 Row: 144 (01/18/2006).
[346] PCO000000002 Row: 150668 (09/18/2015).
[347] PCO000000002 Row: 15986 (04/06/2016).

other strengths such as the 60mg and 80mg if he needs to titrate to effect."[348] (September 2, 2016)

289. Colorado prescribers relied upon Purdue's misrepresentations about the safety and efficacy of higher doses, and began prescribing 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."[349] (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.[350] In response, Purdue's sales representative "[d]iscussed lacke [*sic*] of ceiling dose and end organ damage with OxyContin."[351] 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 OxyContin over 5 years.[352] 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.[353] During that time, Purdue detailed the prescriber 108 times, more than twice a month on average.[354]

- 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

[348] PCO000000002 Row: 167051 (09/02/2016).
[349] PCO000000002 Row: 5712 (12/13/2006).
[350] PCO000000002 Row: 8205 (05/16/2007).
[351] *Id.*
[352] *See* PWG003984533; PCO000000002.
[353] *Id.*
[354] PCO000000002.

functional improvement he will [continue] to titrate if indicated."[355] (November 21, 2007)

- 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.[356]

290. Purdue pressured Colorado health care providers to increase patient dosages, even if 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."[357] (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 would be willing to do this before going away from Butrans."[358] (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."[359] (June 21, 2012)

291. Defendants knew as early as the 1990s that higher doses exposed patients to serious risks and side effects. In 1997, when Purdue and the Sacklers were actively promoting the dangerous misconception that OxyContin was weaker than morphine, Richard Sackler also wanted to "smash [the] critical misconception" that OxyContin "has a ceiling effect."[360] Richard Sackler made these statements even though Purdue and the Sacklers knew from a 1997 internal memo that "[w]hen high doses of an opioid are used for long periods of time, adverse effects

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[355] *Id.* at Row: 11558 (11/21/2007).
[356] *See, e.g., id.* at Row: 90180 (08/10/2012).
[357] *Id.* at Row: 5712 (12/13/2006).
[358] *Id.* at Row: 92010 (09/10/2012).
[359] *Id.* at Row: 87289 (06/21/2012).
[360] PDD1701801144.

such as nausea, vomiting, delirium and myoclonus [*sic*] frequently become dose limiting."[361]

292. For the next two decades and beyond, increasing the doses and extending the duration of patients' opioid treatment became a core strategy for increasing Purdue's profits and the individual Defendants' personal fortunes.

293. Purdue and the individual Defendants knew and intended that Purdue's sales force would push health care providers to prescribe higher doses of opioids. In February 2008, Richard Sackler sent an email (copying Jonathan and Mortimer Sackler) instructing John Stewart and other members of Purdue's Executive Committee and staff to "measure our performance by [prescriptions] by strength, giving higher measures to higher strengths an [*sic*] especially the new strengths [of OxyContin]."[362] And in April 2008, in order to maximize Purdue's strategy to increase dosages and extend treatment durations, Richard Sackler sought data from Russell Gasdia showing the number of Purdue patients whose insurance "limited [them] to 60 tablets/month of any strength[;] limited [them] to number of tablets/dose[;] [and] limited [them] to number of tablets/day."[363]

294. By 2009, Purdue's focus on higher dose prescriptions was already bearing fruit. In March of that year, John Stewart and Richard Sackler discussed a shift in Purdue's strategy away from increasing Purdue's market share of total prescriptions, to increasing Purdue's share of the most profitable opioids, *i.e.* the highest doses.[364] In April 2009, Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, and other Purdue staff reported back to the Sacklers that "for the first time since January 2008, OxyContin 80mg strength tablets exceeded 40mg strength."[365] In August 2009, Executive Committee members, including John Stewart and Russell Gasdia, reported that, while sales of lower dose OxyContin had been declining since 2007, sales of 80mg OxyContin remained consistently high – almost 1,000kg (*one ton*) of oxycodone *per month* from January 2007 to June 2009.[366]

295. In response to a March 2010 request from Richard Sackler, Executive Committee members, including John Stewart and Russell Gasdia, provided a report

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[361] PDD1701785443.
[362] PPLPC012000170948-949.
[363] PPLPC012000179497.
[364] PPLPC012000216786.
[365] PDD9316100601, 624.
[366] PPLPC012000234970-971; PPLPC012000234801; PPLPC012000235543.

showing that Purdue was selling more of its 80mg OxyContin pills than any other dose.[367]

296. As opioid prescriptions reached their peak in Colorado and around the country, in 2012 John Stewart and David Haddox presented Purdue's new marketing campaign to the Sacklers, which sought to further increase the doses being prescribed to patients. The name of that campaign was *Individualize the Dose*. In reality, the campaign was intended to *increase* the dose. *Individualize the Dose* was featured on Purdue's website, www.PurdueHCP.com, and "as part of the program, [Purdue would be] implementing a number of nonpersonal 'behind the scenes' tactics that will help drive appropriate [health care provider] traffic to the site."[368]

297. The *Individualize the Dose* campaign continued into 2013. In January 2013, members of Purdue's Executive Committee, including John Stewart and Russell Gasdia, as well as David Haddox and other Purdue staff, reported back to the Sacklers that Purdue's sales force would place greater emphasis on the savings cards. The Executive Committee and staff reported that Purdue conducted a sensitivity analysis on the savings cards to maximize their impact and, as a result, had increased the dollar value for the cards and set the program period to be 15 months long. The Executive Committee and staff also reported Purdue had given promotional materials to the sales force for distribution to prescribers and that Purdue showed a promotional video to 5,250 physicians in Colorado and around the country on the "Physician's Television Network." Those promotional materials and the promotional video urged prescribers to utilize the savings cards as a means for increasing the doses of prescribed opioids and the duration of opioid treatment.[369]

298. In a May 2013 Board report, Russell Gasdia presented a strategy to mitigate declining sales trends to the Sacklers. Purdue would reverse those negative trends by having the sales force visit prescribers more frequently, continue pushing the *Individualize the Dose* campaign, push for higher redemption rates of the savings cards, and focus on the most prolific opioid prescribers around the country.[370]

299. Later in 2013, John Stewart, Russell Gasdia, and other members of Purdue's Executive Committee reported back to Mortimer, Kathe, Jonathan, Ilene,

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[367] PPLPC012000262892.
[368] PPLPC003516614; PPLPC012000362821; PPLPC037000111998; PPLP4409973.
[369] PPLPC012000407138-140; PPLP003297185.
[370] PPLP004409727-728.

Beverly, Theresa, and David Sackler that McKinsey was analyzing data from individual physicians around the country to "reverse the decline in higher strengths" and the decline in "tablets per [prescription]."[371] McKinsey would also study techniques for keeping patients on opioids longer, including having the sales force "make a lot of calls on physicians with a high number of continuing patients."[372]

300. By the end of 2013, Defendants once again experienced pay off from the push for higher doses and longer treatment durations. In a November 2013 report to the Sacklers, members of Purdue's Executive Committee, including Russell Gasdia, detailed McKinsey's analysis showing that the savings cards earned Purdue and the Sacklers more money by keeping patients on opioids longer – specifically, there was an increase in patients staying on OxyContin longer than 60 days.[373]

301. As the public became more attuned to the deadly impacts of prescription opioids, Defendants were concerned about declines in Purdue's sales numbers. In 2014, Mark Timney (Chair) and other members of Purdue's Executive Committee, reported back to the Sacklers that Purdue was losing hundreds of millions of dollars in sales because prescribers were shifting away from high dosage opioids and limiting the number of pills they were writing prescriptions for. Recognizing the importance of high dosage opioids and long treatment durations to Purdue's profits, the Executive Committee told the Sacklers that key sales priorities were to encourage prescriptions to elderly and opioid naïve patients, and to continue pushing the *Individualize the Dose* campaign, including the use of savings cards, as a means to increase doses and get patients to "stay on therapy longer."[374]

302. In 2015 and 2016, Purdue and the Sacklers doubled down on their efforts to fight back against a growing aversion to prescription opioids. At the end of 2015, the Executive Committee, including Mark Timney, and other Purdue staff, including Craig Landau who was President and CEO of Purdue Canada at the time, presented to the Sacklers a 2016 sales strategy to push prescribers to average 60 pills of Purdue's opioids per prescription, and that they would aim to make enough

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[371] PPLPC012000433412.
[372] PPLPC012000431262; PPLPC012000431266-278.
[373] PPLPC002000186925-926, 930-934.
[374] PPLPC002000181037, 039, 043, 056; PPLPC002000181047-048.

of those pills be high dosage opioids in order to make sure the average pill prescribed contained 33mg of oxycodone.[375]

303. Defendants were well aware of the dangerous and deadly impact their push to increase opioid doses and treatment durations was having on Colorado and the rest of the country. Unconcerned, Defendants continued blindly pursuing ways to profit from the epidemic they created. In June 2016, the Sacklers met to discuss *Project Tango*. Seeing a means to profit from sales of the overdose reversal drug, NARCAN, *Project Tango* identified patients using Purdue's opioid drugs as the target market for NARCAN and called for a study of "*long-term script users*" to "better understand target end-patients" for NARCAN.[376]

304. It was not until 2017, when public scrutiny of opioid use reached a fever pitch, that Purdue's Colorado call notes finally began reflecting a shift toward working with prescribers to lower patients' dosages, and to take patients off opioid treatment.[377]

G. Defendants Misrepresented the Efficacy of Abuse-Deterrent Opioid Formulations

305. In 2010, Purdue introduced a reformulation of OxyContin that it claimed was abuse-deterrent, and Purdue discontinued marketing its original formulation. As a result, 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."[378]

306. Sensing the threat generic oxycodone posed to Purdue's market dominance and profits, Defendants abruptly changed messaging on the addictiveness of their blockbuster opioid product. On July 13, 2012, Purdue submitted a citizen's petition to the FDA arguing that the original OxyContin formulation was prone to abuse.[379] According to Purdue itself, if generic oxycodone

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[375] PPLPC011000069992.
[376] PPLPC011000099222; PPLPC011000099280.
[377] *See generally id.*
[378] *See* 21 C.F.R. § 314.161 (2017).
[379] 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 (last visited June 26, 2019).

were allowed into the market, "abuse of extended release oxycodone could return to the levels experienced prior to the introduction of reformulated [abuse-deterrent] OxyContin."[380]

307. Purdue's citizen petition to the FDA also argued that granting market access to generic oxycodone would exacerbate the public health crisis caused by prescription opioids–a crisis ignited by Purdue's original formulation of the drug.[381] Thus, Purdue finally admitted what Purdue and the Sacklers had known all along–opioids, and OxyContin in particular, posed significant risks to the public that far outweighed any benefits.

308. Purdue's citizen petition had nothing to do with Purdue and the Sacklers' desire to tell the truth about OxyContin or take any responsibility for the opioid epidemic they created. Instead, the intent behind the citizen petition was once again blind pursuit of profits. By blocking approval of ANDAs for generic versions of the original OxyContin formulation, Purdue protected its market position for the release of its new allegedly abuse-deterrent drug.

309. In November 2013, John Stewart announced at a Beneficiaries Meeting, "[o]n April 16, the FDA announced that the NDA for the original formulation of OxyContin was withdrawn for reasons of safety, an achievement of a goal more than 8 years in the making."[382]

310. Purdue called its reformulation of OxyContin an "abuse-deterrent" formulation of its ER opioids. Specifically, the reformulation was a timed-release formulation. Timed-release formulations of drugs can be defeated, by crushing the pill for example, in which case a person can then 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.[383]

311. Purdue's website in 2016 stated that 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

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[380] *Id.* at 44.
[381] *Id.* at 46.
[382] PPLPC051000194011.
[383] Highlights of Prescribing Information: OXYCONTIN, § 9.2 (2015), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022272s027lbl.pdf.

diversion of these prescription pain medications, while ensuring that patients in pain continue to have appropriate access to these important therapies."[384]

312. Purdue was the first opioid manufacturer to create an FDA-approved abuse-deterrent formula. Thus, Purdue was able to position itself to capitalize on the public health crisis created by Purdue's original OxyContin. Purdue and the individual Defendants began aggressively marketing the new allegedly abuse-deterrent formulation. A 2015 marketing plan emphasized "digital tactics to increase [health care professional] awareness of the [abuse-deterrent properties] of OxyContin" and proposed to "expand the [health care professional] base" and "deliver [opioids with abuse-deterrent properties] rationale and brand specific messages."[385]

313. Defendants sought to distinguish themselves and gain market share with Purdue's abuse deterrent reformulation of OxyContin. In response to an objection from United HealthCare that OxyContin "is still addictive in pain patients, and our patients primarily abuse orally," Purdue falsely 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."[386]

314. Contrary to Purdue's representations about its allegedly abuse-deterrent reformulation, there is no evidence that orally administered opioids, regardless of any abuse-deterrent features, are any less addictive. There are no evidence-based, peer-reviewed studies supporting Purdue's claims that its abuse-deterrent formulation of OxyContin is less addictive or less risky than the original OxyContin formulation.[387]

315. The 2016 CDC guidelines found no evidence that abuse-deterrent formulations are an effective risk mitigation strategy.[388] Instead, the 2016

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[384] 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 June 26, 2019).
[385] PWG000435617.
[386] PWG000062741.
[387] 2016 CDC Guideline at 21-22.
[388] *Id.*

guidelines point to another study finding that abuse-deterrent formulations might actually be associated with increased use of other opiates, including heroin.[389]

316. Purdue's claims about its abuse-deterrent formula were not even supported by Purdue itself. In February 2008, while Purdue was analyzing the profitability of an abuse-deterrent formula, John Stewart wrote to Richard, Mortimer, Kathe, Jonathan, Theresa, and Beverly Sackler about a CBS News report on opioid abuse that "even noted that [abuse-deterrent formulas] will not stop patients from the simple act of taking too many pills."[390]

317. Two years later, this reality had not changed. In August 2010, members of Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, reported back to Richard, Mortimer, Kathe, Jonathan, Ilene, and Theresa Sackler that the most common way of abusing oxycodone was by swallowing the pills.[391] Again in February 2011, members of Purdue's Executive Committee, including John Stewart and Craig Landau, reported back to the Sacklers that 83% of patients in substance abuse treatment centers began abusing opioids by swallowing the pills (16% by snorting and 1% by injecting), and that it took, on average, 20 months for a patient to get treatment.[392]

318. Nonetheless, in March 2014, at Russell Gasdia's direction and in coordination with Mark Timney and other Executive Committee members, leaders of Purdue's marketing team commissioned and conducted "qualitative market research to obtain input on positioning options for HYD, an extended release hydrocodone with tamper-resistance properties." The research directed by Russell Gasdia included "individual-depth-interviews" of health care specialists that were conducted in only two cities throughout the country. One of those two interview sessions was conducted in Denver.[393]

319. While the March 2014 research admitted that its findings were "derived from a small sample of specially recruited respondents" and therefore "are not projectable to a larger population," Russell Gasdia rushed to get Purdue's sales force trained on the messaging for the new abuse-deterrent hydrocodone. When one of Purdue's sales managers told Russell Gasdia that "we are jumping the gun too quick" because "this report and the positioning research is NOT complete,"

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[389] *Id.* at 14.
[390] PPLPC012000172201.
[391] PPLPC012000283342-343; PPLPC012000283469.
[392] PDD8901468036-038, 100, 108, 109.
[393] PPLPC12000468229; PPLPC012000468239; PPLPC012000468262; PPLPC022000703957.

(emphasis in original) Russell Gasdia responded derisively to another sales manager, "Houston [w]e have a problem."[394]

320. Defendants' misinformation campaign about the efficacy of Purdue's abuse-deterrent formulations was successful. A 2016 survey revealed that 46% of physicians erroneously believed that abuse-deterrent formulations were less addictive than non-abuse-deterrent formulations.[395] In reality, both formulations are equally addictive.[396]

321. In 2016, Purdue publicly admitted "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."[397]

322. Nevertheless, as recently as April 2018, Dr. Webster, a one-time Purdue Key Opinion Leader, was still touting the benefits of abuse-deterrent opioids in Colorado.[398]

1. Defendants lobbied Colorado's legislature and regulatory agencies to affect legislation and policies supporting Purdue's abuse-deterrent opioid formulations

323. Defendants' plans to capitalize on their new abuse-deterrent opioids included intense state and federal lobbying, including in Colorado, to manipulate the market for these new drugs.

324. In January 2013, responding to requests from the Sacklers, members of Purdue's State Government Affairs team reported back to the Board that Purdue had recruited various state legislators from around the country to co-sign and/or

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[394] PPLPC012000468229; PPLPC012000468262.
[395] Catherine S. Hwang et al., *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32 Clinical J. Pain 279, 281 (2016).
[396] *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).
[397] PWG000439823.
[398] 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.

send letters written by Purdue supporting abuse-deterrent opioids to the FDA. Among other state legislators, Purdue recruited at least three members of Colorado's General Assembly to co-sign and/or send letters to the FDA supporting abuse-deterrent opioids.[399]

325. In September 2014, Purdue's Executive Committee, of which Mark Timney was the Chair, outlined its 2015 "Commercial Strategy Plan," which included strategies to "[p]ass Abuse Deterrent Formulation legislation…in the 2015 legislative session"; "[w]ork[ ] with interested stakeholders, build a collation to support legislation and regulation that encourages the use of ADF"; [and] "[i]ncrease the dialog concerning the value of abuse deterrent formulations of opioids with state elected officials."[400]

326. Under the Sacklers' and Mark Timney's direction, Purdue's 2015 legislative strategy went so far as to propose specific statutory language regarding the accessibility of abuse-deterrent opioids, including "no substitution" language prohibiting the interchange or substitution of a non-abuse-deterrent opioid by a pharmacist for Purdue's abuse-deterrent opioid.[401]

327. The exact same "no substitution" statutory language proposed by the Sacklers, Mark Timney, and Purdue's Executive Committee was introduced in the Colorado General Assembly as HB 15-1214, and Purdue corralled support from local pain advocacy organizations, like the Colorado Pain Initiative, to lobby for the bill's passage.[402]

328. Purdue also sought, and received, support for HB 15-1214 from RADARS. As discussed above, Purdue created RADARS in 2001 and the Sacklers placed individuals on the RADARS's Board of Directors, including five of the eight current members of RADARS's Scientific Advisory Board.[403] After its transfer to the Denver Health and Hospital Authority, Purdue and the individual Defendants continued through at least 2018 to use RADARS to lobby for legislation and other policies supporting Purdue's abuse-deterrent opioids in Colorado and around the country.

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[399] PPLPC032000255061; 064; 068.
[400] PPLP004127109.
[401] PPLP004127112.
[402] PPLPC01800116152-153.
[403] *See supra* ¶ 149.

329. Purdue relied heavily on RADARS to lobby for HB 15-1214, and abuse-deterrent opioids more generally. As Purdue's State Government Affairs team reported in March 2015: "Purdue [State Government Affairs] had dinner with Dr. Rick Dart with RADARS in Denver and he is supportive of our [abuse-deterrent] efforts and willing to provide his collected [abuse-deterrent] data/stats to members of the [Colorado] legislature and the Governor's Consortium folks assigned to study [abuse-deterrent opioids] as a deterrent to [prescription] drug abuse."[404] Richard Dart is the current Executive Director of RADARS and was one of the original Board members tapped by the Sacklers for the organization.[405]

330. In addition to drafting the specific language for HB 15-1214, Purdue provided talking points, demonstration materials, and internal scientific studies for use and distribution at Colorado legislative hearings on the bill, and at least one of Colorado's "Super Core" prescribers testified in favor of the legislation. Notably absent from any of Purdue's legislative language, talking points, demonstration materials, internal studies, RADARS data, and Purdue-sponsored testimony was the dangerous fact, well known by all of the Defendants, that abuse-deterrent OxyContin does nothing to curb addiction from swallowing the pills, which is the most common method for abusing opioids.

331. When representatives from DORA and Colorado's Board of Pharmacy confronted Purdue after the hearings on HB 15-1214 about the "no substitution" language in the bill, Purdue's lobbyists lied, claiming that Purdue was "not part of the drafting of this language but that it was hoped this language would be stripped out [of the bill]."[406]

332. HB 15-1214 ultimately did not pass with the language Purdue proposed, but it did create a Task Force within the Colorado Consortium for Prescription Drug Abuse Prevention to study abuse-deterrent opioids. Although HB 15-1214 did not pass as Purdue intended, Defendants continued to lobby Colorado's legislature and regulatory agencies for legislation and policies favorable to Purdue's bottom line.

333. From the creation of the Consortium's Task Force in 2015 until the release of its report in January 2017, Purdue's State Government Affairs Team regularly reported back to David Haddox and other Purdue executives on the progress of the Task Force's work.

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[404] PPLPC018001163262; PPLPC018001164667; PPLPC018001172262.
[405] *See supra* ¶ 149.
[406] PPLPC018001163262.

334. For example, in June 2016, Purdue's Regional Director for State Government Affairs in Colorado forwarded to David Haddox the Consortium's meeting minutes and a copy of a presentation made at the meeting by a Purdue Key Opinion Leader to the Consortium.[407]

335. In August 2016, David Haddox, along with several other Purdue representatives and Key Opinion Leaders, attended a Consortium meeting at which RADARS gave a presentation about the benefits of abuse-deterrent opioids. In that presentation, RADARS claimed that abuse-deterrent opioids decrease both oral and non-oral opioid abuse.[408] However, as David Haddox and the other individual Defendants had known for years, the vast majority of people abuse opioids orally and abuse-deterrent opioids do nothing to decrease the risk of addiction, overdose, and death caused by swallowing the pills.[409]

336. From September to December 2016, as the Consortium's Task Force finalized its report to Colorado's Legislature on abuse-deterrent opioids, Purdue's State Government Affairs team continued to provide David Haddox and other Purdue executives reports on the Task Force's work, and also sought, received, and passed along David Haddox's input on the Task Force's final report to the Colorado Legislature.[410] David Haddox and other Purdue employees and Colorado Key Opinion Leaders were listed as contributors to the Task Force's final report submitted to the Colorado legislature in December 2016.[411]

337. Defendants monitored and participated in the Consortium's work during 2015 and 2016, and they continued to develop Purdue's next steps to lobby and promote opioids to Colorado's Legislature and regulatory agencies, and to Colorado prescribers and patients.[412]

338. In November 2015, as the Sacklers and Purdue's Executive Committee prepared their state legislative and regulatory strategies for 2016, a Senior Product Manager from Purdue sought input from a Colorado Key Opinion Leader about Purdue's new website regarding abuse-deterrent opioids, www.teamagainstopioidabuse.com, and sought his positions on "impending legislative decisions." In response, the Colorado Key Opinion Leader pointed

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[407] PPLPC017000712636; 637; 661.
[408] PPLPC017000729554; PPLPC024000990917; PPLPC024000990919.
[409] *See supra* ¶¶ 234 & 317.
[410] PPLPC017000734331; PPLPC017000734339; PPLPC019001326121; PLPPC024000995923; PPLPC024000995931.
[411] PPLPC024000995923; PPLPC024000995931.
[412] PPLPC018001380810.

Purdue's Manager to various studies on abuse-deterrent opioids, including one showing that abuse-deterrent opioids had not caused a decline in opioid abuse.[413] With respect to "impending legislative decisions," the Colorado Key Opinion Leader also pointed Purdue's Manager to his March 2015 position paper on HB 15-1214, in which he expressed his opinion that "[c]urrent research does not support a legislated requirement for honoring prescriptions written for abuse-deterrent opioids over non-abuse-deterrent formulations."[414]

339. In December 2015, several of Purdue's district managers from around the country discussed legislative, regulatory, and sales opportunities and strategies for 2016. In analyzing the reason for Purdue's market decline in Colorado since 2012, Purdue's Senior District Sales Manager for Colorado noted that in 2012 Colorado was "#2 in abuse, diversion, overdose, and death only behind [Florida]" and then detailed the decrease in ER opioid sales in Colorado since 2012. The District Sales Manager identified opportunities to reverse those declining sales trends in 2016, including the "goal of working with [the] Consortium [to pass] [abuse-deterrent opioid] legislation."[415]

340. In an April 2016 commercial update to the Sacklers, members of Purdue's Executive Committee identified several legislative and regulatory strategies for 2016 and 2017 to reverse declining opioid sales in Colorado and around the country. The presentation identified for the Sacklers specific regulatory developments in Colorado that were thought to have caused a reduction in Purdue's opioid sales in Colorado – the Colorado Division of Worker's Compensation's 2011 "Chronic Pain Disorder Medical Treatment Guidelines" and the Colorado Medical Board's 2013 and 2014 policies for the use of opioids to treat pain. On a positive note from Defendants' perspective, Purdue staff also noted for the Sacklers that Colorado's Medicaid program gave "Tier 2 Unrestricted" status to Hysingla ER and Butrans, which the Executive Committee estimated would impact 1.3 million Coloradans.[416]

341. The same report also laid out for the Sacklers the Executive Committee's strategies to reverse declining sales trends in Colorado and around the country. Those strategies relied on an aggressive plan to convince Colorado managed care providers to pay for abuse-deterrent opioids and an update to abuse-deterrent state legislation to pass in Colorado and other state legislatures.

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[413] PPLPC032000370509.
[414] *Id.*; PPLPC032000370471.
[415] PPLPC010000082310; 314.
[416] PPLPC016000286167.

Assuming these strategies were successful, the Executive Committee provided maps to the Sacklers detailing "best case scenario" sales projections for Colorado and other states. As presented to the Sacklers, Purdue's "best case scenario" for Colorado was a 1% increase in OxyContin sales and a *7.3%* increase in Hysingla ER sales.[417]

342. In November 2016, Purdue's Operating Committee, which included Mark Timney, met to discuss their progress in meeting the Sacklers' and the Executive Committee's objectives for increasing sales. As an "action completed," the Operating Committee and Mark Timney discussed a presentation given by Purdue to the Colorado Consortium "on the epidemiologic studies for abuse deterrent OxyContin which will lead to a reintroduction of [abuse-deterrent opioid] legislation ion [*sic*] 2017."[418]

343. Because abuse-deterrent opioids, and legislation supporting them, were the key to Defendants' sales strategy, throughout 2016 and 2017, Defendants eagerly anticipated a report from the nonprofit Institute for Clinical and Economic Review ("ICER") on abuse-deterrent opioids. Defendants expected that the ICER report would support Purdue's position on the efficacy of the reformulated drugs.

344. As the release of the ICER's report grew closer, Purdue became concerned that the report would not support their position on abuse-deterrent opioids as expected. A month prior to the release of ICER's report, members of Purdue's leadership, including David Haddox, reached out to Richard Dart to request that the pending report be put on the agenda for RADARS's May 2017 Annual Meeting.[419] Richard Dart was a Clinical Reviewer for the ICER report.[420]

345. On April 28, 2017, a week before the release of ICER's report, Mark Timney informed MNP Consulting, as well as the Sacklers and Craig Landau directly, that to Purdue's surprise, the results of ICER's report "are not positive for [abuse-deterrent opioids]." As a response, Mark Timney sought to highlight "an important change in [ICER's] model and share [Purdue's] proactive approach to address [the ICER] situation" and he assured the Sacklers and Craig Landau that Purdue was "in the process of implementing a detailed stakeholder and

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[417] *Id.*
[418] PPLPC011000127788; 789.
[419] PPLPC017000758880.
[420] Institute for Clinical and Economic Review, *Abuse Deterrent Formulations of Opioids: Effectives and Value* (May 5, 2017), https://icer-review.org/wp-content/uploads/2016/08/NECEPAC_ADF_Draft_Report_05.05.17.pdf.

communication plan in order to put the [ICER's] results and process into perspective."[421]

346. Following up on Mark Timney's report to the Sacklers and Craig Landau, on May 5, 2017 (the day ICER released its report), Purdue's Chief Medical Officer and Vice President of Medical Affairs, the Sacklers, Mark Timney, and Craig Landau discussed Purdue's "robust action plan" to undermine and discredit ICER's report. The "robust action plan" included deploying a select few of Purdue's most reliable Front Groups and Key Opinion Leaders who "agreed to make supportive public statements." One of the four persons being deployed to "make supportive public statements" on Purdue's behalf was Richard Dart, the long-time Board member and current Executive Director of Denver-based RADARS.[422]

347. Purdue's "robust action plan" to undermine the ICER report was put into place immediately. Just as the Sacklers, Mark Timney, and Craig Landau had planned, in July 2017, Richard Dart sent an email to several representatives from the pharmaceutical opioid industry, including representatives from Purdue, discrediting the ICER report's conclusion that abuse-deterrent opioids are not as effective as Purdue had been promoting:

> I was at ICER. A lot of reasonable things were stated, but the meeting was cleverly organized/orchestrated to reach the desired ICER conclusion. One of the 'tricks' used – and the ENTIRE panel fell for it – was the zero sum game. It was repeatedly stated that we only have so many dollars to spend and while [abuse-deterrent opioids] work, it is not the best use of resources.[423] (emphasis in original)

348. In September 2018, after several States and hundreds of local governments sued Purdue for conduct similar to that alleged here, Mortimer and Jonathan Sackler met with several members of Purdue's Executive Committee, including Craig Landau, to devise a strategy to counter the "massive amount of misinformation and fake news that has been pushed out by trial lawyers." That strategy included highlighting several programs the Sacklers launched to "educate physicians and in this case the public about the risks of [OxyContin]." The first

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[421] PPLPC011000145141; 142.
[422] PWG004333152.
[423] PPLPC001000259072.

such program Mortimer and Jonathan Sackler, and the Executive Committee, intended to highlight was Denver-based RADARS.[424]

H. Defendants Misrepresented the Severity of Opioid Withdrawal

349. Purdue claimed that opioid dependence could be managed by tapering the dosage, and they misrepresented the severe symptoms associated with such tapering, including pain associated with opioid withdrawal.

350. 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."[425]

351. Contrary to Purdue's representations, as reflected in Purdue call notes, withdrawal syndrome from OxyContin and other opioids was and is 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 and that he has a hard time getting them tapered off when it's time."[426] (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."[427] (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."[428] (April 16, 2013)

352. Paradoxically, one of the withdrawal symptoms often associated prescription opioids is physical pain.[429] Withdrawal symptoms manifest when a

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[424] PPLPC039001217885.
[425] PTN000000596.
[426] PCO000000002 Row: 99010 (02/01/2013).
[427] PCO000000002 Row: 100796 (03/07/2013).
[428] PCO000000002 Row: 103067 (04/16/2013).

patient develops a tolerance to opioids and becomes physically dependent on them.[430] Tolerance occurs when a 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 their system.[431] 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.[432] When a patient becomes opioid-tolerant, the patient requires increased dosages to deliver the same level of pain relief.[433] Additionally, as a patient becomes physically dependent the patient is at a greater risk for addiction because they may begin to experience "dysphoria (pain, agitation, malaise) and other withdrawal symptoms, which can lead to a cycle of relapse to drug use."[434] 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."[435] Higher and repeated dosages also increase the withdrawal pain that patients experience when they decrease or stop using prescription opioids.[436] The severity of withdrawal pain increases for patients who use opioids long-term and at a higher dose, which makes it more difficult for those patient to stop using opioids, and more likely that those patients will develop an addiction and be at a greater risk of overdose.[437]

353. Purdue's false representations that patients can stop using opioids with mild or no symptoms of withdrawal had no basis in scientific evidence and were contrary to the reports of prescribers. Purdue misrepresented the reality that severe symptoms associated with opioid withdrawal, including physical pain, can be

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[429] Donald Teater, *The Psychological and Physical Side Effects of Pain Medications*, Nat'l Safety Council, at 4, *available at* http://safety.nsc.org/sideeffects.
[430] *Id.*; Thomas Kosten & Tony George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 Sci. Practice Perspectives 13, 14-15 (2002).
[431] Ramsin Benyamin et al., *Opioid Complications and Side Effects*, 11 Pain Physician J., S105, S106 (2008).
[432] 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).
[433] Ramsin Benyamin et al., *Opioid Complications and Side Effects*, 11 Pain Physician J., S105, S106 (2008).
[434] Thomas Kosten & Tony George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 Sci. Practice Perspectives 13, 15-16 (2002).
[435] *Id.* at 15.
[436] *Id.*
[437] *Id.*

difficult to manage, and often causes patients to seek more opioids, which in turn increases the risk of addiction and overdose.

354. In reality, 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. After 30 days of opioid treatment, withdrawal symptoms can be severe, and managing withdrawal symptoms is significantly more difficult than Purdue claims.

I. Defendants Deceptively Disparaged Alternative Pain Treatments

355. Purdue's deceptive marketing campaign not only misrepresented the safety and efficacy of opioids. Purdue's marketing campaign also misrepresented and deliberately undermined the medical community's trust in opioid alternatives, like over-the-counter acetaminophen or NSAIDs.

356. 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" as a basis for arguing that opioids are more appropriate for treatment of pain.

357. *Treatment Options* falsely attributed 10,000 to 20,000 annual deaths to NSAID overdose,[438] when the true figure was closer to 3,200 per year.[439] *Treatment Options* failed to disclose that higher doses of opioids pose a greater risk of dependence, addiction, overdose, and death than NSAIDs.[440] *Treatment Options* did not disclose or mention the 12,000 prescription opioid-related deaths nationwide in 2006[441] (including 123 that year from natural or semi-synthetic opioid analgesics in Colorado).[442] The publication warned that the risks associated with NSAIDs

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[438] *Id.* at 10.
[439] 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).
[440] American Pain Foundation, *Treatment Options: A Guide for People Living with Pain* 12 (Terry Altilio et al. eds., 2007).
[441] Grant Baldwin, PowerPoint, *Overview of the Public Health Burden of Prescription Drug and Heroin Overdoses* (July 1, 2015), *available at* https://www.fda.gov/downloads/drugs/newsevents/ucm454826.pdf.
[442] 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 June 26, 2019).

increase if "taken for more than a period of months," but failed to disclose the severe risks associated with long-term opioid use.[443]

358. At a July 2010 Board meeting in Bermuda, Craig Landau and other members of Purdue's Executive Committee and staff reported back to the Sacklers on their efforts to convince health care providers to prescribe more Butrans. The strategy included targeting patients "taking an NSAID [*sic*] or [acetaminophen] (opioid naïve)" by convincing prescribers that those opioid alternative treatments would not control pain, and that patients would not tolerate the NSAID drugs.[444]

359. APF's Purdue-sponsored *Exit Wounds*, also exaggerated the side effects of opioid alternatives like NSAIDs (*e.g.*, stomach ulcers and gastrointestinal bleeding), and downplayed significantly more serious side effects associated with opioids (*e.g.*, nausea and vomiting, constipation, and mental clouding).[445] *Exit Wounds* failed to disclose the most dangerous consequences of opioid use—addiction, overdose, and death.[446] *Exit Wounds* omitted warnings about the fatal interaction between opioids and anti-anxiety medicines called benzodiazepines (which are commonly prescribed to veterans),[447] and failed to acknowledge that NSAIDs, unlike opioids, are considered safe to take for pain while using benzodiazepines.[448]

360. Purdue continued its misrepresentations about NSAID drugs for more than a decade. At Purdue's 2016 National Sales Meeting, a "Take the Lead" presentation identified "NSAIDs [as a] key opportunity for growth" for Butrans.[449] The presenter then set a goal for Purdue's sales force: 10% of Butrans prescriptions should be conversions from NSAIDs.[450]

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[443] American Pain Foundation, *Treatment Options: A Guide for People Living with Pain* 10 (Terry Altilio et al. eds., 2007).
[444] PPLPC018000404193; PPLPC012000273600.
[445] Derek McGinnis & Stephen R. Braun, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families* 103-111 (2009).
[446] *See generally id.*
[447] *See generally id.*
[448] *See* 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).
[449] PWG000210548.
[450] *Id.*

361. Purdue's sales representatives frequently emphasized to Colorado prescribers the ceiling doses for NSAIDs and acetaminophen in order to position opioids as a safer alternative without a ceiling dose:

- A Purdue sales representative "discussed [the Colorado 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."[451] (October 10, 2006)

- Another Purdue sales representative reported 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."[452] (October 5, 2006)

- In follow up notes for a January 5, 2009 visit to a Colorado prescriber, a Purdue detailer reminded herself to "[p]ush him on combo use and ceiling doses due to Tylenol."[453]

- During another visit, a Purdue detailer "used up front close to get [the Colorado 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."[454] (February 12, 2007)

362. There is no reliable scientific support for Purdue's misrepresentations about the efficacy and safety of opioids as compared to alternative pain treatments. Purdue had no evidence that opioids generally, or Purdue's opioid 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."[455]

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[451] PCO000000002 Row: 4650 (10/10/2006).
[452] PCO000000002 Row: 4547 (10/05/2006).
[453] PCO000000002 Row: 21937 (01/05/2009).
[454] PCO000000002 Row: 6515 (02/12/2007).
[455] PWG000008024.

363. Purdue's deceptive campaign disparaging NSAIDs and other opioid alternatives succeeded in drawing prescribers away from safer pain treatments. 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%.[456]

IV. AFTER CREATING THE OPIOID EPIDEMIC, DEFENDANTS' DECEPTIVE MARKETING CAMPAIGN CONTINUED, AND THEY EVEN TRIED TO CAPITALIZE ON THE OPIOID EPIDEMIC

A. Defendants Continued Making False Representations About Opioids in the Face of Overwhelming Evidence to the Contrary

364. 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 rarely effective for treating chronic non-cancer pain, and those who take opioids face severe risks like addiction, overdose, and death.

365. 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.[457]

366. The CDC *Guideline for Prescribing Opioids for Chronic Pain* published in 2016 concludes that there is no evidence supporting the proposition that opioids are effective for relieving pain or improving function or quality of life. The CDC also found that "patients who do not experience clinically meaningful pain relief in treatment (*i.e.* in 1 month) are unlikely to experience pain relief with longer-term use."[458]

367. In 2016, 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 announced: "[T]he science of opioids for chronic

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[456] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000–2010*, 51 Med. Care 870, 870 (2013).
[457] 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).
[458] 2016 CDC Guideline at 13.

pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh unproven and transient benefits."[459]

368. Real world evidence of prescription opioid use confirms that opioids are less effective for long term chronic pain than Purdue led the country to believe. A 2017 CDC report notes, "[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."[460]

369. In the face of overwhelming contrary evidence and a mounting national opioid epidemic, Defendants continued to promote and sell opioids for a purpose that was proven to be dangerous and ineffective.

370. The Sacklers and other individual Defendants were keenly aware of the deceptive representations being made about opioids in general, and Purdue's opioid drugs specifically. They also knew well the immense damage their conduct was causing in Colorado and the rest of the country.

371. From at least 2007 to 2017, Purdue's Executive Committee and other staff provided detailed quarterly "Reports of Concern" directly to the Sacklers and other individual Defendants. Those reports included aggregate data on the number of "Reports of Concern" and any responsive actions taken. They also detailed information on specific instances of deceptive conduct by Purdue's sales force, and reported back on instances of diversion and abuse of opioids manufactured and sold by Purdue and Rhodes.

372. As examples, in October 2008, the Sacklers received a "Report of Concern" that a Purdue sales representative was characterizing OxyContin "as less abuseable [*sic*] than [IR] opioids."[461] In 2010, the Sacklers received another "Report of Concern" that a Purdue sales representative was "making inappropriate statements when commenting about benefits that [ER opioids] can provide over [IR opioids] (*e.g.* trying to sell based on a comparison to [IR] opioids)."[462] In 2011, the Sacklers received a "Report of Concern" that a Purdue sales representative "recorded call notes discussing peaks and valleys with [the prescriber]," and that

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[459] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501, 1503 (2016).
[460] Centers for Disease Control and Prevention, *Prescribing Data* (Aug. 30, 2017, https://www.cdc.gov/drugoverdose/data/prescribing.html (last visited June 26, 2019).
[461] PPLPC032000101064.
[462] PPLPC049000035811.

another sales representative indicated that a prescriber "likes that patients don't have peaks and valleys with Butrans, and don't wake during the night to take pills."[463]

373. In 2015, the Sacklers were informed about a pill mill "that has been giving out prescriptions of pain pills at a higher rate than most clinics" including the names of the suspicious prescribers.[464]

374. On May 2, 2017, the Sacklers received a "Report of Concern" about a suspicious clinic and prescribers in Colorado:

> Since January 2017, there has been an issue with [a Colorado prescriber]. On January 27, 2017, [Purdue sales representative] was told by [a Colorado Key Opinion Leader] that [the Colorado prescriber] was believed to be under investigation by the DEA. [Purdue sales representative] also stated that Boulder Community Clinic, which [the Colorado prescriber] was the manager, was in the process of being closed. [The Colorado prescriber] has been retired, but [Purdue sales representative] just wanted to give notification of the matter, and would like to be advised on how to proceed in regards to the situation.[465]

375. This particular incident reported directly back to the Sacklers involved a Colorado "Super Core" prescriber and one of Purdue's Colorado Key Opinion Leaders. The Colorado "Super Core" prescriber and Key Opinion Leader both came under investigation by the DEA in 2016 and the Colorado "Super Core" prescriber was later listed in Purdue's secret no-call list, *Region Zero* (described in more detail below).

376. When Defendants became aware of misconduct and the resulting harm, they rarely, if ever, reported the suspicious activity to the appropriate authorities. In the rare instance in which Defendants did report the suspicious activity, it was almost always after they knew the suspicious activity was under investigation by the authorities.

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[463] PPLPC032000217205.
[464] PPLPC032000347074.
[465] PPLPC032000397505.

377. True to form, rather than report suspicious activity to the authorities, or do anything to mitigate the harm caused by the opioid epidemic in Colorado, the Sacklers sought to profit from the havoc they wrought.

B. Defendants Continued to Target "Super Core" and "Core" Prescribers, Including in Colorado

378. Defendants kept close tabs on the doctors who prescribed the most opioids and made them the most money. Purdue maintained lists of high-volume opioid prescribers who were especially responsive to Purdue's marketing, and targeted those prescribers with frequent and aggressive sales detailing.

379. Defendants maintained a list of "Super Core" and "Core" prescribers, and as directed and/or sanctioned by the individual Defendants, Purdue's sales force was ordered to visit these prescribers at least twice a month, or even as frequently as *every week*.[466]

380. Defendants considered Purdue's "Super Core" and "Core" prescribers critical to sales of its opioid drugs and their individual fortunes. In 2011 Russell Gasdia wrote to John Stewart that "Core and Super Core have combined for just under 90% of all Rxs the past few weeks … there are 5,113 Super Cores nationally … I am digging deeper to see how many [Super Cores] have been seen 6 times in first three months as well as those seen more and those seen less."[467] Russell Gasdia also told John Stewart that Purdue had "31,235 Cores nationally."[468]

381. In 2013, Russell Gasdia sent Purdue staff a series of emails raising "serious concern[s]" about the sales force's failure to call on the most prolific prescribers. He demanded an explanation for why some sales representatives visited "off list," noting "we have 46% of reps who didn't follow direction and don't have the correct # of COREs/SUPER COREs."[469] (emphasis in original) Russell Gasdia reproached his team: "Our management team needs to get on this ASAP. We are not getting the job done and when sales targets aren't hit, this first step is to have the right targets. It appears as if the reps have missed the boat."[470]

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[466] PPLP004406102-123; PPLPC012000322209.
[467] PPLPC012000322209.
[468] *Id.*
[469] PPLPC012000407757; PPLPC012000407759.
[470] PPLPC012000408436.

382. To encourage focus on these high-volume prescribers, Purdue executives changed the compensation plan for Purdue sales representatives to pay larger bonuses for increased prescribing by "Super Core" and "Core" prescribers.[471] Purdue sales representatives who influenced the most prolific prescribers won Purdue's top bonuses and prizes. Purdue staff told Russell Gasdia that one Purdue sales representative won Purdue's "Toppers" contest year after year "largely on the prescriptions of 3-4 doctors."[472]

383. In Colorado, nearly one out of ten Colorado health care providers who were listed as Purdue "Super Core" prescribers have had their medical licenses admonished, restricted, suspended, or revoked for reasons relating to opioid prescribing.

384. Many of the public disciplinary documents for these Colorado prescribers reflect the same selling messages Purdue worked so hard to ingrain. Purdue convinced these prescribers that they could rapidly titrate up opioid doses without increased risk, that they could prescribe high doses to their patients with no increased risk, and that patients exhibiting signs of addiction were merely suffering from "pseudoaddiction." While these deceptive messages made Defendants vast sums of money, they were contrary to accepted standards of medical practice, and cost many Colorado "Super Core" prescribers their careers and, more tragically, cost patients their lives:

- Colorado prescriber J.B., M.D. was a Purdue "Super Core" prescriber. He prescribed extremely high doses of opioids and escalated those doses rapidly, just as Purdue had pressured him to do for years. Purdue visited J.B.'s office more than once a month on average from 2008 to 2015, and sometimes as frequently as four times a month. In 2013, J.B. informed a Purdue sales representative that he was put on King Soopers's "no fill" list, meaning that King Soopers pharmacies would no longer fill the opioid prescriptions he wrote. A few months later, J.B. told a Purdue sales representative that he "stopped using OxyContin until [Purdue] came out with the [abuse-deterrent] reformulation." When the representative asked him why, J.B. stated that he had "too many patients taking the drug [ ] not [as] intended." J.B. continued, "with the tamper resistant form I am much more confident in prescribing." A month later, J.B. told the Purdue sales representative that he had got in trouble with the DEA for writing suboxone prescriptions. In response, the Purdue

[471] PPLP003579152.
[472] PPLPC012000461545.

representative "reminded him [that] Butrans is a schedule 3 product" and pressed J.B. to continue prescribing Purdue's opioids. In November 2015, J.B. told a Purdue sales representative "that he is no longer able to write opioids." The next month, the Colorado Medical Board revoked J.B.'s ability to prescribe controlled substances. Despite numerous red flags and evidence of diversion, Purdue's sales force visited J.B. relentlessly right up until the time he was disciplined by the Medical Board. According to Purdue's records, from 2001 to 2015, J.B. prescribed at least 287,839 OxyContin pills to Colorado patients – over 1,600 pills per month.[473]

- Colorado prescriber M.D., M.D., a Purdue "Super Core" prescriber, was detailed aggressively for many years and was repeatedly pressed by Purdue's sales force to convert his IR opioid patients to Purdue's ER opioids. In 2013, M.D. told a Purdue sales representative "he may keep patients on [IR opioids] that long because it works and it's not expensive." The sales representative noted that M.D. "doesn't care that he is not following any sort of pain guidelines" but did not flag this behavior. Less than a year later, Purdue successfully converted M.D.: "OxyContin he is a fan of." From 2006 to 2017, Purdue's sales force visited M.D. almost twice a month on average. In February 2017, M.D. received a letter of admonition for overprescribing oxycodone to a patient who was exhibiting signs of addiction, and for rapidly increasing doses of opioids, just as Purdue had been pressing him to do for all those years. Purdue's sales force visited M.D. at least five more times in the months after he was reprimanded. According to Purdue's records, from 2001 to 2017, M.D. prescribed at least 162,642 OxyContin pills to Colorado patients – over 800 pills per month.[474]

- In September 2009, Colorado prescriber M.C., R.N., a Purdue "Super Core" prescriber, received a letter of admonition for overprescribing narcotics "when there were signs of potential addictive behavior." For years, Purdue had been telling Colorado nurses like M.C. that signs of addiction were simply "pseudoaddiction" caused by undertreated pain, which could be addressed with more opioids at higher doses. M.C. continued to prescribe thousands of opioid pills to his patients, despite red flags of abuse such as "lost prescriptions" and "lost medications." In 2011, M.C. described some of his patients to a Purdue sales representative as

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[473] PCO000000002, lines 98896,101207, 102804.
[474] PCO000000002, lines 111596, 117166.

"pill poppers."[475] The sales representative asked him what a "pill popper" was and M.C. responded that it was "a patient taking 6-8 vicodin [*sic*] daily." Hoping to cash in on M.C.'s "pill poppers" by converting them to Purdue's opioids, the sales representative responded "great" and "went over the conversion guide so [M.C.] knew where to initiate therapy and how to titrate upward." By 2012, Purdue's sales force was visiting M.C. as frequently as every week, pressing him harder and harder to prescribe more opioids. As one Purdue sales manager said about M.C., "[h]e seems like he is reserving [Butrans] for his very hard to treat patients. Maybe focus on dose adjustments, when they need more. He is the one who controls what med to give them… why will he let his patients dictate to him what is best?"[476] In 2017, M.C.'s license was put on probation for overprescribing narcotics at high doses. According to Purdue's records, from 2006 to 2017, M.C. prescribed at least 40,790 OxyContin pills to Colorado patients – more than 300 pills per month.

- Colorado prescriber A.H., M.D., a Purdue "Super Core" prescriber, was admonished by the Colorado Medical Board due to over-prescribing opioids despite aberrant behavior and signs of drug abuse in his patients. But as Purdue often told A.H., signs of addiction in patients are just "pseudoaddiction" and can be treated with more opioids. In early 2016, A.H. informed a Purdue sales representative "he had a bad experience with a script pad being stolen[,] [t]he DEA was involved," and that he had "numerous fake scripts being written for schedule 2 opioids."[477] The sales representative visited A.H. at least three more times after learning of the DEA investigation, leaving Purdue's savings cards and marketing materials at each visit. A.H. was put on a five-year probation and lost his controlled substances prescribing privileges. According to Purdue's records, from 2001 to 2016, A.H. prescribed at least 103,074 OxyContin pills to Colorado patients – almost 600 pills per month.

- Colorado Prescriber L.S., M.D., a Purdue "Super Core" prescriber, was initially resistant to Purdue's high-pressure sales pitch. In one of Purdue's early visits to L.S. in October 2009, a sales representative asked, "why [prescribe] short acting [opioids]?" instead of Purdue's long-acting opioids, to which L.S. responded, "mainly habit."[478] The sales representative continued to pressure L.S. to switch his patients from

[475] PCO00000000, line 73573.
[476] PCO000000002, line 76242.
[477] PCO000000002, line 157610.
[478] PCO000000002, line 34611.

short-acting opioids to Purdue's long-acting opioids. In March 2010, L.S. told the sales representative he had not prescribed any of Purdue's long-acting opioids since the sales representative's last visit. In response, the sales representative pressured L.S. to prescribe "15mg [OxyContin] q12h instead of another vicodin refill" for his patients going forward.[479] Even when L.S. told the sales representatives that his patients "like[ed] their short acting dosing schedule and many have been on for a long time," the sales representative told L.S. "dont [*sic*] give them the option…tell them this is what is going to happen."[480] When L.S. continued to tell the sales representative that "patients have been resistant" and that they "like being in control of their dosing," the Purdue sales representative asked him, "What are you doing to combat that?" The sales representative then told L.S. that he should "go[ ] to long acting […] opioids sooner on the protocol," pushing L.S. to prescribe long-acting opioids much sooner than L.S. otherwise would.[481] The sales representative continued to pressure L.S. to change his prescribing behavior so Defendants could make more money, visiting his office as often as twice a month. During these visits, Purdue's sales representatives repeatedly tried to influence L.S.'s medical decisions, even castigating him for giving his patients "an option" when it came to the drugs being prescribed. In August 2018, the Colorado Medical Board admonished L.S. for prescribing "unusually high doses of opioids" and "escalating the dosage faster than what is common practice." At least one of L.S.'s patients suffered from "hyperalgesia from excessive opioids." L.S.'s medical license was revoked in October 2018. According to Purdue's records, from 2001 to 2016, L.S. prescribed at least 42,006 OxyContin pills to Colorado patients – over 200 pills per month.

- In 2015, Colorado prescriber M.B., M.D., a Purdue "Super Core" prescriber, received a letter of admonition for the treatment of a patient with osteoarthritis. M.B. continued to prescribe opioids to the patient in escalating doses, despite "behavior indicating opioid misuse." Purdue pressed M.B. for years to prescribe opioids for osteoarthritis, visiting him up to three times a month and repeatedly telling him to "titrate the dose" higher and higher.[482] Purdue also told M.B. that signs of opioid misuse were just "pseudoaddiction." The patient M.B. was treating for osteoarthritis overdosed and died in 2012. According to Purdue's records,

[479] PCO000000002, line 125842.
[480] PCO000000002, line 125842.
[481] PCO000000002, line 129316.
[482] PCO00000000, line 127494.

from 2001 to 2017, M.B. prescribed at least 55,107 OxyContin pills to Colorado patients – almost 300 pills per month.

- Colorado prescriber M.S., D.O., a Purdue "Super Core" prescriber, voluntarily surrendered his controlled substances prescribing privileges in May 2016. M.S. had numerous patients showing signs of oxycodone abuse, yet he continued to prescribe high doses of opioids. At least two of M.S.'s patients died of an opioid overdose. Purdue's sales force continued to visit M.S. for more than a year after he surrendered his controlled substances prescribing privileges. While a Purdue sales representative noted that M.S. was "doing admin work" and "not prescribing," the sales force continued to detail M.S.'s staff, stating that "Dr [M.S.] was excited to have me educate [staff members] about Butrans."[483] Even after M.S. surrendered his prescribing privileges, Purdue's sales force visited his office 3-4 times a month to ensure his staff kept prescribing Purdue's opioids. According to Purdue's records, from 2001 to 2015, M.S. prescribed at least 438,846 OxyContin pills to Colorado patients – almost 2,500 pills per month.

385. Defendants ignored numerous red flags from their Colorado "Super Core" and "Core" targets and focused instead on convincing those prescribers to prescribe even more opioids at even higher doses.

386. At least 27 Colorado "Super Core" or "Core" prescribers were eventually listed in Purdue's *Region Zero*, which is a secret no-call list that Purdue maintained of prescribers who had lost their medical licenses or were under investigation.

387. Defendants declined or delayed putting "Super Core" and "Core" prescribers on the "no call list" despite numerous red flags. Instead, as directed and/or sanctioned by the individual Defendants, Purdue relentlessly detailed prescribers right up until the point at which their medical licenses were revoked.

[483] PCO000000002, lines 155660 and 171188.

C. Defendants Tried to Capitalize on the Opioid Epidemic They Created

388. Even after Defendants recognized the immense harm their misconduct caused Colorado and the rest of the country, they continued to do what they do best – hunt down profits.

389. In September 2014, Kathe Sackler participated in a confidential call about a new Purdue project called, *Project Tango*. *Project Tango* was a secret plan to capitalize on the growing opioid epidemic by manufacturing and selling drugs to treat opioid addiction.

390. Kathe Sackler and Purdue's staff acknowledged what they had known all along – that opioids and addiction are "naturally linked." They determined that Purdue could expand across "the pain and addiction spectrum" to become "an end-to-end pain provider." Purdue illustrated this concept with a picture of a funnel guiding patients down the deadly slope from "Pain treatment" to "opioid addiction treatment."[484]

391. Kathe Sackler and the *Project Tango* team determined that the potential "market" of people addicted to opioids, measured in billions of dollars (not lives lost), had doubled from 2009 to 2014.[485]

392. In a shocking about face from Purdue and Defendants' strategy to "blame the addicts," Kathe Sackler's documents reveal the ugly truth about opioid addiction: "This can happen to any-one – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor."[486]

393. Kathe Sackler and her team concluded that the millions of people who became addicted to opioids were the Sacklers' next moneymaking opportunity: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and

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[484] PPLPC017000564600; PPLPC016000255303.
[485] PPLPC017000564601PPLP004411288.
[486] PPLPC017000564601.

addiction." The team specified eight ways that Purdue's efforts to get more people prescribed opioid drugs could now be used to treat their resulting addiction.[487]

394. Kathe Sackler pressed staff to review reports of children being hospitalized after swallowing buprenorphine, which is the active ingredient in Butrans and in the addiction treatment drug Kathe Sackler wanted to sell as an oral film. Mark Timney and David Haddox assured Kathe Sackler that the reports showed children overdosing on pills, not the films, "which is a positive for *Tango*."[488]

395. In February 2015, Kathe Sackler and her team presented their work on *Project Tango* to the rest of the Sacklers. The plan was for a joint venture, controlled by the Sacklers, to sell the addiction treatment medication suboxone.[489]

396. Kathe Sackler's team mapped for the rest of the Sacklers how patients who were addicted to prescription opioids or heroin would become new consumers of Purdue's addiction treatment drugs. The team even analyzed how Purdue could capitalize on "sustained remission" – 40-60% of patients who took suboxone would relapse and need to buy the drug again.[490]

397. Kathe, David, Jonathan, and Mortimer Sackler decided to discontinue *Project Tango* the following month during their March 2015 Business Development Committee meeting.[491]

398. But the Sacklers revived the concept in 2016. Never wanting to miss a profit opportunity, the Sacklers decided to manufacture and sell the overdose reversal drug NARCAN.[492]

399. In 2018, Richard Sackler, through a different company controlled by the Sacklers, received a patent for another opioid addiction treatment drug. Notably, when Richard Sackler applied for that patent in 2007, he acknowledged

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[487] *Id.*
[488] PPLPC020000834158-186.
[489] PPLPC026000138391.
[490] PPLPC002000208957.
[491] PPLPC011000016992.
[492] PPLPC011000099222; PPLPC011000099280-283.

that opioids *are* addictive, called those suffering from addiction "junkies" and asked for a monopoly on Defendants' proposal for treating addiction.[493]

V. DEFENDANTS DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION AND ABUSE OF THEIR OPIOIDS

400. Prescription opioids are controlled substances and scheduled by the DEA due to the high risk of addiction, overdose, and death they pose to patients.

401. Given the high risk of addiction associated with prescription opioids, there is also a high risk that the drugs will be diverted to or through illegitimate channels, *e.g.* stolen or illegitimately prescribed.

402. As manufacturers of controlled substances, Purdue and Rhodes have a duty to reasonably monitor the sale and distribution of their drugs and prevent diversion and oversupply of them into the marketplace. Purdue and Rhodes are required to comply with specific security, record keeping, monitoring, and reporting standards imposed by the Controlled Substances Act ("CSA") and its implementing regulations. The duties imposed by the CSA are designed to identify and prevent diversion of controlled substances like prescription opioids.[494]

403. In line with the duties imposed by the CSA and its implementing regulations, Purdue and Rhodes have common law duties to exercise reasonable care in delivering controlled substances, which includes the duty to truthfully represent the benefits and risks associated with the drugs, to monitor and report any suspicious or criminal activity related to their drugs to the appropriate authorities, and to mitigate any harm caused by their opioids.

404. Purdue and Rhodes were well aware of the duties imposed on them. At the Sacklers' direction, Purdue acknowledged their duties and represented that they would comply with them in 2007 Consent Judgments with several state Attorneys General.

405. Purdue, Rhodes, and all of the individual Defendants have specialized and detailed knowledge of opioid prescribing and dispensing trends in Colorado and

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[493] 2018-01-09, U.S. Patent No. 9,861,628 ("a method of medication-assisted treatment for opioid addiction"); 2007-08-29, international patent publication no. WO 2008/025791 Al.
[494] *See e.g.*, 21 U.S.C. § 823(a)-(b), (e); 21 C.F.R. § 0.100; 21 C.F.R. § 1301.74(b).

throughout the country. They also have the capacity to identify suspicious activity related to prescribing and dispensing opioids, as evidenced by their *Region Zero* program.

406. Purdue and Rhodes had and have access to detailed information and data reflecting opioid prescribing and dispensing trends in Colorado and throughout the country, which they maintain internally and/or purchase from third party vendors. Purdue, Rhodes, and all of the individual Defendants, including the Sacklers, regularly mined this prescribing data to identify high-volume opioid prescribers to target for sales calls.

407. Purdue, Rhodes, and all of the individual Defendants, including the Sacklers, had regular internal discussions about "hot spots" throughout the country, including in Colorado, resulting from the diversion of OxyContin and other opioids. They were also aware of reporting from national and local media about OxyContin diversion and abuse and the harm caused by overprescribing.

408. Purdue, Rhodes, and all of the individual Defendants, including the Sacklers, all had the capability to be, and indeed were, aware that their deceptive and reckless marketing scheme was causing diversion of prescription opioids in Colorado and throughout the country, which led to a "blizzard" of addiction, overdose, and death.

409. Yet Defendants did nothing. Purdue and Rhodes developed internal systems to monitor suspicious activity, but those systems were inadequate, at best. Defendants never utilized their monitoring systems to effectively respond to or mitigate the harms being caused by Purdue and Rhodes's drugs.

410. Defendants received regular internal reports about suspicious activities related to their opioid drugs, but Defendants rarely, if ever, reported such suspicious activity to the appropriate law enforcement or regulatory authorities.

411. When Purdue and Rhodes's pharmaceutical distributing partners did voice concerns about specific orders or pharmacies in Colorado, none of the Defendants would report such concerns to the DEA or other authorities and instead instructed their sales force to continue visiting the suspicious pharmacies.

412. Defendants' repeated failures to adequately monitor and report suspicious prescribers, pharmacies, and/or orders is a breach of their duties to

prevent or mitigate opioid diversion, which resulted in the foreseeable harm caused by the diversion of Purdue and Rhodes's prescription opioids in Colorado.

VI. THE SACKLERS CONTROLLED, DIRECTED, PARTICIPATED IN, AND/OR SANCTIONED DEFENDANTS' DECEPTIVE AND RECKLESS OPIOID BUSINESS

413. Purdue is and has always been a privately held collection of companies controlled by and operated exclusively for the financial benefit of the Sacklers. From at least the launch of OxyContin in 1996 through at least 2018, the Sacklers intimately controlled, directed, participated in, and/or sanctioned and had the ability to stop all of Defendants' conduct alleged herein.

414. In September 1996, at the same time they were launching OxyContin, the Sacklers formed MNP Consulting. MNP stands for "Mundipharma-Napp-Purdue."[495] The Sacklers created MNP Consulting as a corporate instrumentality, or shadow Board of Directors, through which they controlled Purdue, Rhodes, and their other companies, while giving the outward appearance that they were not involved in Purdue or Rhodes's day-to-day operations.[496]

415. Despite the Sacklers' attempts to hide their control over Purdue, inside the company it was well understood that the Sacklers, acting as MNP Consulting's Board of Directors, were overseeing and in control of Purdue. The Sacklers directly authorized and approved all business transactions for their companies, including Purdue and Rhodes, through MNP Consulting and received information on new business ventures and general operational information for their companies.[497] According to its corporate governance documents, MNP Consulting received and evaluated "detailed consolidated financial information regarding the pharmaceutical licensing businesses of the Sackler companies, including monthly sales reports and consolidated income and expense statements and balance sheets and related statements and schedules."[498]

416. The Sacklers, through MNP Consulting, also made recommendations and advised the boards of other Sackler companies, including Purdue and Rhodes, on various business decisions related to prescription opioids. As a recent example, at an April 2017 MNP Consulting Board meeting, Purdue's Executive Director of IP

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[495] PPLPC053000082277.
[496] #2995101.1; PKY181035415.
[497] PPLPC045000017477; PPLPC046000075715; PPLPC036000259693; PPLPC036000278458.
[498] #2995101.1; PPLPC031001515357.

& Technology made a presentation to the Sacklers to obtain approval for funding in order to complete development of Purdue's abuse-deterrent opioids, like abuse-deterrent OxyContin and MS Contin discussed above.[499]

417. As described in more detail below, from 1995 through at least 2018, the Sacklers, as Board members and executives at Purdue, and through MNP Consulting, as well as the other individual Defendants, directed, controlled, participated in, and/or sanctioned the conduct alleged herein. They could have, but failed, to stop the conduct alleged herein.

A. The Sacklers' Direction and Control of Purdue Resulted in Criminal Convictions and Civil Consent Judgments

418. This lawsuit and the thousands of others filed against Purdue, including lawsuits against the individual Defendants named herein, is not the Sacklers' first brush with the law. From the launch of OxyContin in 1996 to 2007, the Sacklers directed and controlled Purdue's conduct – deceptive marketing and sale of Purdue's prescription opioids – that resulted in federal criminal convictions and several civil consent judgments with various State Attorneys General (not Colorado) in 2007.

419. The Sacklers knew then, and know now, that Purdue's deceptive and reckless opioid business was fraudulent, reckless, negligent, and created a public nuisance in Colorado and throughout the United States.

1. The Sacklers form Purdue and launch OxyContin

420. The Sacklers' first drug company was the Purdue Frederick Company, which now-deceased Sackler family members bought in 1952. In 1990, the Sacklers created Purdue Pharma, Inc. and Purdue Pharma L.P. Richard, Mortimer, Kathe, Jonathan, Beverly, Illene, and Theresa Sackler all took seats on Purdue's Board of Directors.

421. Since 1990, the Sacklers have always held a majority of seats on Purdue's Board of Directors. And during many years, Purdue's Board was made up exclusively of Sacklers. From the 1990s through at least 2018, most, if not all, actions taken by Purdue's Board were approved by the Sacklers unanimously. Indeed, the vast majority, if not all, of the Board's meeting minutes from the 1990s

[499] PPLPC031001515358.

through 2018 show no objection by any of the Sacklers to actions approved by the Board, including the conduct alleged herein.

422. For events prior to 2012, Purdue's Board consisted of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler. David Sackler joined the Board in 2012.

423. Richard Sackler became the President of Purdue in 1999 and Jonathan, Kathe, and Mortimer Sackler became Vice Presidents. These Sackler family members served on Purdue's Board during the same time they were executives at the company and continued to serve on the Board until at last 2017 or 2018.

424. The Sacklers have always maintained a tight grip on Purdue's operations. Beginning in 1994, two years before the launch of OxyContin, Jonathan Sackler issued a memorandum to Purdue staff, including several individuals who later served on Purdue's Executive Committee, requiring that "all Quarterly Reports and any other reports" be directed to the Sacklers.[500]

425. Just prior to the release of OxyContin in 1996, the FDA scientist who evaluated OxyContin for approval warned that "care should be taken to limit competitive promotion" of the drug.[501] The Sacklers chose to ignore this warning. Instead, in 1996 they unleashed Purdue's "blizzard" of opioid pills.

426. From the release of OxyContin in 1996, the Sacklers knew that Purdue was misleading health care providers about the dangers of OxyContin.

427. In May 1997, in response to an inquiry from Richard Sackler, former Purdue executive Michael Friedman wrote a memorandum acknowledging that Purdue was "well aware of the [incorrect] view, held by many physicians, that oxycodone is weaker than morphine." In that memorandum, Michael Friedman reiterated Purdue's original strategy to "[make] sure that our initial [sales] detail piece provided reps with the opportunity to sell [OxyContin] for a number of different pain states," and to avoid limiting OxyContin's market to cancer-related pain treatment. Michael Friedman continued, "[d]espite our initial uncertainty, we have been successful beyond our expectations in the non-malignant pain market. Doctors use [OxyContin] in non-malignant pain because it is effective and the

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[500] PDD1701827936.
[501] #785793.1.

'personality' of OxyContin is less threatening to them, and their patients, than that of the morphine alternative." Expressing no concern about the dangerous misconception about the potency of OxyContin, Richard Sackler responded simply, "I agree with you."[502]

428. One month later, in June 1997, Purdue's "OxyContin Team Meeting – Minutes" were sent to Richard Sackler with the accompanying note from staff:

> In recent team meetings, we have discussed the issue that OxyContin is perceived by some physicians, particularly Oncologists, as not being as strong as MS Contin. Although this perception has had some effect with physicians switching to MS Contin with more severe cancer pain patients, it has actually had a positive effect with physicians' use [of OxyContin] in non-cancer pain.
>
> Since oxycodone is perceived as being a 'weaker' opioid than morphine, it has resulted in OxyContin being used much earlier for non-cancer pain. Physicians are positioning [OxyContin] where Percocet, hydrocodone, and Tylenol with Codeine have been traditionally used.
>
> Since the non-cancer pain market is much greater than the cancer pain market, it is important that we allow [OxyContin] to be positioned where it currently is in the physician's mind. If we stress the 'Power of OxyContin' versus morphine, it may help us in the smaller cancer pain market, but hurt us in the larger potential non-cancer pain market. Some physicians may start positioning this product where morphine is used, and wait until pain is severe before using it.
>
> Marketing has decided that the efforts of the Phase IV team should be predominantly focused on expanding OxyContin use for non-cancer pain. Our approach to cancer pain will be to get physicians to use it earlier, instead of products such as Percocet, Vicodin, and Tylenol #3. The sales force can teach the Oncologists to properly

[502] *Id.*

> dose and titrate OxyContin to ensure that they 'stay with' [OxyContin] as the pain increases. By doing this, the Oncologists will realize through experience that OxyContin is effective.
>
> It is important that we be careful not to change the perception of physicians toward oxycodone when developing promotional pieces, symposia, review articles, studies, etc.[503]

429. In response, Richard Sackler, prioritizing sales and profits over truth and safety, simply stated, "I think that you have this issue wellin [*sic*] hand. If there are developments, please let me know."[504]

430. None of the Sacklers ever made any effort to dispel health care providers of the dangerous misconception that OxyContin was less potent than morphine because to do so would mean lower profits and fewer earnings for Defendants.

2. The Sacklers directed and controlled every aspect of Purdue's deceptive marketing campaign

431. From OxyContin's launch in 1996, the Sacklers were obsessed with sales numbers, and were intimately involved in, and directed and controlled, the marketing strategy for promoting opioid treatment generally, and for selling Purdue's opioids specifically.

432. Realizing how integral Purdue's sales force was to Purdue's earnings and the Sacklers' fortune, the Sacklers directed, controlled, participated in, and/or sanctioned directly and/or indirectly via the Executive Committee all the activities of Purdue's sales managers and representatives.

433. The lynchpin of Purdue's marketing strategy was always the deployment of thousands of sales representatives around the country, including in Colorado, to spread the company's deceptive "Core Messages" about opioids. As President, Vice Presidents, and/or members of Purdue's Board, the Sacklers were intimately involved in this vital aspect of Purdue's marketing strategy.

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[503] *Id.*
[504] *Id.*

434. Purdue staff, and beginning in 2003, Purdue's Executive Committee, regularly reported back to the Sacklers on the company's earnings from opioid sales. In a report less than two years after the launch of OxyContin, Michael Friedman advised Richard Sackler that Purdue was earning $20 million per week from the sale of MS Contin and OxyContin. Apparently not satisfied with this sales figure, Richard Sackler responded, "Blah, humbug. Yawn."[505]

435. Beginning as early as 1998 and continuing through at least the early-2000s, the Sacklers also oversaw the distribution of thousands of copies of Purdue's video "I Got My Life Back" via U.S. Mail to health care providers in Colorado and throughout the country. That video featured seven patients who claimed at the time that OxyContin improved their lives. The "I Got My Life Back" video included many of the same misleading "Core Messages" reflected in a January 2001 report from Michael Friedman, David Haddox, and other Purdue staff to the Sacklers (discussed in more detail below)[506], including dangerous misrepresentations by a Purdue-financed physician, Alan Spanos, M.D., about the rate of opioid addiction:

> There's no question that our best, strongest pain medicines are the opioids. But these are the same drugs that have a reputation for causing addiction and other terrible things. Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. They don't wear out, they go on working, they do not have serious medical side effects.[507]

436. Jonathan Sackler especially liked the "I Got My Life Back" video:

> The production values were very good, but what most impressed me was the way it told our story through the patient and doctor interviews. I thought it was the clearest expression of our position that I've ever seen: beautifully structured. The clarity of the patients and the clear evidence of [Quality of Life] improvement was

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[505] #228728.1.
[506] *See infra* ¶¶ 445-460.
[507] Our Amazing World*, Purdue Pharma OxyContin Commercial*, YouTube (Sept. 22, 2016), https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited June 26, 2019); PDD9521403001.

> compelling, and Spanos presented the doctors' issues perfectly.[508]

437. At least as early as 2002, Russell Gasdia directed Purdue's sales force to review the "Spanos Video" as part of their employee "Developmental Product Knowledge Action Plan."[509]

438. Since the distribution of "I Got My Life Back," at least two of the seven patients featured in the video died as active opioid abusers, and a third featured patient became addicted to OxyContin before quitting the drug for fear of overdose. Dr. Spanos later acknowledged, in a July 2012 interview, that his Purdue-backed claim that opioid addiction rates are less than 1% was not based on any long-term studies and that he went too far in suggesting otherwise. He also acknowledged that, "[w]e don't know whether [opioid] success stories are one in five, one in 15, one in 100, one in a thousand … they may be quite rare."[510]

439. Unwilling to leave any aspect of Purdue's operations untouched, the Sacklers and other individual Defendants also tightly controlled public perception of Purdue, the Sacklers, and prescription opioids. When confronted with any negative attention, the Sacklers and other individual Defendants vigorously defended Purdue and the Sacklers' public image.

440. For example, in November 2000, Purdue staff reported to Michael Friedman and David Haddox that *Forbes* was "'sniffing about' the OxyContin abuse story."[511] After David Haddox gave *Forbes* an interview, staff reported back:

> The Sackler family name did not enter the story, nor did he ask for stats on sales, employment or growth. Strange, in that I thought this was a business publication. In any event, I think this interview points out the need for us to take a more proactive approach to telling [Purdue's] story. It would be a shame if the tremendous success Purdue has made in treating people with pain is subsumed in a

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[508] PDD8801145316-317.
[509] PKY181740362.
[510] John Fauber and Ellen Gabler, *What happened to the poster children of OxyContin?*, MILWAUKEE JOURNAL SENTINEL (Sept. 8, 2012), http://archive.jsonline.com/watchdog/watchdogreports/what-happened-to-the-poster-children-of-oxycontin-r65r0lo-169056206.html/?abc=S3DgxOpm (last visited June 26, 2019).
[511] PDD1706196246-248.

> national magazine article about the abuse of pain killers.[512]

441. The next day, Michael Friedman sent the report to the Sacklers and to David Haddox, and outlined a responsive strategy:

> We hope to put out, into the public domain, a story to provide facts that a reporter, such as the one from *Forbes*, might leave out . . . . The story will focus on how the company is leading the way to conquering pain in America. The story will include the billion dollar [in opioid sales] accomplishment but focus more on telling the pain management story. Specifically, how Americans have better pain control options than ever before, and that major strides are being made in helping people live higher quality lives through proper pain management, but that there are still many hurdles to overcome. It also will emphasize Purdue's commitment to proper pain medication education.[513]

442. Mortimer Sackler Sr., Mortimer D.A. Sackler's now-deceased father, responded to the group, putting the issue on the agenda for the next Purdue Board meeting, and agreeing with Michael Friedman's strategy so long as Purdue maintained editorial control over the proposed Purdue-positive story.[514]

443. Around that same time, in late 2000, Purdue staff prepared a "2001 Budget Submission," that was distributed directly to each of Richard, Mortimer, Kathe, Jonathan, Ilene, Beverly, and Theresa Sackler. The "2001 Budget Submission" devoted an entire 385-page section to "Marketing and Sales – Public Affairs." The "2001 Budget Submission" articulated in great detail Purdue's strategy to reverse the medical community's traditional aversion to opioids and increase Purdue's opioid sales by overstating the drug's efficacy and understating the associated risks, including the risk of addiction.[515]

444. The 2001 Budget Submission proposed a broad strategy to combat the public's wariness about opioids by, for example, "[r]ecruit[ing] and train[ing] 2-3

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[512] *Id.*
[513] *Id.*
[514] *Id.*
[515] *See e.g.,* PDD1701857738.

'Partners' per state to advocate for patients' rights to [opioids]" and "[e]xplor[ing] the feasibility of spinning out [Purdue's unbranded marketing campaign] *Partners Against Pain* as a separate 501-c-3 organization to serve as a rallying point and repository for information and assistance to the pain community." The 2001 Budget Submission's broad strategy also included a plan to "[s]upport the field sales organization and market environment for Purdue's [opioids] by securing coverage in national and local media that highlights the undertreatment of pain in America and providing fair balance to counter sensational reports of diversion and abuse in hot spot markets."[516]

445. The 2001 Budget Submission also proposed a strategy for "GroundWork/Message Development" that included:

- "Develop core messages that convey fair balance and support continued access to OxyContin;"

- "Develop 10-minute powerpoint presentation for use by company and third-party spokespeople to communicate core messages to target audiences. Develop Q&A to help spokespeople address in more detail sensitive issues on diversion, addiction and price;"

- "Identify 'strike force' including sales force, medical liaisons, [David] Haddox, R. Hogen, J. Heins, C. Wright and R. Reder. Train the strike force members in the use of sales support press kit, presentation and Q&A for outreach meetings;"

- "Draft and send letter from [David] Haddox to state healthcare professional organizations expressing Purdue's concern over inflammatory rhetoric in the media. Letter will discuss Purdue's efforts to bring fair balance and stress the company's desire to put patients' needs first;"

- "Develop internet strategy to publish issues update on state organizations' web sites;" and

[516] *Id.*

- "Conduct secondary research: (1) in emergency rooms and drug treatment clinics to collect hard data on extent of opioid abuse in region, (2) with state medical society to assess caregivers' perceptions of opioid abuse."[517]

446. The 2001 Budget Submission also proposed some of the deceptive "messages" about opioids that were the foundation for Purdue's years-long misinformation campaign in Colorado and across the country. Some of the deceptive "messages" specifically proposed in the 2001 Budget Submission include:

- "We are concerned about the misuse of OxyContin by a small group of substance abusers. However, we are more concerned that unbalanced news reports on this issue might create fear and reticence among patients who rely on OxyContin to manage their pain and to preserve their quality of life…In fact, for many patients, proper medication with opioids is the best way, and perhaps the only way, to treat their severe pain;"

- "When opioids are prescribed and used in accordance with the approved FDA labeling, they are a safe and effective pain treatment for millions of people around the world…surveys show that addiction is very rare in patients taking opioids under a physician's care;" (citing the Jick letter to the NEJM described above) and

- "Myths and misperceptions about addiction, and mislabeling patients as addicts, can result in the unnecessary withholding of opioid medications from patients in need."[518]

447. In January 2001, former Purdue executives, Michael Friedman, David Haddox, and other staff reported back to the Sacklers on Purdue's efforts to carry out the recommendations detailed in the 2001 Budget Submission, including Purdue's "Media Relations Policy" and "Core Messages."[519]

448. As reported directly back to the Sacklers, Purdue's "Media Relations Policy" included a commitment to "[a]lways correct characterizations of OxyContin as a 'dangerous, highly addictive, heroin-like drug,'" and leaned heavily on "[David]

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[517] *Id.*
[518] *Id.*
[519] PPLPC045000003850.

Haddox as a primary spokesperson – benefiting from his credibility as an MD and his clinical experience."[520]

449. As also reported directly back to the Sacklers, Purdue's "Core Messages" included misrepresentations about the risks associated with OxyContin like, "OxyContin is safe and effective when used in accordance with FDA labeling" and "addiction is rare in patients taking opioids for pain under a physician's care." Those "Core Messages" failed to disclose, or even discuss, the fact that OxyContin poses a significant risk of addiction, overdose, and death, even when taken in accordance with FDA labeling and under a physician's care.[521]

450. As detailed in Michael Friedman and David Haddox's January 2001 report directly to the Sacklers, Purdue's deceptive "Media Relations Policy" and "Core Messages" were distributed to multiple media outlets throughout the country, including to the *Wall Street Journal, USA Today*, and *Denver Post*. By Purdue's estimates, those "Core Messages" made over 25 million "impressions" on the public via media outlets, including almost 900,000 "impressions" via the *Denver Post* alone.[522]

451. Michael Friedman and David Haddox's January 2001 report to the Sacklers also detailed Purdue's unbranded marketing campaign, *Partners Against Pain*. One aspect of the *Partners Against Pain* campaign discussed in the January 2001 report was the patient-centric campaign, "Comfort Kits", which included information sheets with the following misleading statements regarding the safety and efficacy of prescription opioids:

> <u>The Truth About Pain Medicine</u>
> ...
>
> Will I become addicted?
>
> Drug Addiction means using a drug to get 'high' rather than to relieve pain. True addiction very rarely occurs when opioids are being used properly to relieve pain. If your pain gets better, your doctor can reduce the amount you take. Follow your doctor's orders for taking less medicine, just as you do if the amount is increased.

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[520] *Id.*
[521] *Id.*
[522] *Id.*

…

Won't [opioids] eventually lose their effect?

An opioid will not lose its effect if you take if for a long time. Opioids can be taken for months or years, and they will continue to relieve pain. And if your pain worsens, the amount you take may be increased by your doctor to control the additional pain. (emphasis in original)[523]

452. Purdue's "Comfort Kits" downplayed the risk of opioid addiction, overdose, and death, even when taken as prescribed, and failed to disclose the increased risks associated with higher dosages of opioids and longer periods of opioid treatment.

453. Another aspect of *Partners Against Pain* discussed in Michael Friedman and David Haddox's January 2001 report to the Sacklers was the unbranded media campaign "The Truth About Pain Management", which was designed by Purdue to combat negative media reports on the deadly risks associated with prescription opioids.

454. "The Truth About Pain Management" press kit presented to the Sacklers in January 2001 included a quote on the cover: "Untreated pain is America's silent epidemic." This unbranded messaging was integral to Purdue's strategy to distract attention from the deadly risks associated with opioids and relax health care providers' traditional aversion to prescribing opioids for chronic pain.[524]

455. "The Truth About Pain Management" press kit presented to the Sacklers included other deceptive and misleading representations downplaying the risk of addiction. For example, promoting the deceptive conditions, "pseudoaddiction" and "pseudotolerance," concocted by David Haddox. "Pseudoaddiction" was promoted by Purdue to convince doctors that their patients who were exhibiting signs of addiction were really suffering from a *lack* of opioids. "Pseudotolerance" was defined in the press kit as "the need to increase dosage that is not due to tolerance, but due to other factors, such as disease progression, new disease, increased physical activity, lack of compliance, change in medication, drug interaction, addiction, and deviant behavior." "Pseudotolerance" conveniently

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[523] PDD1502330336; PDD1502302682; PPLPC051000029420; PPLPC045000003850.
[524] PPLPC045000003850.

ignores the fact that the vast majority of patients develop opioid tolerance from the very first time they take the drug, even as prescribed, and that opioid tolerance often drives patients down the deadly slope towards opioid dependence and addiction.[525]

456. "The Truth About Pain Management" press kit presented to the Sacklers also included deceptive representations about the safety and efficacy of opioids by Purdue-sponsored Front Groups, like APS and AAPMed, as well as representations by Purdue-paid Key Opinion Leaders, all of which were integral to Purdue's marketing scheme.[526]

457. In late January 2001, a Purdue sales representative reported to Purdue's "Primary Spokesman," David Haddox, on statements made at a community meeting organized by mothers whose children overdosed and died from OxyContin: "Statements were made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor." Just a few days later, that report was sent to Richard Sackler, who proposed forming a "working group for all these issues."[527] The Sacklers' attention to reports like this was not limited to this incident early in the life of OxyContin.

458. Also in January 2001, while Purdue's deceptive video "I Got My Life Back" was still in circulation, Mortimer Sackler forwarded from his personal email address a *New York Times* article to Richard Sackler that detailed 59 OxyContin-related deaths counted by a single police officer over the course of a single year in just one state. The article also described a "troubling number of [OxyContin] cases" reported in six other states. In addition to reporting on the increase in overdoses and deaths caused by OxyContin, the article described "a wave of pharmacy break-ins, emergency room visits and arrests of physicians and other health care workers" related to OxyContin use. Richard Sackler responded to Mortimer Sackler, "This is not too bad. It could have been worse. Thanks for all the support."[528]

459. The following month, after hearing "a rumor that *60 Minutes* is nosing around," Richard Sackler articulated his strategy for protecting Purdue and the Sacklers' image in the face of mounting cases of OxyContin addiction and death: "[W]e will have to mobilize the millions that have serious pain and need our

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[525] PPLPC51000029420.
[526] *Id.*
[527] #171855.1.
[528] PDD8801151727.

product. This we will try to do. Meanwhile, we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."[529]

460. The deceptive "Core Messages" and other marketing strategies presented in the 2001 Budget Submission and Michael Friedman and David Haddox's January 2001 presentation that were crafted, reviewed, and/or sanctioned by the Sacklers and Purdue's leadership at least as early as late-2000 or early-2001, including the *Partners Against Pain* campaign and the "I Got My Life Back" video, were intended to and did serve as the basis for Purdue's deceptive marketing strategy in Colorado and around the country that continued until at least 2018. The same "Core Messages" and other marketing strategies are reflected in the thousands of Purdue sales calls made to prescribers in Colorado, and in the educational and other promotional materials distributed by Purdue to thousands of Colorado prescribers, patients, policy makers, and the public, as detailed throughout this First Amended Complaint.

3. The Sacklers directed entry of felony guilty pleas by Purdue senior executives, and civil consent judgments

461. Between 1996 and 2007, problems for Purdue as a result of Defendants' deceptive marketing strategies and campaign grew from early negative media reports about opioid abuse, to the 2007 federal criminal convictions of high-level Purdue executives and State civil consent judgments, all related to Purdue's deceptive marketing of opioids.

462. By 2006, federal and state prosecutors found evidence that Purdue intentionally deceived health care providers and patients about their opioids. Unwilling or unable to mount a defense, the Sacklers voted to have the Purdue Frederick Company plead guilty to a felony for misbranding OxyContin as less addictive, less subject to abuse, and less likely to cause adverse events and side effects than other pain medications. Unwilling to take responsibility for their company's misdeeds, the Sacklers also voted to have three Purdue executives (Michael Friedman, Paul Goldheim, and Howard Udell) take the fall by pleading guilty as individuals.[530] [531]

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[529] PDD8801133516.

[530] This did not stop the Sacklers from rewarding these individuals handsomely. For example, in 2008 the Sacklers voted to pay Michael Friedman $3 million and Howard Udell more than $5 million for their loyalty to Purdue and to the Sackler family. PKY183212622; PKY183212680

463. In May 2007, the Sacklers again voted to have Purdue plead guilty and agreed to never deceive health care providers and patients about opioids again: "Purdue is pleading guilty as described above because Purdue is in fact guilty."

464. The Sacklers voted to admit, in an Agreed Statement of Facts that, for more than six years, supervisors and employees *intentionally* deceived health care providers about OxyContin. Purdue and the Sacklers admitted that:

> Beginning on or about December 12, 1995, and continuing until on or about June 30, 2000, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.[532]

465. Notably, the admitted *intentional* violations of the law occurred while Richard Sackler was Purdue's President; Jonathan, Kathe, and Mortimer were Purdue Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler controlled Purdue's Board of Directors.

466. In May 2007, the Sacklers also voted to enter into a Corporate Integrity Agreement with the U.S. Government, which required each of the Sacklers to *individually* ensure that Purdue would not deceive health care providers and patients again. The Sacklers further *individually* promised to comply with rules that prohibit deception about opioids. They were required to complete hours of training to ensure that they understood the rules. They were also each *individually* required to report any deception. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler each certified in writing that he or she had read and understood the rules and would obey them.[533]

467. In 2007 the Sacklers also voted to enter into Consent Judgments with several State Attorneys General (not including Colorado). Those Judgments ordered that Purdue:

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[531] PKY183307486; PPLP004031281.
[532] PKY183307494; Agreed Statement of Facts ¶ 20 (May 9, 2007), *available at* https://www.documentcloud.org/documents/279028-purdue-guilty-plea.
[533] *Id.*; PDD1712900054.

> [S]hall not make any written or oral claims that is false, misleading, or deceptive" in the promotion or marketing of OxyContin. The Consent Judgments further required that Purdue provide fair balance about the risks of taking higher dosages of opioids for longer periods of time, as well as about the risks of addiction, overdose, and death associated with all opioids, regardless of dosage.[534]

468. The 2007 Consent Judgments also required that Purdue establish and follow an abuse and diversion detection program to identify high-prescribing doctors who show signs of inappropriate prescribing, stop promoting opioids to them, and report them to the authorities:

> Upon identification of potential abuse or diversion, [Purdue must conduct an inquiry and take appropriate action], which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities.[535]

469. The agreement and promises made by Purdue and the Sacklers to resolve the federal criminal actions and the state Consent Judgments should have ended Purdue and the Sacklers' fraudulent and deceptive conduct for good. Unfortunately, that was not the case. Instead, after the Purdue Frederick Company plead guilty and went out of business, the Sacklers continued their quest for profits by conducting their deceptive and reckless business through Purdue Pharma, Inc. and Purdue Pharma, L.P.

470. In 2007, Jonathan, Kathe, and Mortimer Sackler stepped down as Vice Presidents (Richard Sackler stepped down as President of Purdue in 2003). However, these moves were just for show. The Sacklers continued to own 100% of Purdue, and they continued to control the Board and Purdue's Executive Committee. The Sacklers continued to direct, participate in, cooperate with, and/or sanction Purdue's deceptive and reckless conduct. And, the Sacklers continued to

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[534] *See e.g.*, 2007-05-15 Consent Judgment, Commonwealth of Massachusetts v. Purdue Pharma, L.P., *et al*. No. 07-1967(B), Mass. Super. Ct.
[535] *Id.*

pay themselves billions of dollars in profits from Purdue's deceptive and reckless opioid business.

471. In a July 2007 "Quarterly Report to the Board," Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, and other staff reported back to the Sacklers that Purdue's 2007 gross sales would be approximately $1.3 billion, and stated that Purdue's "continued sales effort behind the brand" was a significant contributor to those sales figures. In that same Quarterly Report, the Executive Committee reported back to the Sacklers that Purdue had 301 "field sales" personnel, by far their largest group of Purdue employees. Notably, at the same time, Purdue had only 34 employees in Drug Discovery and 29 employees in Drug Safety & Pharmacy.[536]

472. Undeterred by reports of the epidemic of opioid overdoses and deaths resulting from Purdue's deceptive and reckless business scheme, Defendants pushed forward with their strategy to have Purdue's sales force continue to work to convince more health care providers to prescribe more opioids, with higher dosages, to more people, for longer periods of time.

473. In an October 2007 "Quarterly Report to the Board," the Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, and other Purdue staff reported back to Kathe, Jonathan, Ilene, Beverly, and Theresa Sackler that Purdue hired more sales representatives and that Purdue was succeeding at promoting its highest doses of opioids: "OxyContin 80mg is at levels not seen in over 2 years."[537] OxyContin 80mg is Purdue's most profitable and most dangerous opioid.

B. The Sacklers Continued to Control and Direct Purdue's Deceptive Marketing Campaign After the 2007 Felony Convictions and Consent Judgments

474. Undeterred by their 2007 legal troubles, Purdue, the Sacklers, and the other individual Defendants continued their deceptive and reckless opioid business consistent with the 2001 Budget Submission and Michael Friedman and David Haddox's January 2001 report. The money at stake was too much to dissuade Defendants from giving up their scheme.

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[536] PWG000300830-36.
[537] PPLPC012000157405-459.

475. Defendants recognized the financial bonanza that could result from an expanding opioids market, especially the increase in sales of high-dosage OxyContin. After receiving an October 2007 Board report on Purdue's sales, Richard Sackler requested the underlying sales data, which showed that Purdue expected to collect more than half of its revenues from the sale of 80mg OxyContin in 2008.[538]

476. From 2008 until the present, the Sacklers ran Purdue as if the 2007 guilty pleas, admissions, and agreements to stop the deceptive and reckless sale of opioids never happened. The Sacklers maintained a firm grip on Purdue's operations, they obsessed over the activities of Purdue's sales force and the money earned for Defendants, and they vigorously defended their corporate and personal images in the face of mounting public anger about the opioid epidemic.

1. The Sacklers obsessively monitored Purdue's revenues and ordered increases in Purdue's sales force

477. At a February 2008 Purdue Board meeting, the Sacklers authorized the expansion of Purdue's sales force by 100 additional representatives, thus enabling Purdue sales representatives to make an additional 12,000 sales visits per month to health care providers in Colorado and around the country.[539]

478. Richard, Jonathan, Kathe, and Mortimer Sackler remained especially steeped in Purdue's forecasts and strategies for increasing sales of the company's opioids, including its highest dosages of the drugs, despite having stepped down from their executive positions at Purdue. In a February 2008 email to Jonathan and Mortimer Sackler, as well as to John Stewart, Richard Sackler ordered that Purdue "measure our performance by [prescription] strength, giving higher measures to higher strengths an[d] especially the new strengths."[540] Richard Sackler directed this strategy, and the other Sacklers approved, even though Purdue, the Sacklers, and the other individual Defendants all knew that higher dosages of opioids and extended treatment periods increased the risks associated with the drugs.[541]

479. In March 2008, Richard Sackler demanded thousands of pieces of data from Purdue's Executive Committee and other staff about sales trends for

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[538] PPLPC012000159168-170.
[539] PPLPC012000159022.
[540] PPLPC012000170948-949.
[541] PDD1701785443.

OxyContin, including data to allow him to analyze the sale of higher dosages.[542] Russell Gasdia, John Stewart, and other members of Purdue's Executive Committee and staff responded to the request on a Sunday morning and Richard Sackler demanded more information that same day, even calling one staff member at home complaining that the sales forecasts were too low for his liking. Because he believed the OxyContin sales forecast for 2008 was too low, Richard Sackler threatened to "recommend the Board not approve it."[543]

480. The Sacklers often contacted members of Purdue's Executive Committee and other staff on weekends and holidays to discuss opioid sales. In one such Saturday evening email (also in March 2008) to Russell Gasdia and John Stewart, Richard Sackler (copying Ilene, Kathe, Jonathan, Mortimer, and Theresa Sackler) expressed his eagerness "to find ways to build our [prescription] loyalty to OxyContin tablets and continue the positive trend in [prescription] growth that began to falter about 6-8 months ago." Feeling the pressure of the Sacklers' round-the-clock demands, Russell Gasdia responded privately to John Stewart, "Dr. Richard has to back off somewhat. He is pulling people in all directions, creating a lot of extra work and increasing pressure and stress."[544]

481. When it came to the sale of Purdue's opioids, the Sacklers did not know how to back off. That same Saturday night in March 2008, Richard Sackler sent another email to Russell Gasdia (copying Kathe, Jonathan, and Mortimer Sackler) directing him to identify tactics for "exceeding 2007 [prescription] numbers on an adjusted basis (adjusted for strength and average number of tablets per [prescription])."[545]

482. Recognizing that Richard Sackler and the rest of his family would "not accept a flat trend the remainder of the year for total oxycodone [ER]," Russell Gasdia reiterated his belief that Purdue's strategy to increase the number of sales representatives, utilize savings cards to increase dosages, focus on managed care insurance plans, and offer new drug strengths would mitigate the negative effects of increased pressures on Purdue's share of the opioid market.[546]

483. Still not satisfied with the sales projections, Richard Sackler followed through on his threat to have the Board reject the 2008 forecast. In its place,

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[542] PPLPC012000174478.
[543] PPLPC012000174477; PPLPC012000174202-204.
[544] PPLPC012000174127.
[545] PPLPC012000175157.
[546] PPLPC012000174161.

Richard Sackler detailed his own sales forecast and proposed to the rest of the Sacklers that he, together with Mortimer Sackler and John Stewart, "reforecast the year and also the 5 year plan for OxyContin tablets . . . ."[547]

484. At the same time, Jonathan, Kathe, and Mortimer Sackler were also pushing Purdue's Executive Committee and other staff to increase their 2008 forecast for OxyContin sales. When one Executive Committee member said that the savings cards would help Purdue maintain 2007 prescription levels in 2008 "in spite of all the pressures," Kathe Sackler demanded to know what "pressures" would keep OxyContin sales from growing, and requested "some quantification of their negative impact on projected sales."[548]

485. In April 2008, Richard Sackler emailed a memo to Ilene, Kathe, Jonathan, and Mortimer Sackler detailing a strategy to protect the family's financial standing by either selling Purdue or milking as much profit as possible. They chose the latter option. To ensure the success of this strategy, Richard Sackler recommended, and the rest of the Sacklers approved, the installation of a John Stewart as Purdue's new CEO, who would be loyal to the company and the family. While David Sackler was not on Purdue's Board at this time, he also participated in this decision.[549]

486. In May 2008, Purdue's Executive Committee, including Russell Gasdia and Craig Landau, forwarded their meeting notes to Richard, Mortimer, Kathe, Jonathan, Theresa, and Beverly Sackler, and to David Haddox, that included a report from one of Purdue's strategic research agencies. That report outlined "KEY MESSAGES THAT WORK" for "a compelling story to tell to the public," including the dangerous lies: "It's not addiction, it's abuse" and "It's about personal responsibility."[550] (emphasis in original)

487. In response to a June 2008 request about Purdue's savings card program, Russell Gasdia reported back to Richard, Mortimer, Kathe, and Jonathan Sackler, and to John Stewart, that 67,951 savings cards had been used 188,212 times for opioid prescriptions.[551] That report also stated that 27% of the savings cards (more than 18,000 people) were used by patients for five opioid

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[547] PPLPC023000164605.
[548] PPLPC012000175155-156.
[549] PDD9316300629-631.
[550] PPLPC012000183254, 256, 259.
[551] PPLPC012000186394-396.

prescriptions.[552] Of little or no concern to the Sacklers and other individual Defendants, 41.3% of patients meet the diagnostic criteria for lifetime opioid use disorder after ***four*** opioid prescriptions.[553]

488. Over the next several years, the Sacklers continued to direct Purdue's Executive Committee and staff to increase the use of saving cards as a means to increase the dosage and the duration of patients' prescription opioid use.

489. In October 2008, members of Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, and other staff reported back to the Sacklers that Purdue's sales force had expanded again, now totaling 414 sales representatives nationally, which resulted in a 59% increase in the number of sales visits to Colorado health care providers from 2008 (9,674 visits) to 2009 (16,272 visits).[554]

490. In November 2008, Purdue's budget for 2009 reflected the Sacklers' emphasis on expanding the sales force further. The Sacklers voted to spend $112.4 million on its sales force in 2009, resulting in over 518,000 visits to health care providers in Colorado and throughout the country.[555]

491. In March 2009, the Sacklers voted to pay Purdue sales representatives and sales managers a 103% bonus because so many Purdue opioids were sold in 2008.[556] The following month, the Sacklers, Russell Gasdia, and Craig Landau were informed that Purdue's 412-strong sales force made dramatic progress promoting high-dosage opioids: "for the first time since January 2008, OxyContin 80mg strength tablets exceeded the 40mg strength."[557] Intent on pushing the higher dosages, the Sacklers told Russell Gasdia and other Purdue executives to hire a "Director of ePromotion" responsible for managing Purdue's "brand websites, *Partners Against Pain* website and the development of other e-based communication and promotion to healthcare professionals."[558]

492. In June 2009, after learning of an increase in a competitor's opioid sales, Richard Sackler exclaimed: "What happened???" Russell Gasdia explained to

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[552] *Id.*
[553] *See supra* ¶ 68.
[554] PDD9316101027; PCO000000002.
[555] PPLP004401590; PKY183212663, 66; PDD9273201117.
[556] PKY183212703-711.
[557] PDD9316100601-624.
[558] PPLPC012000221936.

Richard Sackler that the competitor's increased sales were all about sales representatives:

> They have 500 reps actively promoting to top decile MDs…Their messaging is 'we are not OxyContin,' alluding to not having the 'baggage' that comes with OxyContin. . .
>
> Interestingly, their share is highest with MDs we have not called on due to our downsizing and up until last year, having half as many reps. Where we are competing head to head, we decrease their share by about 50%[559]

493. Not to be bested, the Sacklers approved another expansion of Purdue's sales force: "As approved in the 2009 Budget, 50 New Sales Territories have been created." Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, told Richard, Mortimer, Kathe, Jonathan, Theresa, and Beverly Sackler, as well as David Haddox, that the expansion was focused on the most prolific prescribers because "there are a significant number of the top prescribers of [o]xycodone ER that are not seen – due to the fact that without our current Field Force of 350 representatives we simply do not have the capacity."[560]

494. According to another report in August 2009 from Purdue's Executive Committee, including Russell Gasdia, and other Purdue staff to the Sacklers, the use of savings cards had doubled from the previous year. By June 2009, 169,038 savings cards were used for 545,202 times for opioids prescriptions.[561]

495. Continuing to feel pressure from their competitors, Mortimer Sackler sent an email in September 2009 to Russell Gasdia, Craig Landau, John Stewart, and the other Sacklers demanding to know why OxyContin sales were decreasing in an expanding opioids market, and expressing concern that the sales force was not pushing OxyContin hard enough.[562]

496. In October 2009, after learning that Purdue's sales force was expected to expand to 475 sales representatives, Richard Sackler demanded detailed weekly breakdowns on OxyContin prescriptions. Until then, staff did not produce such

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[559] PPLPC021000235124.
[560] PPLPC012000226604; PPLPC012000226606.
[561] PPLPC012000235543 *compare to supra* ¶ 70, n. 66; PPLPC012000186394-396.
[562]PPLPC012000240032.

weekly reports and believed that providing the detailed reports would be worthless: "For the record, my concerns regarding workload and being able to meet demands of all the reporting, primary research, ad hocs while maintaining quality and reasonable levels of group morale remain." Nonetheless, at the direction of Purdue Executive Committee members John Stewart and Russell Gasdia, staff began creating the weekly reports and sending them directly to the Sacklers with additional detail on the Sales Department's activities.[563] For the next several years, the Sacklers received weekly and monthly reports on Purdue sales activities.

497. When sales forecasts were not to the Sacklers' liking, they took matters into their own hands. In late 2009, Richard and Kathe Sackler were designated by the Board to review sales projections for 2010. At the Purdue Board meeting in November 2009, Richard and Kathe Sackler directed members of Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, and other Purdue staff, including David Haddox, to "identify specific programs that Sales and Marketing will implement to profitably grow the [ER oxycodone] market and OxyContin in light of competition; provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth; clarify the situation with respect to OxyContin being used by 35% of new patients, but only retaining 30% of ongoing patients."[564]

498. Also in November 2009, the Purdue Board voted to spend over $121 million on their sales force in 2010. And in order for Richard and Kathe Sackler to review the 2010 budget and sales projections, they requested a copy "of the McKinsey report on possible ways to increase OxyContin sales and market share."[565]

499. The McKinsey report requested by Richard and Kathe Sackler recommended that Purdue continue pushing opioids on high-volume prescribers by:

> Reinforc[ing] **leadership** through (emphasis in original)
>
> - [Key Opinion Leader] Program

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[563] PPLPC016000007322-339; PPLPC012000241516; PDD9316309168; PPLPC012000241515; PPLPC022000283453; PPLPC012000241515; PPLPC012000241526; PPLPC012000241586; PPLPC012000241586; PPLPC012000241586; PPLPC012000241647; PPLPC022000283690; PPLPC012000242813.
[564] PPLPC012000249328; PPLPC012000249327.
[565] PKY183212802-804; PDD9273201222; PPLPC012000249328; PPLPC012000249327.

- Advisory Boards
- Presence at conferences
- Physician support programs for patients education (including *Partners Against Pain*)

Broaden **access** through (emphasis in original)

- Loyalty/savings cards

500. The Mckinsey report also recommended pressuring opioid-averse prescribers by:

> Rais[ing] physician **comfort levels** through appropriate education and support (emphasis in original)
>
> - Peer to peer education programs
> - Referral program
> - Pain management toolkit
> - Conversion tables
> - Physician and patients educations program (including *Partners Against Pain*)
>
> Broaden **access** through (emphasis in original)
>
> - Loyalty/savings cards[566]

501. In the same November 2009 Purdue Board meeting, Richard Sackler asked members of Purdue's Executive Committee, including John Stewart, and David Haddox, "What are OxyContin's clinical advantages v. Opana ER, MS Contin,

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[566] PPLPC018000346294.

Kadian, Exalgo, Avinza, Nucynta and Duragesic? How are these differences communicated?" In response, and at the direction of John Stewart, Purdue staff sent an email back to the Sacklers, Russell Gasdia, Craig Landau, and David Haddox listing the purported benefits of OxyContin over competing opioids, including that OxyContin reduces pain faster, has less variability in blood levels, and works for more pain conditions than competing opioids. These are all deceptive claims. Staff also reported back that all of the purported benefits of OxyContin "are published in the Full Prescribing Information or in the medical literature and, as such, can be provided to clinicians in various formats to provide clinicians with the information."[567]

502. In December 2009, Richard and Kathe Sackler met with members of Purdue's Executive Committee and sales staff to discuss the 2010 sales projections. Executive Committee members John Stewart and Russell Gasdia, and other Purdue staff, warned Richard and Kathe Sackler that although OxyContin sales were at record levels (nearly $3 billion annually), the decade-long rise in total oxycodone prescriptions was beginning to flatten.[568] Despite these trends, Richard Sackler received reports a few months later showing that Purdue was selling more 80mg OxyContin pills than any other dosage.[569] Purdue's 80mg OxyContin pills are Defendants' most profitable and most dangerous drug.

2. The Sacklers directed and controlled Purdue's efforts to reverse decreasing sales numbers

503. In February 2010, after receiving another report from members of Purdue's Executive Committee and other staff showing national oxycodone prescriptions had begun to flatten, the Sacklers and the Executive Committee, including John Stewart, Russel Gasdia, and Craig Landau, went on the offensive.[570] Purdue's Sales and Marketing Department, led by Russell Gasdia, reported back to the Sacklers that a key objective for 2010 would be to "[m]eet or exceed total prescriber call targets of 545,000" visits to prescribers in Colorado and throughout the country. For the next four years or more, one of the sales force's key objectives was to meet a quota of sales visits, and the Defendants tracked their performance in

[567] PPLPC012000249329.
[568] PPLPC012000247640-642.
[569] PPLPC012000262892.
[570] PPLPC012000247640; PPLPC012000247642.

meeting those quotas. The sales visit quotas rose from 545,000 visits in 2010 to 712,000 visits in 2011, 752,417 visits in 2012, and 744,777 visits in 2013.[571]

504. In order to meet the new sales call quotas, the Sacklers voted to spend $226 million on sales in 2010 and members of Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, reported back to the Sacklers that Purdue now employed 490 sales representatives, which resulted in 18,121 sales visits in Colorado that year.[572] Richard, Mortimer, Kathe, Jonathan, Beverly, and Theresa Sackler, as well as David Haddox, were also informed of McKinsey's estimates that the sales expansion would increase sales of OxyContin by $200-$400 million.[573]

505. The Sacklers required each sales representative to visit an average of 7.5 health care providers per day. In one of their many detailed reports back to the Sacklers on sales visits, Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, reported, in April 2010, to the Sacklers that they were falling short of the 7.5 visit requirement – only managing an average of about 7 visits per day. The Sacklers and the Executive Committee continued to set targets for sales visits and they tracked the results, quarter by quarter. From at least 2010 to 2014, Purdue's sales force averaged about 7 visits to prescribers per day.[574]

506. The sales visit targets were integral to Purdue's success and the Sacklers and other individual Defendants closely tracked the quarterly sales visits for the entire sales force – always more than 100,000 visits per quarter. In Q1 2010 alone, Purdue's 489-strong sales force achieved their goal of making 127,376 visits to health care providers nationally, 4,459 of which occurred in Colorado.[575]

507. The Sacklers also closely tracked the cost of all the sales visits. In April 2010, Purdue's Executive Committee, including John Stewart, Russell Gasdia, and Craig Landau, reported back to the Sacklers that each sales visit to a health care provider cost Purdue $219, and that Purdue was working to lower that per-visit cost to $201 per visit.[576]

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[571] PPLPC012000252797; PPLPC012000322428; PPLPC012000374793; PPLP004367546.
[572] PPLPC012000252778-793; PCO000000002.
[573] PPLPC012000257443; PPLPC012000257446.
[574] PWG000423143.
[575] PWG000423143-159; PCO000000002.
[576] PWG000423143.

508. In June 2010, Purdue's Executive Committee, including Russell Gasdia and Craig Landau, as well as David Haddox and other Purdue staff, gave the Sacklers an updated 10-year plan to increase opioid sales. The 10-year plan stated that Purdue would pay the Sacklers $700 million every year from 2010 to 2020. In order to execute the plan, the Executive Committee and David Haddox told the Sacklers that Purdue would "require significant salesforce support," and Russell Gasdia proposed having each Purdue sales representative make 1,540 sales visits every year. Russell Gasdia further proposed that Purdue expand its sales force to 1,050 representatives by 2015 and begin convincing prescribers to convert their patients from Tylenol to Purdue's soon-to-be-released opioid, Butrans.[577]

509. In July 2010, at a Purdue Board meeting in Bermuda, Russell Gasdia, Craig Landau, and other members of Purdue's Executive Committee presented to the Sacklers again on the planned launch of Butrans, including presentations on strategies to convert patients from non-opioid treatments to Butrans, and tactics for convincing prescribers that their patients needed the new drug. The Sacklers hoped Butrans would be another billion-dollar product. Purdue added another 125 sales representatives to target 82,092 prescribers for Butrans visits.[578]

510. The Sacklers responded to the Butrans presentation with dozens of questions, including requests for more information on tactics for using Purdue's network of paid Key Opinion Leaders to "influence the prescribing of [Butrans]" and sales forecasts for higher dosages of the drug. The Sacklers even asked if Butrans sales could be improved by providing samples of the narcotic to prescribers.[579]

511. The Sacklers were so focused on the continued sale of OxyContin and the release of Butrans that they decided to forgo the purchase of an insomnia drug out of fear that its promotion would distract Purdue's sales force from pushing opioid prescriptions.[580]

512. Richard Sackler attended the Butrans Launch Meeting with Executive Committee members, including Russell Gasdia and John Stewart, in January 2011. He followed up that meeting with an email to Russell Gasdia and John Stewart demanding a briefing on the status of Butrans sales visits:

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[577] PPLPC012000277155-169, 217.
[578] PPLPC018000404193; PPLPC012000273600.
[579] PPLPC012000283164-165.
[580] PPLPC012000283047.

> I'd like a briefing on the field experience and intelligence regarding Butrans. How are we doing, are we encountering the resistance that we expected and how well are we overcoming it, and are the responses similar to, better, or worse than when we marketed OxyContin tablets?[581]

513. In February 2011, after the Sacklers were informed that one week of Butrans prescriptions doubled their projections, Richard Sackler responded, "I had hoped for better results."[582] Ten days later, Richard Sackler asked John Stewart and Russell Gasdia to provide him a detailed report on the ratio of prescriptions per sales visit (divided out by prescriber specialty) and then asked for a Board discussion on the barriers the sales force were encountering during Butrans sales visits.[583]

514. Less than a month later, Richard Sackler was growing impatient with the lack of information coming to him about Butrans sales: "What do I have to do to get a weekly report on Butrans sales without having to ask for it?"[584] When Purdue's Executive Committee, including Russell Gasdia and Craig Landau, followed up with a weekly report to Richard, Mortimer, Jonathan, and Kathe Sackler, Richard Sackler responded, "What else more can we do to energize the sales and grow at a faster rate?"[585]

515. Mortimer Sackler was similarly anxious to receive information about Butrans sales. In an April 2011 email to Russell Gasdia and Richard Sackler, Mortimer Sackler inquired about how Butrans sales in the U.S. compared to Purdue's international launch of the drug. When he did not receive an answer within a few days, Mortimer Sackler responded, "Any answer to this yet?" Russell Gasdia and other Purdue staff rushed to provide the information requested by Mortimer Sackler at the Purdue Board meeting the following week.[586]

516. Also in April 2011, Richard Sackler received a report from a third party about a *New York Times* story, "Administration seeks legislation to require doctors to be trained before prescribing strong painkillers." According to that third

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[581] PPLPC012000308393; PPLPC021000352206.
[582] PPLPC012000311654.
[583] PPLPC012000313544.
[584] PPLPC012000314972.
[585] PPLPC012000316128.
[586] PPLPC012000320101-103.

party, the story also stated: "Abuse of painkillers like OxyContin is epidemic" and "[l]egitimate use may also pose risks to patients." After Richard Sackler forwarded him the story, John Stewart responded that he "spoke about the Times with your father [Raymond Sackler] too, and am looking into ways to connect to them – in hope of them becoming more balanced (*i.e.* less focused on OxyContin/Purdue) in their coverage of this an related issues. Will keep you advised of happenings."[587]

517. By June 2011, the 10-year plan from the Executive Committee and David Haddox to reverse negative sales trends, presented to the Sacklers in June 2010, was already running into trouble. As reported by the Executive Committee back to Richard, Mortimer, Kathe, Jonathan, Beverly, and Theresa Sackler in June 2011, Purdue's opioid sales were hundreds of millions of dollars less than expected, due primarily to doctors not prescribing enough high dosage opioids.[588] The headline presented at the Purdue Board meeting read: "40 and 80mg tablet prescriptions have decreased significantly. The 10mg and 20mg tablet prescriptions initially increased, but given their lower value not enough to offset the higher strength decline." The Executive Committee told the Sacklers: "As a result of the change in prescriptions by strength, OxyContin brand Kgs dispensed are below mid 2010 levels."[589]

518. In order to mitigate the impacts of the declining high-dosage sales, Purdue's Executive Committee assured the Sacklers that Purdue's sales force and paid physician spokespersons would maintain demand. For a "Super Core" of "Very High Potential" opioid prescribers, Purdue's sales force would visit *every week*.[590]

519. The Sacklers were not satisfied and began peppering Russell Gasdia, Craig Landau, John Stewart, and other members of Purdue's Executive Committee and staff with questions and proposals to regain market share. Mortimer Sackler asked about launching a generic version of OxyContin to "capture more cost sensitive patients." Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert. Jonathan Sackler wanted to study changes in the market share for opioids, focusing on dosage strength.[591]

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[587] PPLPC019000517894.
[588] PPLPC012000327303.
[589] PPLP004406102-123.
[590] *Id.*
[591] PPLPC012000331343; PPLPC012000331345.

520. Determined to reverse the negative sales trends, and undeterred by the *New York Times* reporting two months earlier, Richard Sackler sought a meeting with Purdue's District Managers who were day-to-day supervisors of the sales force. Russell Gasdia informed Richard Sackler that management had followed through on the Sacklers' desire to hire 147 new sales representatives. Russell Gasdia also told Richard Sackler that the sales force would focus on convincing prescribers to convert their opioid naïve patients to Butrans.[592]

521. The same day, when Richard Sackler realized that Purdue's managers may have allowed the sales force to visit lower-volume prescribers instead of the targeted high-volume prescribers, he wrote to Russell Gasdia: "How can our managers have allowed this to happen?"[593]

522. Richard Sackler was so concerned that Purdue's sales force was not focusing on high-volume prescribers, he demanded that he personally go into the field to shadow sales representatives for a week – two per day.[594] Recognizing the liability risks this posed to Purdue and Richard Sackler, Russell Gasdia reached out to Purdue's compliance department. In response, compliance staff responded, "LOL – I told him you raised concerns with me. We agreed Richard needs to be mum and be anonymous."[595]

523. Russell Gasdia was not the only Purdue executive concerned about Richard Sackler's request. One executive wrote:

> About 5 last night, John [Stewart] was walking by my office – I yelled out to stop him – and said that you had mentioned to me that Richard wanted to go into the field, and that you had raised concerns with me. John seemed angry, and asked if I had concerns. I told him could be issues and Richard could be out on a limb if he spoke about product at all or got into conversations with [health care providers], or identified himself, especially with FDA Bad Ad possibilities. John agreed Richard would have to

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[592] PPLPC012000329609.
[593] PPLPC012000329706.
[594] PPLPC012000329706.
[595] PPLPC012000329494; PPLPC012000329722.

> be mum throughout, and not identify himself other than as a home office person.[596]

524. In June or July 2011, Richard Sackler did in fact accompany Purdue sales representatives info the field to promote opioids. Upon his return, Richard Sackler argued with Russell Gasdia, Craig Landau, John Stewart, and other Executive Committee members that an FDA-required "contraindication" warning on Butrans's label should have been placed in a "less threatening section" because its placement "implies a danger of untoward reactions and hazards that simply aren't there. . . ."[597]

525. The Butrans "contraindication" Richard Sackler referenced read: "Butrans is also contraindicated in the management of: acute pain or in patients who require opioid analgesia for a short period of time, postoperative pain, mild pain, or intermittent pain (eg, use on an as-needed basis)." Russell Gasdia, John Stewart, and other Executive Committee members explained to Richard Sackler that the FDA required the "contraindication" in part because of "[t]he concern on the long term effects [of Butrans] once the patient has reached steady state and not being able to titrate down quickly or worse not thinking about removing the patch could be a real issue."[598]

526. Richard Sackler's time in the field with Purdue's sales representatives did not end there. In July 2011, Russell Gasdia, John Stewart, and other Executive Committee members prepared to involve Richard Sackler even more intimately in Purdue's day-to-day marketing activities. Towards those ends, Russell Gasdia wrote to Richard Sackler:

> In addition to field contacts with representatives, you may want to consider attending one of the upcoming conventions where we will be attending. At each of the ones I listed below, we will have a promotional booth for OxyContin & Butrans. In addition, we are sponsoring educational programs for Butrans and OxyContin in the form of a 'Product Theater.'
>
> This would provide you the opportunity to be on the convention floor, observing numerous presentations being

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[596] PPLPC012000329783.
[597] PPLPC001000091102.
[598] *Id.*

> provided by our representatives and see a wide range of interactions over the course of a day. In addition, we can arrange for one-on-one meetings with key opinion leaders who are attending, many of them are approved consultants/advisors for us and you can have some open conversations regarding the market, perceptions around Butrans and OxyContin. Finally, you could observe the Product Theaters we are implementing.[599]

527. The Sacklers were so obsessed with Purdue's sales force that they even involved themselves in the scheduling of sales visits. By January 2012, Purdue had increased its sales force to 632 representatives.[600] Yet, in February 2012, Russell Gasdia reported to the Sacklers on a drop in opioid prescriptions driven by a decrease in sales visits during the winter holidays and because of a mandatory National Sales Meeting.[601] Not wanting prescribers to go even a month without a personal visit from a Purdue sales representative, Mortimer Sackler suggested in an email to Russell Gasdia (copying Richard, Kathe, Jonathan, and Theresa Sackler):

> Wouldn't it be better to have the reps get back to work for January and back in front of doctors who enter the new year refreshed and ready to take on new information and challenged and hold the sales meeting the beginning of Feb? At least then the doctors will have gotten at least one reminder visit from our reps in the last month whereas now they might go two months without seeing one of our reps?[602]

528. Richard Sackler responded minutes later (copying the same individuals): "Maybe the thing to have done was not have the [National Sales Meeting] at all."[603]

529. After learning from his weekly sales reports that Purdue's opioid prescriptions temporarily dropped over the 2012 President's Day holiday week,

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[599] PPLPC012000336250.
[600] PPLPC012000362250, 291.
[601] PPLPC026000095656.
[602] *Id.*
[603] *Id.*

Richard Sackler responded, "This is bad." Growing exasperated with Richard Sackler's micromanagement, Russel Gasdia pleaded with John Stewart:

> It isn't constructive to spend too much time on [the weekly sales reports] as opposed to expending energy within my department of identifying the problem, developing the solutions and gaining implementation. Anything you can do to reduce the direct contact of Richard into the organization is appreciated. I realize he has a right to know and is highly analytical, but diving into the organization isn't always productive.[604]

530. John Stewart empathized with Russell Gasdia's complaint, but saw no solution to the Sacklers' obsession with sales data:

> I work on this virtually every day, some with more success than others. You are right about the ultimate solution, and in the meantime when [Richard Sackler] does ask for data – I find it best to just give it to him, but at the same time repeat what i/we [*sic*] feel. Do ask David [Purdue's Director of Forecasting, Analytics & Market Research] to keep copying me on his replies to [Richard Sackler], since it is those that spur me to get involved directly.[605]

531. In a June 2012 Board update, John Stewart, Russell Gasdia, and other Executive Committee members presented the Sacklers with data showing that opioid savings cards led to 60% more patients remaining on OxyContin longer than 90 days. In that same presentation, the Sacklers reviewed Purdue's internal data showing that the savings cards kept more patients on opioids for 90 days, 120 days, 150 days, 180 days, 240 days, and even an entire year.[606]

532. In January 2013, John Stewart, Russell Gasdia, Craig Landau, David Haddox, and the Purdue sales force, continued the Sacklers' strategy to push savings cards as a means to increase opioid dosages and the duration of patients' opioid treatment. Specifically, John Stewart, Russell Gasdia, Craig Landau, and

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[604] PPLPC012000368569.
[605] *Id.*
[606] PPLPC012000382119.

other Executive Committee members told the Sacklers that the savings cards were redeemed 44,877 times in Q4 2012 with 696,551 total redemptions for all of 2012.[607]

533. In mid-2013, John Stewart made a presentation to the Sacklers blaming a decrease in sales on a reduction in high dosage opioid prescriptions. To reverse that trend, John Stewart, Russell Gasdia, and other Executive Committee members planned to increase sales visits, focus on the *Individualize the Dose* campaign, and promote the savings cards.[608] At the same time, the Executive Committee reported back to the Sacklers that Purdue was using the savings cards on sales visits, and sending them via U.S. mail and email to prescribers in Colorado and around the country, to get patients to "remain on therapy longer."[609]

534. By July 2013, when opioid use was at its apex in Colorado and throughout the country, the Sacklers grew increasingly concerned about negative sales projections for opioids – projections blamed on the public's growing wariness about long-term opioid therapy. Purdue asked McKinsey to analyze these trends and make recommendations for reversing the projected declines.

535. At the end of July 2013, the Sacklers met to discuss McKinsey's report, *Identifying Granular Growth Opportunities for OxyContin: First Board Update*. In that report, McKinsey confirmed that Purdue's sales visits generated opioid prescriptions and urged an increase of the sales force and of the quota for sales visits. McKinsey also recommended that Purdue exert more control over the sale force's target list to focus on prescribers that provide the biggest payoff – high-volume prescribers and those willing to prescribe high dosage opioids. McKinsey also recommended to the Sacklers that Purdue's sales staff should push savings cards in neighborhoods with high concentrations of Walgreens pharmacies. In order to target the promotion of high dosage opioids, McKinsey also recommended that Purdue obtain "prescriber level milligram data" so the company could analyze the doses prescribed by individual health care providers.[610]

536. In August 2013, the Sacklers met again to discuss a follow-up report from McKinsey, *Identifying Granular Growth Opportunities for OxyContin:*

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[607] PPLPC012000407139.
[608] PPLPC012000424611, 621.
[609] PPLP004367557.
[610] PPLP004409871.

Addendum to July 18th and August 5th Updates. In the Addendum, McKinsey recommended that Purdue take immediate steps to increase sales.[611]

537. First, McKinsey recommended that Purdue focus its sales force intensely on high-volume opioid prescribers. According to McKinsey, the more prolific opioid prescribers write "25 times as many OxyContin scripts" as lower volume prescribers. McKinsey also reported that increased attention by the sales force on these high-volume prescribers would cause them to write even more opioid prescriptions.[612]

538. Second, McKinsey urged the Sacklers to fight back against efforts by the DEA, U.S. DOJ, and others to curb illegal drug sales. For example, according to McKinsey, after Walgreens admitted to filling illegitimate opioid prescriptions a "deep examination of Purdue's available pharmacy purchasing data shows that Walgreens had reduced its units by 18%." Even worse for Purdue's bottom line and the Sacklers' fortune, "the Walgreens data also shows a significant impact on higher OxyContin dosages," specifically 80mg OxyContin. McKinsey urged the Sacklers to lobby Walgreens to relax its controls and/or develop a "direct-to-patient mail order" business so Purdue could skip pharmacies all together.[613]

539. Third, McKinsey suggested that the Sacklers insist on increasing sales with monthly accountability. McKinsey understood what was at stake for the Defendants' fortunes: "the value at stake is significant – hundreds of millions, not tens of millions." McKinsey was confident in their recommendations and urged Purdue and the Sacklers to make a "clear go-no go decision to 'Turbocharge the Sales Engine.'"[614]

540. In September 2013, implementing McKinsey's recommendations, John Stewart initiated *Project Turbocharge* in order to increase OxyContin sales.[615] The *Turbocharge* campaign would soon thereafter be rebranded internally by Purdue as the *Evolve to Excellence* ("E2E") campaign.[616] E2E would be the theme of the 2014 National Sales Meeting and Purdue "integrated McKinsey into various teams, in order to provide added resources and support, as [Purdue] begins to implement this

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[611] PPLP004409892.
[612] *Id.*
[613] PPLP004409896-897.
[614] PPLP004409897-898.
[615] PPLPC012000436626.
[616] PPLPC012000441854-858; PPLPC012000442736.

project. [McKinsey's] experiences with other clients will help [Purdue] to increase our effectiveness."[617]

541. In September and October 2013, the Sacklers met to discuss further implementation of McKinsey's recommendations, including McKinsey's recommendation that Purdue push back on the federal government's crackdown on suspicious opioid prescribing and dispensing. Specifically, the Sacklers discussed the DEA's crackdown on opioid dispensing at CVS and Walgreens, and how Purdue could get around the new safeguards with McKinsey-recommended mail-order pharmacies, specialty pharmacies, or Purdue-to-patient direct opioid dispensing.[618]

542. Also in October 2013, Mortimer Sackler and the other Sacklers requested from the Executive Committee, including Russell Gasdia and John Stewart, "the breakdown of OxyContin market share by strength."[619] Russell Gasdia, John Stewart, and the rest of the Executive Committee told the Sacklers that "high dose prescriptions are declining" and "there are fewer patients titrating to the higher strengths from the lower ones."[620] The Executive Committee explained the continued downward trends by pointing to pharmacies that implemented "good faith dispensing" and prescribers that had come under pressure from the DEA for suspicious opioid prescribing.[621]

543. Later that month, the Sacklers met to discuss budgets and forecasts for 2014.[622] Russell Gasdia and John Stewart told the Sacklers that growing opioid aversion in the health care community was causing prescribers to prescribe fewer opioid pills and lower strengths, which would cost Defendants millions of dollars in lost sales.[623] To combat this threat, the decision was made that Purdue's sales force would increase their visits to health care providers to 7.3 per day and that they would make 758,164 visits in 2014.[624]

544. In November 2013, the Executive Committee, including Mark Timney, told the Sacklers that the savings cards were paying off. A July 2013 analysis showed that the savings cards being distributed by Purdue's sales force and via U.S. mail, email, and online to tens of thousands health care providers were increasing

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[617] PPLPC012000441611, 614; PPLPC012000441799; PPLPC012000442736.
[618] PPLP004409919; PPLP004409965-972.
[619] PPLPC012000448835.
[620] PPLPC012000448832-833.
[621] PPLPC012000448833.
[622] PPLPC012000448832; PPLP004409987.
[623] PPLP004409989.
[624] PPLP004409999.

revenues by keeping patients on OxyContin 60 days and longer.[625] The Executive Committee also reported back to the Sacklers that the savings cards were being pushed by the sales force on sales visits, as well as by mail, email, and online to tens of thousands of prescribers in Colorado and throughout the country.[626] In none of these meetings did the Sacklers, or anyone else, discuss whether Purdue should disclose the increased risks associated with longer durations of opioid treatment or whether Purdue should disclose to prescribers or patients that the savings cards were intended to and did cause patients to be on opioids longer.

545. The Sacklers' strategy to keep patients on opioids longer was also implemented for Purdue's Butrans launch. Also in November 2013, members of the Executive Committee, including Mark Timney, reported back to the Sacklers that sales and marketing had generated 266,842 new Butrans prescriptions and the savings cards generated especially "high returns."[627] Soon after becoming CEO in 2014, Mark Timney reviewed the same savings card analysis and similarly showed no interest in disclosing the true intent behind, and the risks associated with, Purdue's savings cards.[628]

546. Even as Purdue's opioid sales declined in a more competitive opioid market, the Sacklers continued to push their sales team to use savings cards as a means to increase sales by getting patients on opioids longer. In Colorado, Purdue's sales representatives pushed the savings cards on health care providers or patients in Colorado at least 34,000 times since 2006.[629]

547. Only a few months after its launch, in December 2013, John Stewart was already providing reports to Kathe Sackler and Russell Gasdia on the weekly growth of Butrans and OxyContin under the McKinsey-inspired E2E campaign:

> Burans [*sic*] has had a fourth consecutive week of hitting a new 'high,' and appears to break through the 12,000 [prescriptions] per week level. OxyContin prescriptions were up slightly, but certainly not to a record level. Also, the growth in OxyContin is primarily occurring in the lower strengths – so total kilograms (which track more closely with actual sales) are still showing a declining

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[625] PPLPC002000186925.
[626] PPLPC002000186925-926, 933-934.
[627] PPLPC002000186921-23, 937.
[628] PPLPC002000186910.
[629] PCO000000002.

> trend. Nevertheless, both trends are more positive than was the case a few months back, and when the E2E Project (the changes arising out of the McKinsey analysis) is fully implemented there will certainly be additional increases.[630]

548. Also in late 2013, Jonathan Sackler surveyed media reports on the opioid epidemic, concerned that the reporting was biased against Purdue's role in the crisis. Around the same time, staff contacted Richard Sackler because there were concerns that Purdue's "internal documents" could cause problems if investigations of the opioid crisis expanded. Early the next year, staff expressed the same concerns to Jonathan Sackler.[631]

549. In June 2014, responding to stories published by the *Los Angeles Times* in 2012 and 2013 about opioid deaths and Purdue's *Region Zero* program, members of the Executive Committee, including Mark Timney, gave the Sacklers an update on their efforts to "mitigate the impact" of the stories:

> As you may recall, one of our efforts to mitigate the impact of a potential negative *Los Angeles Times* (LAT) story involved assisting a competing outlet in marginalizing the LAT's unbalanced coverage by reporting the facts before the LAT story ran. The following *Orange County Register* story, developed in close coordination with Purdue, achieved its goal. This fact-based narrative robs the LAT account of its newsworthiness and contradicts many of the claims we expected that paper to make.[632]

550. A few weeks later, after receiving a call from a *L.A. Times* reporter, Richard Sackler asked for all communications between Purdue and the *L.A. Times*. In seeking comment from Richard Sackler, the *L.A. Times* reporter told him, "[w]e are going to these extraordinary lengths to contact you because we want to get [the story] right. Given your family's generations of work building Purdue and your own long history at the company, I would imagine you share that desire."[633]

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[630] PPLPC012000454422.
[631] PPLPC020000748356; PPLPC020000748356.
[632] PPLPC022000741863.
[633] PPLPC024000872837.

551. Also in June 2014, the Sacklers removed Russell Gasdia as Vice President of Sales and Marketing. However, the Sacklers continued to be just as involved in his successor's day-to-day activities.[634] As Russell Gasdia warned his successor, "there are times this becomes a tennis match with Dr. Richard [Sackler]."[635]

552. Later that year, after reviewing news reports about the State of Kentucky's lawsuit against Purdue for deceptive marketing of opioids, Purdue staff discussed their concerns that Purdue faced claims of more than a billion dollars that "would have a crippling effect on Purdue's operations and jeopardize Purdue's long-term viability." Purdue's communications staff, in an email exchange that included David Haddox, appeared less concerned: "I'm quite pleased with where we ended up. There's almost nothing on the Sacklers and what is there is minimal and buried in the back."[636]

553. The 2014 turnover in sales management did not change the Sacklers' thirst for detailed sales projections. The Sacklers continued to direct and control the new Vice President of Sales and Marketing and Purdue's entire sales operation. On New Year's Eve 2014, Richard Sackler told Mark Timney and other Executive Committee members and staff that he wanted to explore a confidential plan for the price of OxyContin going forward.[637]

554. A few days later, in early January 2015, Richard Sackler requested a meeting with Mark Timney and other Executive Committee members, as well as with sales staff, to review plans for selling higher dosages of OxyContin.[638] Richard Sackler demanded data within five days on:

> [U]nit projections by strength, mg by strength … pricing expectations by strength … individual strength's market totals and our share going backward to 2011 or 12 and then forward to 2019 or 2020 … the same information for Hysingla … [and] the history of OxyContin tablets from launch to the present.[639]

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[634] PPLPC012000483200.
[635] PPLPC012000483223.
[636] PPLPC014000279784-786; PPLPC017000579723.
[637] PPLPC021000713329-330.
[638] PPLPC021000713328.
[639] PPLPC022000797067-068.

555. When Mark Timney told Richard Sackler the requested work would take three weeks, Richard Sackler responded, "[t]hat's longer than I had hoped for," and he directed Executive Committee members and marketing staff to start sending him responsive materials immediately.[640]

556. In April 2015, staff told the Sacklers that sales of 80mg OxyContin were down 20% and that the average prescription had declined by eight pills since 2011.

557. As 2015 ended, and the Sacklers again began expanding Purdue's sales force for 2016, Mark Timney and the rest of the Executive Committee prepared to address wide-ranging concerns raised by the Sacklers.[641] Kathe and Mortimer Sackler wanted a breakout of productivity data by indication versus prescriber specialty for each opioid drug. Richard Sackler sought details on how staff was calculating 2016 mg/tablet trends. Jonathan Sackler sought a follow-up briefing on how public health efforts to prevent opioid addiction would affect OxyContin sales.[642]

3. The Sacklers tried to profit from the opioid epidemic

558. Purdue's opioid sales continued to decline from 2015 to 2018, but the Defendants would not avert their laser focus on Purdue's sales force as a way to recapture the high-volume opioid sales from years earlier. Ever the profit seekers, Defendants began also exploring how they could profit from the opioid epidemic they fueled.

559. In June 2016, for example, the Sacklers met to discuss Purdue's *Project Tango* – a plan to sell opioid abuse and overdose treatments – and devise a specific plan to sell the overdose antidote NARCAN. The Executive Committee, including Mark Timney, reported back to the Sacklers that "[NARCAN] could provide $24M in net sales to Purdue." The Sacklers knew exactly how to capitalize on the growing market for NARCAN to reverse the deadly impacts of the opioid epidemic Defendants caused.[643] Even though he was President and CEO of Purdue Canada at this time, Craig Landau also participated in this report to the Sacklers.

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[640] PPLPC022000797067.
[641] PPLPC011000069975, 69977, 70000.
[642] PPLPC011000073228; PPLPC011000073230.
[643] PPLPC011000099222; PPLPC011000099280-283, 348.

560. Recognizing how effective their sales force was at influencing health care providers and increasing opioid prescriptions, the Sacklers, Mark Timney, Craig Landau, and Executive Committee members specifically identified patients on Purdue and Rhodes's opioids as the target market for NARCAN. Their plan called for studying "long-term script users" to "better understand target end-patients" for NARCAN. Likewise, they identified the high-volume opioid prescribers they had been targeting for years as the best target market for NARCAN; they planned to "leverage the current Purdue sales force" to "drive direct promotion [of NARCAN] to targeted opioid prescribers." Defendants even shamelessly sought to profit from government efforts to use NARCAN to save lives, including the Colorado Attorney General's efforts.[644]

561. As the opioid epidemic continued to ravage Colorado and the rest of the country, Mark Timney received regular internal reports in 2016 that summarized media coverage of the opioid epidemic, including stories of people overdosing, drug abuse chatroom chatter, and more.[645] In September 2016, Mark Timney and the Sacklers also received "Communications Strategy Recommendations" from a third party consultant. The primary "Goal" of that strategy was to "**contain and mitigate the reputational harm to Purdue Pharma and the Sackler family as a result of multiple investigations and litigation, press leaks and critical media coverage.**" (emphasis in original) While the secondary "Goals" of that strategy included highlighting Purdue's "awareness of" and "leadership in helping address the problem," they also sought to "educate the media, regulators, politicians, law enforcement and the general public about Purdue Pharma's modest market share – 'share the spotlight' with other market participants" and " shift attention to fentanyl and other opioids." The strategy also recommended deploying Mark Timney to "humanize the Company."[646]

562. The strategy also recommended that Purdue continue its well-worn and effective efforts to "secure commitments from third-party surrogates to convey messaging and act as independent advocates for the Company, including doctors, academics, policymakers and other key opinion leaders."[647]

563. The "leadership" Purdue sought to highlight included a focus on Purdue's abuse-deterrent formulas for opioids.[648] The strategy conveniently did not disclose that fact that abuse-deterrent OxyContin could be just as easily abused by

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[644] *Id.*
[645] PPLPC023000922832-836.
[646] PPLPC021000863236.
[647] *Id.*
[648] *Id.*

swallowing the pills – a fact well known to Purdue, the Sacklers, and the other individual Defendants.

564. In January 2017, Jonathan Sackler and Mark Timney met with a U.S. Senator about the "future of Purdue," including the company's promotion of abuse-deterrent OxyContin and other opioids.[649]

565. In that same year, Craig Landau drafted a letter to send to insurance carriers accusing Purdue's competitors of deceiving prescribers about abuse-deterrent forms of oxycodone – the very same thing Purdue had been doing years. Craig Landau also admitted what Purdue had known for years, that "no [abuse-deterrent opioid] is abuse-proof and no [abuse-deterrent opioid] prevents or reduces the risk of addiction for a patient taking the medication." Craig Landau also ironically acclaimed that "[Purdue] firmly believe[s] that too many opioids are prescribed today."[650] Of course, Craig Landau did not acknowledge Purdue's decades-long strategy to flood the market with prescription opioids in order to boost Purdue's profits and line the Sacklers' pockets with billions of dollars.

566. While the faces around them changed over the years, the Sacklers at all times controlled and directed Purdue and/or participated in, cooperated with, or sanctioned Purdue's conduct. In his May 2017 presentation to the Sacklers, aptly entitled "Sackler Pharma Enterprise," soon-to-be Purdue CEO, Craig Landau, acknowledged what had always been true about Purdue's business: "Three distinct business types (branded [prescriptions]/Biosimilars, consumer/[over-the-counter], generics) are being run through four separate regions (five if Rhodes is included), with the *Board of Directors serving as the 'de-facto' CEO*."[651] (emphasis added)

VII. DEFENDANTS' DECEPTIVE AND RECKLESS CAMPAIGN HAD A TREMENDOUS IMPACT ON COLORADO HEALTH CARE PROVIDERS AND THE PUBLIC

567. Defendants' decades-long misinformation campaign played out in Colorado, as it has throughout the country, with dire consequences. Purdue, Rhodes, the Sacklers, and the other individual Defendants were well aware of these consequences but, tempted by billions of dollars in profit, they ignored their duty to mitigate the harm being caused to Colorado by their deceptive and reckless business practices.

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[649] PPLPC011000133807-808.
[650] PPLPC016000318811.
[651] PPLPC020001106306.

A. Defendants' Deceptive and Reckless Campaign Influenced Colorado Prescribers Resulting in Skyrocketing Opioid Sales

568. Purdue's unbranded marketing campaign, facilitated by Purdue's sales force, Front Groups, and Key Opinion Leaders, effectively relaxed Colorado prescribers' skepticism about prescribing opioids and expanded their use throughout the State.

569. Purdue's sales force used unbranded opioid CME materials 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."[652] (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."[653] (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."[654] (May 12, 2010)

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[652] PCO000000002 Row: 40448 (02/22/2010).
[653] PCO000000002 Row: 41442 (03/11/2010).
[654] PCO000000002 Row: 44690 (05/12/2010).

570. 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:

- 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."[655] (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!"[656] (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."[657]

- 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]."[658]

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[655] PCO000000001 Row: 2303 (01/31/2011).
[656] PCO000000001 Row: 4686 (10/11/2012).
[657] PCO000000002 Row: 108682 (08/05/2013).
[658] PCO000000002 Row: 108265 (07/29/2013).

- And, as one Colorado family medicine practitioner told a Purdue sales representative, "she just has never been comfortable [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."[659] (July 2, 2015)

571. Purdue designed its sales and marketing practices to overcome Colorado 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 force for extended periods of time, significantly increased the number of prescriptions they wrote, resulting in more opioid use in Colorado and increased incidents of opioid diversion, addiction, overdose, and death.

B. Defendants Failed to Monitor and Report Suspicious Prescribers in Colorado

572. As manufacturers of highly addictive and dangerous controlled substances, Defendants, including Purdue and Rhodes, had a duty to report suspicious and/or illegal prescribing of their opioids to the proper authorities. Under common law, Defendants have a duty to exercise reasonable care in the delivery of their narcotic substances into Colorado's marketplace. By flooding Colorado with excessive amounts of prescription opioids, many of which Purdue, Rhodes, and the individual Defendants knew were being diverted to or through illegitimate channels for consumption, and by failing to report any Colorado prescribers suspected of engaging in such diversion, Defendants breached that duty and created a foreseeable risk of harm to Colorado.

573. From at least the early 2000s, Purdue and Rhodes maintained internal systems to monitor suspicious opioid-related activities, including RADARS and another called the "Abuse and Diversion Detection" ("ADD") system. The ADD system, and any others like it used by Purdue and/or Rhodes, were wholly inadequate to fulfill thier stated purpose to detect and prevent abuse and diversion of Purdue and Rhodes's opioids. The ADD system, for example, was comprised of *ad hoc* manual reviews of sales force call notes, media reports, internet searches, and prescribing records to identify instances of opioid abuse, diversion, and/or other adverse events.[660] The ADD system did little, if anything, to stem the flood of

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[659] PCO000000002 Row: 146748 (02/07/2015).
[660] PPLPC011000127202.

Purdue and Rhodes's opioids into illegitimate or illegal prescription and consumption channels in Colorado and throughout the country.

574. Despite their deep flaws, Defendants used internal monitoring systems, like ADD, to monitor suspicious prescribers until at least as late as 2016. Purdue, for example, used the ADD system to identify *Region Zero* prescribers, as discussed in more detail below. However, as an indication of how inadequate the ADD system was, Defendants rarely, if ever, reported any *Region Zero* or other suspicious prescribers to the appropriate authorities. In the rare instance in which Defendants did report suspicious opioid prescribers to the authorities, it was almost always after Defendants knew that the prescriber was already under investigation by the authorities.

1. Region Zero

575. Defendants' failure to monitor and report suspicious prescribers was not for lack of information about such suspicious individuals. Purdue and Rhodes maintained vast amounts of data on individual health care providers and their prescribing of Purdue and Rhodes's opioids, as well as for opioids sold by their competitors. At all relevant times, Defendants were in possession of national, regional, state, and local prescriber and patient-level data that they purchased from third party vendors, including IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science. In many instances, this data allowed Defendants to track Purdue and Rhodes's opioid prescriptions by individual prescriber per month going back decades.

576. While the prescribing data maintained by Defendants was rarely used to report suspicious prescribers, it was integral to their scheme to expand the prescription opioid market. The prescribing data was regularly and thoroughly mined by Purdue and Rhodes, with the assistance of McKinsey, to identify high-volume prescribers. That information was then passed on to the Sacklers and other individual Defendants in order for them to direct more effective marketing strategies.

577. The prescribing data was specifically used to identify "Super Core" and "Core" prescribers in Colorado, as discussed above. Defendants' use of this data for their financial gain oftentimes ran head-on into their duty to monitor suspicious prescribers and report them to the authorities. When Defendants did identify suspicious prescribers, they rarely reported them to the authorities. Instead,

Defendants simply moved the suspicious prescribers into an internal do-not-call list called *Region Zero* and watched as those suspicious prescribers continued to prescribe Purdue and Rhodes's opioids.

578. Information on the *Region Zero* prescribers were reported directly to the Sacklers and other individual Defendants. For example, at the July 2010 Board meeting in Bermuda, the Sacklers asked Purdue's Executive Committee about opioid sales generated by prescribers suspected of opioid diversion and abuse, *i.e. Region Zero* prescribers. Russell Gasdia, Craig Landau, and other members of Purdue's Executive Committee assured the Sacklers that Purdue tracked prescriptions by *Region Zero* prescribers and "no call" pharmacies, including the exact prescriptions, units, and dollars earned from each prescriber.[661] At that time, Russell Gasdia, Craig Landau and other member of Purdue's Executive Committee told the Sacklers that Purdue had identified seven Colorado prescribers likely involved in opioid diversion and abuse. Executive Committee members gave the Sacklers the specific names of the suspicious Colorado prescribers, the physical address for each prescriber, along with the exact number of prescriptions written and dollars of revenue generated for Defendants by each prescriber.[662]

579. Defendants tracked *Region Zero* providers in Colorado for years, and by 2018 there were at least 67 Colorado prescribers listed in *Region Zero*. At least 27 of those *Region Zero* prescribers were originally Purdue "Super Core" or "Core" targets. Of the 67 *Region Zero* prescribers in Colorado, Purdue placed 49 of them on the no-call list due to concerns about their OxyContin prescribing. From 2001 to 2017, those 49 *Region Zero* prescribers in Colorado prescribed *at least* 7.9 million OxyContin pills, which averaged more than 160,000 OxyContin pills each.[663]

580. Despite maintaining detailed information on *Region Zero* prescribers and no-call pharmacies, Purdue, Rhodes, the Sacklers, and the other individual Defendants ignored suspicious prescribers and pharmacies so long as they were making Defendants money. Purdue moved suspicious prescribers to *Region Zero* and sales representatives stopped visiting them only after the authorities became involved, and oftentimes well after Defendants knew an investigation was opened.

581. For many Colorado patients, Defendants' scant reporting was too little too late. Colorado prescribers had been subjected to years of Purdue's aggressive deception, and even when red flags were raised, Purdue's sales force continued to

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[661] PPLPC012000283169-170.
[662] PPLPC012000283162; PPLPC012000283175.
[663] PWG003984539

push these health care providers to prescribe more opioids at higher doses. As a result, thousands of Colorado patients became addicted to opioids and/or died from overdoses. The following prescribers were all Purdue "Super Core" prescribers and later moved to *Region Zero* after they came under investigation by authorities.

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

582. 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.

583. Purdue's detailers visited Dr. O.C. over 340 times from January 2006 to February 2016, or almost three times every month.[664] They also visited Ms. A.G. specifically over 315 times from May 2006 to January 2016, also almost three times every month.[665]

584. 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."[666]

585. According to Purdue's records, Dr. O.C. was the top OxyContin prescriber in Colorado, writing over 19,000 prescriptions for OxyContin alone from January 1998 to October 2016.[667] 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.[668]

586. 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

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[664] PCO000000002.
[665] *Id.*
[666] *Id.* at Row: 12185 (01/03/2008).
[667] PWG003984533.
[668] PWG003984539.

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.[669]

587. On one of those post-disciplinary sales calls, on June 3, 2014, during which Purdue's detailer wanted to determine Dr. O.C.'s "biggest problem with long acting opioids," 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."[670] In response, Purdue's detailer coached Dr. O.C. on "how he talks to families about addiction."[671]

588. 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. Many of those prescriptions were for OxyContin and/or generic oxycodone.

589. 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.[672] That amounted to over 900,000 OxyContin pills, almost 50% of which were 40mg or stronger and almost 10% of which were 80mg.[673]

590. 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 and diversion."[674] When Ms. A.G. first started working for Dr. O.C. , she 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]."[675]

591. 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

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[669] PCO000000002.
[670] *Id.* at Row: 123661 (06/03/2014).
[671] *Id.*
[672] PWG003984533.
[673] PWG003984539.
[674] PCO000000002 Row: 153 (01/19/2006).
[675] *Id.* at Row: 2019 (05/15/2006).

"she seems to be surprised because she had been trained that OxyContin leads to abuse."[676]

592. Although Purdue's internal records show that Ms. A.G. wrote more and more prescriptions for OxyContin,[677] Purdue was not satisfied and their detailers continued to push Ms. A.G. to prescribe OxyContin to more of her patients, utilizing the drug "sooner in the process."[678]

593. 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.

594. Ms. A.G.'s license was voluntarily surrendered in February 2017 after the Board of Nursing Examiners 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.

Dr. D.H., M.D.

595. 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.

596. Purdue began detailing Dr. D.H. in November 2008.[679] 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.[680] Only a couple of weeks later, on January 9, 2009, Purdue's detailer visited Dr. D.H. again to discuss Purdue's savings cards and Dr. D.H. "agreed to switch his patients who fit the criteria."[681]

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[676] *Id.* at Row: 3014 (07/17/2006).
[677] PWG003984533; PWG003984539.
[678] PCO000000002 Row: 18277 (10/01/2008).
[679] PCO000000002.
[680] *Id.* at Row: 21392 (12/15/2008).
[681] *Id.* at Row: 22194 (01/09/2009).

597. 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."[682] As early as this visit, the Purdue sales representative noted that Dr. D.H. "does worry about some [patients] abusing the meds."[683]

598. 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."[684] 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."[685]

599. 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.[686]

600. 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. 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 generic oxycodone 30mg tablets and 60 Opana 30mg tablets, an oxycodone drug manufactured by one of Purdue's competitors.

601. 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 generic 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

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[682] *Id.* at Row: 23078 (02/09/2009).
[683] *Id.*
[684] *Id.* at Row: 30122 (07/16/2009).
[685] *Id.* at Row: 39581 (02/03/2010).
[686] *Id.* at Row: 45921 (06/04/2010).

OxyContin tablets and increased the other generic oxycodone prescription to 600 30mg tablets.

602. 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.[687]

603. 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.

604. 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.[688]

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

605. 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 OxyContin or generic oxycodone tablets.

Dr. K.C., D.O.

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

607. Purdue's sales representatives began detailing Dr. K.C. on January 26, 2006, with the goal of making him a high-volume 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."[689]

608. 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."[690] 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."[691]

609. On April 6, 2010, after 19 more sales visits, a Purdue sales representative asked Dr. K.C. about an alleged forged prescription reported to 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."[692]

610. 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

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[689] PCO000000002 Row: 8104 (05/10/2007).
[690] *Id.* at Row: 18287 (10/01/2008).
[691] *Id.*
[692] *Id.* at Row: 42855 (04/06/2010).

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."[693] The May 13 visit was Purdue's last to Dr. K.C.'s office.[694] 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.

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

612. Between January 26, 2006 and May 13, 2010, Purdue visited Dr. K.C.'s office 95 times, nearly twice a month.[695]

613. 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]."

614. Dr. K.C. was one of the Colorado *Region Zero* prescribers reported by Russell Gasdia, Craig Landau, and other Purdue staff directly to the Sacklers at the July 2010 Board meeting in Bermuda.[696]

615. 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.

616. Defendants rarely, if ever, reported suspicious opioid prescribers to federal, state, or local authorities in Colorado. In the rare instance in which

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[693] *Id.* at Row: 44767 (05/13/2010).
[694] *See generally, id.*
[695] *See generally* PCO000000002.
[696] *See supra* ¶ 578.

Defendants did report suspicious prescribers, it was almost always after Defendants knew that the prescriber was under investigation by the authorities. For example, Defendants did report Dr. K.C., Dr. O.C., and Ms. A.G. to the authorities, but according to Purdue's records, only after Defendants knew those individuals were under investigation or had been subject to disciplinary action.

C. Defendants' Deceptive and Reckless Campaign Resulted in Significant Harm and Losses to the State of Colorado and its Citizens

617. Defendants' deceptive and reckless conduct, as alleged in this First Amended Complaint, which occurred in the course of Defendants' 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 Defendants, and will continue to do so for years to come.

618. In 2006 alone, more than 2.9 million opioid prescriptions were written in Colorado, a rate of approximately 62.2 prescriptions dispensed per 100 persons.[697] Approximately 15,000 of those were prescriptions for OxyContin alone, which equates to about 1.3 million OxyContin tablets that year.[698]

619. Opioid prescribing in Colorado peaked in 2012 at nearly 3.9 million prescriptions, a rate of 73.5 prescription per 100 residents.[699] Approximately 123,000 of those were for OxyContin prescriptions alone, which equates to approximately 8.3 million OxyContin tablets distributed in Colorado that year.[700]

620. From 2006 to 2012, opioid prescriptions in Colorado increased by about 30%.[701] OxyContin prescriptions in Colorado during the same time increased by

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[697] 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 June 26, 2019).
[698] PWG003984533; PWG003984539.
[699] 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 June 26, 2019).
[700] PWG003984533; PWG003984539.
[701] 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 June 26, 2019); 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 June 26, 2019); Center for Disease Control and Prevention, *U.S. Prescribing Rates, 2012*

approximately 700%, and the number of OxyContin tablets distributed in Colorado during that time increased by approximately 500%.[702]

621. 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.[703] For most years, this translated to an opioid prescription for two out of every three Coloradans.

622. 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.[704] During this period, opioid-related overdose deaths in Colorado (excluding heroin) increased more than 409%.[705] 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.[706]

623. Overdose deaths in Colorado over the last two years would have been even worse had the Attorney General not facilitated the supply of naloxone 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 potentially prevent death. Since mid-2016, there have been more than 400 overdose reversals in Colorado using naloxone.[707]

624. 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

(July 31, 2017), https://www.cdc.gov/drugoverdose/maps/rxstate2012.html (last visited June 26, 2019); United States Census Bureau (Mar. 23, 2017), https://www2.census.gov/programs-surveys/popest/datasets/2010-2016/counties/totals/ (last visited June 26, 2019).

[702] PWG003984533; PWG003984539.

[703] 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 June 26, 2019).

[704] 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 June 26, 2019).

[705] *Id.*

[706] *Id.*

[707] Interim Committee Opioid and Other Substance Use Disorder Committee, Testimony of [former] 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 (last visited June 26, 2019).

Coloradans, and opioid-related hospitalizations for an overdose were at the rate of 18.6 per 100,000 Coloradans.[708] 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.[709]

625. 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 1328 in 2006 to nearly 2,400 in 2016.[710] 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[711]—with most facilities having long waiting periods to serve new patients.

626. Many rural communities throughout Colorado have no OTP facilities and few, if any, practitioners providing medication-assisted treatment on an out-patient basis.[712] Thus, as a result of Defendants' conduct, there is significant need for dramatically expanded OTP and outpatient services.

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[708] 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.

[709] 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 June 26, 2019).

[710] 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.

[711] Colorado Department 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*.

[712] 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 June 26, 2019).

627. The impact of Defendants' 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%.[713] 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 percent increase in just eight years.[714]

628. Additional impacts in Colorado caused by Defendants' 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.

629. The State of Colorado has been harmed by Defendants' conduct directed to and occurring in Colorado and is expending its resources to address the opioid epidemic created by Defendants, and will continue to do so. State programs impacted by Defendants' 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;
- State workers' compensation benefits;
- Criminal justice system, including law enforcement, criminal prosecutions, probation, community corrections, imprisonment, and parole;
- College/university health facilities;
- Increased costs for first responders, including the provision of naloxone to first responders across Colorado;
- Adult protective services;

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[713] Sarah C. Haight et al., *Opioid Use Disorder at Delivery Hospitals—United States, 1999*-2014, 67 Morbidity & Mortality Weekly Report 845, 847 (2018).
[714] 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 June 26, 2019).

- 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.

630. The damages suffered by the State of Colorado and its citizens were foreseeable by Defendants.

631. Defendants' conduct was the proximate cause of the injuries suffered by the State of Colorado and its citizens.

VIII. THE SACKLERS DRAINED PURDUE OF MONEY AND ASSETS ATTEMPTING TO AVOID RESPONSIBILITY FOR THE OPIOID EPIDEMIC THEY CREATED

632. Shortly after the Sacklers voted to have Purdue and the company's executives plead guilty in 2007 and agree to the States' Consent Judgments, the family began draining Purdue of *billions* of dollars and other assets for their personal benefit.

633. The Sacklers fraudulently transferred billions of dollars and assets for their personal benefit through a complex web of corporate entities, all of which the Sacklers owned and directed. That web of corporate entities includes, but is not limited to, Coventry Technologies, L.P., PLP Associates Holdings, L.P., PLP Associates Holdings, Inc., Rosebay Medical Company, L.P., The Beacon Company, Purdue Holdings, L.P., and BR Holdings Associates, L.P.

634. Coventry Technologies, L.P. owns Rhodes and directs the profits from Rhodes's generic opioids to trusts owned and operated for the benefit of the Sacklers. Coventry Technologies, L.P. also owns other Rhodes and Purdue

affiliates, like Rhodes Technologies, Inc., which at least as early as 2005 sold all of the oxycodone Purdue used to manufacture OxyContin.

635. PLP Associates Holdings, L.P. is a limited partner of Purdue Holdings, L.P. The partners of PLP Associates Holdings, L.P. are PLP Associates, Inc. and BR Holdings Associates, L.P.

636. Purdue Holdings, L.P. n/k/a Pharmaceutical Research Associates, L.P. wholly owns the limited partnership interest in Defendant Purdue Pharma, L.P. and is 95% owned by PLP Associates Holdings, L.P.

637. BR Holdings Associates, L.P. is wholly owned by PLP Associates Holdings, L.P.

638. Rosebay Medical Company, L.P. is owned by certain trusts that operate for the benefit of one of more of the Sacklers. Rosebay Medical Company, L.P.'s general partner is Rosebay Medical Company, Inc., whose Board of Directors includes Richard and Jonathan Sackler.

639. The Beacon Company is owned by certain trusts that operate for the benefit of one or more of the Sacklers.

A. The Sacklers Drained Billions of Dollars from Purdue in Response to Legal Actions

640. On April 18, 2008, Richard Sackler emailed a memo to Illene, David, Kathe, Jonathan, and Mortimer Sackler detailing a strategy to protect the family's financial standing by either selling Purdue or milking as much profit as possible.[715] That same day, Purdue's Board voted to direct Purdue to pay the Sacklers $50 million via PLP Associates Holdings, L.P.[716]

641. From 2008 to 2018, as the opioid epidemic in Colorado and around the country blazed on, and as Defendants faced growing legal threats to their personal and business interests, the Sacklers, directly and/or through MNP Consulting, voted dozens of times to have Purdue transfer *billions* of dollars to their family through various entities and trusts that they control, including without limitation, PLP Associates Holdings, L.P., Rosebay Medical Company, L.P., The Beacon

[715] PDD9316300629-631.
[716] PKY183212631-633.

Company, and Purdue Holdings, L.P. n/k/a Pharmaceutical Research Associates, L.P.. For example, from 2008 through 2016, the Sacklers directly and/or through MNP Consulting conspired to and caused Purdue to distribute to PLP Associates Holdings, L.P. and ultimately to themselves through their trusts and other companies, without objection, the following transfers:

- On April 18, 2008, **$50,000,000**;
- On June 27, 2008, **$250,000,000**;
- On September 25, 2008, **$199,012,182**;
- On March 5, 2009, **$200,000,000**;
- On June 26, 2009, **$162,000,000**;
- September 23, 2009, **$173,000,000**;
- On February 4, 2010, **$236,650,000**;
- On April 1, 2010, **$141,000,000**;
- On September 10, 2010, **$240,000,000**;
- On December 2, 2010, **$100,000,000**;
- On April 6, 2011, **$189,700,000**;
- On June 24, 2011, **$200,000,000**;
- On September 1, 2011, **$140,800,000**;
- On February 19, 2013, **$196,000**;
- On October 13, 2013, **$365,246**;

- On November 10, 2014, **$940,000**;
- On December 1, 2014, **$57,400,000**;
- On December 16, 2014, **$15,600,000**;
- On January 14, 2015, **$710,500**;
- On March 26, 2015, **$2,160,000**;
- On June 12, 2015, **$612,500**;
- On September 8, 2015, **$135,000,000**;
- On September 9, 2015, **$539,000**;
- On October 26, 2015, **$1,975,000**;
- On November 16, 2015, **$370,930** and **$1,975,000**;
- On November 30, 2015, **$60,000,000**;
- On December 10, 2015, **$196,000**;
- On January 4, 2015, **$107,000,000**;
- On January 8, 2016, **$563,500**;
- On March 21, 2016, **$343,000**;
- On April 19, 2016, **$441,000**; and

- On May 18, 2016, **$1,700,000** and **$186,000**[717]

642. The transfers listed above are just a few examples of those made at the direction of the Sacklers from Purdue to themselves directly or through the Sackler entities identities described above. In total, from 2008 to 2018, the Sacklers directed ***more than $4 billion*** to themselves and/or the trusts they control for their family's benefit. The Sacklers and the other individual Defendants exercised extensive and effective control over Purdue's sales efforts in Colorado and knowingly benefitted from Purdue's deceptive and reckless conduct in Colorado.

643. When the Sacklers conspired to and directed Purdue to transfer money to themselves, they knew and intended to collect money from the sale of opioids in Colorado. Further, the Sacklers and other individual Defendants knew and intended to deprive those harmed in Colorado of any effective remedy against and resource for the recovery of damages from Purdue. For example, when the U.S. Center for Disease Control warned that high doses of opioids endanger patients' lives, Purdue staff reported back to the Sacklers in April 2016 on the estimated number of patients in each state, including in Colorado, on Purdue's high dosage opioids, the estimated number of annual prescriptions being written for Purdue's high dosage opioids in each state, and the amount of money Purdue was earning from those high dosage opioids in each State.[718]

644. Purdue's April 2016 report to the Sacklers identified 6,790 patients in Colorado who were taking the company's high dosage opioids, which equated to 41,471 annual prescriptions of the dangerous high dosage opioids in Colorado. More importantly to the Sacklers, Purdue was earning approximately $20,735,253 annually from the sale of their high dosage opioids in Colorado alone, or 2.4% of Purdue's high dose opioid market.[719]

B. The Sacklers Transferred Valuable Assets from Purdue to Rhodes

645. After Purdue lost the patents for its branded prescription opioids, like OxyContin, Rhodes became the primary vehicle through which the Sacklers profited

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[717] PKY183212631-633; PKY183212647; PKY183212654; PKY183212662; PKY183212705; PKY183212742; PKY183212772; PKY183212818; PKY183212829; PKY183212844; PKY183212869-870; PKY183212896-897; PKY183212924-925; PKY183212927-928; PPLP004367403; PPLP004415959; PPLP004416115; PPLPC012000368627; PPLPC002000186913; PPLPC016000266403; PPLPC011000036000; PPLPC021000904588

[718] PPLPC016000286167; PWG003984518-545.

[719] *Id.*

from the generic opioid market. Purdue's deceptive unbranded promotion of all prescription opioids and deceptive peddling of OxyContin, and other Purdue branded opioids, cultivated Rhodes' extraordinary rise to the top of the generic opioid market. Rhodes is one of the largest manufacturers of off-patent generic opioids in the United States.

646. According to the *Financial Times*, in 2016, Rhodes had a substantially larger share of the prescription opioid market than Purdue.[720] By 2018, even in the face of a more competitive opioid market, Purdue and Rhodes's combined market share still gave the Sacklers the seventh largest share of the prescription opioid market in the U.S.[721]

647. Rhodes is one of the four largest generic opioid manufacturers in Colorado. In 2017 alone, Colorado prescribers wrote 222,588 prescriptions for Rhodes's opioids, totaling more 13 million units (pills or patches).[722]

648. Rhodes also benefits from reimbursements by Colorado's Medicaid program. In 2018, for example, Colorado Medicaid reimbursed $1,031,361 for 38,202 of Rhodes's opioids.[723] These reimbursements represent only a fraction of the totals earned by Purdue, Rhodes, and the Sacklers from the sale of their opioids in Colorado.

649. The Sacklers had full knowledge of Purdue's relationship with Rhodes and Purdue's efforts to sell more opioids via Rhodes's generic line. Purdue and the Sacklers oversaw and approved Rhodes's business activities, which in turn was overseen and controlled by the Sacklers directly and/or through MNP Consulting. The Sacklers personally received the agendas for Rhodes's Board of Directors meetings, and also personally received Rhodes's financial statements, revenue projections, and earnings reports.[724] Some of the Sacklers even served on some of Rhodes's Executive Committees. For example, in 2015, Theresa (Chairperson),

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[720] David Crow, *How Purdue's, 'One-Two' Punch Fueled the Market for Opioids*, Financial Times, Sept. 9, 2018, available at https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c (last visited June 26, 2019).
[721] Amy Baxter, *Billionaire Drugmaker Granted Patent for Opioid Addiction*, Health Exec. Sept. 10, 2018, available at https://www.healthexec.com/topics/healthcare-economics/billionaire-drugmaker-granted-patent-addiction (last visited June 26, 2019).
[722] PPCPC021000925465.
[723] State Medicaid Drug Utilization Data, Centers for Medicaid and CHIP Services (CMS), https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html (last visited June 26, 2019).
[724] #2995101.1.

Kathe, and Jonathan Sackler all served on Rhodes's Governance Committee. And in 2017, Rhodes's Business Development Committee included Mortimer, Kathe, Jonathan, and David Sackler.

650. At least as early as 2005, Purdue purchased all, or nearly all, of its oxycodone for the manufacturing of OxyContin from Rhodes Technologies, Inc., which like Rhodes, is owned by Coventry Technologies, L.P. Sales agreements like the one between Purdue and Rhodes Technologies, Inc. for oxycodone, were presented to and approved by the Sacklers.[725] The proceeds from such sales agreements were directed by Coventry Technologies, L.P. to trusts owned by and operated for the benefit of the Sacklers.

651. Despite being registered as a separate entity from Purdue, the Sacklers ran Rhodes like they did Purdue and made "little distinction [] internally between the two companies."[726] Rhodes and Purdue use the same employee handbook, and Purdue owns the factories that make most of Rhodes's opioids.[727]

652. The Sacklers have been, and continue to be, directly involved in Rhodes's daily operations, including their opioid sales, just as they were with Purdue. The Sacklers used Purdue and Rhodes to grow the broader prescription opioids market so that they could ultimately profit from the sale of their specific opioids in the expanded market. Purdue's sales force was incentivized not only to increase the sale of Purdue's opioids, but to increase the sale of prescription opioids as an entire class of drugs.[728] Indeed, part of the bonus structure for Purdue's sales force was based on the size of the overall opioid market.[729] The sales force was therefore incentivized to relax prescribers' aversion to all prescription opioids, and then pressure them to prescribe Purdue and/or Rhodes's specific opioids. This scheme translated into immense profits for the Sacklers from the sale of both brand name and generic prescription opioids.

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[725] PPLPC045000010754.
[726] Amy Baxter, *Billionaire Drugmaker Granted Patent for Opioid Addiction*, Health Exec. Sept. 10, 2018, available at https://www.healthexec.com/topics/healthcare-economics/billionaire-drugmaker-granted-patent-addiction (last visited June 26, 2019).
[727] *Id.*; David Crow, *Billionaire Sackler Family Owns Second Opioid Drugmaker*, Financial Times (Sept. 9, 2018), available at https://www.ft.com/content/2d21cf1a-b2bc-11e8-99ca-68cf89602132 (last visited June 26, 2019).
[728] David Crow, *How Purdue's, 'One-Two' Punch Fueled the Market for Opioids*, Financial Times, Sept. 9, 2018. Available at https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c (last visited June 26, 2019).
[729] *Id.*

653. The Sacklers created the incentive structure for both Purdue and Rhodes with the intention to expand the overall prescription opioid market and then capitalize by increasing the sales of Purdue's branded opioids, *e.g.* OxyContin, and Rhodes's generic equivalents, *e.g.* generic oxycodone. Rhodes targeted Colorado and intended to benefit from its generic drug substitution laws which require a generic opioid be substituted when available.[730]

654. The Sacklers continue to operate their opioid enterprise and profit from the epidemic they created through Purdue and Rhodes. In just the last few years, the Sacklers directed several fraudulent transfers of funds and other assets to Rhodes through one or more of the Sackler entities described above. Below are some examples of those fraudulent transfers.

655. On August 23, 2016, in order to allow Rhodes to develop appropriate regulatory strategies for manufacturing abuse-deterrent opioids, the Sacklers directed Purdue to transfer the following assets and funds to Rhodes:

- A Patent/License Agreement between Grünenthal GmbH and Purdue for TRF/Morphine ER;

- All rights, title, and interest in and to MS Contin, which was licensed to Purdue by Mundipharma A.G., a Swiss company affiliated with and/or owned and controlled by the Sacklers; and

- All rights, title, and interest in and to most Dilaudid opioids, except for the injectable form, which is to remain with Purdue.[731]

656. The Sacklers transferred these assets to Rhodes as follows:

- $40 million worth of opioid products and $198,544 through Purdue Holdings, L.P.;

- Purdue Holdings, L.P. then transferred the opioid products to PLP Associates Holdings, L.P. as well as $99,491 to Purdue Pharma, Inc. and $99,053 to PLP Associates Holdings, Inc.;

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[730] *See* Colo. Rev. Stat. § 12-42.5-122.
[731] PPLP004417632.

- PLP Associates Holdings, L.P. then transferred the opioid products to BR Holdings Associates, L.P., which in turn transferred 50% of its undivided interest in the opioid products to the Beacon Company and 50% to Rosebay Medical Company, L.P.; and

- The Beacon Company and Rosebay Medical Company, L.P. then each transferred their undivided interests in the opioid products to Coventry Technologies, L.P. and then Coventry Technologies, L.P. transferred 100% of its rights in the opioid products to Rhodes. [732]

657. The August 2016 transfer resulted from the "[r]ecommendation of the Board of Directors of MNP Consulting Limited," *i.e.* the Sacklers.[733]

658. On December 8, 2016, the Sacklers directed Purdue to assign and transfer certain patents for a Suboxone film, an opioid addiction treatment drug, to Rhodes.[734] The Sacklers directed the transfer as follows:

- Purdue transferred its patents and $286,896 in cash to Purdue Holdings, L.P., assuming a $57.8 million valuation for the patents;

- Purdue Holdings, L.P. then transferred the patents to PLP Associates Holdings, L.P. $143,765 to Purdue Pharma, Inc., and $143,131 to PLP Associates Holdings, Inc.

- PLP Associates Holdings, L.P. then transferred the patents to BR Holdings Associates, L.P., which then transferred 50% of its undivided interest in the patents to the Beacon Company and 50% to Rosebay Medical Company, L.P.; and

- The Beacon Company and Rosebay Medical Company, L.P. then each transferred their undivided interests in the patents to Coventry Technologies, L.P. which in turn transferred 100% of its rights in the patents to Rhodes.[735]

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[732] *Id.*
[733] PPLP004417632-33.
[734] *See supra* ¶ 399.
[735] PPLP004117649

659. When the Sacklers directed Purdue to transfer funds, assets, and Suboxone patents to Rhodes, through one or more of the Sackler entities identified above, they knew and intended to benefit from the continued sale of opioids in Colorado, as well as from opioid addiction drugs they intended to sell in Colorado in order to profit from the epidemic they created.

C. The Sacklers Made Unlawful Preferential Transfers to Purdue Corporate Insiders Craig Landau and Mark Timney

660. On January 31, 2018, Purdue and/or the Sacklers approved a retention program for President and CEO, Craig Landau, which provided him four $3 million payments in 2020, 2022, 2024, and 2026, if he continued in his position with Purdue.[736]

661. On February 14, 2018, Purdue and/or the Sacklers approved a $6 million prepayment to Craig Landau for the first two retention payments that were originally due in 2020 and 2022.[737]

662. On June 8, 2018, Purdue and/or the Sacklers increased Craig Landau's salary from $1.5 million to $2.5 million.[738] Additionally, on the same date, Purdue and/or the Sacklers revised Craig Landau's retention agreement so that he would receive $3 million for March 2018-2019 and $3 million for March 2019-2020 (which the $6 million prepayment originally approved as described above), plus $2 million in retention payments for each of the following years. Purdue and/or the Sacklers agreed that if Craig Landau was terminated without cause or resigned for good reason, he would receive 2 years salary totaling $5 million plus a retention award between $2-$3 million.[739]

663. On July 23, 2018, Purdue and/or the Sacklers approved another change to the retention agreement which provides that if Craig Landau terminates his relationship with Purdue for "Good Reason" he will be entitled to receive the next payment then due under the retention arrangement agreement.[740]

664. On information and belief, Purdue was insolvent at the time it authorized the acceleration of these payments to Craig Landau.

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[736] PPLP004417741.
[737] PPLP004417750.
[738] PPLP004417769.
[739] *Id*.
[740] PPLP004417741.

665. On June 30, 2017, Purdue and/or the Sacklers approved separation payments to be made to Mark Timney of $1.82 million on March 15, 2018 and $1.72 million on March 15, 2019.[741]

666. On information and belief, Purdue was insolvent at the time it authorized these payments to Mark Timney.

FIRST CLAIM FOR RELIEF

(Violation of the Colorado Consumer Protection Act: C.R.S § 6-1-105(1)(e))
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

667. Plaintiff incorporates herein by reference all of the allegations against Defendants in this First Amended Complaint.

668. Through the above-described conduct in the course of their business, occupation, or vocation, Defendants knowingly and/or recklessly made false representations as to the characteristics, uses, benefits, and quantities of opioids generally and Purdue's opioid drugs specifically by misrepresenting, among other things, the efficacy of opioids for treating chronic non-cancer pain, the risks associated with prescription opioids, and the effective treatment duration of their opioids, all in violation of the CCPA, § 6-1-105(1)(e), C.R.S.

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

670. Defendants misrepresented nearly all of the essential characteristics of opioids, as well as some of the more 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;

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[741] PPLP004416483.

- Opioids are not addictive, and to the extent they are, patients' addiction can be easily managed;

- Opioid withdrawals are not severe, and are easy to manage;

- Opioids are more effective and less risky than opioid alternative treatments, like NSAIDs;

- Opioids are effective for longer durations of treatment than is supported by the evidence;

- Opioids do not have a ceiling dose and therefore can be used without limitation, when in fact the ceiling doses for opioids are imposed by adverse reactions caused by increased doses, including overdose, respiratory depression, and other serious adverse events;

- Patients showing signs of addiction are really suffering from "pseudoaddiction," the solution to which is prescribing more opioids; and

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

671. Defendants knowingly, intentionally, and/or recklessly engaged in unlawful deceptive trade practices and knowingly made false representations as to the characteristics, uses, benefits, and quantities of opioids generally and Purdue's opioid drugs specifically in order to expand the use of opioids in Colorado and reap the corresponding profits.

SECOND CLAIM FOR RELIEF

(Violation of the Colorado Consumer Protection Act: C.R.S. § 6-1-105(1)(u))
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

672. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

673. Through the above-described conduct in the course of their business, occupation, or vocation, Defendants knowingly and/or recklessly failed to disclose material information about opioids generally, and Purdue's drugs specifically– information that they have known since at least the launch of OxyContin in 1996–

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.

674. From the time that they launched Purdue's flagship opioid, OxyContin, Defendants knew that none of the representations they made, directly or indirectly, about the safety and efficacy of opioid treatment were based on reliable scientific evidence. Yet Defendants advanced Purdue's false messaging about opioids through their Front Groups and Key Opinion Leaders in order to give the guise 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 public.

675. Defendants failed to disclose that their representations about the efficacy of opioids, including the effective duration of Purdue's opioids, that opioids were beneficial for treating chronic non-cancer pain, and that higher doses of opioids were safe and effective, were not based on any reliable scientific evidence. Defendants further failed to disclose that the Front Groups and Key Opinion Leaders Purdue used to disseminate Defendants' misinformation campaign were paid and controlled by Purdue.

676. Defendants also failed to disclose the increased risk of dependence, addiction, and overdose associated with higher dosages of opioids and longer durations of opioid treatment. In order to increase Purdue's profits and the Sacklers' family fortunes, Defendants pushed Colorado prescribers to increase the dosages being prescribed to patients and the duration of patients' opioid treatments. Among other strategies, Defendants used savings cards as a means for increasing dosages and durations of treatment without disclosing the true intent behind the program and the increased risks of dependence, addiction, and overdose associated with such treatment increases. Prescribers, patients, and other members of the public relied on the representations Purdue made to them without having knowledge of this material information.

677. Defendants knowingly and/or recklessly engaged in unlawful deceptive trade practices by failing to disclose that their representations about the safety and efficacy of opioids, and Purdue's drugs specifically, were not supported by reliable scientific evidence. Defendants failed to disclose that Purdue funded and directed the content of the information provided to the public by their Front Groups and Key Opinion Leaders with the intent to influence Colorado prescribers, consumers, and the public. Defendants also failed to disclose the increased risk of dependence,

addiction, and overdose associated with increased dosages of opioids and longer durations of opioid treatment in an effort to earn more money for Purdue and the Sacklers. This information was material to Colorado health care providers, patients, and the public, and Defendants knowingly, intentionally, and/or recklessly withheld it in order to increase sales.

THIRD CLAIM FOR RELIEF

(Violation of the Colorado Consumer Protection Act: C.R.S. § 6-1-105(1)(g))
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

678. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

679. Through the above-described conduct in the course of their business, occupation, or vocation, Defendants represented that opioids generally, and Purdue's opioids speficially, 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.

680. Defendants knowingly, intentionally, and/or recklessly sought to convince prescribers, patients, and the public that opioids are a safe and effective means of treating chronic non-cancer pain. Through Purdue's Front Groups, Key Opinion Leaders, and sales representatives, Defendants sought to convince health care providers that opioids generally, and Purdue's drugs in particular, were effective at treating chronic non-cancer pain. Defendants never had any reliable evidence to support this representation. Defendants also knew that since OxyContin's inception, actual evidence-based, peer-reviewed studies proved otherwise.

681. Defendants also made more specific misrepresentations about the efficacy of some of the particular elements of Purdue's drugs, including but not limited to, about the effective duration of Purdue's opioids, and that Purdue's abuse-deterrent formulations would discourage opioid misuse.

682. Defendants 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 Defendants' representations, these risks far outweigh the limited benefits of prescription opioid treatment.

683. When the evidence laid bare the falsity of Defendants' claims about the addictiveness of opioids, they manufactured and promoted a deceptive health condition known as "pseudoaddiction" to convince Colorado prescribers that opioids were safer than the evidence suggested. Defendants 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.

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

685. Defendants knowingly, intentionally, and/or recklessly engaged in unlawful deceptive trade practices. Defendants represented that opioids generally, and Purdue's drugs in particular, were of a particular standard and quality–that they were safe and effective methods of treating pain–with little-to-no evidence supporting their claims. And when reliable evidence undermined their claims, Defendants persisted with their deceptive scheme in order to increase Purdue's profits and the Sackler family's fortunes.

FOURTH CLAIM FOR RELIEF

(Violation of the Colorado Consumer Protection Act: C.R.S. § 6-1-105(1)(b))
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

686. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

687. Through the above-described conduct in the course of their business, occupation, or vocation, Defendants knowingly and/or recklessly 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.

688. Purdue's Front Groups and Key Opinion Leaders presented themselves as reliable independent sources of information about, and advocates for, the safety and efficacy of opioids generally, and Purdue's drugs specifically. Far from being independent, the Front Groups and Key Opinion Leaders were nothing more than paid mouthpieces for Defendants. As directed and/or sanctioned by the individual Defendants, Purdue provided direct and indirect funding to write, edit, publish, and disseminate the literature and CMEs created by the Front Groups and Key Opinion Leaders. Defendants directly and indirectly controlled or influenced the content of these publications and presentations. The content of the literature and presentations published and promoted by the Front Groups and Key Opinion Leaders were only released to the public after being reviewed and approved by Defendants.

689. As directed and/or sanctioned by the individual Defendants, Purdue's Front Groups and Key Opinion Leaders represented that they were presenting reliable, fact-based evidence about the efficacy and safety of opioids. In reality, they had no reliable evidence supporting their deceptive claims that opioids were effective for the treatment of chronic non-cancer pain or that the benefits of opioid treatment outweighed the risks.

690. Defendants directly, and indirectly through Purdue's Front Groups and Key Opinion Leaders, distributed and referenced this literature widely without disclosing the close relationship between Purdue and its surrogates.

691. Defendants knowingly, intentionally, and/or recklessly engaged in unlawful deceptive trade practices. Defendants directly and indirectly misrepresented that the publications, journal articles, brochures, literature, CMEs, and other presentations that were created, published, and disseminated by the Front Groups and Key Opinion Leaders were independent and reliable sources of information when in fact they were deceptive and controlled or influenced by Purdue.

FIFTH CLAIM FOR RELIEF

(Violation of the Colorado Consumer Protection Act: C.R.S § 6-1-105(1)(c))
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

692. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

693. Through the above-described conduct in the course of their business, occupation, or vocation, Defendants knowingly and/or recklessly made false representations as to Purdue's affiliation, connection, or association with Front Groups and Key Opinion Leaders, 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.

694. Purdue's Front Groups and Key Opinion Leaders presented themselves as independent and reliable sources of information about, and advocates for, the safety and efficacy of opioids for treatment of chronic non-cancer pain. The Front Groups and Key Opinion Leaders were integral to Defendants' 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 Key Opinion Leaders disseminated written materials, hosted CMEs, and conducted speaking programs parroting Defendants' 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.

695. In reality, Purdue paid millions of dollars in grants and personal payments to the Front Groups and Key Opinion Leaders so that they would push Defendants' campaign to expand opioid use in Colorado and throughout the country, and increase Purdue's profits and the Sackler family's fortunes. The content of the materials, speeches, and CMEs published and promoted by the Front Groups and Key Opinion Leaders were sponsored by Purdue and only released to the public after being reviewed, approved, and/or edited by Defendants.

696. Defendants knowingly, intentionally, and/or recklessly engaged in unlawful deceptive trade practices. Defendants never disclosed their affiliation, connection, or association with the Front Groups or Key Opinion Leaders because such a revelation would undermine Defendants' portrayal of the Front Groups and Key Opinion Leaders as independent and reliable sources of information for prescribers, patients, policymakers, and the public.

SIXTH CLAIM FOR RELIEF

(Violation of the Colorado Consumer Protection Act: C.R.S. § 6-1-105(1)(h))
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

697. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

698. Through the above-described conduct in the course of their business, occupation, or vocation, Defendants knowingly, intentionally, and/or recklessly 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.

699. Seeking to protect and expand their dominance of the pain treatment market, Defendants set out to undermine Purdue's biggest non-opioid competitors– over-the-counter pain pills and prescription NSAIDs. Defendants deployed their marketing machine, consisting of Front Groups, Key Opinion Leaders, 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.

700. Defendants also sought to undermine the market position of opioid alternatives by presenting false comparisons between opioids and non-opioid pain treatments. Defendants falsely claimed that opioids have no ceiling dose, as compared to NSAIDs, when all reliable evidence shows the ceiling dose for opioids is imposed by adverse reactions caused by increased doses and durations of treatments, including addiction, overdose, respiratory depression, and other serious adverse events. And conspicuously absent from Defendants' representations about NSAID-related death rates was the fact that the death rate associated with opioids was significantly higher than those associated with NSAIDs and other opioid-alternative pain treatments.

701. Defendants knowingly, intentionally, and/or recklessly engaged in unlawful deceptive trade practices. Defendants 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. Defendants' strategy was effective as it resulted in decreased market share for opioid alternatives and increased market share for opioids generally and especially for Purdue's opioids.

SEVENTH CLAIM FOR RELIEF

(Violation of the Colorado Consumer Protection Act: C.R.S. § 6-1-105(1)(nnn))
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

702. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

703. Through the above-described conduct in the course of their business, occupation, or vocation, Defendants knowingly, intentionally, and/or recklessly engaged in an unfair, unconscionable, deceptive, deliberately misleading, false, or fraudulent act or practice, all in violation of the CCPS, § 6-1-105(1)(nnn), C.R.S.

704. In order to expand the general prescription opioid market and increase sales of their own opioid drugs, Defendants deployed and participated in a decades-long deceptive and reckless marketing campaign to mislead Colorado health care providers, patients, and the general public about the safety and efficacy of prescription opioids. Driven by profits over truth and fairness, Defendants ignored warnings that its opioid business, including its deceptive marketing campaign, was causing thousands of people in Colorado to die from opioid overdoses, and many thousands more to become addicted to the drugs.

705. Defendants' unfair, unconscionable, deceptive, misleading, false, or fraudulent representations about prescription opioids 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 they are, patients' addiction can be easily managed;
- Opioid withdrawals are not severe, and are easy to manage;
- Opioids are more effective and less risky than opioid alternative treatments, like NSAIDs;

- Opioids are effective for longer durations of treatment than is supported by the evidence;

- Opioids do not have a ceiling dose and therefore can be used without limitation, when in fact the ceiling doses for opioids are imposed by adverse reactions caused by increased doses, including overdose, respiratory depression, and other serious adverse events;

- Patients showing signs of addiction are really suffering from "pseudoaddiction," the solution to which is prescribing more opioids; and

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

706. Defendants indirectly disseminated these deceptive representations through Purdue's network of Front Groups and Key Opinion Leaders in order to make Colorado health care providers, patients, and the public believe the information being presented about the safety and efficacy of prescription opioids was based on reliable and independent scientific evidence and being delivered by reliable and independent experts. Defendants never disclosed Purdue's control over its surrogates or its control over the information and materials being disseminated by them. Defendants also never disclosed the lack of reliable evidence supporting the information and materials disseminated by Purdue's surrogates.

707. Defendants directly reinforced the deceptive messaging spread by Purdue's surrogates using their army of sales representatives in Colorado and around the country. At Defendants' direction, Purdue's sales force targeted health care providers in Colorado they knew were likely to be high-volume prescribers, as well as those they knew lacked the expertise or experience to question Purdue's misinformation campaign. Defendants targeted prescribers they knew were engaged in suspicious conduct related to opioids up until those prescribers came under investigation by law enforcement or regulatory authorities. Defendants knew that their deceptive campaign was influencing opioid prescribing in Colorado, and having devastating impacts on the State and its citizens, and did nothing to report the suspicious activity related to Purdue's opioids or mitigate the harm they were causing.

708. Defendants and Purdue's surrogates disseminated these deceptive representations to the Colorado legislature and regulatory agencies in an effort to influence or change State laws, regulations, and/or policies about prescription opioids.

709. Defendants knowingly or recklessly engaged in unfair, unconscionable, deceptive, deliberately misleading, false, or fraudulent acts or practices in order to expand the prescription opioid market and increase sales of Purdue's own opioid drugs in Colorado and reap the corresponding profits.

EIGHTH CLAIM FOR RELIEF

(Public Nuisance)

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., Rhodes Pharmaceuticals, L.P., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

710. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

711. By engaging in the conduct described in this First Amended Complaint, Defendants created or were 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 or injured thousands of its citizens.

712. Defendants engaged in a deceptive campaign to market, sell, and distribute opioids generally and Purdue and Rhodes'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.

713. Defendants also failed to adequately monitor suspicious activity related to Purdue and Rhodes's opioids, failed to report suspicious prescribers, pharmacies, and/or orders to the appropriate authorities after learning that Purdue and/or Rhodes's opioids had been diverted for illegitimate or illegal consumption, and failed to take any meaningful steps to mitigate the harm caused by their misconduct. Defendants' failure to monitor suspicious opioid-related activity, report suspicious opioid prescribers, pharmacies, and/or orders, and mitigate the harm caused by their misconduct led directly to an epidemic of opioid addiction, illness, and death, which resulted in substantial public injuries to the State of Colorado.

714. Among the rights common to the public is the right to public health. Defendants caused and continued an epidemic of opioid addiction, illness, and death, which has caused significant injury to the public health and interfered with the public's comfortable enjoyment of life and property.

715. The public nuisance created by Defendants' actions and omissions is substantial and unreasonable, it has caused harm and continues to cause significant harm to the State of Colorado. The harm inflicted outweighs any potentially offsetting benefit.

716. Defendants knew or should have known that their deceptive and reckless branded and unbranded promotion of opioid use would create an ongoing public nuisance.

717. 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 users, is a matter of great public interest to the State.

718. 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.

719. 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 Defendants' deceptive, reckless, and illegal conduct in promoting opioids to treat chronic non-cancer pain, the State reimbursed opioid prescriptions for chronic non-cancer pain.

720. The State has also had to use public funds to remediate the impacts of the opioid epidemic caused by Defendants. Due to Defendants' failure to prevent or mitigate the diversion of Purdue and Rhodes's opioids, including their failure to monitor and report suspicious activity related to their opioids, the State has paid for services to address the harms caused to the State's citizens and to the healthcare, criminal justice, and other social service programs the State provides to its citizens.

721. The State has suffered and continues to suffer injuries from a public health crisis of opioid addiction, overdose, injury, and death that Defendants knowingly created and perpetuated. As a result, the State has borne the financial costs to manage the impacts of that crisis, including:

- 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

(Negligence)

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., Rhodes Pharmaceuticals, L.P., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

722. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

723. Defendants 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. Defendants had a duty to truthfully, and with full disclosure, market their prescription opioids. Defendants also had a duty to monitor and report any suspicious activity related to Purdue and Rhodes's opioids, including a duty to report any suspicious opioid prescribers, pharmacies, and/or orders in Colorado, and a duty to mitigate the harm caused by their drugs.

724. Defendants knew or should have known that their 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, Defendants not only breached their duty of care, but acted with reckless indifference, implementing an aggressive and deceptive branded and unbranded marketing scheme designed to deceive doctors and patients, as well as policymakers and the public, in order to increase the use and dosages of prescription opioids generally as well as Purdue and Rhodes's own drugs.

725. Defendants also knew or should have known that Purdue and Rhodes's opioids were being diverted for illegitimate or illegal consumption and breached their duty by failing to maintain adequate programs to monitor suspicious activity and by failing to report suspicious prescribers, pharmacies, and/or orders to the appropriate authorities.

726. Defendants' 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

diversion, addiction, overdose, and death. The State of Colorado has suffered financial and physical harm to its business and property due to the devastating effects of the opioid crisis that stemmed in large measure from the intentional, knowing, and reckless behavior of Defendants.

727. As a sophisticated pharmaceutical company, Purdue and its owners and operators were fully aware of the FDA rules and regulations governing its conduct and marketing practices. Defendants 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.

728. Defendants were aware from Purdue's internal sales data, adverse reports, publicly available studies and reports, and other sources that their deceptive marketing was expanding the use of opioids for treating chronic non-cancer pain and causing public harm. Defendants were also internally aware that Purdue and Rhodes's opioids were being diverted for illegitimate or illegal consumption, and failed to adequately monitor suspicious activity and report suspicious prescribers, pharmacies, and/or orders to the appropriate authorities.

729. The State has used public funds to reimburse opioid prescriptions covered by the State's employee and retiree health plans, the State's Medicaid program, and the State's Workers' Compensation Program. Due to Defendants' 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.

730. The State has also used public funds to remediate the immense harm caused to the State and its citizens by Defendants' negligent monitoring and reporting of suspicious activity related to Purdue and Rhodes's opioids. Due to Defendants' negligence in failing to adequately monitor and report suspicious activities related to Purdue and Rhodes's opioids, the State has used public funds for healthcare, criminal justice, and other social services to remediate the harm caused by Defendants' negligence.

731. Further, the State has suffered and continues to suffer from a public health crisis of opioid addiction, overdose, injury, and death that Defendants knowingly helped create and perpetuate. As a result, the State has borne the financial costs to manage the impacts of that crisis, including:

- 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 Misrepresentation)
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

732. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

733. Defendants 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.

734. From the time that they launched their flagship opioid, OxyContin, Defendants knew that none of the representations Purdue made about the safety and efficacy of opioid treatment were based on any reliable scientific evidence. Yet Defendants advanced their deceptive and misleading messaging about opioids through Front Groups and Key Opinion Leaders 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.

735. Defendants' misrepresentations about the efficacy of opioids and their aggressive misinformation campaign 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 of Colorado would rely on this false information and increase the use of opioids.

736. The State has suffered and continues to suffer from a public health crisis of opioid addiction, overdose, injury, and death that Defendants knowingly

helped create and perpetuate. As a result, the State has borne the financial costs to manage the impacts of that crisis, including:

- 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.

ELEVENTH CLAIM FOR RELIEF

(Fraudulent Concealment)

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

737. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

738. Defendants knowingly and intentionally concealed material facts regarding opioids generally and Purdue's drugs specifically with the intent to induce Colorado health care providers to rely on their 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.

739. 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, Defendants had a duty to disclose material information about the addictive and potentially deadly nature of opioid drugs.

740. From the time that Defendants launched Purdue's flagship opioid, OxyContin, they intentionally and knowingly concealed material information regarding the lack of reliable scientific evidence about the safety and efficacy of opioid treatment. Defendants used Front Groups and Key Opinion Leaders to advance their 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.

741. Defendants intentionally and knowingly concealed material information about the efficacy of opioids. Defendants' 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.

742. The State has suffered and continues to suffer from a public health crisis of opioid addiction, overdose, injury, and death that Defendants knowingly helped create and perpetuate. As a result, the State has borne the financial costs to manage the impacts of that crisis, including:

- 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.

TWELFTH CLAIM FOR RELIEF

(Violation of the Colorado Organized Crime Control Act: C.R.S. §§ 18-17-104(3) and 18-17-104(4))

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, David Haddox, and Russell Gasdia)

743. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint. For purposes of this civil claim under COCCA, Plaintiff also identifies John Stewart and McKinsey & Company as unnamed co-conspirators and members of the enterprises described below that engaged in the pattern of racketeering activity alleged herein. Plaintiff does not name John Stewart or McKinsey & Company as Defendants for its COCCA claim or any other claim alleged in this action.

744. Purdue Pharma L.P., Purdue Pharma, Inc., and MNP Consulting Limited each constitute "enterprises" within the meaning of C.R.S. § 18-17-103(2). Additionally, Purdue Pharma L.P., Purdue Pharma, Inc., MNP Consulting Limited, Richard Sackler, Mortimer Sackler, Jonathan Sackler, Kathe Sackler, Illene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, Russell Gasdia, Mark Timney, Craig Landau, and David Haddox, as well as John Stewart and McKinsey & Company, acted together as a group associated in fact, and that association itself constituted an "enterprise" for the relevant years within the meaning of C.R.S. § 18-17-103(2).

745. Purdue Pharma L.P., Purdue Pharma, Inc., MNP Consulting Limited, Richard Sackler, Mortimer Sackler, Jonathan Sackler, Kathe Sackler, Illene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, Russell Gasdia, Mark Timney, Craig Landau, and David Haddox, as well as John Stewart and McKinsey & Company, are COCCA persons employed by, or associated with, the COCCA enterprises within the meaning of C.R.S. § 18-17-104(3).

746. Through their conduct alleged herein, Purdue Pharma L.P., Purdue Pharma, Inc., MNP Consulting Limited, Richard Sackler, Mortimer Sackler, Jonathan Sackler, Kathe Sackler, Illene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, Russell Gasdia, Mark Timney, Craig Landau, and David Haddox, as well as John Stewart and McKinsey & Company, all conducted and/or participated in their affairs of the COCCA enterprises, directly or indirectly, through a pattern of racketeering activity within the meaning of C.R.S. § 18-17-103(3).

747. Purdue Pharma L.P., Purdue Pharma, Inc., MNP Consulting, Richard Sackler, Mortimer Sackler, Jonathan Sackler, Kathe Sackler, Illene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, Russell Gasdia, Mark Timney, Craig Landau, and David Haddox, as well as John Stewart and McKinsey & Company, also conspired or endeavored to violate C.R.S. § 18-17-104(3), in violation of C.R.S. § 18-17-104(4).

748. The conduct alleged herein constitutes "racketeering activity" under § 18-17-103(5)(a), C.R.S., and 18 U.S.C. § 1961(1)(B) because it included mail and wire fraud under 18 U.S.C. §§ 1341 and 1343.

749. As alleged above, Purdue Pharma L.P., Purdue Pharma, Inc., MNP Consulting Limited, Richard Sackler, Mortimer Sackler, Jonathan Sackler, Kathe Sackler, Illene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, Russell Gasdia, Mark Timney, Craig Landau, and David Haddox, as well as John

Stewart and McKinsey & Company, with the intent to defraud, developed and deployed a promotional scheme to defraud Colorado health care providers, patients, the public, and the State of Colorado regarding the safety and efficacy of opioids generally and Purdue's opioids specifically. Defendants, John Stewart, and McKinsey & Company developed fraudulent messages about the safety and efficacy of opioids generally and Purdue's opioids specifically and knew that they would disseminate, and did disseminate, those messages to Colorado health care providers, patients, the public, and the State via U.S. mail, or other interstate carriers, and via telephone, email, internet websites, or other wires, in connection with the execution of their fraudulent scheme.

750. Purdue Pharma L.P., Purdue Pharma, Inc., MNP Consulting Limited, Richard Sackler, Mortimer Sackler, Jonathan Sackler, Kathe Sackler, Illene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, Russell Gasdia, Mark Timney, Craig Landau, and David Haddox, as well as John Stewart and McKinsey & Company, engaged in a "pattern of racketeering activity" because their conduct included the dissemination of thousands of fraudulent messages from at least 1996 through at least 2018 about the safety and efficacy of opioids generally and Purdue's opioids specifically that constitute mail fraud and wire fraud and which are related to the conduct of the enterprise.

751. The State has been directly and proximately injured in its business or property by reason of the predicate acts (mail and wire fraud) and Defendants' violations of C.R.S. §§ 18-17-104(3) and 18-17-104(4). But for Defendants' employment by or participation in, directly or indirectly, the enterprises described above through a pattern of racketeering activity, the State would not have paid for opioid prescriptions or the costs associated with remediating a widespread epidemic of opioid addiction, overdoses, and death. Because of Defendants' predicate acts and violations of C.R.S. §§ 18-17-104(3) and 18-17-104(4), the State and its citizens have suffered monetary damage to its business and property.

THIRTEENTH CLAIM FOR RELIEF

(Violation of the Colorado Organized Crime Control Act:
C.R.S. §§ 18-17-104(1), (2), and (4))
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., Rhodes Pharmaceuticals, L.P., MNP Consulting Limited, and all of the Sacklers)

752. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint. For purposes of this civil COCCA claim, Plaintiff also specifically incorporates herein by reference all of the allegations against Purdue Pharma L.P., Purdue Pharma, Inc., MNP Consulting

Limited, Richard Sackler, Mortimer Sackler, Jonathan Sackler, Kathe Sackler, Illene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, Russell Gasdia, Mark Timney, Craig Landau, and David Haddox, as well as John Stewart and McKinsey & Company, in paragraphs 743 to 751 herein.

753. As set forth in this First Amended Complaint, Purdue Pharma L.P., Purdue Pharma, Inc., Rhodes Pharmaceuticals, L.P., MNP Consulting Limited, Richard Sackler, Mortimer Sackler, Jonathan Sackler, Kathe Sackler, Illene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, and David Sackler knowingly received proceeds derived, directly or indirectly, from a pattern of racketeering activity, in violation of § 18-17-104(1)(a), C.R.S.

754. As set forth in this First Amended Complaint, Purdue Pharma L.P., Purdue Pharma, Inc., Rhodes Pharmaceuticals, L.P., MNP Consulting Limited, Richard Sackler, Mortimer Sackler, Jonathan Sackler, Kathe Sackler, Illene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, and David Sackler knowingly acquired or maintained, directly or indirectly, an interest in or control of any enterprise, in violation of § 18-17-104(2), C.R.S.

755. As set forth in this First Amended Complaint, Purdue Pharma L.P., Purdue Pharma, Inc., Rhodes Pharmaceuticals, L.P., MNP Consulting Limited, Richard Sackler, Mortimer Sackler, Jonathan Sackler, Kathe Sackler, Illene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, and David Sackler conspired or endeavored to violate §§ 18-17-104(1)(a) and (2), C.R.S., in violation of § 18-17-104(4), C.R.S.

FOURTEENTH CLAIM FOR RELIEF

(Violation of the Colorado Uniform Fraudulent Transfer Act – Intentionally Fraudulent Transfers: C.R.S. § 38-8-105(1)(a))

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, and all of the Sacklers)

756. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

757. Plaintiff is a "Creditor" holding "Claims" against Purdue as those terms are defined in Section 38-8-102(3) and (5), C.R.S.

758. The Sacklers are "Insiders" by Purdue as that term is defined in Section 38-8-102(8)(a), (b) and (d), C.R.S.

759. Upon information and belief, all transfers of property, including, without limitation, those transfers set forth in paragraphs 641 to 642 herein, by Purdue to the Sacklers between 2008 and 2018 were made with the actual intent, of Purdue and the Sacklers, to hinder, delay, or defraud Plaintiff in violation of § 38-8-105(1)(a), C.R.S.

760. Plaintiff's Claims against Purdue arose both before and after Purdue transferred property to the Sacklers.

761. Accordingly, Plaintiff is entitled to judgment under §§ 38-8-105(1)(a), 108(1), and 109, C.R.S., (1) avoiding all such transfers, (2) enjoining any further disposition by Purdue and the Sacklers of the property transferred, and (3) granting judgment for Plaintiff and against Purdue and the Sacklers for one and one-half the value of the assets transferred or for one and one-half the amount necessary to satisfy Plaintiff's claims, whichever is less, plus actual costs.

FIFTEENTH CLAIM FOR RELIEF

(Violation of the Colorado Uniform Fraudulent Transfer Act – Intentionally Fraudulent Transfers: C.R.S. § 38-8-105(1)(a))

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., and Rhodes Pharmaceuticals, L.P.)

762. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

763. Rhodes is an "Insider" of Purdue as that term is defined in § 38-8-102(8)(d), C.R.S.

764. Upon information and belief, all transfers of property, including, without limitation, those transfers set forth in paragraphs 645 to 658 herein, by Purdue to Rhodes between 2016 and 2018 were made with the actual intent, of Purdue and Rhodes, to hinder, delay, or defraud Plaintiff in violation of § 38-8-105(1)(a), C.R.S.

765. Plaintiff's Claims against Purdue arose both before and after Purdue transferred property to Rhodes.

766. Accordingly, Plaintiff is entitled to judgment under §§ 38-8-105(1)(a), 108(1), and 109, C.R.S., (1) avoiding all such transfers, (2) enjoining any further disposition by Purdue or Rhodes of the property transferred, and (3) granting

judgment for Plaintiff and against Purdue and Rhodes for one and one-half the value of the assets transferred or for one and one-half the amount necessary to satisfy Plaintiff's claims, whichever is less, plus actual costs.

SIXTEENTH CLAIM FOR RELIEF

(Violation of the Colorado Uniform Fraudulent Transfer Act – Constructively Fraudulent Transfers: C.R.S. § 38-8-105(1)(b))

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, and all of the Sacklers)

767. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

768. Upon information and belief, all transfers of property, including, without limitation, those transfers set forth in paragraphs 641 to 642 herein, by Purdue to the Sacklers between 2014 and 2018 were made without the receipt of reasonably equivalent value in exchange therefor, and (1) Purdue engaged or was about to engage in business or transactions for which its remaining assets were unreasonably small in relation to such business or transactions, or (2) Purdue believed or reasonably should have believed that it would incur debts beyond its ability to pay as such became due, all in violation of § 38-8-105(1)(b), C.R.S.

769. Accordingly, Plaintiff is entitled to judgment under §§ 38-8-105(1)(b), 108(1) and 109(2), C.R.S., (1) avoiding all such transfers, (2) enjoining any further disposition by Purdue or the Sacklers of the property transferred, and (3) granting judgment for Plaintiff and against Purdue and the Sacklers for the value of the assets transferred or for the amount necessary to satisfy Plaintiff's claims, whichever is less.

SEVENTEENTH CLAIM FOR RELIEF

(Violation of the Colorado Uniform Fraudulent Transfer Act – Constructively Fraudulent Transfers: C.R.S. § 38-8-105(1)(b))

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, and Rhodes Pharmaceuticals, L.P.)

770. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

771. Upon information and belief, all transfers of property, including, without limitation, those transfers set forth in paragraphs 645 to 658 herein, by

Purdue to Rhodes between 2016 and 2018 were made without the receipt of reasonably equivalent value in exchange therefor, and (1) Purdue engaged or was about to engage in business or transactions for which its remaining assets were unreasonably small in relation to such business or transactions, or (2) Purdue believed or reasonably should have believed that it would incur debts beyond its ability to pay as such became due, all in violation of § 38-8-105(1)(b), C.R.S.

772. Accordingly, Plaintiff is entitled to judgment under §§ 38-8-105(1)(b), 108(1) and 109(2), C.R.S., (1) avoiding all such transfers, (2) enjoining any further disposition by Purdue or Rhodes of the property transferred, and (3) granting judgment for Plaintiff and against Purdue and Rhodes for the value of the assets transferred or for the amount necessary to satisfy Plaintiff's claims, whichever is less.

EIGHTEENTH CLAIM FOR RELIEF

(Violation of the Colorado Uniform Fraudulent Transfer Act – Constructively Fraudulent Transfers: C.R.S. § 38-8-106(1))

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, and all of the Sacklers)

773. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

774. Upon information and belief, all transfers of property, including, without limitation, those transfers set forth in paragraphs 641 to 642 herein, by Purdue to the Sacklers between 2014 and 2018 were made without the receipt of reasonably equivalent value in exchange therefor, and Purdue was insolvent at the time of such transfers or became insolvent as a result of such transfers, all in violation of § 38-8-106(1), C.R.S.

775. Accordingly, Plaintiff is entitled to judgment under §§ 38-8-106(1), 108(1) and 109(2), C.R.S., (1) avoiding all such transfers, (2) enjoining any further disposition by Purdue or the Sacklers of the property transferred, and (3) granting judgment for Plaintiff and against Purdue and the Sacklers for the value of the assets transferred or for the amount necessary to satisfy Plaintiff's claims, whichever is less.

NINETEENTH CLAIM FOR RELIEF

(Violation of the Colorado Uniform Fraudulent Transfer Act – Constructively Fraudulent Transfers: C.R.S. § 38-8-106(1))

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, and Rhodes Pharmaceuticals, L.P.)

776. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

777. Upon information and belief, all transfers of property, including, without limitation, those transfers set forth in paragraphs 645 to 658 herein, by Purdue to Rhodes between 2016 and 2018 were made without the receipt of reasonably equivalent value in exchange therefor, and Purdue was insolvent at the time of such transfers or became insolvent as a result of such transfers, all in violation of § 38-8-106(1), C.R.S.

778. Accordingly, Plaintiff is entitled to judgment under §§ 38-8-106(1), 108(1) and 109(2), C.R.S., (1) avoiding all such transfers, (2) enjoining any further disposition by Purdue or Rhodes of the property transferred, and (3) granting judgment for Plaintiff and against Purdue and Rhodes for the value of the assets transferred or for the amount necessary to satisfy Plaintiff's claims, whichever is less.

TWENTIETH CLAIM FOR RELIEF

(Violation of the Colorado Uniform Fraudulent Transfer Act – Preferential Transfers: C.R.S. § 38-8-106(2))

(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., all of the Sacklers, Craig Landau, and Mark Timney)

779. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

780. Upon information and belief, all transfers of property by Purdue to the Sacklers and to Craig Landau and Mark Timney between 2017 and 2019 were made to insiders for antecedent debts, and Purdue was insolvent at the time of such transfers and had reasonable cause to believe it was insolvent, all in violation of § 38-8-106(2), C.R.S.

781. Accordingly, Plaintiff is entitled to judgment under §§ 38-8-106(2), 108(1) and 109(2), C.R.S., to (1) avoid all such transfers, (2) enjoin any further

disposition by Purdue, the Sacklers, Craig Landau, and Mark Timney of the property transferred, and (3) grant judgment for Plaintiff and against Purdue, the Sacklers, Craig Landau, and Mark Timney for the value of the assets transferred or for the amount necessary to satisfy Plaintiff's claims, whichever is less.

TWENTY-FIRST CLAIM FOR RELIEF
(Civil Conspiracy to Fraudulently Transfer Assets)
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, and all of the Sacklers)

782. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

783. The Sacklers controlled, directed, participated in, cooperated with, and/or sanctioned all of Purdue's conduct alleged in this First Amended Complaint.

784. Upon information and belief, between 2008 and 2018, Purdue and the Sacklers entered into an agreement or agreements upon a course of action to transfer systematically and fraudulently the assets of Purdue to the Sacklers, in violation of CUFTA and to defraud Plaintiff. In furtherance of such agreement or agreements, Purdue did transfer assets to the Sacklers in violation of CUFTA, §§ 38-8-105 and 106, C.R.S., damaging Plaintiff as a proximate result thereof.

785. Accordingly, Plaintiff is entitled to judgment for Plaintiff and against Purdue and the Sacklers for the value of the assets transferred or for the amount necessary to satisfy Plaintiff's claims, whichever is less, and for an award of exemplary damages to Plaintiff and against Purdue and the Sacklers in an amount not to exceed the amount of actual damages awarded at trial.

TWENTY-SECOND CLAIM FOR RELIEF
(Civil Conspiracy to Fraudulently Transfer Assets)
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., Rhodes Pharmaceuticals, L.P., and MNP Consulting Limited)

786. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

787. Upon information and belief, between 2008 and 2018, Purdue and Rhodes entered into an agreement or agreements upon a course of action to transfer systematically and fraudulently the assets of Purdue to Rhodes, in violation of

CUFTA and to defraud Plaintiff. In furtherance of such agreement or agreements, Purdue did transfer assets to Rhodes in violation of CUFTA, §§ 38-8-105 and 106, C.R.S., damaging Plaintiff as a proximate result thereof.

788. Accordingly, Plaintiff is entitled to judgment for Plaintiff and against Purdue and Rhodes for the value of the assets transferred or for the amount necessary to satisfy Plaintiff's claims, whichever is less, and for an award of exemplary damages to Plaintiff and against Purdue and Rhodes in an amount not to exceed the amount of actual damages awarded at trial.

TWENTY-THIRD CLAIM FOR RELIEF

(Civil Conspiracy to Defraud)
(Against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., MNP Consulting Limited, all of the Sacklers, Mark Timney, Craig Landau, and David Haddox)

789. Plaintiff incorporates herein by reference all of the allegations against Defendants contained in this First Amended Complaint.

790. Upon information and belief, between 1995 and 2018, Defendants entered into an agreement or agreements upon a course of action knowingly and intentionally to make material misrepresentations to the State, and to Colorado prescribers and patients, regarding the safety and efficacy of prescription opioids generally, and Purdue's opioids in particular, with the specific intent to induce the State, and Colorado prescribers and patients, to rely upon such misrepresentations. In furtherance of such agreement or agreements, as directed and/or sanctioned by the individual Defendants, Purdue did make material misrepresentations to the State, and to Colorado prescribers and patients, who reasonably relied upon same and were damaged as a proximate result thereof.

791. Accordingly, Plaintiff is entitled to judgment for Plaintiff and against Defendants for an amount of actual damages as awarded at trial, and for an award of exemplary damages to Plaintiff and against Defendants in an amount not to exceed the amount of actual damages awarded at trial.

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 Defendants' above-described conduct to be in violation of the CCPA, §§ 6-1-105(1)(b), (c), (e), (g), (h), (u), and (nnn).

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

C. Orders necessary to prevent Defendants' 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 Defendants' deceptive practices, pursuant to § 6-1-110(1) of the CCPA.

E. An Order requiring Defendants to forfeit and pay civil penalties pursuant to §§ 6-1-112(1)(a) and 6-1-112(1)(c) of the CCPA.

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

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

H. An Order requiring the payment of treble damages and attorneys' fees and costs of investigation as permitted by § 18-17-106(7) of COCCA.

I. An Order for all appropriate remedies under § 38-8-108(1) of CUFTA.

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

K. Any such further Orders or other relief as the Court may deem just and proper under common law, the CCPA, COCCA, and/or CUFTA.

JURY DEMAND

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

Dated this 1st day of July, 2019.

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