

Ron Kilgard, No. 005902
Gary Gotto, No. 007401
KELLER ROHRBACK L.L.P.
3101 North Central Avenue, Suite 1400
Phoenix, AZ 85012
Phone: (602) 248-0088
Fax: (602) 248-2822
rkilgard@kellerrohrback.com
ggotto@kellerrohrback.com

Attorneys for Plaintiff
(additional counsel listed on signature page)

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Hopi Tribe,

Plaintiff,

vs.

Endo Health Solutions, Inc.; Endo
Pharmaceuticals, Inc.; Par Pharmaceutical,
Inc.; Par Pharmaceutical Companies, Inc.;
Janssen Pharmaceuticals, Inc.; Johnson &
Johnson; Teva Pharmaceuticals Industries,
Ltd.; Teva Pharmaceuticals USA, Inc.;
Cephalon, Inc.; Allergan PLC f/k/a Actavis
PLC; Allergan Finance, LLC f/k/a Actavis,
Inc. f/k/a Watson Pharmaceuticals, Inc.;
Watson Laboratories, Inc.; Actavis LLC;
Actavis Pharma, Inc. f/k/a Watson Pharma,
Inc; Mallinckrodt PLC; Mallinckrodt, LLC;
SpecGX LLC; Mylan Pharmaceuticals, Inc.;
West-Ward Pharmaceuticals Corp.; Hikma
Pharmaceuticals PLC; KVK-Tech, Inc.;
Sandoz, Inc.; Amneal Pharmaceuticals, LLC;
Amneal Pharmaceuticals, Inc.; Impax
Generics; Impax Laboratories, Inc.; Cardinal
Health, Inc.; McKesson Corporation;
AmerisourceBergen Drug Corporation;
Walgreens Boots Alliance Inc. a/k/a

No.

COMPLAINT

Walgreen Co.; Walmart, Inc.; CVS Health Corporation; CVS Pharmacy, Inc.; and John and Jane Does 1 through 100, Inclusive,

Defendants.

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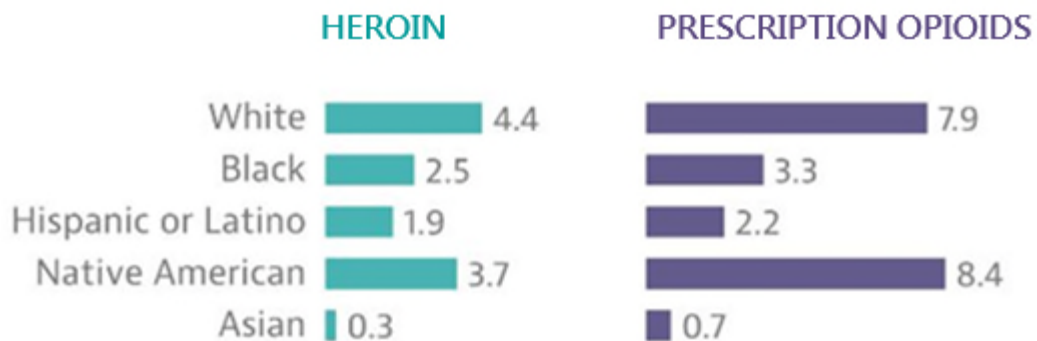
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I. INTRODUCTION

1. The United States is experiencing the worst human-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids.

2. Since 2000, more than 400,000 Americans have lost their lives to an opioid overdose, more than five times as many American lives as were lost in the entire Vietnam War. On any given day, 134 people will die from opioid overdoses in the United States. Drug overdoses are now the leading cause of death for Americans under age fifty. The recent increases in drug overdose deaths have been so steep that they have contributed to reductions in the country’s life expectancy over the last three years, a pattern unprecedented since World War II.

Overdose Deaths by Race in 2014 per 100,000 people



3. While the opioid epidemic is generally perceived as a crisis that is “overwhelmingly white,”¹ the opioid overdose death rate for Native Americans has for

¹ *Why Is The Opioid Epidemic Overwhelmingly White?*, All Things Considered, NPR (Nov. 4, 2017, 5:43pm), <https://www.npr.org/2017/11/04/562137082/why-is-the-opioid-epidemic-overwhelmingly-white>; see also, e.g., German Lopez, *When a drug epidemic’s victims are white*, Vox (Apr. 4, 2107, 8:00am), <https://www.vox.com/identities/2017/4/4/15098746/opioid-heroin-epidemic-race>.

years been the same or higher than that for whites. According to data from the Centers for Disease Control and Prevention (“CDC”), in 2014, Native Americans had the highest death rate from prescription opioid overdoses of any ethnic group in the United States.²

4. Similarly, from 1999 to 2009, the incidence rate ratio of prescription opioid deaths was higher for Native Americans than any other ethnic group—slightly higher (0.86) than for non-Hispanic whites, 7.5 times higher than for African Americans, and 13 times higher than for Asian American/Pacific Islanders.³

5. But overdoses are not the whole story, as the opioid epidemic has had a devastating effect on Native families and communities in other ways. An entire generation of Native Americans is growing up in the shadow of the opioid epidemic, with far-reaching consequences compounded by the historical trauma that Native communities have endured. Children whose parents are addicted to opioids—including babies born with opioid dependencies as a result of their mothers’ opioid use during pregnancy—often must be removed from their homes.

6. To protect its welfare and continued sovereignty, the Hopi Tribe (“the Tribe”) has dedicated resources to confronting the opioid epidemic.

² Dan Nolan and Chris Amico, *How Bad is the Opioid Epidemic?*, Frontline (Feb. 23, 2016), <https://www.pbs.org/wgbh/frontline/article/how-bad-is-the-opioid-epidemic/> (headings revised for clarity).

³ Susan Calcaterra, Jason Glanz, and Ingrid A. Binswanger, *National Trends in Pharmaceutical Opioid Related Overdose Deaths Compared to other Substance Related Overdose Deaths: 1999-2009*, 131(3) *Drug Alcohol Depend.*, 263-70 (Aug. 1, 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935414/>.

7. But despite the Tribe's efforts, the opioid epidemic has impacted the Tribe—a direct result of Defendants' continued aggressive promotion and excessive distribution of opioids, conduct which they concealed, as described below.

8. Opioids have reshaped reality for the Tribe in numerous ways. At pharmacies on the Reservation, people have tried to purchase opioid pills or fentanyl patches from patients who were picking up prescriptions. Homes have been broken into by those seeking opioids. A social services employee heard from residents who started carrying their prescribed opioids with them because of prior break-ins.

9. But while the Tribe has committed resources to fight the opioid crisis, fully addressing the crisis also requires that those responsible for it pay for their conduct and abate the nuisance and harms they have inflicted on the Tribe.

10. The opioid epidemic is no accident. On the contrary, it is the foreseeable consequence of Defendants' reckless and misleading promotion of potent narcotics as safe and effective treatment for pain, and their relentless distribution of hundreds of millions of pills into American communities when they knew or should have known those pills were being diverted to illicit use.

11. Purdue Pharma, L.P., Purdue Pharma, Inc. and The Purdue Frederick Company, Inc. (hereafter "Purdue") set the stage for the opioid epidemic, through the production and promotion of its blockbuster drug, OxyContin. Purdue sought Chapter 11 bankruptcy protection on September 15, 2019, and thus is not named as a defendant here.

12. Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, the late Beverly Sackler, Theresa Sackler, David A.

Sackler, and the Trust for the Benefit of Members of the Raymond Sackler Family (hereafter “Sacklers” or “Sackler Family”) are or were variously the direct or indirect operators, owners, or relatives of the owners, of Purdue and/or its affiliates. The Sacklers are currently protected from suit by a preliminary injunction entered by the Bankruptcy Court in the Purdue bankruptcy on October 11, 2019, and thus are not named as defendants here.

13. Purdue’s affiliate Rhodes Pharmaceuticals L.P. and Rhodes Pharmaceuticals Inc. marketed generic prescription opioids, including a generic version of OxyContin. Rhodes Technologies manufactured and supplied oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations. Rhodes Technologies, Inc. manufactured and supplied oxycodone to Purdue, or has managed Rhodes Technologies in doing so. Rhodes Pharmaceuticals L.P., Rhodes Pharmaceuticals Inc., Rhodes Technologies, and Rhodes Technologies, Inc. are referred to herein collectively as “Rhodes.”

14. Rhodes Pharmaceuticals, L.P. and Rhodes Technologies sought Chapter 11 bankruptcy protection along with Purdue on September 15, 2019, and thus are not named as defendants here. Rhodes Pharmaceuticals, Inc. and Rhodes Technologies, Inc. are currently protected from suit by a preliminary injunction entered by the Bankruptcy Court in the Purdue bankruptcy on October 11, 2019, and thus are not named as defendants here.

15. Purdue introduced a drug with a narcotic payload many times higher than that of previous prescription painkillers, while executing a sophisticated, multi-pronged

marketing campaign to change prescribers' perception of the risk of opioid addiction and to portray opioids as effective treatment for chronic pain. Purdue pushed its message of opioids as a low-risk panacea on doctors and the public through every available avenue, including through direct marketing, front groups, key opinion leaders, unbranded advertising, and hundreds of sales representatives who visited doctors and clinics on a regular basis.

16. As sales of OxyContin and Purdue's profits surged, Defendants Endo, Janssen, Teva, Actavis, and Mallinckrodt—as explained in further detail below—added additional prescription opioids, aggressive sales tactics, and dubious marketing claims of their own to the deepening crisis. They paid hundreds of millions of dollars to market and promote the drugs, notwithstanding their dangers, and pushed bought-and-paid-for “science” supporting the safety and efficacy of opioids that lacked any basis in fact or reality. Obscured from the marketing was the fact that prescription opioids are not much different than heroin—indeed on a molecular level, they are virtually indistinguishable.

17. The opioid epidemic simply could not have become the crisis it is today without an enormous supply of pills. After the aggressive and misleading marketing of branded opioids like OxyContin and Opana ignited the epidemic, generic opioids fanned the flames. Rhodes and Defendants Mallinckrodt, Actavis, Teva, and Endo manufactured and shipped enormous volumes of generic opioids to communities across the United States, including Plaintiff's. Defendants McKesson, Cardinal Health, and AmerisourceBergen raked in huge profits from the distribution of branded and generic opioids alike. These companies knew precisely the quantities of potent narcotics they

were delivering to communities across the country, including areas surrounding the Reservation. Yet not only did these Defendants intentionally disregard their monitoring and reporting obligations under federal law, they also actively sought to evade restrictions and obtain higher quotas to enable the distribution of even larger shipments of opioids. Defendants Walgreens, Walmart, and CVS distributed and dispensed enormous quantities of opioids in communities around the country, including areas surrounding the Reservation, while failing to implement effective controls against diversion and ignoring the aggregate data in their possession that would have revealed red flags of diversion at a storewide or regional level.

18. Defendants' efforts were remarkably successful: since the mid-1990s, opioids have become the most prescribed class of drugs in America. Between 1991 and 2011, opioid prescriptions in the U.S. tripled from 76 million to 219 million per year.⁴ In 2013, health care providers wrote more than 249 million prescriptions for opioid pain medication, enough for every adult in the United States to have more than one bottle of pills.⁵ In terms of annual sales, the increase has been ten-fold; before the FDA approved

⁴ Nora D. Volkow, MD, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, Appearing before the Senate Caucus on International Narcotics Control, NIH Nat'l Inst. on Drug Abuse (May 14, 2014), <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

⁵ *CDC Guideline for Prescribing Opioids for Chronic Pain*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf (last visited Dec. 27, 2019).

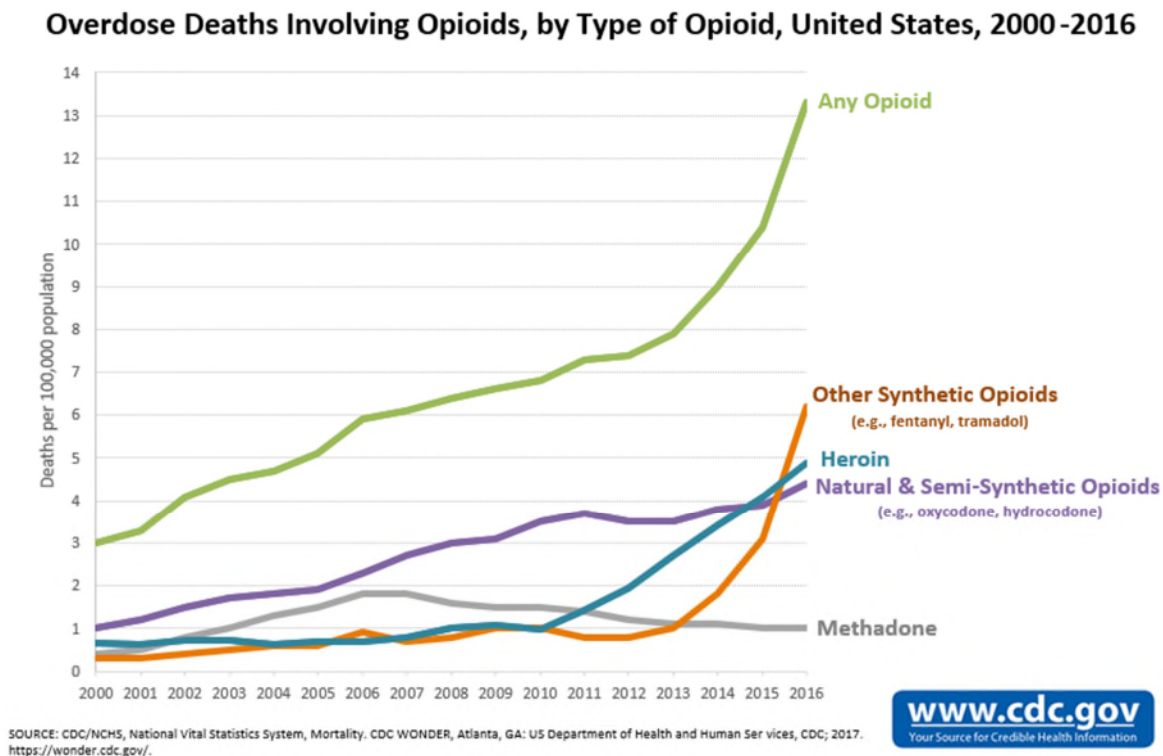
OxyContin in 1995, annual opioid sales hovered around \$1 billion. By 2015, they increased to almost \$10 billion. By 2020, revenues are projected to grow to \$18 billion.⁶

19. But Defendants' profits have come at a steep price. Opioids are now the leading cause of accidental death in the U.S., surpassing deaths caused by car accidents. Opioid overdose deaths (which include prescription opioids as well as heroin) have risen steeply over the past two decades, from approximately 8,048 in 1999, to 20,422 in 2009, to over 33,091 in 2015. The epidemic of overdose deaths shows no sign of slowing: instead, the grim toll climbed to 42,249 in 2016, and to 49,068 in 2017.⁷ As shown in the graph below, the surge in opioid-related deaths in the past few years is tied to synthetic opioids such as fentanyl, which is many times more powerful than other opioids but often illicitly manufactured to look like generic oxycodone. Fatal overdoses involving heroin have also increased significantly since 2011. Nearly half of all opioid overdose deaths involve a prescription opioid like those manufactured by Defendants,⁸ and, as discussed further below, the increase in overdoses from non-prescription opioids such as heroin and illicitly manufactured fentanyl is directly attributable to Defendants' success in expanding the market for opioids of any kind.

⁶ *Report: Opioid pain sales to hit \$18.4B in the U.S. by 2020*, CenterWatch (July 17, 2017), <https://www.centerwatch.com/articles/13351>.

⁷ *Overdose Death Rates*, NIH Nat'l Inst. on Drug Abuse, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (revised Jan. 2019); *Drug Overdose Death Data*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last reviewed June 27, 2019).

⁸ *Understanding the Epidemic*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last reviewed Dec. 19, 2018).



20. To put these numbers in perspective: in 1970, when a heroin epidemic swept the U.S., there were fewer than 3,000 heroin overdose deaths. And in 1988, around the height of the crack epidemic, there were fewer than 5,000 crack overdose deaths recorded. In 2005, at its peak, methamphetamine was involved in approximately 4,500 deaths.

21. Beyond the human cost, the CDC has estimated that the total economic burden of prescription opioid abuse costs the United States \$78.5 billion per year, which includes increased costs for health care and addiction treatment, increased strains on

human services and criminal justice systems, and substantial losses in workforce productivity.⁹

22. But even these estimates are conservative. The Council of Economic Advisers—the primary advisor to the Executive Office of the President—recently issued a report estimating that, as of 2015, the economic cost of the opioid crisis was \$504 billion—over six times larger than the most comprehensive study that preceded it.¹⁰ Whatever the final tally, there is no doubt that this crisis has had a profound economic impact.

23. Although the Tribe has dedicated resources to confronting the opioid epidemic’s damage to the community, it cannot provide all the services that its members need now and will continue to need for the foreseeable future.

24. Because of the persistent nature of drug addiction, these services must be provided on a long-term basis. Even if all opioid prescribing ceased tomorrow, this crisis, and the burdens it imposes on the Tribe, would remain. Defendants—who made billions of dollars in profits as a result of excessively promoting and distributing opioids—should

⁹ *CDC Foundation’s New Business Pulse Focuses on Opioid Overdose Epidemic*, Ctrs. for Disease Control and Prevention (Mar. 15, 2017), <https://www.cdc.gov/media/releases/2017/a0315-Business-Pulse-opioids.html>.

¹⁰ *The Underestimated Cost of the Opioid Crisis*, The Council of Econ. Advisers (Nov. 2017), <https://static.politico.com/1d/33/4822776641cfbac67f9bc7dbd9c8/the-underestimated-cost-of-the-opioid-crisis-embargoed.pdf>; Curtis Florence, Feijun Luo, Chao Zhou, & Likang Xu, *The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States*, 2013, 54 *Med. Care* 901 (Oct. 2016), https://www.researchgate.net/publication/308339245_The_Economic_Burden_of_Prescription_Opioid_Overdose_Abuse_and_Dependence_in_the_United_States_2013.

be held accountable for the damage they caused and provide the Tribe with the resources it needs to fully address the ongoing consequences of the epidemic.

25. Defendants orchestrated this crisis. Despite knowing about the true hazards of their products, Defendants misleadingly advertised their opioids as safe and effective for treating chronic pain and pushed hundreds of millions of pills into the marketplace for consumption. Through their sophisticated and well-orchestrated campaign, Defendants touted the purported benefits of opioids to treat pain and downplayed the risks of addiction. Moreover, even as the deadly toll of prescription opioid use became apparent to Defendants in years following OxyContin's launch, Defendants persisted in aggressively selling and distributing prescription opioids while evading their monitoring and reporting obligations, so that excessive quantities of addictive opioids continued to pour into and around the Reservation and other communities around the United States.

26. Defendants consistently, deliberately, and recklessly made, and continue to make, false and misleading statements regarding: the low risk of addiction to opioids, opioids' effectiveness for chronic pain and ability to improve patients' quality of life with long-term use, the lack of risk associated with higher dosages of opioids, the need to prescribe more opioids to treat withdrawal symptoms, and that risk-mitigation strategies and abuse-deterrent technologies allow doctors to safely prescribe opioids, among other things. In addition, Defendants made and continued to make misleading representations about their compliance with their obligations to maintain effective controls against diversion and to report suspicious orders in connection with the sale of opioids.

27. Because of Defendants' misconduct, the Tribe is experiencing public health and other impacts and has suffered economic damages, including but not limited to increased costs related to criminal justice and social services. The Tribe has already incurred costs in responding to the crisis and will continue to do so in the future.

28. Accordingly, the Tribe brings this action to hold Defendants liable for their misrepresentations regarding the benefits and risks of prescription opioids, as well as for their failure to monitor, detect, investigate, and report suspicious orders of those products. This conduct (i) violates the Arizona Consumer Fraud Act (CFA), A.R.S. §44-1521 *et seq*, (ii) constitutes a public nuisance under Arizona law, (iii) constitutes negligence under Arizona law, (iv) constitutes wanton negligence under Arizona law, (v) has unjustly enriched Defendants, and (vi) violates the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq*.

II. PARTIES

Hopi Tribe

29. The Hopi Tribe is a federally recognized sovereign Indian tribe. The Tribe is governed by an elected Tribal Council, with its principal place of business in Kykotsmovi Village, Arizona.

30. The Tribe exercises inherent governmental authority within the Reservation and on behalf of the health and welfare of the Tribe and its members, children, and grandchildren.

31. The Reservation is located in northeastern Arizona in Navajo and Coconino Counties. The Reservation covers approximately 1.5 million acres and includes thirteen

villages. Members of the Tribe who are affected by the actions and conduct of the Defendants alleged herein live on the Reservation, as well as in the surrounding areas.

32. There are an estimated 14,617 enrolled members of the Tribe.

Approximately 9,227 people live on the Reservation.

33. The Tribe provides government services including a court system, law enforcement, a housing authority, a child welfare system, and additional social services. Many tribal members depend on the Tribe for services.

34. The Tribe operates a variety of enterprises in locations across Arizona, including the Hopi Cultural Center, Flagstaff Properties, and Walpi Housing.¹¹

35. By deceptively marketing and promoting highly addictive opioids in and around the Reservation, and distributing them around the Reservation, Defendants have harmed and continue to harm the Tribe by forcing the Tribe to incur costs.

Endo

36. Defendant Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Endo Health Solutions Inc. Both are Delaware corporations with their principal place of business in Malvern, Pennsylvania. Collectively, these entities are referred to as “Endo.”

37. Each Endo entity acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

¹¹ *Our Entities*, Hopi Tribe Econ. Dev. Corp. (2020), <http://htedc.com/entities/> (last accessed Feb. 26, 2020).

38. Endo manufactures, promotes, sells, markets, and distributes opioids such as Percocet, Opana, and Opana ER.

39. Endo generates substantial sales from its opioids. For example, opioids accounted for more than \$400 million of Endo's overall revenues of \$3 billion in 2012, and Opana ER generated more than \$1 billion in revenue for Endo in 2010 and 2013.

Par Pharmaceutical

40. Defendant Par Pharmaceutical, Inc. is a New York corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Defendant Par Pharmaceutical Companies, Inc. and holds itself out as "an Endo International Company."

41. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York.

42. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are referred to collectively as "Par Pharmaceutical." Par Pharmaceutical is an affiliate of Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc.

43. At all relevant times, Par Pharmaceutical has packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. Further, Par Pharmaceutical manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

44. Based on the private ARCOS data made available to Plaintiff, drugs sold and manufactured by Par Pharmaceutical represent a substantial market share in Plaintiff's jurisdiction during the relevant time period.

45. Par Pharmaceutical's conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

Janssen and Johnson & Johnson

46. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Collectively, these entities are referred to as "Janssen."

47. Both entities above acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

48. Johnson & Johnson is the only company that owns more than 10% of Janssen Pharmaceuticals, Inc., and corresponds with the FDA regarding the drugs manufactured by Janssen Pharmaceuticals, Inc. Johnson & Johnson also paid prescribers to speak about opioids manufactured by Janssen Pharmaceuticals, Inc. In short, Johnson & Johnson controls the sale and development of the drugs manufactured by Janssen Pharmaceuticals, Inc.

49. Janssen manufactures, promotes, sells, markets, and distributes opioids such as Duragesic, Nucynta, and Nucynta ER. Janssen stopped manufacturing Nucynta and Nucynta ER in 2015.

50. Janssen generates substantial sales revenue from its opioids. For example, Duragesic accounted for more than \$1 billion in sales in 2009, and Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

Cephalon and Teva

51. Defendant Cephalon, Inc. (“Cephalon”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Defendant Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation and a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

52. Cephalon manufactures, promotes, sells, and distributes opioids, including Actiq and Fentora, in the United States.

53. Teva Ltd., Teva USA, and Cephalon work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon-branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which are distributed with Cephalon opioids, disclose

that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

54. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.¹² Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012—the year following the Cephalon acquisition in October 2011—attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including sales of Fentora.¹³ Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Teva Ltd. would conduct those companies’ business in the United States itself.

55. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Collectively, these entities are referred to as “Teva.”

Allergan, Actavis, and Watson

56. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan, Inc.

¹² Actiq, <http://www.actiq.com/> (last visited Dec. 27, 2019).

¹³ *Teva Pharm. Indus. Ltd. Form 20-F*, U.S. Sec. and Exchange Commission (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

in March 2015, and the combined company changed its name to Allergan plc in June 2015. Actavis plc (formerly known as Actavis Limited) was incorporated in Ireland in May 2013 for the merger between Actavis, Inc. and Warner Chilcott plc.

57. Defendant Watson Pharmaceuticals, Inc. acquired Actavis Group in October 2012 and changed its name to Actavis, Inc. as of January 2013.

58. Defendant Allergan Finance, LLC (formerly known as Actavis, Inc.) is based in Parsippany, New Jersey. It operates as a subsidiary of Allergan plc.

59. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

60. Defendant Actavis Pharma, Inc. is registered to do business in the State of Washington as a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

61. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

62. Each of these defendants and entities is owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Defendant Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis/Watson products ultimately inure to its benefit. Collectively, these defendants and entities are referred to as “Actavis.”

63. Actavis manufactures, promotes, sells, and distributes opioids in the United States, including the branded drugs Kadian and Norco and generic versions of Kadian,

Duragesic, and Opana. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

Mallinckrodt

64. Defendant Mallinckrodt plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt in June of that year. Mallinckrodt began as a U.S.-based company, with the founding of Mallinckrodt & Co. in 1867; Tyco International Ltd. acquired the company in 2000. In 2008, Tyco Healthcare Group separated from Tyco International and renamed itself Covidien.

65. Defendant Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt plc.

66. Formed in 2017, Defendant SpecGX LLC is a Delaware limited liability company with its principal place of business in St. Louis, Missouri, and is a wholly owned subsidiary of Defendant Mallinckrodt plc. SpecGX LLC manufactures Mallinckrodt's generic products and bulk active pharmaceutical ingredients (APIs).

67. Mallinckrodt plc, Mallinckrodt, LLC, and SpecGX LLC are referred to collectively as "Mallinckrodt."

68. Mallinckrodt manufactures, markets, and sells drugs in the United States. As of 2012, it was the largest U.S. supplier of opioid pain medications. In particular, it is one of the largest manufacturers of oxycodone in the U.S.

69. Mallinckrodt currently manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In addition, Mallinckrodt previously developed, promoted, and sold the following branded opioid products: Magnacet, TussiCaps, and Xartemis XR.

70. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

71. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials; (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York; and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

72. In 2017, Mallinckrodt agreed to settle for \$35 million the Department of Justice's allegations regarding excessive sales of oxycodone in Florida. The Department

of Justice alleged that even though Mallinckrodt knew that its oxycodone was being diverted to illicit use, it nonetheless continued to incentivize and supply these suspicious sales, and it failed to notify the DEA of the suspicious orders in violation of its obligations as a registrant under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (“CSA”).

Mylan Pharmaceuticals, Inc.

73. Defendant Mylan Pharmaceuticals, Inc. (“Mylan”), is a West Virginia corporation with its principal place of business in Canonsburg, Pennsylvania.

74. At all relevant times, Mylan has packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. Further, Mylan manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

75. Based on the private ARCOS data made available to Plaintiff, drugs sold and manufactured by Mylan represent a substantial market share in Plaintiff’s jurisdiction during the relevant time period.

76. Mylan’s conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

West-Ward Pharmaceuticals Corp.

77. Defendant West-Ward Pharmaceuticals Corp. is a Delaware corporation with its principal place of business located in Eatontown, New Jersey. West-Ward Pharmaceuticals Corp. is the United States agent and subsidiary of Defendant Hikma Pharmaceuticals PLC, a London-based global pharmaceutical company.

78. West-Ward Pharmaceuticals Corp. and Hikma Pharmaceuticals PLC are collectively referred to as “West-Ward.”

79. At all relevant times, West-Ward has packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. Further, West-Ward manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

80. Based on the private ARCOS data made available to Plaintiff, drugs sold and manufactured by West-Ward represent a substantial market share in Plaintiff’s jurisdiction during the relevant time period.

81. West-Ward’s conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

KVK-Tech, Inc.

82. Defendant KVK Tech, Inc. (“KVK”) is a Pennsylvania corporation with its principal place of business in Newton, Pennsylvania.

83. At all relevant times, KVK has packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. Further, KVK manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

84. Based on the private ARCOS data made available to Plaintiff, drugs sold and manufactured by KVK represent a substantial market share in Plaintiff's jurisdiction during the relevant time period.

85. KVK's conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

Sandoz Inc.

86. Defendant Sandoz, Inc. ("Sandoz USA") is a Colorado corporation with its principal place of business located in Princeton, New Jersey. Sandoz USA distributes the drugs that its parent, Sandoz Germany, develops and manufactures. Sandoz USA and Sandoz Germany are both owned by Novartis International AG. Defendant Sandoz USA is defined to include its manager, officers, employees, and agents acting on its behalf.

87. At all relevant times, Sandoz has packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. Further, Sandoz

manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

88. Based on the private ARCOS data made available to Plaintiff, drugs sold and manufactured by Sandoz USA represent a substantial market share in Plaintiff's jurisdiction during the relevant time period.

89. Sandoz's conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

Amneal Pharmaceuticals

90. Defendant Amneal Pharmaceuticals, LLC, is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey.

91. Amneal Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business in Bridgewater, New Jersey.

92. Amneal Pharmaceuticals, Inc. and Amneal Pharmaceuticals, LLC are collectively referred to as "Amneal."

93. At all relevant times, Amneal, and all related entities including but not limited to Defendant Impax Laboratories, Inc. and Defendant Impax Generics, has packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. Further, Amneal manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

94. Based on the private ARCOS data made available to Plaintiff, drugs sold and manufactured by Amneal represent a substantial market share in Plaintiff's jurisdiction during the relevant time period.

95. Amneal's conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

96. Defendants Endo, Janssen, Teva, Actavis, and Mallinckrodt are collectively referred to as the "Marketing Defendants." These Marketing Defendants together with Par Pharmaceutical, Mylan, West-Ward, KVK, Sandoz USA, and Amneal are collectively referred to as the "Manufacturing Defendants."

AmerisourceBergen

97. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania.

98. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies" with "over \$145 billion in annual revenue."

99. AmerisourceBergen is licensed as a "wholesale distributor" to sell prescription and non-prescription drugs, including opioids, in Arizona. It operates a warehouse in Phoenix, Arizona.

Cardinal Health

100. Defendant Cardinal Health, Inc. (“Cardinal Health”) is an Ohio Corporation with its principal place of business in Dublin, Ohio.

101. According to its 2017 Annual Report, Cardinal Health is “a global, integrated healthcare services and products company serving hospitals, healthcare systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide . . . deliver[ing] medical products and pharmaceuticals.” In 2017 alone, Cardinal Health generated revenues of nearly \$130 billion.

102. Cardinal Health is licensed as a “wholesale distributor” to sell prescription and non-prescription drugs, including opioids, in Arizona. It operates a warehouse in Tolleson, Arizona.

McKesson

103. Defendant McKesson Corporation (“McKesson”) is a Delaware Corporation with its principal place of business in San Francisco, California.

104. McKesson is the largest pharmaceutical distributor in North America, delivering nearly one-third of all pharmaceuticals used in this region.

105. According to its 2017 Annual Report, McKesson “partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.” Additionally, McKesson’s pharmaceutical distribution business operates and serves thousands of customer locations through a network of twenty-seven distribution centers,

as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all fifty states and Puerto Rico.

106. For the fiscal year ending March 31, 2017, McKesson generated revenues of \$198.5 billion.

107. McKesson is licensed as a “wholesale distributor” to sell prescription and non-prescription drugs, including opioids, in Arizona. It operates a warehouse in Tolleson, Arizona.

108. Collectively, McKesson, AmerisourceBergen, and Cardinal Health account for approximately 85% of all drug shipments in the United States.

109. McKesson, AmerisourceBergen, and Cardinal Health collectively are referred to as the “Distributor Defendants.”

Walgreens

110. Defendant Walgreens Boots Alliance Inc. a/k/a Walgreen Co. (“Walgreens”) is a Delaware corporation with its principal place of business in Illinois. Walgreens, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in Plaintiff’s communities.

111. Based on the private ARCOS data made available to Plaintiff, drugs sold and distributed by Walgreens represent a substantial market share in Plaintiff’s jurisdiction during the relevant time period.

112. Walgreens' conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

Walmart

113. Defendant Walmart, Inc. is a Delaware corporation with its principal place of business in Arkansas. Walmart, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walmart, Inc. distributed prescription opioids throughout the United States, including in Plaintiff's communities.

114. Based on the private ARCOS data made available to Plaintiff, drugs sold and distributed by Walmart, Inc. represent a substantial market share in Plaintiff's jurisdiction during the relevant time period.

115. Walmart, Inc.'s conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

CVS

116. Defendant CVS Health Corporation ("CVS Health") is a Delaware corporation with its principal place of business in Rhode Island. CVS Health, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and also operates retail stores, including in and around Plaintiff's geographical area, that sell prescription medicines, including opioids.

117. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a wholly owned subsidiary of CVS Health. Defendant CVS Pharmacy, Inc. is both a DEA registered “distributor”¹⁴ and a DEA registered “dispenser”¹⁵ of prescription opioids and is registered to do business in Arizona.

118. Defendants CVS Health Corporation and CVS Pharmacy, Inc. are collectively referred to as “CVS.” CVS conducts business as a licensed wholesale distributor and dispenser. At all times relevant to this Complaint, CVS distributed and/or dispensed prescription opioids throughout the United States, including in Arizona and the area surrounding the Hopi Reservation specifically.

119. Walgreens, Walmart, Inc., and CVS collectively are referred to as the “Retail Pharmacy Defendants.”

120. The Retail Pharmacy Defendants also functioned as distributors of opioids in that they distributed opioids to their own retail locations.¹⁶ With respect to their distribution conduct, the Retail Pharmacy Defendants are subject to the same statutory and common-law duties as all distributors of controlled substances.

John and Jane Does 1-100, inclusive

121. In addition to the Defendants identified herein, the true names, roles, and/or capacities in the wrongdoing alleged herein of Defendants named John and Jane Does 1

¹⁴ 21 U.S.C. § 802(11) and § 822(a)(1).

¹⁵ 1 U.S.C. § 802(10) and § 822(a)(2).

¹⁶ On information and belief, CVS distributed hydrocodone combination products to its retail locations until 2014.

through 100, inclusive, are currently unknown to Plaintiff, and thus, are named as Defendants under fictitious names as permitted by the rules of this Court. Plaintiff will amend this complaint and identify their true identities and their involvement in the wrongdoing at issue, as well as the specific causes of action asserted against them when they become known.

III. JURISDICTION AND VENUE

122. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332. The Court also has federal question subject matter jurisdiction arising out of Plaintiff's RICO claims pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1961, *et seq.*

123. Venue in this Court is proper under 28 U.S.C. § 1391(b) and 18 U.S.C. § 1965 because Defendants regularly transact business in this District, a significant portion of the acts, omissions, and transactions complained of occurred in this District.

124. This Court has personal jurisdiction over Defendants because *inter alia*, they conduct business in Arizona and have purposefully availed themselves of the privilege of conducting business in Arizona. Defendants have sufficient minimum contacts with Arizona to render the exercise of personal jurisdiction over it by this Court consistent with traditional notions of fair play and substantial justice.

IV. FACTUAL ALLEGATIONS

A. History and Background of Medical Use of Opioids

125. The term “opioid” refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids.¹⁷ Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression. In addition, opioids cause sedation and constipation.

126. Most of these effects are medically useful in certain situations, but respiratory depression is the primary limiting factor for the use of opioids. While the body develops tolerance to the analgesic and euphoric effects of opioids relatively quickly, this is not true with respect to respiratory depression. At high doses, opioids can and often do arrest respiration altogether. This is why the risk of opioid overdose is so high, and why many of those who overdose simply go to sleep and never wake up.

127. Natural opioids are derived from the opium poppy and have been used since antiquity, going as far back as 3400 B.C. The opium poppy contains various opium alkaloids, three of which are used commercially today: morphine, codeine, and thebaine.

128. A 16th-century European alchemist, Paracelsus, is generally credited with developing a tincture of opium and alcohol called laudanum, but it was a British

¹⁷ At one time, the term “opiate” was used for natural opioids, while “opioid” referred to synthetic substances manufactured to mimic opiates. Now, however, most medical professionals use “opioid” to refer broadly to natural, semi-synthetic, and synthetic opioids. A fourth class of opioids, endogenous opioids (e.g., endorphins), is produced naturally by the human body.

physician a century later who popularized the use of laudanum in Western medicine. “Sydenham’s laudanum” was a simpler tincture than Paracelsus’s and was widely adopted as a treatment not only for pain, but for coughs, dysentery, and numerous other ailments. Laudanum contains almost all of the opioid alkaloids and is still available by prescription today.

129. Chemists first isolated the morphine and codeine alkaloids in the early 1800s, and the pharmaceutical company Merck began large-scale production and commercial marketing of morphine in 1827. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. It was upper- and middle-class white women, however, who comprised the majority of opioid addicts in the late 19th-century United States, using opioid preparations widely available in pain elixirs, cough suppressants, and patent medicines. By 1900, an estimated 300,000 people were addicted to opioids in the United States,¹⁸ and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms.

130. Trying to develop a drug that could deliver opioids’ potent pain relief without their addictive properties, chemists continued to isolate and refine opioid alkaloids. Heroin, first synthesized from morphine in 1874, was marketed commercially by the Bayer Pharmaceutical Company beginning in 1898 as a safe alternative to

¹⁸ Nick Miroff, *From Teddy Roosevelt to Trump: How drug companies triggered an opioid crisis a century ago*, Washington Post (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca.

morphine. Heroin's market position as a safe alternative was short-lived, however; Bayer stopped mass-producing heroin in 1913 because of its dangers. German chemists then looked to the alkaloid thebaine, synthesizing oxymorphone and oxycodone from thebaine in 1914 and 1916, respectively, with the hope that the different alkaloid source might provide the benefits of morphine and heroin without the drawbacks.

131. But each opioid was just as addictive as the one before it, and eventually the issue of opioid addiction could not be ignored. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."¹⁹

132. Concerns over opioid addiction led to national legislation and international agreements regulating narcotics: the International Opium Convention, signed at the Hague in 1912, and, in the U.S., the Harrison Narcotics Tax Act of 1914. Opioids were no longer marketed as cure-alls and instead were relegated to the treatment of acute pain.

133. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids, but these opioids were generally produced in combination with other drugs, with relatively low opioid content. For example, Percodan, produced by Defendant Endo since 1950, is oxycodone and aspirin, and contains just under 5 mg of

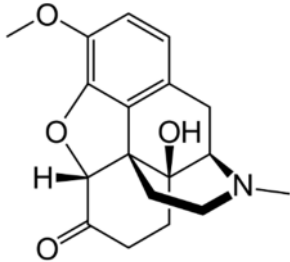
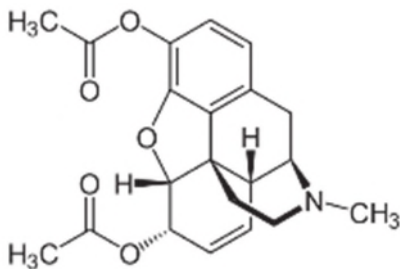
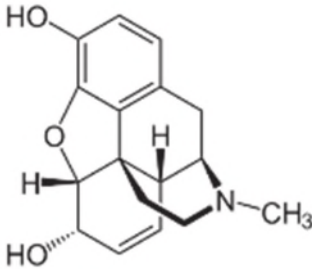
¹⁹ *Id.*

oxycodone. Percocet, manufactured by Endo since 1971, is the combination of oxycodone and acetaminophen, with dosage strengths delivering between 2.5 mg and 10 mg of oxycodone. Vicodin, a combination of hydrocodone and acetaminophen, was introduced in the U.S. in 1978 and is sold in strengths of 5 mg, 7.5 mg, and 10 mg of hydrocodone. Defendant Janssen also manufactured a drug with 5 mg of oxycodone and 500 mg of acetaminophen, called Tylox, from 1984 to 2012.

134. In contrast, OxyContin, the product with the dubious honor of the starring role in the opioid epidemic, is pure oxycodone. Purdue initially made it available in the following dosage strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. In other words, the weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times as much as that.

135. Prescription opioids are essentially pharmaceutical heroin; they are synthesized from the same plant, have similar molecular structures, and bind to the same receptors in the human brain. It is no wonder then that there is a straight line between prescription opioid abuse and heroin addiction. Indeed, studies show that over 80% of new heroin addicts between 2008 and 2010 started with prescription opioids.²⁰

²⁰ CM Jones, *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers - United States, 2002-2004 and 2008-2010*, 132(1-2) Drug Alcohol Depend. 95-100 (Sept. 1, 2013), <https://www.ncbi.nlm.nih.gov/pubmed/23410617>.

Oxycodone	Heroin	Morphine
		

136. Medical professionals describe the strength of various opioids in terms of “morphine milligram equivalents” (“MME”). According to the CDC, dosages at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

137. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin’s twice-daily dosing, the 50 MME/day threshold is reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.²¹

²¹ The wide variation in the MME strength of prescription opioids renders misleading any effort to capture “market share” by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focused its business on branded, highly potent pills, causing it to be responsible for a significant percent of the total amount of MME in circulation even though it currently claims to have a small percent of the market share in terms of pills or prescriptions.

138. As journalist Barry Meier wrote in his 2003 book *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death*, “In terms of narcotic firepower, OxyContin was a nuclear weapon.”²²

139. Fentanyl, an even more potent and more recent arrival in the opioid tale, is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959 by Dr. Paul Janssen under a patent held by Janssen Pharmaceuticals, fentanyl is increasingly prevalent in the market for opioids created by Defendants’ promotion, with particularly lethal consequences. In many instances, illicit fentanyl is manufactured to look like oxycodone tablets, in the light blue color and with the “M” stamp of Defendant Mallinckrodt’s 30mg oxycodone pills. These lookalike pills have been found around the country.²³

B. The Sackler Family Played a Pivotal Role in Setting the Stage for the Worst Man-Made Epidemic in Modern Medical History

1. The Sackler family pioneered the integration of advertising and medicine.

140. Given the history of opioid use in the U.S. and the medical profession’s resulting wariness, the commercial success of Defendants’ prescription opioids would not

²² Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* (Rodale 2003).

²³ See e.g., Sharon Bogan, *Illicit fentanyl found locally in fake opioid pills*, Pub. Health Insider (Oct. 2, 2017), <https://web.archive.org/web/20190804203642/https://publichealthinsider.com/2017/10/02/illicit-fentanyl-found-locally-in-fake-opioid-pills/>; *Mislabeled painkillers “a fatal overdose waiting to happen,”* CBS News (Feb. 29, 2016, 10:46am), <https://www.cbsnews.com/news/mislabeled-painkillers-a-fatal-overdose-waiting-to-happen/>.

have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

141. As it turned out, Purdue was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, surpassing the wealth of storied families like the Rockefellers, the Mellons, and the Busches.²⁴ Because of Purdue and, in particular, OxyContin, the Sacklers' net worth was \$13 billion as of 2016. Until 2018, Sackler family members made up the majority of the Purdue board, and all of the company's profits go to Sackler family trusts and entities.²⁵ Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

142. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called The Purdue Frederick Company in 1952. While all three brothers were accomplished psychiatrists, it was Arthur, the oldest, who directed the Sackler story, treating his brothers more as his protégés than colleagues, putting them both through medical school and essentially dictating their paths. It was Arthur who created the Sackler family's wealth, and it was Arthur who created the pharmaceutical

²⁴ Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, *Forbes* (July 1, 2015, 10:17am), <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/#3045688775e0>.

²⁵ David Armstrong, *The man at the center of the secret OxyContin files*, *Stat News* (May 12, 2016), <https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/>.

advertising industry as we know it—laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

143. Arthur Sackler was both a psychiatrist and a marketing executive, and, by many accounts, a brilliant and driven man. He pursued two careers simultaneously, as a psychiatrist at Creedmoor State Hospital in New York and the president of an advertising agency called William Douglas McAdams. Arthur pioneered both print advertising in medical journals and promotion through physician “education” in the form of seminars and continuing medical education courses. He understood intuitively the persuasive power of recommendations from fellow physicians and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.²⁶

144. It was Arthur who, in the 1960s, made Valium into the first \$100-million drug, so popular it became known as “Mother’s Little Helper.” His expertise as a psychiatrist was key to his success; as his biography in the Medical Advertising Hall of Fame notes, it “enabled him to position different indications for Roche’s Librium and Valium—to distinguish for the physician the complexities of anxiety and psychic tension.”²⁷ When Arthur’s client, Roche, developed Valium, it already had a similar drug,

²⁶ Meier, *supra* note 22, at 204.

²⁷ *MAHF Inductees, Arthur M. Sackler*, Med. Advert. Hall of Fame, <https://www.mahf.com/mahf-inductees/> (last visited Dec. 27, 2019).

Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called “psychic tension”—essentially stress—and pitched Valium as the solution.²⁸ The campaign, for which Arthur was compensated based on volume of pills sold,²⁹ was a remarkable success.

145. Arthur’s entrepreneurial drive led him to create not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*, which he distributed for free to doctors nationwide. Arthur also conceived a company now called IMS Health Holdings Inc., which monitors prescribing practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies like Defendants, who utilize it to tailor their sales pitches to individual physicians.

146. Even as he expanded his business dealings, Arthur was adept at hiding his involvement in them. When, during a 1962 Senate hearing about deceptive pharmaceutical advertising, he was asked about a public relations company called Medical and Science Communications Associates, which distributed marketing from drug companies disguised as news articles, Arthur was able to truthfully testify that he never was an officer for nor had any stock in that company. But the company’s sole shareholder was his then-wife. Around the same time, Arthur also successfully evaded an investigative journalist’s attempt to link the Sacklers to a company called MD

²⁸ Meier, *supra* note 22, at 202; *One Family Reaped Billions From Opioids*, WBUR On Point (Oct. 23, 2017), <http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions-from-opioids>.

²⁹ WBUR On Point interview, *supra* note 28.

Publications, which had funneled payments from drug companies to an FDA official named Henry Welch, who was forced to resign when the scandal broke.³⁰ Arthur had set up such an opaque and layered business structure that his connection to MD Publications was only revealed decades later when his heirs were fighting over his estate.

147. Arthur Sackler did not hesitate to manipulate information to his advantage. His legacy is a corporate culture that prioritizes profits over people. In fact, in 2007, federal prosecutors conducting a criminal investigation of Purdue's fraudulent advertising of OxyContin found a "corporate culture that allowed this product to be misbranded with the intent to defraud and mislead."³¹ Court documents from the prosecution state that "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 . . ."³² Half a century after Arthur Sackler wedded advertising and medicine, Purdue employees were following his playbook, putting product sales over patient safety.

2. The Sacklers were personally involved in the development and aggressive marketing of OxyContin.

148. After the Sackler brothers acquired The Purdue Frederick Company in 1952, Purdue sold products ranging from earwax remover to antiseptic, and it became a

³⁰ Meier, *supra* note 22, at 210-14.

³¹ Naomi Spencer, *OxyContin manufacturer reaches \$600 million plea deal over false marketing practices*, World Socialist Web Site (May 19, 2007), <https://www.wsws.org/en/articles/2007/05/oxy-m19.html>.

³² Agreed Statement of Facts, *United States v. Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running Purdue because that would have been a conflict of interest. Raymond Sackler became Purdue's head executive while Mortimer Sackler ran Purdue's UK affiliate.

149. Raymond's son, Richard S. Sackler, began working for Purdue as an assistant to the president in 1971. In addition to holding various other roles at Purdue, including leading the firm's R&D division and the sales and marketing division, Richard Sackler was named president in 1999. In 2003, Richard Sackler resigned from his role as president to become co-chair of Purdue's board of directors.³³ He participated extensively in the invention, marketing, and sale of OxyContin.

150. In addition to Richard Sackler's involvement, other members of the Sackler family maintained substantial control over Purdue by occupying the majority of the board seats at Purdue from 1990 to 2018. In 1999, when Richard Sackler became Purdue's president, Jonathan, Kathe, and Mortimer Sackler were all vice presidents of Purdue.³⁴ Years later, when Purdue was mired in investigations by federal and state authorities, they resigned their positions as vice presidents, but they remained members of Purdue's board of directors. Ilene Sackler Lefcourt and Theresa Sackler served on Purdue's board of directors beginning in the early 1990s. David A. Sackler served on Purdue's board of

³³ Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), <http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/>.

³⁴ First Amended Complaint at ¶179, *Commonwealth of Mass. v. Purdue Pharma L.P.*, C.A. No. 1884-cv-01808 (BLS2) (Mass. Super. Ct. Jan. 31, 2019) [hereinafter MA Complaint].

directors beginning in 2012. Beverly Sackler, wife of Raymond Sackler, served on Purdue's board from 1993 to 2017, resigning shortly after Raymond's death in 2017. Other Sackler family members resigned in 2018, and as of April 2019, according to Purdue, no Sackler family members remained on Purdue's board.³⁵

151. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin. It quickly became Purdue's best seller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond Sackler's oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company. Richard Sackler had grand ambitions for the company; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big."³⁶ Richard Sackler believed Purdue should develop another use for its "Contin" timed-release system.

152. In 1990, Purdue's VP of clinical research, Robert Kaiko, sent a memo to Richard Sackler and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, the relatively

³⁵ Paul Schott, *Sacklers quit Purdue Pharma board amid shifts for OxyContin maker*, Stamford Advocate (Nov. 4, 2019, 4:44pm), <https://www.stamfordadvocate.com/business/article/Sacklers-quit-Purdue-Pharma-board-signaling-13742946.php>.

³⁶ Christopher Glazek, *supra* note 33.

weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxycodine," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it eventually pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin'" held among physicians.³⁷

153. Moreover, Purdue's internal emails reveal that Richard Sackler, Kathe Sackler, and other Purdue executives personally knew that doctors incorrectly believed that OxyContin was weaker than morphine, leading them to prescribe it much more frequently.³⁸ Despite knowing that oxycodone is 1.5 times more potent than morphine, Richard Sackler directed staff not to tell doctors the truth about oxycodone's potency—as that would have likely reduced sales.³⁹

154. For Purdue and OxyContin to be "*really* big," Purdue needed to both distance its new product from the traditional view of narcotic addiction risk and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's

³⁷ *United States v. Purdue Frederick Co.*, *supra* note 32.

³⁸ MA Complaint, *supra* note 34, at ¶ 176.

³⁹ *Id.*

top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase.⁴⁰ As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

155. The Sacklers recognized OxyContin as the means by which Purdue, and their own fortune, could become “really big.” As Purdue’s Senior Vice President in charge of sales, Richard Sackler made an ominous prediction at the launch party for OxyContin. He foretold that “the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white....”⁴¹ To create this “blizzard of prescriptions,” the Sacklers perpetuated deceptions about the safety of OxyContin and pressed Purdue’s sales team to sell ever-increasing volumes of OxyContin, incentivizing sales of the more expensive (and more dangerous) higher doses.

156. Internal documents also reveal the extent to which the Sacklers’ greed motivated their unrelenting drive to sell more pills. For example, in one such email, Richard Sackler reacted to sales of over \$20 million *per week* with a “yawn”:

In 1999, when employee Michael Friedman reported to Richard Sackler that Purdue was making more than \$20,000,000 per week, Richard replied immediately, at midnight, that the sales were “not so great.” “After all, if we

⁴⁰ Meier, *supra* note 22, at 269.

⁴¹ First Amended Complaint at ¶ 273, *The People of the State of New York v. Purdue Pharma L.P., et al.*, No. 400016/2018 (Sup. Ct. Suffolk Cnty. Mar. 28, 2019) [hereinafter NY Complaint].

are to do 900M this year, we should be running at 75M/month. So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?”⁴²

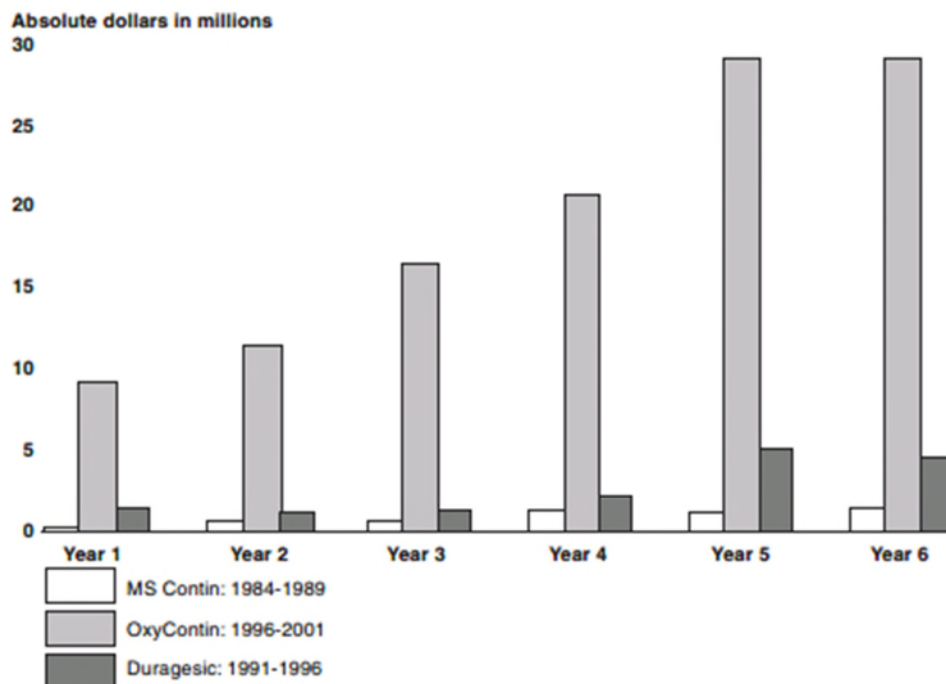
157. Despite the fact that there has been little or no change in the amount of pain reported in the U.S. over the last twenty years, Purdue recognized an enormous untapped market for its new drug. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, “There are 50 million patients in this country who have chronic pain that’s not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that.”⁴³

158. In pursuit of these 50 million potential customers and Richard Sackler’s “blizzard of prescriptions,” Purdue poured resources into OxyContin’s sales force and advertising. As shown below, Purdue’s early promotional spending on OxyContin dwarfed spending on MS Contin or Defendant Janssen’s spending on Duragesic:⁴⁴

⁴² MA Complaint, *supra* note 34, at ¶ 178.

⁴³ *Id.* at ¶ 156.

⁴⁴ *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. Gen. Acct. Off. Rep. to Cong. Requesters at 22 (Dec. 2003), <http://www.gao.gov/new.items/d04110.pdf>.

Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales

Source: DEA and IMS Health, Integrated Promotional Service Audit.

Note: Dollars are 2002 adjusted.

159. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners. Today, one in every five patients who present themselves to physicians' offices with non-cancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receives an opioid prescription.⁴⁵

⁴⁵ Deborah Dowell, M.D., Tamara M. Haegerich, Ph.D., and Roger Chou, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Ctrs. for Disease Control and Prevention (Mar. 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> [hereinafter 2016 CDC Guideline].

3. Following reports of OxyContin abuse and federal investigations, the Sacklers continued to promote opioids but took steps to shield their assets from judgment.

160. Purdue's aggressive sales push quickly led to reports of OxyContin abuse and fatal overdoses. Both Purdue as a company and the Sacklers as individuals knew about significant abuse of OxyContin in the first years after the drug's introduction in 1996.⁴⁶ In early 1999, Purdue's general counsel, Howard Udell, wrote to another Purdue official that the company had learned of references on the internet to the abuse of Purdue's opioid products.⁴⁷ Prosecutors wrote that Richard Sackler was told in 1999 about discussions in internet chatrooms about snorting OxyContin.⁴⁸ Richard Sackler's knowledge in the late 1990s of OxyContin's status as a highly sought-after street drug was confirmed in his deposition testimony from earlier litigation, only released to the public in February 2019.⁴⁹

161. Yet at a 2001 congressional hearing on the increase in opioid abuse, Purdue President Michael Friedman testified that Purdue first became aware of the abuse of

⁴⁶ Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. Times (May 29, 2018), <https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html?login=email&auth=login-email>.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ David Armstrong, *Sackler Embraced Plan to Conceal OxyContin's Strength from Doctors, Sealed Testimony Shows*, ProPublica (Feb. 21, 2019, 1:45pm), <https://www.propublica.org/article/richard-sackler-oxycontin-oxycodone-strength-conceal-from-doctors-sealed-testimony>.

OxyContin in April 2000, after news reports of people abusing the drug recreationally in Maine.⁵⁰ None of the Sacklers attempted to correct this misrepresentation.

162. Purdue has generated estimated sales of more than \$35 billion from opioids since 1996, while raking in more than \$3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of \$3 billion in 2015 represent a four-fold increase from its 2006 sales of \$800 million.

163. In addition, in November 2007, just months after Purdue pleaded guilty for deceiving patients and doctors, the Sacklers established Rhodes Pharmaceuticals L.P., a manufacturer of generic opioids, to continue profiting from the epidemic they helped create. This development expanded the operations of Rhodes Technologies, Inc., which was primarily involved with manufacture of bulk active pharmaceutical ingredients. The connection between the Sacklers and Rhodes was not widely known until the publication of a 2018 *Financial Times* article.⁵¹

164. In public statements responding to the opioid crisis, Purdue has claimed a minimal role, stating, for example, that OxyContin accounted for only 1.4% of all opioid

⁵⁰ Patrick Radden Keefe, *The Family That Built an Empire of Pain*, New Yorker (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

⁵¹ See David Crow, *How Purdue's 'One-Two' Punch Fueled the Market for Opioids*, Fin. Times (Sept. 9, 2018), <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>.

analgesic prescriptions written between October 2017 and September 2018.⁵² But the Sacklers' establishment and control of Rhodes Pharmaceuticals L.P. means that the Sacklers are responsible for a larger market share than that. As *Financial Times* reported, "Rhodes is a much larger producer of opioids by volume, and the combined companies accounted for 14.4m prescriptions that year, giving them an overall market share of 6 percent in 2016."⁵³

165. The Sacklers are beneficial owners of and exercise control over not only Rhodes Pharmaceuticals L.P., but all four Rhodes entities. The Sacklers thus have profited not only from Purdue's earnings on excessive prescription opioid sales, but also from the sales of opioids by multiple additional corporate entities.

166. Purdue did little to change policies regarding the promotion of opioids, and the Sacklers were intimately involved in continuing the misconduct. After the 2007 guilty plea, the Sacklers directed Purdue to hire hundreds of additional sales representatives.⁵⁴ The Sacklers also required their sales representatives to average at least 7.5 prescribers daily, as well as having those prescribers agree to increasing prescriptions.

167. Richard Sackler was especially involved in overseeing and directing sales operations. He personally went into the field, for example, to supervise Purdue's sales

⁵² *Common Myths About OxyContin (oxycodone HCl) Extended-Release Tablets CII, Purdue Pharma*, <https://web.archive.org/web/20190910153705/https://www.purduepharma.com/news-media/common-myths-about-oxycotin/> (last visited Dec. 27, 2109).

⁵³ Crow, *supra* note 51.

⁵⁴ NY Complaint, *supra* note 41, at ¶ 394.

representatives.⁵⁵ As a result of his time in the field, he argued with Vice President Russell Gasdia that legally required warnings about opioids were unnecessary and that a warning “implies a danger of untoward reactions and hazards that simply aren’t there.”⁵⁶

168. The other Sacklers remained deeply involved in sales as well. In 2012, for example, Mortimer Sackler suggested Purdue reschedule an annual sales meeting from January to February so that sales representatives could “get back to work for January and back in front of doctors who enter the new year refreshed...”⁵⁷ Richard Sackler proposed canceling the meeting entirely.⁵⁸

169. Despite the company’s outward appearances, the Sacklers recognized that the increased pressure on the company required loyalty to the family. In 2010, Purdue staff provided the Sacklers a 10-year plan for Purdue’s opioid sales, under which the Sacklers would receive at least \$700 million per year from 2010 to 2020.⁵⁹

170. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company’s annual opioid sales of \$3 billion in 2015 represent a four-fold increase from its 2006 sales of \$800 million.

171. Nonetheless, the Sacklers found themselves on the defensive more and more often after 2010. For example, in late 2017, insurance provider Cigna made public

⁵⁵ *Id.* at ¶ 393.

⁵⁶ MA Complaint, *supra* note 34, at ¶ 356.

⁵⁷ NY Complaint, *supra* note 41, at ¶ 396.

⁵⁸ *Id.*

⁵⁹ *Id.* at ¶ 420.

statements about how opioid companies influence prescribing and dosing.⁶⁰ Cigna also replaced OxyContin on its list of covered drugs with a competitor's drug. Upon learning this, Richard Sackler suggested Purdue replace Cigna as the insurance provider for Purdue's company health plan.⁶¹

172. Bowing to increasing pressure and scrutiny, the Sacklers resigned from the Purdue board of directors in 2018.⁶²

4. In response to enforcement actions in the United States, the Sacklers have moved their aggressive opioid marketing—and their wealth—overseas.

173. Since at least 1999, the Sacklers have known of the high potential for abuse of OxyContin. Rather than take steps to ameliorate the damage they have caused—or to prevent additional harm—the Sacklers instead began to shift profits from Purdue and related entities to their own private trusts and accounts in order to shield them from creditors. The entities to which the Sacklers transferred funds include PLP Associates Holding L.P., Rosebay Medical Company L.P, and Beacon Company. These transfers

⁶⁰ See Karen Eldred, *Cigna is Committed to Reducing Opioid Use: Removing Oxycontin from Group Commercial Drug Lists on 1/1/18*, Cigna (Oct. 4, 2017), <https://www.cigna.com/newsroom/news-releases/2017/cigna-is-committed-to-reducing-opioid-use-removing-oxycontin-from-group-commercial-drug-lists-on-1118> (“While drug companies don’t control prescriptions, they can help influence patient and doctor conversations by educating people about their medications.”).

⁶¹ MA Complaint, *supra* note 34, at ¶ 490.

⁶² See Beth Mole, *Damning court docs show just how far Sacklers went to push OxyContin*, ARS Technica (Jan. 19, 2019, 5:00am), <https://arstechnica.com/science/2019/01/family-behind-oxycontin-called-addicts-criminals-while-pushing-pills/>.

were and are fraudulent, unjustly enriching the Sacklers and shielding funds available for the execution of any judgment against Purdue.

174. At the time of Purdue’s 2007 guilty plea—in which The Purdue Frederick Company, Inc. officially pled guilty—Purdue Pharma L.P. identified a total of 215 “related and associated entities” in its Non-Prosecution Agreement with the United States. These associated entities include, for example, petroleum and real estate companies, and twenty-five entities registered in Bermuda or the British Virgin Islands. The Sacklers—while directing Purdue to push its highly addictive drug into the poorest corners of Appalachia and to target Medicaid patients and veterans—availed themselves of the legal gray area available only to the wealthy, establishing international shell companies to hold and reinvest their profits. Securities filings show, for example, that the Sacklers have directed Purdue to purchase shares in various pharmaceutical investments, and then transferred those shares immediately to Rosebay Medical Company L.P. and Beacon Company.

175. Over the years, the Sacklers have voted to distribute billions of dollars to themselves through such associated entities. Between 2008 and 2016, the Sacklers voted to distribute over \$2 billion of Purdue’s profits to PLP Associates Holding L.P.⁶³ The Sacklers also voted to distribute approximately \$1.8 billion to Rosebay Medical Company L.P. and Beacon Company between 2008 and 2014.⁶⁴

⁶³ Amended Complaint at ¶ 151, *State of Connecticut v. Purdue Pharma L.P.*, C.A. No. X07 HHD-CV-19-6105325-S (Conn. Super. Ct. May 6, 2019).

⁶⁴ *Id.* at ¶¶ 153-154.

176. Many of the associated entities identified in Purdue’s 2007 list of “associated entities” are part of the Mundipharma network of companies, which was started by the Sacklers and remains under their control. Mundipharma is integral in allowing the Sacklers to both move their wealth overseas and continue to profit from the sale of addictive opioids as government entities in the United States work to rein in opioid prescribing. In contrast to the Sacklers’ well-documented obsession with attaching their family name to art museum wings, endowed chairs at universities, and the like, the Sacklers have omitted their name from official statements about Mundipharma’s founding. Press release after press release describes the Mundipharma networks as “founded in 1956 by doctors.”⁶⁵ Mundipharma International’s website provides more detail (and corrects the date), but still leaves its founders nameless: “Founded in the US by two physicians in 1952 and still privately owned, the network has a presence in over 120 countries.”⁶⁶ But the Austrian arm of the network is more forthright:

The Austrian company Mundipharma Ges.m.b.H. is part of a privately owned network of independent associated companies that operates internationally. The founding history dates back to 1952, when the two brothers Mortimer D. Sackler, M.D. and Raymond R. Sackler, M.D. bought the US-based company Purdue. Blessed with the necessary pioneering spirit, the owners developed a network of independent associated companies that is currently represented in numerous European countries and worldwide. The

⁶⁵ See, e.g., *Purdue Pharma L.P. Announces Strategic Investment in Oncology R&D*, Market Watch (Nov. 14, 2017), <https://www.marketwatch.com/press-release/purdue-pharma-lp-announces-strategic-investment-in-oncology-rd-2017-11-14>; *Mundipharma strengthens position as a leader in biosimilars with acquisition of development company Cinfa Biotech*, Mundipharma (Oct. 10, 2018), <https://www.mundipharma.com/wp-content/uploads/2018/10/201008-Deal-release-FINAL.pdf>.

⁶⁶ *About Mundipharma*, Mundipharma, <https://www.mundipharma.com/about-mundipharma/> (last visited Dec. 27, 2019).

tradition of a family business has propagated over the years and is still reflected, e.g. in long-term and trusting relationships.⁶⁷

177. As the corporate history webpages of various Mundipharma entities explain, it was Mundipharma that developed the prolonged-release morphine sulfate tablet in 1973,⁶⁸ which was later sold in the U.S. as MS Contin and which would be applied to oxycodone to create OxyContin. At that time, “Mundipharma” included Purdue, the UK-based Napp Pharmaceuticals Limited, which the Sacklers had acquired in 1966, and Ireland-based Napp Laboratories, which developed the fateful timed-release coating in 1973.

178. Today, the Mundipharma network generates over \$3.4 billion in annual revenue, primarily from opioids.⁶⁹ As noted above, Mundipharma is privately owned. Little public information is available regarding that ownership. However, the information that is available reveals that companies and trusts established by the Sacklers own various parts of the Mundipharma network. For example, trusts for the benefit of Richard and Jonathan Sackler owned half of Mundipharma Research Ltd. in Cambridge, England.⁷⁰ Rosebay Medical Company L.P.—owned by trusts for the benefit of the Sacklers—is one

⁶⁷ *History*, Mundipharma, <https://mundipharma.at/geschichte/> (last visited Dec. 27, 2019).

⁶⁸ *See, e.g.*, Mundipharma Malaysia website stating “Mundipharma developed prolonged release technology for treating chronic pain” in 1973, Mundipharma, <https://web.archive.org/web/20190720121401/http://www.mundipharma.com.my:80/about-us> (last visited Feb. 26, 2020); *History*, Mundipharma, <http://www.mundipharma.ie/history> (last visited Feb. 26, 2020).

⁶⁹ Bruce Einhorn, Timothy Annett, and Tim Loh, *OxyContin Billionaires Chase Global Profits to Offset U.S. Woes*, Bloomberg (March 30, 2019), <https://www.bloomberg.com/news/articles/2019-03-30/oxycontin-billionaires-chase-global-profits-to-offset-u-s-woes>.

⁷⁰ *Id.*

of the two owners of Mundipharma's Australian business, according to data from the Australian Securities and Investments Commission, and is one of the two current shareholders in Mundipharma Pharmaceuticals Sdn. Bhd., the network's Malaysian branch, according to the Companies Commission of Malaysia.⁷¹

179. Under the name of Mundipharma, the Sacklers are employing the exact same playbook in South America, China, India, and other developing markets as they did in the United States.

180. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage. . .

Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . .

In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of

⁷¹ *Id.*

overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.⁷²

181. The Sacklers' pivot to untapped markets, after extracting substantial profits from communities like the Tribe and leaving the Tribe to address the resulting damage, underscores that their actions have been knowing, intentional, and motivated by profits throughout this entire tragic story.

C. The Booming Business of Addiction.

1. Other Manufacturing Defendants leapt at the opioid opportunity.

182. Purdue created a market in which the prescription of powerful opioids for a range of common aches and pains was not only acceptable but encouraged—but it was not alone. Defendants Endo, Janssen, Mallinckrodt, Teva, and Actavis positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin while misrepresenting the safety and efficacy of their products. In addition, Rhodes manufactured multiple generic opioids, profiting from the same misleading marketing and expanded market for these dangerous drugs.

183. Endo, which for decades had sold Percocet and Percodan, both containing relatively low doses of oxycodone, moved quickly to develop a generic version of

⁷² Letter from Cong. of the U.S., to Dr. Margaret Chan, Dir.-Gen., World Health Org. (May 3, 2017), https://web.archive.org/web/20181222034138/https://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf.

extended-release oxycodone to compete with OxyContin, receiving tentative FDA approval for its generic version in 2002. As Endo stated in its 2003 Form 10-K, it was the first to file an application with the FDA for bioequivalent versions of the 10, 20, and 40 mg strengths of OxyContin, which potentially entitled it to 180 days of generic marketing exclusivity—“a significant advantage.”⁷³ Purdue responded by suing Endo for patent infringement, litigating its claims through a full trial and a Federal Circuit appeal—unsuccessfully. As the trial court found, and the appellate court affirmed, Purdue obtained the oxycodone patents it was fighting to enforce through “inequitable conduct”—namely, suggesting that its patent applications were supported by clinical data when in fact they were based on an employee’s “insight and not scientific proof.”⁷⁴ Endo began selling its generic extended-release oxycodone in 2005.

184. At the same time as Endo was battling Purdue over generic OxyContin—and as the U.S. was battling increasingly widespread opioid abuse—Endo was working on getting another branded prescription opioid on the market. In 2002, Endo submitted applications to the FDA for both immediate-release and extended-release tablets of oxymorphone, branded as Opana and Opana ER.

185. Like oxycodone, oxymorphone is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan, in injectable, suppository, and oral tablet forms. But the oral tablets proved

⁷³ *Endo Pharm. Holdings, Inc. Form 10-K*, U.S. Sec. and Exchange Comm’n, at 4 (Mar. 15, 2004), http://media.corporate-ir.net/media_files/irol/12/123046/reports/10K_123103.pdf.

⁷⁴ *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1131 (Fed. Cir. 2006).

highly susceptible to abuse. Called “blues” after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin, and even had its moment in the limelight as the focus of the movie *Drugstore Cowboy*. As the National Institute on Drug Abuse observed in its 1974 report, “Drugs and Addict Lifestyle,” Numorphan was extremely popular among addicts for its quick and sustained effect.⁷⁵ Endo withdrew oral Numorphan from the market in 1979, reportedly for “commercial reasons.”⁷⁶

186. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted off a product it had previously shelved after widespread abuse, and pushed it into the marketplace with a new trade name and a potent extended-release formulation.

187. The clinical trials submitted with Endo’s first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone, an opioid antagonist used to counter the effects of an overdose. Endo then submitted new “enriched enrollment” clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, and obtained approval. Endo began marketing Opana and Opana ER in 2006.

⁷⁵ John Fauber and Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015), <https://www.medpagetoday.com/psychiatry/addictions/51448>.

⁷⁶ *Id.*

188. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that “the agency is seeking removal based on its concern that the benefits of the drug may no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse.”⁷⁷ On July 6, 2017, Endo agreed to withdraw Opana ER from the market.⁷⁸ Before its withdrawal from the market, Opana ER generated substantial profits for Endo—more than \$1 billion in revenue in 2010, for example, and again in 2013.

189. Janssen, which already marketed the Duragesic (fentanyl) patch, developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of chronic pain in 2011. Janssen earned more than \$1 billion in sales of Duragesic in 2009, and Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

190. Teva also manufactures Actiq, a fentanyl lozenge, and Fentora, a fentanyl tablet. As noted above, fentanyl is an extremely powerful synthetic opioid. According to the DEA, as little as two milligrams is a lethal dosage for most people. Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients

⁷⁷ *News Release: FDA requests removal of Opana ER for risks related to abuse*, U.S. Food & Drug Admin., (June 8, 2017), <https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse>.

⁷⁸ *Endo pulls opioid as U.S. seeks to tackle abuse epidemic*, Reuters (July 6, 2017, 9:59am), <https://www.reuters.com/article/us-endo-intl-opana-idUSKBN19R2II>.

16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.”⁷⁹ Fentora has been approved by the FDA only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”⁸⁰

191. In 2008, Teva subsidiary Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

192. Actavis acquired the rights to Kadian, extended-release morphine, in 2008, and began marketing Kadian in 2009. Actavis’s opioid products also include Norco, a brand-name hydrocodone and acetaminophen pill, first approved in 1997. But Actavis, primarily a generic drug maker, pursued opioid profits through generics, selling generic versions of OxyContin, Opana, and Duragesic. In 2013, it settled a patent lawsuit with Purdue over its generic version of “abuse-deterrent” OxyContin, striking a deal that would allow it to market its abuse-deterrent oxycodone formulation beginning in 2014. Actavis anticipated over \$100 million in gross profit from generic OxyContin sales in 2014 and 2015.

⁷⁹ *Prescribing Information, ACTIQ®*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf (last visited Dec. 27, 2019).

⁸⁰ *Prescribing Information, FENTORA®*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf (last visited Dec. 27, 2019).

193. Mallinckrodt's generic oxycodone achieved enough market saturation to have several street names: "M's," based on the imprint on the pills, "blues" because of the pale blue color of the pills, "roxies," or "mallies." Mallinckrodt's oxy 30s were extremely popular pills for misuse and abuse, and enormous quantities of Mallinckrodt's pills went to cash purchases and non-medical use. As noted above, Mallinckrodt was the subject of a federal investigation based on diversion of its oxycodone in Florida, where 500 million of its pills were shipped between 2008 and 2012. Federal prosecutors alleged that 43,991 orders from distributors and retailers were excessive enough to be considered suspicious and should have been reported to the DEA.

194. Mallinckrodt also pursued a share of the branded opioid market. In 2007, Mallinckrodt launched Magnacet, an oxycodone and acetaminophen combination pill. In 2008, Mallinckrodt (then Covidien) launched TussiCaps, a hydrocodone and chlorpheniramine capsule, marketed as a cough suppressant. And in 2009, Mallinckrodt acquired the U.S. rights to Exalgo, a potent extended-release hydromorphone tablet, and began marketing it in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014. In anticipation of Xartemis

XR's approval, Mallinckrodt hired approximately 200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."⁸¹

195. These companies' aggressive promotion of their branded opioids dramatically expanded the market for these potent and addictive drugs as a class—and much of the demand was filled by generic opioids. Defendants Mallinckrodt, Actavis, Endo, and Teva all sold generic opioids in addition to their branded products. Purdue and the Sacklers were also in the generic business through Rhodes. These Defendants manufactured and shipped massive quantities of generic opioids to communities across the U.S., including Plaintiff's, while failing to uphold their responsibilities to monitor and report suspicious orders.

196. All told, the Manufacturing Defendants have reaped enormous profits from the addiction crisis they spawned.

2. Distributor Defendants knowingly supplied dangerous quantities of opioids while advocating for limited oversight and enforcement.

197. The Distributor Defendants track and keep a variety of information about the pharmacies and other entities to which they sell pharmaceuticals. For example, the Distributor Defendants use "know your customer" questionnaires that track the number and types of pills their customers sell, absolute and relative amounts of controlled substances they sell, whether the customer purchases from other distributors, and types of medical providers in the areas, among other information.

⁸¹ Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Bus. Journal (Dec. 30, 2013), <http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>.

198. These questionnaires and other sources of information available to the Distributor Defendants provide ample data to put the Distributor Defendants on notice of suspicious orders, pharmacies, and doctors.

199. Nevertheless, the Distributor Defendants refused or failed to identify, investigate, or report suspicious orders of opioids to the DEA. Even when the Distributor Defendants had actual knowledge that they were distributing opioids to drug diversion rings, they refused or failed to report these sales to the DEA.

200. By not reporting suspicious opioid orders or known diversions of prescription opioids, not only were the Defendants able to continue to sell opioids to questionable customers, Defendants ensured that the DEA had no basis for decreasing or refusing to increase production quotas for prescription opioids.

201. The Distributor Defendants collaborated with each other and with the Manufacturing Defendants to maintain distribution of excessive amounts of opioids. One example of this collaboration came to light through Defendants' work in support of legislation called the Ensuring Patient Access and Effective Drug Enforcement (EPAEDE) Act, which was signed into law in 2016 and limited the DEA's ability to stop the flow of opioids. Prior to this law, the DEA could use an "immediate suspension order" to halt suspicious shipments of pills that posed an "imminent" threat to the public. The EPAEDE Act changed the required showing to an "immediate" threat—an impossible standard given the fact that the drugs may sit on a shelf for a few days after shipment. The law effectively neutralized the DEA's ability to bring enforcement actions against distributors.

202. The legislation was drafted by a former DEA lawyer, D. Linden Barber, who is now a senior vice president at Defendant Cardinal Health. Prior to leaving the DEA, Barber had worked with Joseph Rannazzisi, then the chief of the DEA's Office of Diversion Control, to plan the DEA's fight against the diversion of prescription drugs. So when Barber began working for Cardinal Health, he knew just how to neutralize the effectiveness of the DEA's enforcement actions. Barber and other promoters of the EPAEDE Act portrayed the legislation as maintaining patient access to medication critical for pain relief. In a 2014 hearing on the bill, Barber testified about the "unintended consequences in the supply chain" of the DEA's enforcement actions. But by that time, communities across the United States, including Plaintiff Hopi Tribe, were grappling with the "unintended consequences" of Defendants' reckless promotion and distribution of narcotics.

203. Despite egregious examples of drug diversion from around the country, the promoters of the EPAEDE Act were successful in characterizing the bill as supporting patients' rights. One of the groups supporting this legislation was the Alliance for Patient Access, a "front group" as discussed further below, which purports to advocate for patients' rights to have access to medicines, and whose 2017 list of "associate members and financial supporters" included Defendants Endo, Johnson & Johnson, Actavis, Mallinckrodt, and Teva. In a 2013 "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse," the Alliance for Patient Access

asserted multiple “unintended consequences” of regulating pain medication, including a decline in prescriptions as physicians feel burdened by regulations and stigmatized.⁸²

204. The Distributor Defendants are also part of the activities of the Alliance for Patient Access, although their involvement is hidden. One example of their involvement was revealed by the metadata of an electronic document: the letter from the Alliance for Patient Access in support of the EPAEDE Act. That document was created by Kristen Freitas, a registered lobbyist and the vice president for federal government affairs of the Healthcare Distributors Alliance (HDA)—the trade group that represents Defendants McKesson, Cardinal Health, and AmerisourceBergen.

205. Upon information and belief, the collaboration on the EPAEDE Act is just one example of how the Manufacturing Defendants and the Distributor Defendants, through third-party “front groups” like the Alliance for Patient Access and trade organizations like HDA, worked together behind the scenes to ensure that the flow of dangerous narcotics into communities across the country would not be restricted, and Defendants collaborated in other ways that remain hidden from public view.

206. Another example of collaboration between the Manufacturing Defendants, Distributor Defendants, and Front Groups is the Pain Care Forum, a coalition of drug makers, trade groups and non-profit organizations supported by funding from the pharmaceutical industry. The Pain Care Forum worked behind the scenes to shape federal

⁸² *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Inst. for Patient Access (Oct. 2013), https://web.archive.org/web/20140909180752/http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

and state policies regarding the use of prescription opioids, working to prevent national, state, or local responses to the growing opioid crisis from interrupting industry profits. The Manufacturing Defendants worked together through the Pain Care Forum, and the Distributor Defendants actively participated in the Pain Care Forum through the HDA as well.

207. The Distributor Defendants have been the subject of numerous enforcement actions by the DEA. In 2008, for example, McKesson was fined \$13.3 million and agreed to strengthen its controls by implementing a three-tiered system that would flag buyers who exceeded monthly thresholds for opioids. As the opioid crisis deepened, the DEA's Office of Diversion Control, led by Rannazzisi, stepped up enforcement, filing fifty-two immediate suspension orders against suppliers and pill mills in 2010 alone. Defendant Cardinal Health was fined \$34 million by the DEA in 2013 for failing to report suspicious orders.

208. The Distributor Defendants were not simply passive transporters of opioids. They intentionally failed to report suspicious orders and actively pushed back against efforts to enforce the law and restrict the flow of opioids into communities like the Hopi Tribe.

3. Retail Pharmacy Defendants were on notice of and contributed to the diversion of prescription opioids.

209. Retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as

both distributors and retail sellers of opioids. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

210. Each of the Retail Pharmacy Defendants does substantial business across the United States. This business includes the distribution and sale of prescription opioids.

211. Statewide ARCOS data confirms that the Retail Pharmacy Defendants distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone, in area surrounding the Hopi Reservation. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to and around the Hopi Reservation. The Retail Pharmacy Defendants failed to take meaningful action to stop this diversion despite their knowledge of it, and thus contributed substantially to the diversion problem.

212. The Retail Pharmacy Defendants maintain extensive data on all of the drugs they dispensed, including opioids. Through this data, the Retail Pharmacy Defendants have direct knowledge of patterns and instances of improper distribution, prescribing, sale, and use of prescription opioids in communities throughout the country, including in Arizona and the area surrounding the Hopi Reservation. They used the data to evaluate their own sales activities and workforce. The Retail Pharmacy Defendants also provided data regarding individual doctors to drug companies, which targeted those prescribers with their marketing, in exchange for rebates or other forms of consideration. The Retail Pharmacy Defendants' data could and should have been used to help stop

diversion. Instead, the Retail Pharmacy Defendants dispensed opioids at rates that far exceeded those necessary for legitimate medical use by the local population. The failure of the Retail Pharmacy Defendants to maintain effective controls against diversion, including to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, as well as to maintain effective policies and procedures to guard against diversion from their retail stores, substantially contributed to the opioid epidemic in and around the Hopi Reservation.

213. Each participant in the supply chain of opioid distribution, including the Retail Pharmacy Defendants, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity. The Retail Pharmacy Defendants are required to register as distributors or dispensers pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74.

214. According to the CDC, opioid prescriptions, as measured by number of prescriptions and MMEs per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. Not all of these prescriptions were legitimate. Yet, the Retail Pharmacy Defendants failed to maintain effective controls against diversion at both the wholesale and retail level, systematically ignoring red flags of diversion. Instead, they prioritized profits over public health and safety. Despite their legal obligations as registrants under the CSA, the Retail Pharmacy Defendants knowingly allowed widespread diversion to occur.

215. Upon information and belief, the Retail Pharmacy Defendants failed to establish or adequately implement policies that would allow their pharmacists and pharmacy technicians to conduct due diligence related to prescriptions for opioid painkillers and in fact implemented policies that did the opposite, mandating or incentivizing high-volume sales and rapid processing of prescriptions. Upon information and belief, the Retail Pharmacy Defendants also failed to effectively respond to concerns raised by their own employees regarding suspected diversion of opioids. In addition, the Retail Pharmacy Defendants did not take steps to analyze their own dispensing data for red flags of diversion. The Retail Pharmacy Defendants had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

216. As acknowledged in an article CVS published in the New England Journal of Medicine, “[p]harmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular.” Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H., *Abusive Prescribing of Controlled Substances - A Pharmacy View*, N. ENGL. J. MED. 369;11, Sept. 12., 2013, at 989-991. The DEA has identified “both pharmaceutical distributors and chain pharmacies as part of the problem” contributing to opioid abuse and related deaths. *Id.*

217. The Retail Pharmacy Defendants have a particular “advantage” in meeting their obligations under the CSA because these entities can use “aggregated information on all prescriptions filled at the chain” in order to examine “patterns” of opioids and other “high-risk drugs” and target “inappropriate prescribing.” *Id.* at 990. For example, a chain

pharmacy should properly use its chainwide dispensing data to identify “high risk prescribers” by “benchmarking” prescription data based on “several parameters,” including “volume of prescriptions for high-risk drugs,” “the proportion of the prescriber’s prescriptions that were for such [high-risk] drugs, as compared with the volume and proportion for others in the same specialty and region,” cash payment, ages of patients, and the prescriber’s ratio of “prescriptions for noncontrolled substances with prescriptions for controlled substances.” *Id.* This “[a]nalysis of aggregated data” from chain pharmacies can “target patterns of abuse,” in the face of “the growing use of controlled substances and resulting illnesses and deaths.” *Id.* Accordingly, as CVS explains, “innovative use of transparent data is only prudent.” *Id.*

218. As CVS counseled, Defendants may not ignore red flags of illegal conduct and must use the information available to them to identify, report, and not fill prescriptions that seem indicative of diversion. This includes reviewing the aggregated information available to them. Specifically, the Retail Pharmacy Defendants had a duty to analyze data and store-level information for known red flags such as (a) multiple prescriptions to the same patient using the same doctor; (b) multiple prescriptions by the same patient using different doctors; (c) prescriptions of unusual size and frequency for the same patient; (d) orders from out-of-state patients or prescribers; (e) an unusual or disproportionate number of prescriptions paid for in cash; (f) prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription drug “cocktails”; and (g) volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose.

219. The Retail Pharmacy Defendants knew or should have known that the quantities of opioids they were distributing and dispensing was unreasonable and contributing to the opioid crisis engulfing the country.

4. Defendants knowingly prioritized profits over people by failing to report or block pill mills and overprescribing doctors.

220. Around the country, certain doctors or pain clinics ended up doing brisk business dispensing opioid prescriptions. As Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, observed, this business model meant doctors would “have a practice of patients who’ll never miss an appointment and who pay in cash.”⁸³

221. Moreover, the Manufacturing Defendants’ sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting enormous quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions. Eventually, the DEA’s diversion unit raided the clinic, and prosecutors filed criminal charges against the doctors. But Purdue’s sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue’s top-ranked

⁸³ Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* 314 (Bloomsbury Press 2015).

sales representative.⁸⁴ In response to news stories about this clinic, Purdue issued a statement, declaring that “if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not.”⁸⁵

222. Another pill mill, this one in Los Angeles, supplied OxyContin to a drug dealer in Everett, Washington. Purdue was alerted to the existence of this pill mill by one of its regional sales managers, who in 2009 reported to her supervisors that when she visited the clinic with her sales representative, “it was packed with a line out the door, with people who looked like gang members,” and that she felt “very certain that this was an organized drug ring[.]” She wrote, “This is clearly diversion. Shouldn’t the DEA be contacted about this?” But her supervisor at Purdue responded that while they were “considering all angles,” it was “really up to [the wholesaler] to make the report.” This clinic was the source of 1.1 million pills trafficked to Everett, which is a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.⁸⁶ Similarly, Purdue received repeated reports in 2008 from a sales representative who visited a family practice doctor in Bothell, Washington; the sales representative informed Purdue that many of this doctor’s patients were men in their

⁸⁴ Meier, *supra* note 22, at 298-300.

⁸⁵ *Id.*

⁸⁶ Harriet Ryan, Scott Glover, and Lisa Girion, *How black-market OxyContin spurred a town's descent into crime, addiction and heartbreak*, L.A. Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-everett/>; Harriet Ryan, Lisa Girion, and Scott Glover, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, L.A. Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

twenties who did not appear to be in pain, who sported diamond studs and \$350 sneakers, and who always paid for their 80 mg OxyContin prescriptions in cash. Despite being repeatedly alerted to the doctor's conduct, Purdue did not take any action to report it until three years later.

223. Whenever examples of opioid diversion and abuse have drawn media attention, the Manufacturing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the "bad actor" doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."⁸⁷

224. But given the closeness with which all Defendants monitored prescribing patterns, including through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Rather, it appears Purdue and other Defendants used the IMS Health data to target pill mills and sell more pills. Indeed, a Purdue executive referred to

⁸⁷ Meier, *supra* note 22, at 179.

Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

225. In addition, the Manufacturing Defendants had the ability to know who the ultimate customers of their pills were due to their control of "chargeback" data. Chargebacks are available when distributors purchase the drugs at an established wholesale price, but then sell the drugs at a discounted price based on contract pricing the Manufacturing Defendants have offered to the indirect customers. The distributor honors the contract pricing but then submits a chargeback request to the manufacturer to recover the difference. In order to get the chargeback, distributors must provide detailed information about the indirect customer and about the product sold. As a result, Manufacturing Defendants are collecting data on the indirect customers of their products and know exactly how many of their pills are going where. And like the Distributor Defendants, Manufacturing Defendants are also subject to the monitoring and reporting requirements of the CSA.

226. The Manufacturing Defendants tracked their pills through chargeback and IMS data and/or received reports from sales representatives making in-person visits. They had the ability, and the obligation, to monitor and report suspicious orders. But pill mills were highly lucrative. Defendants knowingly allowed certain clinics to dispense staggering quantities of potent opioids and then feigned surprise when the most egregious examples eventually made the nightly news.

5. Widespread prescription opioid use broadened the market for heroin and fentanyl.

227. Defendants' scheme achieved a dramatic expansion of the U.S. market for opioids, prescription and non-prescription alike. Heroin and fentanyl use has surged—a foreseeable consequence of Defendants' successful promotion of opioid use coupled with the sheer potency of their products.

228. In his book *Dreamland: The True Tale of America's Opiate Epidemic*, journalist Sam Quinones summarized the easy entrance of black tar heroin in a market primed by prescription opioids:

His black tar, once it came to an area where OxyContin had already tenderized the terrain, sold not to tapped-out junkies but to younger kids, many from the suburbs, most of whom had money and all of whom were white. Their transition from Oxy to heroin, he saw, was a natural and easy one. Oxy addicts began by sucking on and dissolving the pills' timed-release coating. They were left with 40 or 80 mg of pure oxycodone. At first, addicts crushed the pills and snorted the powder. As their tolerance built, they used more. To get a bigger bang from the pill, they liquefied it and injected it. But their tolerance never stopped climbing. OxyContin sold on the street for a dollar a milligram and addicts very quickly were using well over 100 mg a day. As they reached their financial limits, many switched to heroin, since they were already shooting up Oxy and had lost any fear of the needle.⁸⁸

229. In a study examining the relationship between the abuse of prescription opioids and heroin, researchers found that 75% of those who began their opioid abuse in the 2000s reported that their first opioid was a prescription drug.⁸⁹ As the graph below

⁸⁸ Quinones, *supra* note 83, at 165-66.

⁸⁹ Theodore J. Cicero, PhD, Matthew S. Ellis, MPE, Hilary L. Surratt, PhD, *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71(7) JAMA Psychiatry 821-826 (2014), <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575>.

illustrates, prescription opioids replaced heroin as the first opioid of abuse beginning in the 1990s.



From: **The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years**

JAMA Psychiatry. 2014;71(7):821-826. doi:10.1001/jamapsychiatry.2014.366

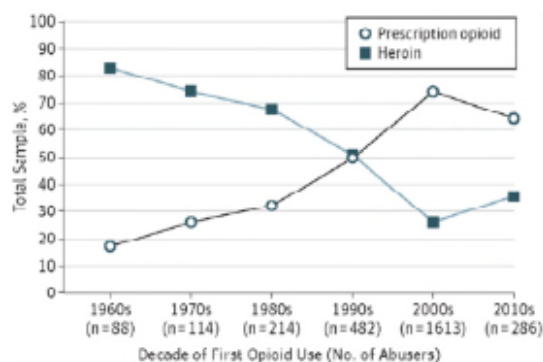


Figure Legend:

Percentage of the Total Heroin-Dependent Sample That Used Heroin or a Prescription Opioid as Their First Opioid of Abuse Data are plotted as a function of the decade in which respondents initiated their opioid abuse.

230. The researchers also found that nearly half of the respondents who indicated that their primary drug was heroin actually preferred prescription opioids, because the prescription drugs were legal, and perceived as “safer and cleaner.” But, heroin’s lower price point is a distinct advantage. While an 80 mg OxyContin might cost \$80 on the street, the same high can be had from \$20 worth of heroin.

231. As noted above, there is little difference between the chemical structures of heroin and prescription opioids. Between 2005 and 2009, Mexican heroin production increased by over 600%. And between 2010 and 2014, the amount of heroin seized at the U.S.-Mexico border more than doubled.

232. From 2000 to 2017, fatal overdoses related to heroin in the U.S. increased by 766% – from 1,842 deaths in 2000 to 15,958 deaths in 2017.⁹⁰

233. Along with heroin use, fentanyl use is on the rise, as a result of America's expanded appetite for opioids. But fentanyl, as noted above, is fifty times more potent than heroin, and overdosing is all too easy. In 2013, fentanyl caused 3,000 overdose deaths. By 2017, the number of deaths attributed to the potent synthetic opioid had risen to 29,000. Deaths involving fentanyl increased more than 45% in 2017 alone.⁹¹

234. As Dr. Caleb Banta-Green, senior research scientist at the University of Washington's Alcohol and Drug Abuse Institute, told The Seattle Times in August 2017, "The bottom line is opioid addiction is the overall driver of deaths. People will use whatever opioid they can get. It's just that which one they're buying is changing a bit."⁹²

235. In addition to the expanded market for opioids of all kinds, the opioid epidemic has contributed to a resurgence in methamphetamine use, as some opioid users turn to the stimulant to counter the effects of opioids.⁹³ Co-use of methamphetamine and

⁹⁰ *Overdose Death Rates*, *supra* note 7.

⁹¹ Josh Katz and Margot Sanger-Katz, 'The Numbers Are So Staggering.' *Overdose Deaths Set a Record Last Year*, N.Y. Times (Nov. 29, 2018), <https://www.nytimes.com/interactive/2018/11/29/upshot/fentanyl-drug-overdose-deaths.html>.

⁹² *Opioids: The Leading Cause of Drug Deaths in Seattle Area*, U. of Wash. Sch. of Pub. Health (Aug. 25, 2017), <https://sph.washington.edu/news-events/news/opioids-leading-cause-drug-deaths-seattle-area>.

⁹³ See, e.g., *Opioids and methamphetamine: a tale of two crises*, 391(10122) The Lancet 713 (Feb. 24, 2018), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)30319-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30319-2/fulltext); Brenda Goodman, MA, *Experts Warn of Emerging 'Stimulant Epidemic'*, WebMD (Apr. 3, 2018), <https://www.webmd.com/mental-health/addiction/news/20180403/experts-warn-of-emerging-stimulant-epidemic>.

opioids has nearly doubled in the last six years. From 2011 to 2017, the percentage of opioid users seeking treatment who reported also using methamphetamine in the prior month jumped from 19% to 34%.⁹⁴ This increase in co-use did not occur with any other drug class.⁹⁵ The two drugs' opposite modes of action balance each other out, making co-use appealing to opioid users who need to be active at certain times. As one article explained, "[f]or addicts, the drugs pair: Heroin is a downer and methamphetamine is an upper."⁹⁶ Researchers studying the "twin epidemics" have found that some opioid users will turn to methamphetamine as a substitute to opioids to stave off withdrawals if they cannot obtain opioids.⁹⁷ And as opioids become more difficult to obtain and afford, users increasingly turn to cheap methamphetamine.⁹⁸ Co-use of opioids and methamphetamines is rising around the United States, compounding the issues that local governments face in combating the opioid epidemic.⁹⁹

⁹⁴ Matthew Ellis, Zachary Kasper, Theodore Cicero, *Twin epidemics: The surging rise of methamphetamine use in chronic opioid users*, 193 *Drug and Alcohol Depend.* 14 (Dec. 2018), <https://doi.org/10.1016/j.drugalcdep.2018.08.029>.

⁹⁵ *Id.*

⁹⁶ Michelle Theriault Boots, *The silent fallout of the opioid epidemic? Meth.*, Anchorage Daily News (Mar. 30, 2018), <https://www.adn.com/alaska-news/2018/03/19/the-silent-fallout-of-the-opioid-epidemic-meth/#>.

⁹⁷ Randy Dotinga, *Methamphetamine use climbing among opioid users*, Clinical Psychology News (June 29, 2018), <https://www.mdedge.com/psychiatry/article/169254/addiction-medicine/methamphetamine-use-climbing-among-opioid-users>.

⁹⁸ Rachel Martin, *In Rural Ohio, An Opioid Crisis Becomes A Meth Crisis*, NPR (June 6, 2018, 5:11am), <https://www.npr.org/2018/06/06/617422943/in-rural-ohio-an-opioid-crisis-becomes-a-meth-crisis>.

⁹⁹ Ellis, *supra* note 94.

D. The Marketing Defendants Promoted Prescription Opioids Through Several Channels.

236. Despite knowing the devastating consequences of widespread opioid use, the Marketing Defendants engaged in a sophisticated and multi-pronged promotional campaign designed to achieve just that. By implementing the strategies pioneered by Arthur Sackler, these Defendants were able to achieve the fundamental shift in the perception of opioids that was key to making them blockbuster drugs.

237. The Marketing Defendants disseminated their deceptive statements about opioids through several channels.¹⁰⁰ First, these Defendants aggressively and persistently pushed opioids through sales representatives. Second, these Defendants funded third-party organizations that appeared to be neutral, but in fact served as additional marketing departments for drug companies. Third, these Defendants utilized prominent physicians as paid spokespeople—“Key Opinion Leaders”—to take advantage of doctors’ respect for and reliance on the recommendations of their peers. Finally, these Defendants also used print and online advertising, including unbranded advertising, which is not reviewed by the FDA.

238. The Marketing Defendants spent substantial sums and resources in making these communications. For example, Purdue spent more than \$200 million marketing OxyContin in 2001 alone.¹⁰¹

¹⁰⁰ The specific misrepresentations and omissions are discussed below in Section E.

¹⁰¹ *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of Paul Goldenheim, Vice President for Research, Purdue Pharma), <https://www.gpo.gov/fdsys/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm>.

1. The Marketing Defendants aggressively deployed sales representatives to push their products.

239. The Marketing Defendants communicated to prescribers directly in the form of in-person visits and communications from sales representatives. The Marketing Defendants' sales representatives provided health care providers with pamphlets, visual aids, and other marketing materials designed to increase the rate of opioids prescribed to patients. These sales representatives knew the doctors they visited relied on the information they provided, and that the doctors had minimal time or resources to investigate the materials' veracity independently.

240. The Marketing Defendants' tactics through their sales representatives—also known as “detailers”—were particularly aggressive. In 2014, the Marketing Defendants collectively spent well over \$100 million on detailing branded opioids to doctors.

241. Each sales representative has a specific sales territory and is responsible for developing a list of about 105 to 140 physicians to call on who already prescribe opioids or who are candidates for prescribing opioids.

242. When Purdue launched OxyContin in 1996, its 300-plus sales force had a total physician call list of approximately 33,400 to 44,500. By 2000, nearly 700 representatives had a total call list of approximately 70,500 to 94,000 physicians. Each sales representative was expected to make about thirty-five physician visits per week and typically called on each physician every three to four weeks, while each hospital sales

representative was expected to make about fifty physician visits per week and call on each facility every four weeks.¹⁰²

243. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"¹⁰³ According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."¹⁰⁴

244. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist that the most common objection he heard about prescribing OxyContin was that "it's just too addictive."¹⁰⁵ In order to overcome that objection and hit their "target," May and other sales representatives were taught to say, "The delivery system is believed to reduce the abuse liability of the drug."¹⁰⁶ May repeated that line to doctors even though he "found out pretty fast that it wasn't true."¹⁰⁷ He and his coworkers learned quickly that people were figuring out how to remove the

¹⁰² *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 44, at 20.

¹⁰³ Meier, *supra* note 22, at 102.

¹⁰⁴ *Id.*

¹⁰⁵ David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), *New Yorker* (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

¹⁰⁶ Keefe, *supra* note 50; see also Meier, *supra* note 22, at 102 ("Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of the drug.").

¹⁰⁷ Keefe, *supra* note 50.

time-releasing coating, but they continued making this misrepresentation until Purdue was forced to remove it from the drug's label.

245. Purdue trained its sales representatives to misrepresent the addiction risk in other ways. May explained that he and his coworkers were trained to “refocus” doctors on “legitimate” pain patients, and to represent that “legitimate” patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less “habit-forming” than painkillers that need to be taken every four hours. Similarly, former Purdue sales manager William Gergely told a Florida state investigator in 2002 that sales representatives were instructed to say that OxyContin was “virtually non-addicting” and “non-habit-forming.”¹⁰⁸

246. As Shelby Sherman, a Purdue sales representative from 1974 to 1998, told a reporter regarding OxyContin promotion, “It was sell, sell, sell. We were directed to lie. Why mince words about it?”¹⁰⁹

247. The Marketing Defendants utilized lucrative bonus systems to encourage their sales representatives to stick to the script and increase opioid sales in their territories. Purdue paid \$40 million in sales incentive bonuses to its sales representatives in 2001 alone, with annual bonuses ranging from \$15,000 to nearly \$240,000.¹¹⁰ The

¹⁰⁸ Fred Schulte and Nancy McVicar, *Oxycontin Was Touted As Virtually Nonaddictive, Newly Released State Records Show*, Sun Sentinel (Mar. 6, 2003), http://articles.sun-sentinel.com/2003-03-06/news/0303051301_1_purdue-pharma-oxycontin-william-gergely.

¹⁰⁹ Glazek, *supra* note 33.

¹¹⁰ Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/>.

training memo described above, in keeping with a Wizard of Oz theme, reminded sales representatives: “A pot of gold awaits you ‘Over the Rainbow’!”¹¹¹

248. As noted above, these Defendants have also spent substantial sums to purchase, manipulate, and analyze prescription data available from IMS Health, which allows them to track initial prescribing and refill practices by individual doctors, and in turn to customize their communications with each doctor. The Marketing Defendants’ use of this marketing data was a cornerstone of their marketing plan,¹¹² and continues to this day.

249. The Marketing Defendants also aggressively pursued family doctors and primary care physicians perceived to be susceptible to their marketing campaigns. The Marketing Defendants knew that these doctors relied on information provided by pharmaceutical companies when prescribing opioids, and that, as general practice doctors seeing a high volume of patients on a daily basis, they would be less likely to scrutinize the companies’ claims.

250. Furthermore, the Marketing Defendants knew or should have known the doctors they targeted were often poorly equipped to treat or manage pain comprehensively, as they often had limited resources or time to address behavioral or cognitive aspects of pain treatment or to conduct the necessary research themselves to determine whether opioids were as beneficial as these Defendants claimed. In fact, the majority of doctors and dentists who prescribe opioids are not pain specialists. For

¹¹¹ Meier, *supra* note 22, at 103.

¹¹² Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 110.

example, a 2014 study conducted by pharmacy benefit manager Express Scripts reviewing narcotic prescription data from 2011 to 2012 concluded that of the more than 500,000 prescribers of opioids during that time period, *only* 385 were identified as pain specialists.¹¹³

251. When the Marketing Defendants presented these doctors with sophisticated marketing material and apparently scientific articles that touted opioids' ability to easily and safely treat pain, many of these doctors began to view opioids as an efficient and effective way to treat their patients.

252. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative in Florida wrote about working for a particularly driven regional manager named Chris Sposato and described how Sposato would drill the sales team on their upselling tactics:

It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."

The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Miami District reps have told me that on work sessions with [Sposato] they would sit in the car and role play for as long as it took until [Sposato] was convinced the rep was delivering the message with perfection.

¹¹³ *A Nation in Pain*, Express Scripts (Dec. 9, 2014), <https://www.express-scripts.com/corporate/drug-trend-report/nation-pain-us-opioid-trends>.

253. The Marketing Defendants used not only incentives but competitive pressure to push sales representatives into increasingly aggressive promotion. One Purdue sales representative recalled the following scene: “I remember sitting at a round table with others from my district in a regional meeting while everyone would stand up and state the highest dose that they had suckered a doctor to prescribe. The entire region!!”

254. Sales representatives knew that the prescription opioids they were promoting were dangerous. For example, May had only been at Purdue for two months when he found out that a doctor he was calling on had just lost a family member to an OxyContin overdose.¹¹⁴ And as another sales representative wrote on a public forum:

Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got “sold” on the 80mg) and their teen son/daughter/child’s teen friend finds the pill bottle and takes out a few 80’s... next they’re at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don’t wake up (because they don’t understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

255. The Marketing Defendants rewarded their sales representatives with bonuses when doctors whom they had detailed wrote prescriptions for their company’s drug. Because of this incentive system, sales representatives stood to gain significant bonuses if they had a pill mill in their sales region. Indeed, Defendants often helped their sales representatives find and target such pill mills.

¹¹⁴ Remnick, *supra* note 105.

256. The high volume of prescriptions written by doctors at pill mills translated directly to higher bonuses for the sales representatives detailing those pill mills. As a result, sales representatives continued to promote opioids even at known pill mills.

257. The Marketing Defendants applied this combination of intense competitive pressure and lucrative financial incentives because they knew that sales representatives, with their frequent in-person visits with prescribers, were incredibly effective. In fact, manufacturers' internal documents reveal that they considered sales representatives their "most valuable resource."

2. The Marketing Defendants bankrolled seemingly independent "front groups" to promote opioid use and fight restrictions on opioids.

258. The Marketing Defendants funded, controlled, and operated third-party organizations that communicated to doctors, patients, and the public the benefits of opioids to treat chronic pain. These organizations—also known as "front groups"—appeared independent and unbiased. But in fact, they were but additional paid mouthpieces for the drug manufacturers. These front groups published prescribing guidelines and other materials that promoted opioid treatment as a way to address patients' chronic pain. The front groups targeted doctors, patients, and lawmakers, all in coordinated efforts to promote opioid prescriptions.

259. The Marketing Defendants spent significant financial resources contributing to and working with these various front groups to increase the number of opioid prescriptions written.

260. The most prominent front group utilized by the Marketing Defendants was the **American Pain Foundation** (APF), which received more than \$10 million from opioid drug manufacturers, including Defendants, from 2007 through 2012. For example, Purdue contributed \$1.7 million and Endo also contributed substantial sums to the APF.¹¹⁵

261. Throughout its existence, APF's operating budget was almost entirely comprised of contributions from prescription opioid manufacturers. For instance, nearly 90% of APF's \$5 million annual budget in 2010 came from "donations" from some of the Marketing Defendants, and by 2011, APF was entirely dependent on grants from drug manufacturers, including from Purdue and Endo. Not only did Defendants control APF's purse strings, APF's board of directors was comprised of doctors who were on Defendants' payrolls, either as consultants or speakers at medical events.¹¹⁶

262. Although holding itself out as an independent advocacy group promoting patient well-being, APF consistently lobbied against federal and state proposals to limit opioid use.

263. Another prominent front group was the **American Academy of Pain Medicine** (AAPM), which has received over \$2.2 million in funding since 2009 from opioid drug manufacturers, including Defendants. Like APF, AAPM presented itself as an independent and non-biased advocacy group representing physicians practicing in the

¹¹⁵Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011, 9:15am), <https://www.propublica.org/article/the-champion-of-painkillers>.

¹¹⁶*Id.*

field of pain medicine, but in fact was just another mouthpiece the Marketing Defendants used to push opioids on doctors and patients.¹¹⁷

264. Both the APF and the AAPM published treatment guidelines and sponsored and hosted medical education programs that touted the benefits of opioids to treat chronic pain while minimizing and trivializing their risks. The treatment guidelines the front groups published—many of which are discussed in detail below—were particularly important to Defendants in ensuring widespread acceptance for opioid therapy to treat chronic pain. Defendants realized, just as the CDC has, that such treatment guidelines can “change prescribing practices,” because they appear to be unbiased sources of evidence-based information, even when they are in reality marketing materials.

265. For instance, the AAPM, in conjunction with the **American Pain Society** (APS), issued comprehensive guidelines in 2009 titled “Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain – Evidence Review” (“2009 Guidelines”). The 2009 Guidelines promoted opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence to support this statement. Unsurprisingly, the Marketing Defendants have widely referenced and promoted these guidelines, issued by front groups these Defendants funded and controlled. These 2009 Guidelines are still available online today.¹¹⁸

¹¹⁷ Tracy Weber and Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 9:14am), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>.

¹¹⁸ *Clinical Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, Am. Pain Soc’y,

266. The **Alliance for Patient Access** (APA), discussed above, was established in 2006, along with the firm that runs it, Woodberry Associates LLC. The APA describes itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care,” but its list of “Associate Members and Financial Supporters” contains thirty drug companies, including each of the Marketing Defendants named in this lawsuit. In addition, the APA’s board members include doctors who have received hundreds of thousands of dollars in payments from drug companies. As discussed above, the APA has been a vocal critic of policies restricting the flow of opioids and has supported efforts to curtail the DEA’s ability to stop suspicious orders of prescription drugs.

267. The “white paper” issued by the APA in 2013 also echoed a favorite narrative of the Marketing Defendants, the supposed distinction between “legitimate patients” on the one hand and “addicts” on the other, asserting that one “unintended consequence” of regulating pain medication would be that “[p]atients with legitimate medical needs feel stigmatized, treated like addicts.”¹¹⁹

268. Another group utilized by the Marketing Defendants to encourage opioid prescribing practices, a University of Wisconsin-based organization known as the **Pain & Policy Studies Group**, received \$2.5 million from pharmaceutical companies to promote opioid use and discourage the passing of regulations against opioid use in medical

<https://web.archive.org/web/20190319204811/http://americanpainsociety.org/uploads/education/guidelines/chronic-opioid-therapy-cnnp.pdf> (last visited Dec, 27, 2019).

¹¹⁹ *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, *supra* note 82.

practice. The Pain & Policy Studies Group wields considerable influence over the nation's medical schools as well as within the medical field in general.¹²⁰ Purdue was the largest contributor to the Pain & Policy Studies Group, paying approximately \$1.6 million between 1999 and 2010.¹²¹

269. The **Federation of State Medical Boards** (FSMB) of the United States is a national non-profit organization that represents the seventy-state medical and osteopathic boards of the United States and its territories and co-sponsors the United States Medical Licensing Examination. Beginning in 1997, FSMB developed model policy guidelines around the treatment of pain, including opioid use. The original initiative was funded by the Robert Wood Johnson Foundation, but subsequently AAPM, APS, the University of Wisconsin Pain & Policy Studies Group, and the American Society of Law, Medicine, & Ethics all made financial contributions to the project.

270. FSMB's 2004 Model Policy encourages state medical boards "to evaluate their state pain policies, rules, and regulations to identify *any regulatory restrictions or barriers that may impede the effective use of opioids* to relieve pain."¹²² (Emphasis added).

¹²⁰ *The Role of Pharmaceutical Companies in the Opioid Epidemic*, Addictions.com, <https://www.addictions.com/opiate/the-role-of-pharmaceutical-companies-in-the-opioid-epidemic/> (last visited Dec. 27, 2019).

¹²¹ John Fauber, *UW group ends drug firm funds*, Journal Sentinel (Apr. 20, 2011), <http://archive.jsonline.com/watchdog/watchdogreports/120331689.html>.

¹²² *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, Fed'n of St. Med. Boards of the U.S., Inc. (May 2004), https://dprfiles.delaware.gov/medicalpractice/Model_Policy_Treatment_Pain.pdf.

271. One of the most significant barriers to convincing doctors that opioids were safe to prescribe to their patients for long-term treatment of chronic pain was the fact that many of those patients would, in fact, become addicted to opioids. If patients began showing up at their doctors' offices with obvious signs of addiction, the doctors would, of course, become concerned and likely stop prescribing opioids. And, doctors might stop believing the Marketing Defendants' claims that addiction risk was low.

272. To overcome this hurdle, the Marketing Defendants promoted a concept called "pseudoaddiction." These Defendants told doctors that when their patients appeared to be addicted to opioids—for example, asking for more and higher doses of opioids, increasing doses themselves, or claiming to have lost prescriptions in order to get more opioids—this was not actual addiction. Rather, the Marketing Defendants told doctors what appeared to be classic signs of addiction were actually just signs of undertreated pain. The solution to this "pseudoaddiction": more opioids. Instead of warning doctors of the risk of addiction and helping patients to wean themselves off powerful opioids and deal with their actual addiction, the Marketing Defendants pushed even more dangerous drugs onto patients.

273. The FSMB's Model Policy gave a scientific veneer to this fictional and overstated concept. The policy defines "pseudoaddiction" as "[t]he iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-

seeking behaviors that are commonly seen with addiction” and states that these behaviors “resolve upon institution of effective analgesic therapy.”¹²³

274. In May 2012, Senate Finance Committee Chairman Max Baucus and senior Committee member Chuck Grassley initiated an investigation into the connections of the Marketing Defendants with medical groups and physicians who have advocated increased opioid use.¹²⁴ In addition to Purdue, Endo, and Janssen, the senators sent letters to APF, APS, AAPM, FSMB, the University of Wisconsin Pain & Policy Studies Group, the Joint Commission on Accreditation of Healthcare Organization, and the Center for Practical Bioethics, requesting from each “a detailed account of all payments/transfers received from corporations and any related corporate entities and individuals that develop, manufacture, produce, market, or promote the use of opioid-based drugs from 1997 to the present.”¹²⁵

275. On the same day as the senators’ investigation began, APF announced that it would “cease to exist, effective immediately.”¹²⁶

¹²³ *Id.*

¹²⁴ *Baucus, Grassley Seek Answers about Opioid Manufacturers’ Ties to Medical Groups*, U.S. Senate Comm. on Fin. (May 8, 2012), <https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medical-groups>.

¹²⁵ Charles E. Grassley & Max Baucus, *Letter from U.S. Senate Comm. on Fin. to Am. Pain Found.*, U.S. Senate Comm. On Fin. (May 8, 2012), <https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Foundation2.pdf>.

¹²⁶ Charles Ornstein and Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57pm), <https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups>.

3. “It was pseudoscience”: the Marketing Defendants paid prominent physicians to promote their products.

276. The Marketing Defendants retained highly credentialed medical professionals to promote the purported benefits and minimal risks of opioids. Known as “Key Opinion Leaders” or “KOLs,” these medical professionals were often integrally involved with the front groups described above. The Marketing Defendants paid these KOLs substantial amounts to present at Continuing Medical Education (“CME”) seminars and conferences, and to serve on their advisory boards and on the boards of the various front groups.

277. The Marketing Defendants also identified doctors to serve as speakers or attend all-expense-paid trips to programs with speakers.¹²⁷ The Marketing Defendants used these trips and programs—many of them lavish affairs—to incentivize the use of opioids while downplaying their risks, bombarding doctors with messages about the safety and efficacy of opioids for treating long-term pain. Although often couched in scientific certainty, the Marketing Defendants’ messages were false and misleading, and helped to ensure that millions of Americans would be exposed to the profound risks of these drugs.

278. It is well documented that this type of pharmaceutical company symposium influences physicians’ prescribing, even though physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.¹²⁸ For example,

¹²⁷ Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 110.

¹²⁸ *Id.*

doctors who were invited to these all-expenses-paid weekends in resort locations like Boca Raton, Florida, and Scottsdale, Arizona, wrote twice as many prescriptions as those who did not attend.¹²⁹

279. The KOLs gave the impression they were independent sources of unbiased information, while touting the benefits of opioids through their presentations, articles, and books. KOLs also served on committees and helped develop guidelines such as the 2009 Guidelines described above that strongly encouraged the use of opioids to treat chronic pain.

280. One of the most prominent KOLs for the Marketing Defendants' opioids was Dr. Russell Portenoy. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'"¹³⁰

281. As one organizer of CME seminars, who worked with Portenoy and Purdue, pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor.

¹²⁹ Harriet Ryan, Lisa Girion and Scott Glover, *OxyContin goes global — "We're only just getting started"*, L.A. Times (Dec. 18, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part3/>.

¹³⁰ Quinones, *supra* note 83, at 314.

With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified."¹³¹

282. In recent years, some of the Marketing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.¹³² Dr. Portenoy himself specifically admitted that he overstated the drugs' benefits and glossed over their risks, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."¹³³ He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . . We didn't know then what we know now."¹³⁴

283. Dr. Portenoy did not need "the standards of 2012" to discern evidence-based science from baseless claims, however. When interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."¹³⁵

284. Dr. Portenoy was perhaps the most prominent KOL for prescription opioids, but he was far from the only one. In fact, Dr. Portenoy and a doctor named Perry

¹³¹ *Id.* at 136.

¹³² See, e.g., John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012), <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (finding that a key Endo KOL acknowledged that opioid marketing went too far).

¹³³ Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal (Dec. 17, 2012, 11:36am), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

¹³⁴ *Id.*

¹³⁵ Meier, *supra* note 22, at 277.

Fine co-wrote *A Clinical Guide to Opioid Analgesia*, which contained statements that conflict with the CDC's 2016 *Guideline for Prescribing Opioids for Chronic Pain*, such as the following examples regarding respiratory depression and addiction:

At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (ie, for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.¹³⁶

285. Dr. Fine is a Professor of Anesthesiology at the University of Utah School of Medicine's Pain Research Center. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.¹³⁷

286. In 2011, he and Dr. Scott Fishman, discussed below, published a letter in *JAMA* called "Reducing Opioid Abuse and Diversion," which emphasized the importance

¹³⁶ Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

¹³⁷ Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) *JAMA* 1445 (Oct. 5, 2011), <https://jama.network.com/journals/jama/article-abstract/1104464?redirect=true>.

of maintaining patient access to opioids.¹³⁸ The editors of *JAMA* found that both doctors had provided incomplete financial disclosures and made them submit corrections listing all their ties to the prescription painkiller industry.¹³⁹

287. Dr. Fine also failed to provide full disclosures as required by his employer, the University of Utah. For example, Dr. Fine told the university that he had received under \$5,000 in 2010 from Johnson & Johnson for providing “educational” services, but Johnson & Johnson’s website states that the company paid him \$32,017 for consulting, promotional talks, meals and travel that year.¹⁴⁰

288. In 2012, along with other KOLs, Dr. Fine was investigated for his ties to drug companies as part of the Senate investigation of front groups described above. When Marianne Skolek, a reporter for the online news outlet Salem-News.com and a critic of opioid overuse, wrote an article about him and another KOL being investigated, Dr. Fine fired back, sending a letter to her editor accusing her of poor journalism and saying that she had lost whatever credibility she may have had. He criticized her for linking him to Purdue, writing, “I have never had anything to do with Oxycontin development, sales, marketing or promotion; I have never been a Purdue Pharma speaker”—neglecting to

¹³⁸ Perry G. Fine, MD and Scott M. Fishman, MD, *Reducing Opioid Abuse and Diversion*, 306 (4) *JAMA* 381 (July 27, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104144?redirect=true>.

¹³⁹ *Incomplete Financial Disclosures in: Reducing Opioid Abuse and Diversion*, 306 (13) *JAMA* 1446 (Oct. 5, 2011), <https://jamanetwork.com/journals/jama/fullarticle/1104453>.

¹⁴⁰ Weber and Ornstein, *Two Leaders in Pain Treatment*, *supra* note 117.

mention, of course, that he served on Purdue's advisory board, as the *JAMA* editors had previously forced him to disclose.¹⁴¹

289. Another Utah physician, Dr. Lynn Webster, was the director of Lifetree Clinical Research & Pain Clinic in Salt Lake City from 1990 to 2010, and in 2013 was the president of AAPM (one of the front groups discussed above). Dr. Webster developed a five-question survey he called the Opioid Risk Tool, which he asserted would "predict accurately which individuals may develop aberrant behaviors when prescribed opioids for chronic pain."¹⁴² He published books titled *The Painful Truth: What Chronic Pain Is Really Like and Why It Matters to Each of Us* and *Avoiding Opioid Abuse While Managing Pain*.

290. Dr. Webster and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the opioid industry's promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills. Tina Webb, a Lifetree patient who overdosed in 2007, was taking as many as thirty-two pain pills a day in the year before she died, all while under doctor supervision.¹⁴³ Carol Ann Bosley, who sought treatment for pain at Lifetree after a

¹⁴¹ Marianne Skolek, *Doctor Under Senate Investigation Lashes Out at Journalist*, Salem News (Aug. 12, 2012, 8:45pm), <http://www.salem-news.com/articles/august122012/perry-fine-folo-ms.php>.

¹⁴² Lynn Webster and RM Webster, *Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool* 6 (6) Pain Med. 432 (Nov.-Dec. 2005), <https://www.ncbi.nlm.nih.gov/pubmed/16336480>.

¹⁴³ Jesse Hyde and Daphne Chen, *The untold story of how Utah doctors and Big Pharma helped drive the national opioid epidemic*, Deseret News (Oct. 26, 2017, 12:01am),

serious car accident and multiple spine surgeries, quickly became addicted to opioids and was prescribed increasing quantities of pills; at the time of her death, she was on seven different medications totaling approximately 600 pills a month.¹⁴⁴ Another woman, who sought treatment from Lifetree for chronic low back pain and headaches, died at age forty-two after Lifetree clinicians increased her prescriptions to fourteen different drugs, including multiple opioids, for a total of 1,158 pills a month.¹⁴⁵

291. By these numbers, Lifetree resembles the pill mills and “bad actors” that the Marketing Defendants blame for opioid overuse. But Dr. Webster was an integral part of Defendants’ marketing campaigns, a respected pain specialist who authored numerous CMEs sponsored by Endo and Purdue. And the Marketing Defendants promoted his Opioid Risk Tool and similar screening questionnaires as measures that allow powerful opioids to be prescribed for chronic pain.

292. Even in the face of patients’ deaths, Dr. Webster continues to promote a pro-opioid agenda, even asserting that alternatives to opioids are risky because “[i]t’s not hard to overdose on NSAIDs or acetaminophen.”¹⁴⁶ He argued on his website in 2015 that DEA restrictions on the accessibility of hydrocodone harm patients, and in 2017

<https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html>.

¹⁴⁴ Stephanie Smith, *Prominent pain doctor investigated by DEA after patient deaths*, CNN (Dec. 20, 2013, 7:06am), <http://www.cnn.com/2013/12/20/health/pain-pillar/index.html>.

¹⁴⁵ *Id.*

¹⁴⁶ *APF releases opioid medication safety module*, Drug Topics (May 10, 2011), <https://www.drugtopics.com/clinical-news/apf-releases-opioid-medication-safety-module>.

tweeted in response to CVS Caremark’s announcement that it will limit opioid prescriptions that “CVS Caremark’s new opioid policy is wrong, and it won’t stop illegal drugs.”¹⁴⁷

293. Another prominent KOL is Dr. Scott M. Fishman, the Chief of the Department of Pain Medicine at University of California, Davis. He has served as president of APF and AAPM, and as a consultant and a speaker for Purdue, in addition to providing the company grant and research support. He also has had financial relationships with Endo and Janssen. He wrote a book for the FSMB called *Responsible Opioid Use: A Physician’s Guide*, which was distributed to over 165,000 physicians in the U.S.

294. Dr. Fishman and Dr. Fine, along with Dr. Seddon Savage, published an editorial in *The Seattle Times* in 2010, arguing that Washington legislation proposed to combat prescription opioid abuse would harm patients, particularly by requiring chronic pain patients to consult with a pain specialist before receiving a prescription for a moderate to high dose of an opioid.¹⁴⁸

295. These KOLs and others—respected specialists in pain medicine—proved to be highly effective spokespeople for the Marketing Defendants.

¹⁴⁷ Lynn Webster, MD, @LynnRWebsterMD Tweet, Twitter (Dec. 7, 2017, 1:45pm), <https://twitter.com/LynnRWebsterMD/status/938887130545360898>.

¹⁴⁸ Perry G. Fine, Scott M. Fishman, and Seddon R. Savage, *Bill to combat prescription abuse really will harm patients in pain*, *Seattle Times* (Mar. 16, 2010, 4:39pm), https://web.archive.org/web/20180603005112/http://old.seattletimes.com/html/opinion/2011361572_guest17fine.html.

4. The Marketing Defendants used “unbranded” advertising as a platform for their misrepresentations about opioids.

296. The Marketing Defendants also aggressively promoted opioids through “unbranded advertising” to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as “disease awareness”—encouraging consumers to “talk to your doctor” about a certain health condition without promoting a specific product. A trick often used by pharmaceutical companies, unbranded advertising gives the pharmaceutical companies considerable leeway to make sweeping claims about health conditions or classes of drugs. In contrast, a “branded” advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as “fair balance.” Branded advertising is also subject to FDA review for consistency with the drug’s FDA-approved label.

297. Unbranded advertising allows pharmaceutical manufacturers to sidestep those requirements; “fair balance” and consistency with a drug’s label are not required.

298. By engaging in unbranded advertising, the Marketing Defendants were and are able to avoid FDA review and issue general statements to the public including that opioids improve function, that addiction usually does not occur, and that withdrawal can easily be managed. The Marketing Defendants’ unbranded advertisements either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks.

299. Through the various marketing channels described above—all of which the Marketing Defendants controlled, funded, and facilitated, and for which they are legally responsible—these Defendants made false or misleading statements about opioids despite the lack of scientific evidence to support their claims, while omitting the true risk of addiction and death.

E. Specific Misrepresentations Made by the Marketing Defendants.

300. All the Marketing Defendants have made and/or continue to make false or misleading claims in the following areas: (1) the low risk of addiction to opioids, (2) opioids' efficacy for chronic pain and ability to improve patients' quality of life with long-term use, (3) the lack of risk associated with higher dosages of opioids, (4) the need to prescribe more opioids to treat withdrawal symptoms, and (5) that risk-mitigation strategies and abuse-deterrent technologies allow doctors to safely prescribe opioids for chronic use. These illustrative but non-exhaustive categories of the Marketing Defendants' misrepresentations about opioids are described in detail below.

1. The Marketing Defendants falsely claimed that the risk of opioid abuse and addiction was low.

301. Collectively, the Marketing Defendants have made a series of false and misleading statements about the low risk of addiction to opioids over the past twenty years. The Marketing Defendants have also failed to take sufficient remedial measures to correct their false and misleading statements.

302. The Marketing Defendants knew that many physicians were hesitant to prescribe opioids other than for acute or cancer-related pain because of concerns about

addiction. Because of this general perception, sales messaging about the low risk of addiction was a fundamental prerequisite misrepresentation.

303. Purdue launched OxyContin in 1996 with the statement that OxyContin's patented continuous-release mechanism "is believed to reduce the abuse liability." This statement, which appeared in OxyContin's label and which sales representatives were taught to repeat verbatim, was unsupported by any studies, and was patently false. The continuous-release mechanism was simple to override, and the drug correspondingly easy to abuse. This fact was known, or should have been known, to Purdue prior to its launch of OxyContin, because people had been circumventing the same continuous-release mechanism for years with MS Contin, which in fact commanded a high street price because of the dose of pure narcotic it delivered. In addition, with respect to OxyContin, Purdue researchers notified company executives, including Raymond and Richard Sackler, by email that patients in their clinical trials were abusing the drug despite the timed-release mechanism.¹⁴⁹

304. In 2007, as noted above, Purdue pleaded guilty to misbranding a drug, a felony under the Food, Drug, and Cosmetic Act. 21 U.S.C. § 331(a)(2). As part of its guilty plea, Purdue agreed that certain Purdue supervisors and employees had, "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" in the following ways:

¹⁴⁹ WBUR On Point interview, *supra* note 28.

Trained PURDUE sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;

Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;

Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.¹⁵⁰

305. All these statements were false and misleading. But Purdue had not stopped there. Purdue—and later the Defendants—manipulated scientific research and utilized respected physicians as paid spokespeople to convey its misrepresentations about low addiction risk in much more subtle and pervasive ways, so that the idea that opioids used for chronic pain posed a low addiction risk became so widely accepted in the medical community that Defendants were able to continue selling prescription opioids for chronic pain—even after Purdue's criminal prosecution.

¹⁵⁰ *United States v. Purdue Frederick Co.*, *supra* note 32; *see also*, Plea Agreement, *United States v. Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

306. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

307. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction “rare” for patients treated with opioids.¹⁵¹ They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

¹⁵¹ Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980), <https://www.nejm.org/doi/10.1056/NEJM198001103020221>.

ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER

HERSHEL JICK, M.D.

Boston Collaborative Drug
Surveillance Program

Waltham, MA 02154

Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.

2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol*. 1978; 18:180-8.

308. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study, and that one could not conclude anything about long-term use of opioids from his figures.¹⁵² Dr. Jick also recalled that no one from drug companies or patient advocacy groups contacted him for more information about the data.¹⁵³

309. Nonetheless, the Marketing Defendants regularly invoked this letter as proof of the low addiction risk in connection with taking opioids despite its obvious shortcomings. These Defendants' egregious misrepresentations based on this letter included claims that *less than one percent* of opioid users become addicted.

¹⁵² Meier, *supra* note 22, at 174.

¹⁵³ *Id.*

310. The limited facts of the study did not deter the Marketing Defendants from using it as definitive proof of opioids’ safety. The enormous impact of the Marketing Defendants’ misleading amplification of this letter was well documented in another letter published in NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy . . .¹⁵⁴

311. Unfortunately, by the time of this analysis and the CDC’s findings in 2016, the damage had already been done. “It’s difficult to overstate the role of this letter,” said Dr. David Juurlink of the University of Toronto, who led the analysis. “It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern.”¹⁵⁵

312. The Marketing Defendants successfully manipulated the 1980 Porter and Jick letter as the “evidence” supporting their fundamental misrepresentation that the risk of opioid addiction was low when opioids were prescribed to treat pain. For example, in

¹⁵⁴ Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 New Eng. J. Med. 2194-95 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article>.

¹⁵⁵ *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT News (May 31, 2017), <https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

its 1996 press release announcing the release of OxyContin, Purdue advertised that the “fear of addiction is exaggerated” and quoted the chairman of the American Pain Society Quality of Care Committee, who claimed that “there is very little risk of addiction from the proper uses of these [opioid] drugs for pain relief.”¹⁵⁶

PR Newswire

May 31, 1996, Friday - 15:47 Eastern Time

NEW HOPE FOR MILLIONS OF AMERICANS SUFFERING FROM PERSISTENT

The fear of addiction is exaggerated.

One cause of patient resistance to appropriate pain treatment – the fear of addiction – is largely unfounded. According to Dr. Max, “Experts agree that most pain caused by surgery or cancer can be relieved, primarily by carefully adjusting the dose of opioid (narcotic) pain reliever to each patient’s need, and that there is very little risk of addiction from the proper uses of these drugs for pain relief.”

Paul D. Goldenheim, M.D., Vice President of **Purdue Pharma** L.P. in Norwalk, Connecticut, agrees with this assessment. “Proper use of medication is an essential weapon in the battle against persistent pain. But too often fear, misinformation and poor communication stand in the way of their legitimate use.”

¹⁵⁶ Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain*, L.A. Times (May 31, 1996, 3:47pm), <http://documents.latimes.com/oxycontin-press-release-1996/>.

313. Dr. Portenoy, the Purdue KOL mentioned previously, also stated in a promotional video from the 1990s that “the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.”¹⁵⁷



314. Purdue also specifically used the Porter and Jick letter in its 1998 promotional video, “I got my life back,” in which Dr. Alan Spanos says, “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*.”¹⁵⁸



¹⁵⁷ Catan and Perez, *supra* note 133.

¹⁵⁸ Our Amazing World, *Purdue Pharma OxyContin Commercial*, <https://www.youtube.com/watch?v=Er78Dj5hyeI> (last visited Dec. 27, 2019) (emphasis added).

315. The Porter and Jick letter was also used on Purdue's "Partners Against Pain" website, which was available in the early 2000s, where Purdue claimed that the addiction risk with OxyContin was very low.¹⁵⁹

316. The Porter and Jick letter was used frequently in literature given to prescribing physicians and to patients who were prescribed OxyContin.¹⁶⁰

317. In addition to the Porter and Jick letter, the Marketing Defendants exaggerated the significance of a study published in 1986 regarding cancer patients treated with opioids. Conducted by Dr. Portenoy and another pain specialist, Dr. Kathleen Foley, the study involved only 38 patients, who were treated for non-malignant cancer pain with low doses of opioids (the majority were given less than 20 MME/day, the equivalent of only 13 mg of oxycodone).¹⁶¹ Of these thirty-eight patients, only two developed problems with opioid abuse, and Dr. Portenoy and Dr. Foley concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse . . ."¹⁶² Notwithstanding the small sample size, low doses of opioids involved, and the fact that all the patients were cancer patients, the Marketing

¹⁵⁹ Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 110.

¹⁶⁰ Art Van Zee, M.D., *The OxyContin Abuse Problem: Spotlight on Purdue Pharma's Marketing* (Aug. 22, 2001), <https://web.archive.org/web/20170212210143/https://www.fda.gov/ohrms/dockets/dockets/01n0256/c000297-A.pdf>.

¹⁶¹ Russell K. Portenoy and Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 *Pain* 171-86 (1986), <https://www.ncbi.nlm.nih.gov/pubmed/2873550>.

¹⁶² *Id.*

Defendants used this study as “evidence” that high doses of opioids were safe for the treatment of chronic non-cancer pain.

318. The Marketing Defendants’ repeated misrepresentations about the low risk of opioid addiction were so effective that this concept became part of the conventional wisdom. Dr. Nathaniel Katz, a pain specialist, recalls learning in medical school that previous fears about addiction were misguided, and that doctors should feel free to allow their patients the pain relief that opioids can provide. He did not question this until one of his patients died from an overdose. Then, he searched the medical literature for evidence of the safety and efficacy of opioid treatment for chronic pain. “There’s not a shred of research on the issue. All these so-called experts in pain are dedicated and have been training me that opioids aren’t as addictive as we thought. But what is that based on? It was based on nothing.”¹⁶³

319. At a hearing before the House of Representatives’ Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue continued to emphasize “legitimate” treatment, dismissing cases of overdose and death as something that would not befall “legitimate” patients: “Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional.”¹⁶⁴

¹⁶³ Quinones, *supra* note 83, at 188-89.

¹⁶⁴ *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/pdf/CHRG-107hhrg75754.pdf>.

320. Purdue spun this baseless “legitimate use” distinction out even further in a patient brochure about OxyContin, called “A Guide to Your New Pain Medicine and How to Become a Partner Against Pain.” In response to the question, “Aren’t opioid pain medications like OxyContin Tablets ‘addicting’? Even my family is concerned about this,” Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes:

Drug addiction means using a drug to get “high” rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

321. Similarly, Dr. David Haddox, Senior Medical Director for Purdue, cavalierly stated, “[w]hen this medicine is used appropriately to treat pain under a doctor’s care, it is not only effective, it is safe.”¹⁶⁵ He went so far as to compare OxyContin to celery, because even celery would be harmful if injected: “If I gave you a stalk of celery and you ate that, it would be healthy for you. But if you put it in a blender and tried to shoot it into your veins, it would not be good.”¹⁶⁶

322. Purdue sales representatives also repeated these misstatements regarding the low risk for addiction to doctors across the country.¹⁶⁷ Its sales representatives targeted primary care physicians in particular, downplaying the risk of addiction and, as

¹⁶⁵ Roger Alford, *Deadly OxyContin abuse expected to spread in the U.S.*, Charleston Gazette (Feb. 9, 2001).

¹⁶⁶ *Id.*

¹⁶⁷ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. Times (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

one doctor observed, “promot[ing] among primary care physicians a more liberal use of opioids.”¹⁶⁸

323. Purdue sales representatives were instructed to “distinguish between iatrogenic addiction (<1% of patients) and substance abusers/diversion (about 10% of the population abuse something: weed; cocaine; heroin; alcohol; valium; etc.).”¹⁶⁹

324. Purdue also marketed OxyContin for a wide variety of conditions and to doctors who were not adequately trained in pain management.¹⁷⁰

325. As of 2003, Purdue’s Patient Information guide for OxyContin contained the following language regarding addiction:

Concerns about abuse, addiction, and diversion should not prevent the proper management of pain. The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare. However, data are not available to establish the true incidence of addiction in chronic pain patients.

326. Although Purdue has acknowledged it has made some misrepresentations about the safety of its opioids,¹⁷¹ it has done nothing to address the ongoing harms of their misrepresentations; in fact, it continues to make those misrepresentations today.

¹⁶⁸ Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 110.

¹⁶⁹ Meier, *supra* note 22, at 269.

¹⁷⁰ *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 44.

¹⁷¹ Following the conviction in 2007 of three of its executives for misbranding OxyContin, Purdue released a statement in which they acknowledged their false statements. “Nearly six years and longer ago, some employees made, or told other employees to make, certain statements about OxyContin to some health care professionals that were inconsistent with the F.D.A.-approved prescribing information for OxyContin and the express warnings it contained about risks associated with the medicine. The statements also violated written company policies requiring adherence to the prescribing information.”

327. Defendant Endo also made dubious claims about the low risk of addiction. For instance, it sponsored a website, PainKnowledge.com, on which in 2009 it claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”¹⁷² The website has since been taken down.

328. In another website, PainAction.com—which is still currently available today—Endo also claimed that “most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”¹⁷³

329. In a pamphlet titled “Understanding Your Pain: Taking Oral Opioid Analgesics,” Endo assured patients that addiction is something that happens to people who take opioids for reasons other than pain relief, “such as unbearable emotional problems”¹⁷⁴:

¹⁷² German Lopez, *The growing number of lawsuits against opioid companies, explained*, Vox (Oct. 17, 2019, 6:10pm), <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-epidemic-lawsuits-purdue-oxycotin>.

¹⁷³ *Opioid medication and addiction*, Pain Action (Aug. 17, 2017), <https://www.painaction.com/opioid-medication-addiction/>.

¹⁷⁴ *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharms. (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

Some questions you may have are:

Is it wrong to take opioids for pain?

- ◆ No. Pain relief is an important medical reason to take opioids as prescribed by your doctor. Addicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.

How can I be sure I'm not addicted?

- ◆ Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
- ◆ Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve your pain and improve your function. You are not addicted.

330. In addition, Endo made statements in pamphlets and publications that most health care providers who treat people with pain agree that most people do not develop an addiction problem. These statements also appeared on websites sponsored by Endo, such as Opana.com.

331. On its website PrescribeResponsibly.com, which was active until at least 2018, Defendant Janssen stated that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”¹⁷⁵

Use of Opioid Analgesics in Pain Management



Other Opioid Analgesic Concerns

Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and questions of addiction.^{15,16} By the same token, patients report similar concerns about developing an addiction to opioid analgesics.¹⁷ While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics analgesic therapy.¹⁸



¹⁷⁵ Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <https://web.archive.org/web/20190221055503/http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

332. Similarly, in a 2009 patient education video titled “Finding Relief: Pain Management for Older Adults,” Janssen sponsored a video by the American Academy of Pain Medicine that indicated that opioids are rarely addictive. The video has since been taken down.¹⁷⁶

333. Janssen also approved and distributed a patient education guide in 2009 that attempted to counter the “myth” that opioids are addictive, claiming that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”¹⁷⁷

334. In addition, all the Marketing Defendants used third parties and front groups to further their false and misleading statements about the safety of opioids.

335. For example, in testimony for the Hearing to Examine the Effects of the Painkiller OxyContin, Focusing on Risks and Benefits, in front of the Senate Health, Education, Labor and Pensions Committee in February 2002, Dr. John D. Giglio, Executive Director of the APF, the organization which, as described above, received the majority of its funding from opioid manufacturers, including Purdue, stated that “opioids are safe and effective, and only in rare cases lead to addiction.”¹⁷⁸ Along with Dr. Giglio’s testimony, the APF submitted a short background sheet on “the scope of the

¹⁷⁶ Molly Huff, *Finding Relief: Pain Management for Older Adults*, Ctrs. for Pain Mgmt. (Mar. 9, 2011), <http://centersforpain.com/news/-Finding-Relief-Pain-Management-for-Older-Adults>.

¹⁷⁷ Lopez, *supra* note 172.

¹⁷⁸ *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of John D. Giglio, M.A., J.D., Executive Director, American Pain Foundation), <https://www.help.senate.gov/imo/media/doc/Giglio.pdf>.

undertreatment of pain in the U.S.,” which asserted that “opioids are often the best” treatment for pain that hasn’t responded to other techniques, but that patients and many doctors “lack even basic knowledge about these options and fear that powerful pain drugs will [c]ause addiction.” According to the APF, “most studies show that less than 1% of patients become addicted, which is medically different from becoming physically dependent.”¹⁷⁹

336. The APF further backed up Purdue in an amicus curiae brief filed in an Ohio appeals court in December 2002, in which it claimed that “medical leaders have come to understand that the small risk of abuse does not justify the withholding of these highly effective analgesics from chronic pain patients.”¹⁸⁰

337. In a 2007 publication titled “Treatment Options: A Guide for People Living with Pain,” APF downplayed the risk of addiction and argued that concern about this risk should not prevent people from taking opioids: “Restricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction.”¹⁸¹ APF also tried to normalize the dangers of opioids by listing opioids as one of several “[c]ommon

¹⁷⁹ *Id.*

¹⁸⁰ Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.

¹⁸¹ *Treatment Options: A Guide for People Living with Pain*, Am. Pain Found., <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last visited Dec. 27, 2019).

drugs that can cause physical dependence,” including steroids, certain heart medications, and caffeine.¹⁸²

338. The Marketing Defendants’ repeated statements about the low risk of addiction when taking opioids as prescribed for chronic pain were blatantly false and were made with reckless disregard for the potential consequences.

2. The Marketing Defendants falsely claimed that opioids were proven effective for chronic pain and would improve quality of life.

339. Not only did the Marketing Defendants falsely claim that the risk of addiction to prescription opioids was low, these Defendants represented that there was a significant upside to long-term opioid use, including that opioids could restore function and improve quality of life.¹⁸³

340. Such claims were viewed as a critical part of the Marketing Defendants’ marketing strategies. For example, an internal Purdue report from 2001 noted the lack of data supporting improvement in quality of life with OxyContin treatment:

Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine...We do not have such data to support OxyContin promotion...In addition, Janssen has been using the “life uninterrupted” message in promotion of Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less about their pain.” This is a competitive advantage based on our inability to make any quality of life claims.¹⁸⁴

¹⁸² *Id.*

¹⁸³ This case *does not* request or require the Court to specifically adjudicate whether opioids are appropriate for the treatment of chronic, non-cancer pain—though the scientific evidence strongly suggests they are not.

¹⁸⁴ Meier, *supra* note 22, at 281.

341. Despite the lack of data supporting improvement in quality of life, Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association in 2002, proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside his grandson.¹⁸⁵ This ad earned a warning letter from the FDA, which admonished, “It is particularly disturbing that your November ad would tout ‘Life With Relief’ yet fail to warn that patients can die from taking OxyContin.”¹⁸⁶

342. Purdue also consistently tried to steer any concern away from addiction and focus on its false claims that opioids were effective and safe for treating chronic pain. At a hearing before the House of Representatives’ Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Michael Friedman, Executive Vice President and Chief Operating Officer of Purdue, testified that “even the most vocal critics of opioid therapy concede the value of OxyContin in the legitimate treatment of pain,” and that “OxyContin has proven itself an effective weapon in the fight against pain, returning many patients to their families, to their work, and to their ability to enjoy life.”¹⁸⁷

343. Purdue sponsored the development and distribution of an APF guide in 2011 which claimed that “multiple clinical studies have shown that opioids are effective

¹⁸⁵ *Id.* at 280.

¹⁸⁶ Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, Wall Street Journal (Jan. 23, 2003, 12:01am), <https://www.wsj.com/articles/SB1043259665976915824>.

¹⁸⁷ *Oxycontin: Its Use and Abuse*, *supra* note 164.

in improving daily function, psychological health, and health-related quality of life for chronic pain patients.” This guide is still available today.

344. Purdue also ran a series of advertisements of OxyContin in 2012 in medical journals titled “Pain vignettes,” which were styled as case studies of patients with persistent pain conditions and for whom OxyContin was recommended to improve their function.

345. Purdue and Endo also sponsored and distributed a book in 2007 to promote the claim that pain relief from opioids, by itself, improved patients’ function. The book remains for sale online today.

346. Endo’s advertisements for Opana ER claimed that use of the drug for chronic pain allowed patients to perform demanding tasks like construction and portrayed Opana ER users as healthy and unimpaired.

347. Endo’s National Initiative on Pain Control (NIPC) website also claimed in 2009 that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.”

348. Endo further sponsored a series of CME programs through NIPC which claimed that chronic opioid therapy has been “shown to reduce pain and depressive symptoms and cognitive functioning.”

349. Through PainKnowledge.org, Endo also supported and sponsored guidelines that stated, among other things, that “Opioid Medications are a powerful and

often highly effective tool in treating pain,” and that “they can help restore comfort, function, and quality of life.”¹⁸⁸

350. In addition, Janssen sponsored and edited patient guides which stated that “opioids may make it easier for people to live normally.” The guides listed expected functional improvements from opioid use, including sleeping through the night, and returning to work, recreation, sex, walking, and climbing stairs.

351. Janssen also sponsored, funded, and edited a website which featured an interview edited by Janssen that described how opioids allowed a patient to “continue to function.” This video is still available today.

352. Furthermore, sales representatives for the Marketing Defendants communicated and continue to communicate the message that opioids will improve patients’ function, without appropriate disclaimers.

353. The Marketing Defendants’ statements regarding opioids’ ability to improve function and quality of life are false and misleading. As the CDC’s Guideline for Prescribing Opioids for Chronic Pain (the “2016 CDC Guideline” or “Guideline”)¹⁸⁹ confirms, not a single study supports these claims.

354. In fact, to date, there have been no long-term studies that demonstrate that opioids are effective for treating long-term or chronic pain. Instead, reliable sources of information, including from the CDC in 2016, indicate that there is “[n]o evidence” to

¹⁸⁸*Informed Consent for Using Opioids to Treat Pain*, Painknowledge.org (2007), https://www.mainequalitycounts.org/image_upload/Opioid%20Informed%20Consent%20Formatted_1_23_2008.pdf.

¹⁸⁹ 2016 CDC Guideline, *supra* note 45.

show “a long-term benefit of opioids in pain and function versus no opioids for chronic pain.”¹⁹⁰ By contrast, significant research has demonstrated the colossal dangers of opioids. The CDC, for example, concluded that “[e]xtensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)” and that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder.”¹⁹¹

3. The Marketing Defendants falsely claimed doctors and patients could increase opioid usage indefinitely without added risk.

355. The Marketing Defendants also made false and misleading statements claiming that there is no dosage ceiling for opioid treatment. These misrepresentations were integral to the Marketing Defendants’ promotion of prescription opioids for two reasons. First, the idea that there was no upward limit was necessary for the overarching deception that opioids are appropriate treatment for chronic pain. As discussed above, people develop a tolerance to opioids’ analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. Second, the dosing misrepresentation was necessary for the claim that OxyContin and competitor drugs allowed 12-hour dosing.

356. Twelve-hour dosing is a significant marketing advantage for any medication, because patient compliance is improved when a medication only needs to be taken twice a day. For prescription painkillers, the 12-hour dosing is even more significant because shorter-acting painkillers did not allow patients to get a full night’s

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

sleep before the medication wore off. A Purdue memo to the OxyContin launch team stated that “OxyContin’s positioning statement is ‘all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,’” and further that “[t]he convenience of q12h dosing was emphasized as the most important benefit.”¹⁹²

357. Purdue executives therefore maintained the messaging of 12-hour dosing even when many reports surfaced that OxyContin did not last 12 hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills.

358. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should “convinc[e] the physician that there is no need” for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses. The manager directed representatives to discuss with physicians that there is “no[] upward limit” for dosing and ask “if there are any reservations in using a dose of 240mg-320mg of OxyContin.”¹⁹³

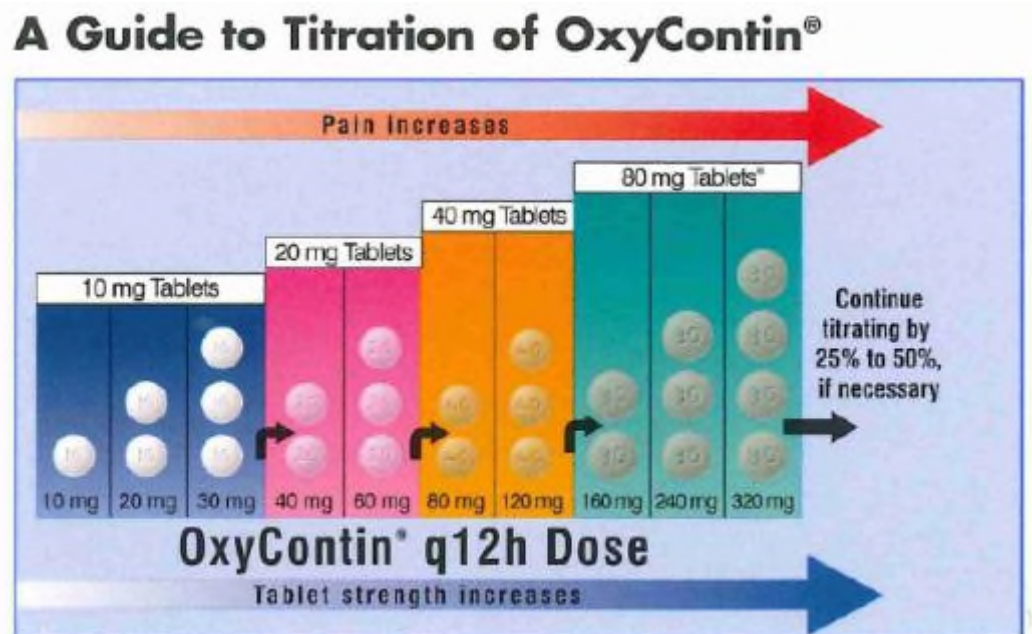
359. As doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue directed its sales representatives to “refocus” physicians on 12-hour

¹⁹² *OxyContin launch*, L.A. Times (May 5, 2016), <http://documents.latimes.com/oxycontin-launch-1995/>.

¹⁹³ *Sales manager on 12-hour dosing*, L.A. Times (May 5, 2016), <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/>.

dosing. One sales manager instructed her team that anything shorter “needs to be nipped in the bud. NOW!!”¹⁹⁴

360. These misrepresentations were incredibly dangerous. As noted above, opioid dosages at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. Notwithstanding the risks, Purdue’s 2003 Conversion Guide for OxyContin contained the following diagram for increasing dosage up to 320 mg:



361. In a 2004 response letter to the FDA, Purdue tried to address concerns that patients who took OxyContin more frequently than 12 hours would be at greater risk of side effects or adverse reactions. Purdue contended that the peak plasma concentrations

¹⁹⁴ Harriet Ryan, Lisa Girion, and Scott Glover, 'You Want a Description of Hell?' OxyContin's 12-Hour Problem, L.A. Times (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

of oxycodone would not increase with more frequent dosing, and therefore no adjustments to the package labeling or 12-hour dosing regimen were needed.¹⁹⁵ But these claims were false, and Purdue's suggestion that there was no upper limit or risk associated with increased dosage was incredibly misleading.

362. Suggesting that it recognized the danger of its misrepresentations of no dose ceiling, Purdue discontinued the OxyContin 160 mg tablet in 2007 and stated that this step was taken "to reduce the risk of overdose accompanying the abuse of this dosage strength."¹⁹⁶

363. But still Purdue and the Marketing Defendants worked hard to protect their story. In March 2007, Dr. Gary Franklin, Medical Director for the Washington State Department of Labor & Industries, published the *Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain*. Developed in collaboration with providers in Washington State who had extensive experience in the evaluation and treatment of patients with chronic pain, the guideline recommended a maximum daily dose of opioids to protect patients.

364. In response, Purdue sent correspondence to Dr. Franklin specifically indicating, among other things, that "limiting access to opioids for persons with chronic pain is not the answer" and that the "safety and efficacy of OxyContin doses greater than

¹⁹⁵ *Purdue Response to FDA, 2004*, L.A. Times (May 5, 2016), <http://documents.latimes.com/purdue-response-fda-2004/>.

¹⁹⁶ *OxyContin Tablets Risk Management Program*, Purdue Pharma L.P., <https://web.archive.org/web/20170215064438/https://www.fda.gov/ohrms/dockets/DOCKETS/07p0232/07p-0232-cp00001-03-Exhibit-02-Part-1-vol1.pdf> (revised May 18, 2007).

40 mg every 12 hours in patients with chronic nonmalignant pain” was well established. Purdue even went so far as to represent to Dr. Franklin that even if opioid treatment produces significant adverse effects in a patient, “this does not preclude a trial of another opioid.”

365. In 2010, Purdue published a Risk Evaluation and Mitigation Strategy (“REMS”) for OxyContin, but even the REMS does not address concerns with increasing dosage, and instead advises prescribers that “dose adjustments may be made every 1-2 days”; “it is most appropriate to increase the q12h dose”; the “total daily dose can usually be increased by 25% to 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration.”¹⁹⁷

366. In 2012, APF claimed on its website that there was no “ceiling dose” for opioids for chronic pain.¹⁹⁸ APF also made this claim in a guide sponsored by Purdue, which is still available online.

367. Accordingly, Purdue continued to represent both publicly and privately that increased opioid usage was safe and did not present additional risk at higher doses.

¹⁹⁷ *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., <https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf> (last modified Nov. 2010).

¹⁹⁸ Noah Nesin, M.D., FAAFP, *Responsible Opioid Prescribing*, PCHC, https://www.mainequalitycounts.org/image_upload/Noah%20Nesin%20Slides_Responsible%20Opioid%20Prescribing%20MCPC2.pdf (last visited Dec. 27, 2019).

368. Janssen also made the same misrepresentations regarding the disadvantages of dosage limits for other pain medicines in a 2009 patient education guide, while failing to address the risks of dosage increases with opioids.

369. Endo, on a website it sponsors, PainKnowledge.com, also made the claim in 2009 that opioid dosages could be increased indefinitely.

370. In the “Understanding Your Pain” pamphlet discussed above, Endo assures opioid users that concern about developing tolerance to the drugs’ pain-relieving effect is “not a problem,” and that “[t]he dose can be increased” and “[y]ou won’t ‘run out’ of pain relief.”¹⁹⁹

ENDO
PHARMACEUTICALS

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Web: www.endo.com

Understanding Your Pain

Taking Oral Opioid Analgesics

This brochure was developed by
Margo McCallary, RN, MS, FAAN, and
Chris Pascoe, RN, MS, FAAN authors of *Pain: Clinical Manual* (2nd ed. Mosby: 1999).
Edited by Russell K. Portney, MD.

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Remember: The more the pain medicine works, the more your pain goes away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.

• **Addiction:** If you take too much, you may become addicted. If you are addicted, you may need to stop taking the medicine. You are not alone.

• **Ask yourself:** Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve your pain and improve your function. You are not addicted.

IF I TAKE THE OPIOID NOW, WILL IT WORK LATER WHEN I REALLY NEED IT?

Know patients with chronic pain worry about this, but it isn't a problem.

• The dose can be increased as other medicines can be added.

• You won't "run out" of your relief.

WHAT CAN I DO ABOUT SIDE EFFECTS?

Talk to your doctor, nurse, or pharmacist about the side effects of opioids. If they

cause, remember that most opioid side effects can be treated or prevented.

Constipation

• Constipation from opioids is very common, but it can be prevented. If it does occur, it can be treated.

• Prevention is the best approach. If you take opioids daily, you need to eat more fiber and drink more liquids than you usually do. Many people also need to take a laxative. The most common type is a combination of stool softener and mild stimulant laxative. Those that can be purchased without a prescription include Peri-Colace® capsules or Sytrop and Senokot® tablets. Ask your pharmacist about less expensive generic forms.

Nausea or vomiting (stomach issues)

• This does not always occur, but if it does, it can be treated. Ask your doctor, nurse, or pharmacist for medicine to relieve this. After a few days, the nausea usually stops.

• Try eating small and breathing slowly through your mouth.

• Nausea medicines that you can buy without a prescription include Dramamine® tablets and Emetrol® oral solution.

• If your pain is under good control, you may be able to reduce the nausea by taking a lower dose of opioid.

Drowsiness (Sleepiness)

• Some degree of sleepiness would be normal when you start taking an opioid, but after a few days the drowsiness usually goes away.

¹⁹⁹ *Understanding Your Pain: Taking Oral Opioid Analgesics*, supra note 174.

371. Dosage limits with respect to opioids are particularly important not only because of the risk of addiction but also because of the potentially fatal side effect of respiratory depression. Endo's "Understanding Your Pain" pamphlet minimized this serious side effect, calling it "slowed breathing," declaring that it is "very rare" when opioids are used "appropriately," and never stating that it could be fatal:

"Slowed breathing"

- ◆ The medical term for "slowed breathing" is "respiratory depression."
- ◆ This is very rare when oral opioids are used appropriately for pain relief.
- ◆ If you become so sleepy that you cannot make yourself stay awake, you may be in danger of slowed breathing. Stop taking your opioid and call your doctor immediately.

4. The Marketing Defendants falsely instructed doctors and patients that more opioids were the solution when patients presented symptoms of addiction.

372. Not only did the Marketing Defendants hide the serious risks of addiction associated with opioids, they actively worked to prevent doctors from taking steps to prevent or address opioid addiction in their patients.

373. One way that the Marketing Defendants worked to obstruct appropriate responses to opioid addiction was to push the concept of "pseudoaddiction." Dr. David Haddox—who later became a Senior Medical Director for Purdue—published a study in 1989 coining the term, which he characterized as "the iatrogenic syndrome of abnormal

behavior developing as a direct consequence of inadequate pain management.”²⁰⁰

(“Iatrogenic” describes a condition induced by medical treatment.) In other words, he claimed that people on prescription opioids who exhibited classic signs of addiction—“abnormal behavior”—were not addicted, but rather simply suffering from under-treatment of their pain. His solution for pseudoaddiction? More opioids.

374. Although this concept was formed based on a single case study, it proved to be a favorite trope in the Marketing Defendants’ marketing schemes. For example, using this study, Purdue informed doctors and patients that signs of addiction are actually the signs of under-treated pain which should be treated with even more opioids. Purdue reassured doctors and patients, telling them that “chronic pain has been historically undertreated.”²⁰¹

375. The Marketing Defendants continued to spread the concept of pseudoaddiction through the APF, which even went so far as to compare opioid addicts to coffee drinkers. In a 2002 court filing, APF wrote that “[m]any pain patients (like daily coffee drinkers) claim they are ‘addicted’ when they experience withdrawal symptoms associated with physical dependence as they decrease their dose. But unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain . . .”²⁰²

²⁰⁰ David E. Weissman and J. David Haddox, *Opioid pseudoaddiction--an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), <https://www.ncbi.nlm.nih.gov/pubmed/2710565>.

²⁰¹ *Oxycontin: Its Use and Abuse*, *supra* note 164.

²⁰² APF Brief Amici Curiae, *supra* note 180, at 10-11.

376. In a 2007 publication titled “Treatment Options: A Guide for People Living with Pain,” the APF claimed: “*Physical dependence is normal*; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does **NOT** mean you are addicted.”²⁰³ In this same publication, the APF asserted that “people who are not substance abusers” may also engage in “unacceptable” behaviors such as “increasing the dose without permission or obtaining the opioid from multiple sources,” but that such behaviors do not indicate addiction and instead reflect a “desire to obtain pain relief.”²⁰⁴



Side effects

The most common side effects of opioids include constipation, nausea and vomiting, dizziness (sleepiness), mental clouding and itching. Some people may also experience drowsiness or difficulty urinating. Respiratory depression, a decreased rate and depth of breathing, is a serious side effect associated with overdose.

The good news is that most side effects go away after a few days. However, side effects may continue in some people. Constipation is most likely to persist. Some pain experts believe all patients started on an opioid also should be taking a stool softener or a laxative. Others believe that this treatment is appropriate only if a patient is prone to developing significant constipation because of advanced age, prior diet, other diseases, or the use of other constipating drugs. Your healthcare provider can give advice on what to eat and what medicines to use to treat constipation. Always make certain to drink plenty of fluids and be as active as possible.

If any of the other side effects don't go away, they can also be treated. Be certain to tell your provider if you are having any problems. Serious side effects such as delirium or respiratory depression can occur if the dose is increased too quickly, especially in someone who is just starting to take opioids. Tell your provider if you are unable to concentrate or think clearly after you have been taking an opioid for a few days. Report other medications you may be taking that make you sleepy. Do not drive when you first start taking these drugs or immediately after the dose has been increased. Most persons will adapt to these medicines over time and can drive safely while taking them for pain control. If side effects remain troublesome, your provider may switch you to a different opioid. The amount of pain relief can be maintained after such a switch and often the side effects can be reduced.

Common drugs that can cause physical dependence

- Opioids
- Stimulants
- Sedatives
- Steroids
- Certain Antidepressants
- Certain Heart Medications
- Caffeine

Tolerance, physical dependence and addiction

You and your healthcare provider may worry about tolerance, physical dependence and addiction. It's sometimes easy to confuse the meaning of these words. Tolerance refers to the situation in which a drug becomes less effective over time. However, many persons with persistent pain don't develop tolerance and stay on the same dose of opioid for a long time. Many times when a person needs a larger dose of a drug, it's because their pain is worse or the problem causing their pain has changed.

Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, goosebumps, anxiety) if the drug is suddenly stopped or the dose is lowered too quickly. **Physical dependence is normal; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does NOT mean you are addicted.** In fact, many non-addictive drugs can produce physical dependence. To prevent withdrawal from occurring, the dose of the medication must be decreased slowly.

If you believe that you no longer need to take the opioid medication or want to reduce the dose, it is essential to speak to your provider. They will guide you on how to decrease your dose over time to prevent the experience of withdrawal.

²⁰³ *Treatment Options: A Guide for People Living with Pain*, supra note 181.

²⁰⁴ *Id.*

377. Purdue published a REMS for OxyContin in 2010, and in the associated Healthcare Provider Training Guide stated that “[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior.”²⁰⁵

378. Purdue worked, and continues to work, to create confusion about what addiction is. For example, Purdue continues to emphasize that abuse and addiction are separate and distinct from physical dependence. Regardless of whether these statements may be technically correct, they continue to add ambiguity over the risks and benefits of opioids.

379. Endo sponsored an NIPC CME program in 2009 which promoted the concept of pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding its projects, developing content, and reviewing NIPC materials.

380. A 2001 paper which was authored by a doctor affiliated with Janssen stated that “[m]any patients presenting to a doctor’s office asking for pain medications are accused of drug seeking. In reality, most of these patients may be undertreated for their pain syndrome.”²⁰⁶

²⁰⁵ *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 197.

²⁰⁶ Howard A. Heit, MD, FACP, FASAM, *The truth about pain management: the difference between a pain patient and an addicted patient*, 5 *European Journal of Pain* 27-29 (2001), <http://www.med.uottawa.ca/courses/totalpain/pdf/doc-34.pdf>.

381. In 2009, on a website it sponsored, Janssen stated that pseudoaddiction is different from true addiction “because such behaviors can be resolved with effective pain management.”²⁰⁷

382. Indeed, on its currently active website PrescribeResponsibly.com, Janssen defines pseudoaddiction as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately, the inappropriate behavior ceases.”²⁰⁸

What a Prescriber Should Know Before Writing the First Prescription



TABLE 1: Definitions

8. **Pseudoaddiction** is a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases.²⁵



²⁰⁷ Chris Morran, *Ohio: Makers Of OxyContin, Percocet & Other Opioids Helped Fuel Drug Epidemic By Misleading Doctors, Patients*, Consumerist (May 31, 2017, 2:05pm), <https://consumerist.com/2017/05/31/ohio-makers-of-oxycontin-percocet-other-opioids-helped-fuel-drug-epidemic-by-misleading-doctors-patients/>.

²⁰⁸ Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly,

383. As set forth in more detail below, these statements were false and misleading as evidenced by, *inter alia*, the findings made by the CDC in 2016. Indeed, there is simply no evidence that pseudoaddiction is a real phenomenon. As research compiled by the CDC and others makes clear, pseudoaddiction is pseudoscience—nothing more than a concept Defendants seized upon to help sell more of their actually addictive drugs.

5. The Marketing Defendants falsely claimed that risk-mitigation strategies, including tapering and abuse-deterrent technologies, made it safe to prescribe opioids for chronic use.

384. Even when the Marketing Defendants acknowledge that opioids pose some risk of addiction, they dismiss these concerns by claiming that addiction can be easily avoided and addressed through simple steps. In order to make prescribers feel more comfortable about starting patients on opioids, the Marketing Defendants falsely communicated to doctors that certain screening tools would allow them to reliably identify patients at higher risk of addiction and safely prescribe opioids, and that tapering the dose would be sufficient to manage cessation of opioid treatment. Both assertions are false.

385. For instance, as noted above, Purdue published a REMS for OxyContin in 2010, in which it described certain steps that needed to be followed for safe opioid use.

<https://web.archive.org/web/20190106014101/http://www.prescriberesponsibly.com/articles/before-prescribing-opioids> (last modified July 2, 2015).

Purdue stressed that all patients should be screened for their risk of abuse or addiction, and that such screening could curb the incidence of addiction.²⁰⁹

386. The APF also proclaimed in a 2007 booklet, sponsored in part by Purdue, that “[p]eople with the disease of addiction may abuse their medications, engaging in unacceptable behaviors like increasing the dose without permission or obtaining the opioid from multiple sources, among other things. Opioids get into the hands of drug dealers and persons with an addictive disease as a result of pharmacy theft, forged prescriptions, Internet sales, and even from other people with pain. It is a problem in our society that needs to be addressed through many different approaches.”²¹⁰

387. On its current website for OxyContin,²¹¹ Purdue acknowledges that certain patients have higher risk of opioid addiction based on history of substance abuse or mental illness—a statement which, even if accurate, obscures the significant risk of addiction for all patients, including those without such a history, and comports with statements it has recently made that it is “bad apple” patients, and not the opioids, that are arguably the source of the opioid crisis:

Assess each patient’s risk for opioid addiction, abuse, or misuse prior to prescribing OxyContin, and monitor all patients receiving OxyContin for the development of these behaviors and conditions. Risks are increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). The potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed opioids such as OxyContin, but use in such patients necessitates intensive counseling about the risks and proper use of OxyContin along with intensive monitoring for signs of addiction, abuse, and misuse.

²⁰⁹ *Oxycontin Risk Evaluation and Mitigation Strategy*, *supra* note 197.

²¹⁰ *Treatment Options: A Guide for People Living with Pain*, *supra* note 181.

²¹¹ OxyContin, <https://www.oxycontin.com/index.html> (last visited Dec. 27, 2019).

388. Additionally, on its website, Purdue referred to publicly available tools that can assist with prescribing compliance, such as patient-prescriber agreements and risk assessments.²¹²

389. Purdue continues to downplay the severity of addiction and withdrawal and claims that dependence can easily be overcome by strategies such as adhering to a tapering schedule to successfully stop opioid treatment. On the current website for OxyContin, it instructs that “[w]hen discontinuing OxyContin, gradually taper the dosage. Do not abruptly discontinue OxyContin.”²¹³ And on the current OxyContin Medication Guide, Purdue also states that one should “taper the dosage gradually.”²¹⁴ As a general matter, tapering is a sensible strategy for cessation of treatment with a variety of medications, such as steroids or antidepressants. But the suggestion that tapering is sufficient, or simple, following chronic and continuous opioid use is misleading and dangerous, and it sets patients up for withdrawal and addiction.

390. In its “Dear Healthcare Professional” letter in 2010, Purdue instructed doctors to gradually taper someone off OxyContin to prevent signs and symptoms of withdrawal in patients who were physically dependent.²¹⁵ Nowhere does Purdue warn

²¹² *ER/LA Opioid Analgesics REMS*, Purdue, <https://web.archive.org/web/20190422185531/http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/rem/> (last visited Dec. 27, 2019).

²¹³ Oxycontin.com, *supra* note 211.

²¹⁴ *OxyContin Full Prescribing Information*, Purdue Pharma LP, <http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o> (last visited Dec. 27, 2019).

²¹⁵ *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 197.

doctors or patients that tapering may be inadequate to safely end opioid treatment and avoid addiction.

391. Other Marketing Defendants make similar claims. For instance, Endo suggests that risk-mitigation strategies enable the safe prescription of opioids. In its currently active website, Opana.com, Endo states that assessment tools should be used to assess addiction risk, but that “[t]he potential for these risks should not, however, prevent proper management of pain in any given patient.”²¹⁶

392. On the same website, Endo makes similar statements about tapering, stating “[w]hen discontinuing OPANA ER, gradually taper the dosage.”²¹⁷

393. Janssen also states on its currently active website, PrescribeResponsibly.com, that the risk of opioid addiction “can usually be managed” through tools such as “opioid agreements” between patients and doctors.²¹⁸

394. Each Marketing Defendant’s statements about tapering misleadingly implied that gradual tapering would be sufficient to alleviate any risk of withdrawal or addiction while taking opioids.

395. The Marketing Defendants have also made and continue to make false and misleading statements about the purported abuse-deterrent properties of their opioid pills to suggest these reformulated pills are not susceptible to abuse. In so doing, the

²¹⁶ *Opana ER*, Endo Pharmaceuticals, Inc., <http://www.opana.com> (last visited Dec. 27, 2019).

²¹⁷ *Id.*

²¹⁸ Heit & Gourlay, *supra* note 208.

Marketing Defendants have increased their profits by selling more pills for substantially higher prices.

396. For instance, since at least 2001, Purdue has contended that “abuse resistant products can reduce the incidence of abuse.”²¹⁹ Until recently, Purdue’s website touted abuse-deterrent properties by saying they “can make a difference.”²²⁰

397. On August 17, 2015, Purdue announced the launch of a new website, “Team Against Opioid Abuse,” which it said was “designed to help healthcare professionals and laypeople alike learn about different abuse-deterrent technologies and how they can help in the reduction of misuse and abuse of opioids.”²²¹ This website appears to no longer be active.

398. A 2013 study which was authored by at least two doctors who at one time worked for Purdue stated that “[a]buse-deterrent formulations of opioid analgesics can reduce abuse.”²²² In another study from 2016 with at least one Purdue doctor as an

²¹⁹ *Oxycontin: Its Use and Abuse*, *supra* note 164.

²²⁰ *Opioids with Abuse-Deterrent Properties*, Purdue, <https://web.archive.org/web/20180302203422/http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/> (last visited Dec. 27, 2019).

²²¹ *Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com*, Purdue (Aug. 17, 2015), <https://web.archive.org/web/20170404120618/http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/>.

²²² Paul M. Coplan, Hrishikesh Kale, Lauren Sandstrom, Craig Landau, and Howard D. Chilcoat, *Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release oxycodone with abuse-deterrent characteristics*, 22 (12) *Pharmacoepidemiol Drug Saf.* 1274-82 (Sept. 30, 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4283730/>.

author, the authors claimed that abuse decreased by as much as 99% in some situations after abuse-deterrent formulations were introduced.²²³

399. Interestingly, one report found that the original safety label for OxyContin, which instructed patients not to crush the tablets because it would have a rapid release effect, may have inadvertently given opioid users ideas for techniques to get high from these drugs.²²⁴

400. In 2012, Defendant Endo replaced the formula for Opana ER with a new formula with abuse-deterrent properties that it claimed would make Opana ER resistant to manipulation from users to snort or inject it. But the following year, the FDA concluded:

While there is an increased ability of the reformulated version of Opana ER to resist crushing relative to the original formulation, study data show that the reformulated version's extended-release features can be compromised when subjected to other forms of manipulation, such as cutting, grinding, or chewing, followed by swallowing.

Reformulated Opana ER can be readily prepared for injection, despite Endo's claim that these tablets have "resistance to aqueous extraction (i.e., poor syringeability)." It also appears that reformulated Opana ER can be prepared for snorting using commonly available tools and methods.

The postmarketing investigations are inconclusive, and even if one were to treat available data as a reliable indicator of abuse rates, one of these investigations also suggests the troubling possibility that a higher percentage

²²³ Paul M. Coplan, Howard D. Chilcoat, Stephen Butler, Edward M. Sellers, Aditi Kadakia, Venkatesh Harikrishnan, J. David Haddox, and Richard C. Dart, *The effect of an abuse-deterrent opioid formulation (OxyContin) on opioid abuse-related outcomes in the postmarketing setting*, 100 Clin. Pharmacol. Ther., 275-86 (June 22, 2016), <http://onlinelibrary.wiley.com/doi/10.1002/cpt.390/full>.

²²⁴ *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 170.

of reformulated Opana ER abuse is via injection than was the case with the original formulation.²²⁵

401. Despite the FDA's determination that the evidence did not support Endo's claims of abuse-deterrence, Endo advertised its reformulated pills as "crush resistant" and directed its sales representatives to represent the same to doctors. Endo improperly marketed Opana ER as crush-resistant, when Endo's own studies showed that the pill could be crushed and ground. In 2016, Endo reached an agreement with the Attorney General of the State of New York that required Endo to discontinue making such statements.²²⁶

402. Mallinckrodt likewise promoted its branded opioids, Exalgo and Xartemis XR, as having abuse-deterrent properties, even though the FDA did not approve ADF labeling for either drug. For both Exalgo and Xartemis XR, Mallinckrodt trained its sales representatives to tell doctors that the pills were tamper-resistant in that they were harder to crush and to inject, and that the drugs were less likely to provide euphoria to users. Mallinckrodt pushed its branded products as solutions to rampant opioid abuse while continuing to profit from the high rate of abuse of its generics.

²²⁵ *FDA Statement: Original Opana ER Relisting Determination*, U.S. Food & Drug Admin. (May 10, 2013), <https://wayback.archive-it.org/7993/20171102214123/https://www.fda.gov/Drugs/DrugSafety/ucm351357.htm>.

²²⁶ Press Release, Attorney General Eric T. Schneiderman, *A.G. Schneiderman Announces Settlement with Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing of Prescription Opioid Drugs*, N.Y. State Office of the Atty. General, (Mar. 3, 2016), <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals>.

403. The Marketing Defendants’ assertions that their reformulated pills could curb abuse and that other risk-mitigation strategies enabled doctors to safely prescribe high doses of long-acting opioids were false and misleading.

404. Ultimately, even if a physician prescribes opioids after screening for abuse risk, advising a patient to taper, and selecting brand-name, abuse-deterrent formulations, chronic and continuous opioid use still comes with significant risks of addiction and abuse. The Marketing Defendants’ statements to the contrary were designed to create a false sense of security and assure physicians that they could safely prescribe potent narcotics to their patients.

F. Research Demonstrates that the Manufacturing Defendants’ Claims are False.

405. Contrary to the Manufacturing Defendants’ misrepresentations about the benefits and risks of opioids, growing evidence suggests that using opioids to treat chronic pain leads to overall negative outcomes, delaying or preventing recovery and providing little actual relief, all while presenting serious risks of overdose.

406. For example, Dr. Gary Franklin, Medical Director of the Washington State Department of Labor and Industries (“L&I”), together with its chief pharmacist, Jaymie Mai, conducted a thorough analysis of all recorded deaths in the state’s workers’ comp system. They published their findings in the *American Journal of Industrial Medicine* in 2005 and again in 2012.²²⁷

²²⁷ Gary M. Franklin, M.D., MPH, Jaymie Mai, Pharm.D., Thomas Wickizer, Ph.D., Judith A. Turner, Ph.D., Deborah Fulton-Kehoe, Ph.D., MPH, and Linda Grant, BSN, MBA, *Opioid dosing trends and mortality in Washington State Workers’ Compensation, 1996-2002*, 48 Am. J. Ind. Med. 91-99 (2005).

407. Their research showed that the total number of opioid prescriptions paid for by the Workers' Compensation Program tripled between 1996 and 2006.²²⁸ Not only did the number of prescriptions balloon, so too did the doses; from 1996 to 2002 the mean daily morphine equivalent dose ("MED") nearly doubled, and remained that way through 2006.²²⁹ As injured workers were given more prescriptions of higher doses of opioids, the rates of opioid overdoses among that population jumped, from zero in 1996 to more than twenty in 2005. And in 2009, over thirty people receiving opioid prescriptions through the workers' compensation program died of an opioid overdose.²³⁰

408. Additional research from L&I demonstrates that the use of opioids to treat pain after an injury actually prevents or slows a patient's recovery. In a study of employees who had suffered a low back injury on the job, Dr. Franklin determined that among those who were prescribed opioids soon after the injury, employees who were given high doses of opioids, or for periods of more than a week, were far more likely to experience negative health outcomes than the employees who were given smaller doses or for a shorter term.

409. Specifically, the study showed that, after adjusting for the baseline covariates, injured workers who received a prescription opioid for more than seven days

²²⁸ Gary M. Franklin, M.D., MPH, Jaymie Mai, Pharm.D., Thomas Wickizer, Ph.D., Judith Turner, Ph.D., Mark Sullivan, M.D., Ph.D., Thomas Wickizer, Ph.D., and Deborah Fulton-Kehoe, Ph.D., *Bending the Prescription Opioid Dosing and Mortality Curves: Impact of the Washington State Opioid Dosing Guideline*, 55 Am. J. Ind. Med. 325, 327 (2012).

²²⁹ *Id.* at 327-28.

²³⁰ *Id.* at 328.

during the first six weeks after the injury were 2.2 times more likely to remain disabled a year later than workers with similar injuries who received no opioids at all. Similarly, those who received two prescriptions of opioids for the injury were 1.8 times more likely to remain disabled a year after their injury than workers who received no opioids at all, and those receiving daily doses higher than 150 MED were more than twice as likely to be on disability a year later, compared to workers who received no opioids.²³¹

410. In sum, not only do prescription opioids present significant risks of addiction and overdose, but they also hinder patient recovery after an injury. This dynamic presents problems for employers, too, who bear significant costs when their employees do not recover quickly from workplace injuries. Employers are left without their labor force and may be responsible for paying for the injured employee's disability for long periods of time.

G. The 2016 CDC Guideline and Other Recent Analyses Confirm That the Marketing Defendants' Statements About the Risks and Benefits of Opioids Are Patently False.

411. Contrary to the statements made by the Marketing Defendants in their well-orchestrated campaign to tout the benefits of opioids and downplay their risks, recent studies confirm the Marketing Defendants' statements were false and misleading.

412. The CDC issued its *Guideline for Prescribing Opioids for Chronic Pain* on March 15, 2016.²³² The 2016 CDC Guideline, approved by the FDA, "provides

²³¹ Franklin, GM, Stover, BD, Turner, JA, Fulton-Kehoe, D, Wickizer, TM, *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199, 201-202.

²³² 2016 CDC Guideline, *supra* note 45.

recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.” The Guideline also assesses the risks and harms associated with opioid use.

413. The 2016 CDC Guideline is the result of a thorough and extensive process by the CDC. The CDC issued the Guideline after it “obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee.” The recommendations in the 2016 CDC Guideline were further made “on the basis of a systematic review of the best available evidence . . .”

414. The CDC went through an extensive and detailed process to solicit expert opinions for the Guideline:

CDC sought the input of experts to assist in reviewing the evidence and providing perspective on how CDC used the evidence to develop the draft recommendations. These experts, referred to as the “Core Expert Group” (CEG) included subject matter experts, representatives of primary care professional societies and state agencies, and an expert in guideline development methodology. CDC identified subject matter experts with high scientific standing; appropriate academic and clinical training and relevant clinical experience; and proven scientific excellence in opioid prescribing, substance use disorder treatment, and pain management. CDC identified representatives from leading primary care professional organizations to represent the audience for this guideline. Finally, CDC identified state agency officials and representatives based on their experience with state guidelines for opioid prescribing that were developed with multiple agency stakeholders and informed by scientific literature and existing evidence-based guidelines.

415. The 2016 Guideline was also peer-reviewed pursuant to “the final information quality bulletin for peer review.” Specifically, the Guideline describes the following independent peer-review process:

[P]eer review requirements applied to this guideline because it provides influential scientific information that could have a clear and substantial impact on public- and private-sector decisions. Three experts independently reviewed the guideline to determine the reasonableness and strength of recommendations; the clarity with which scientific uncertainties were clearly identified; and the rationale, importance, clarity, and ease of implementation of the recommendations. CDC selected peer reviewers based on expertise, diversity of scientific viewpoints, and independence from the guideline development process. CDC assessed and managed potential conflicts of interest using a process similar to the one as described for solicitation of expert opinion. No financial interests were identified in the disclosure and review process, and nonfinancial activities were determined to be of minimal risk; thus, no significant conflict of interest concerns were identified.

416. The findings in the 2016 CDC Guideline both confirmed the existing body of scientific evidence regarding the questionable efficacy of opioid use and contradicted Defendants’ statements about opioids.

417. For instance, the Guideline states “[e]xtensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)” and that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder.” The Guideline further confirms there are significant symptoms related to opioid withdrawal, including drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction. These findings contradict statements made by Defendants regarding the

minimal risks associated with opioid use, including that the risk of addiction from chronic opioid use is low.

418. The Guideline also concludes that there is “[n]o evidence” to show “a long-term benefit of opioids in pain and function versus no opioids for chronic pain . . .” Furthermore, the Guideline indicates that “continuing opioid therapy for 3 months substantially increases the risk of opioid use disorder.” Indeed, the Guideline indicates that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.” These findings flatly contradict claims made by the Defendants that there are minimal or no adverse effects of long-term opioid use, or that long-term opioid use could actually improve or restore a patient’s function.

419. In support of these statements about the lack of long-term benefits of opioid use, the CDC concluded that “[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.” The CDC further found that “evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

420. With respect to opioid dosing, the Guideline reports that “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.” The CDC specifically explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC also states that there is an “increased risk[] for opioid use disorder, respiratory depression, and death at higher dosages.” As a result, the CDC advises doctors to “avoid increasing dosage” above 90 MME per day. These findings contradict statements made by Defendants that increasing dosage is safe and that under-treatment is the cause for certain patients’ aberrant behavior.

421. The 2016 CDC Guideline also contradicts statements made by Defendants that there are reliable risk-mitigation tactics to reduce the risk of addiction. For instance, the Guideline indicates that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”

422. Finally, the 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies—even when they work—“do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes.” In particular, the CDC found as follows:

The “abuse-deterrent” label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

Accordingly, the CDC’s findings regarding “abuse-deterrent technologies” directly contradict Purdue and Endo’s claims that their new pills deter or prevent abuse.

423. Notably, in addition to the findings made by the CDC in 2016, the Washington State Agency Medical Directors’ Group (AMDG)—a collaboration among several Washington State Agencies—published its *Interagency Guideline on Prescribing Opioids for Pain* in 2015. The AMDG came to many of the same conclusions as the CDC did. For example, the AMDG found that “there is little evidence to support long term efficacy of [chronic opioid analgesic therapy, or “COAT”] in improving function and pain, [but] there is ample evidence of its risk for harm . . .”²³³

424. In addition, as discussed above, in contrast to Defendants’ statements that the 1980 Porter and Jick letter provided evidence of the low risk of opioid addiction in pain patients, the NEJM recently published a letter largely debunking the use of the Porter and Jick letter as evidence for such a claim.²³⁴ The researchers demonstrated how the Porter and Jick letter was irresponsibly cited and, in some cases, “grossly misrepresented,” when in fact it did not provide evidence supporting the broad claim of

²³³ *Interagency Guideline on Prescribing Opioids for Pain*, Agency Med. Directors’ Group (June 2015), <http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf>.

²³⁴ Leung, et al., *supra* note 154.

low addiction risk for all patients prescribed opioids for pain. As noted above, Dr. Jick reviewed only files of patients administered opioids in a hospital setting, rather than patients sent home with a prescription for opioids to treat chronic pain.

425. The authors of the 2017 letter described their methodology as follows:

We performed a bibliometric analysis of this [1980] correspondence from its publication until March 30, 2017. For each citation, two reviewers independently evaluated the portrayal of the article's conclusions, using an adaptation of an established taxonomy of citation behavior along with other aspects of generalizability . . . For context, we also ascertained the number of citations of other stand-alone letters that were published in nine contemporaneous issues of the *Journal* (in the index issue and in the four issues that preceded and followed it).

We identified 608 citations of the index publication and noted a sizable increase after the introduction of OxyContin (a long-acting formulation of oxycodone) in 1995 . . . **Of the articles that included a reference to the 1980 letter, the authors of 439 (72.2%) cited it as evidence that addiction was rare in patients treated with opioids. Of the 608 articles, the authors of 491 articles (80.8%) did not note that the patients who were described in the letter were hospitalized at the time they received the prescription, whereas some authors grossly misrepresented the conclusions of the letter . . .** Of note, affirmational citations have become much less common in recent years. In contrast to the 1980 correspondence, 11 stand-alone letters that were published contemporaneously by the *Journal* were cited a median of 11 times.²³⁵ (Emphasis added).

426. The researchers provided examples of quotes from articles citing the 1980 letter and noted several shortcomings and inaccuracies with the quotations. For instance, the researchers concluded that these quotations (i) “overstate[] conclusions of the index

²³⁵ *Id.* (emphasis added).

publication,” (ii) do[] not accurately specify its study population,” and (iii) did not adequately address “[l]imitizations to generalizability.”²³⁶

Quote	Reference	Comment
"This pain population with no abuse history is literally at no risk for addiction."	Kowal N. What is the issue?: pseudoaddiction or undertreatment of pain. <i>Nurs Econ</i> 1998;17(6):348-9	
"In truth, however, the medical evidence overwhelmingly indicates that properly administered opioid therapy rarely if ever results in "accidental addiction" or "opioid abuse"."	Libby RT. Treating Doctors as Drug Dealers: The Drug Enforcement Administration's War on Prescription Painkillers. <i>The Independent Review</i> 2006;10(4):511-545.	
"Fear of addiction may lead to reluctance by the physician to prescribe. [...] However, there is no evidence that this occurs when prescribing opioids for pain."	Iles S, Catterall JR, Hanks G. Use of opioid analgesics in a patient with chronic abdominal pain. <i>Int J Clin Pract</i> 2002;56(3):227-8.	
"In reality, medical opioid addiction is very rare. In Porter and Jick's study on patients treated with narcotics, only four of the 11,882 cases showed psychological dependency."	Liu W, Xie S, Yue L, et al. Investigation and analysis of oncologists' knowledge of morphine usage in cancer pain treatment. <i>Oncotargets Ther</i> 2014;7:729-37.	Overstates conclusions of the index publication does not accurately specify its study population. Limitations to generalizability are not otherwise explicitly mentioned.
"Physicians are frequently concerned about the potential for addiction when prescribing opiates; however, there have been studies suggesting that addiction rarely evolves in the setting of painful conditions."	Curtis LA, Morrell TD, Todd KH. Pain Management in the Emergency Department 2006;8(7).	
"Although medicine generally regards anecdotal information with disdain (rigorously controlled double-blind clinical trials are the "gold standard"), solid data on the low risk of addiction to opioid analgesics and the manageability of adverse side effects have been ignored or discounted in favor of the anecdotal, the scientifically unsupported, and the clearly fallacious."	Rich BA. Prioritizing pain management in patient care. Has the time come for a new approach. <i>Postgrad Med</i> 2001;110(3):15-7.	
"The Boston Drug Surveillance Program reviewed the charts of nearly 12,000 cancer pain patients treated over a decade and found only four of them could be labeled as addicts."	Levy MH. Pharmacologic management of cancer pain. <i>Semin Oncol</i> 1994;21(5):718-39.	Incorrectly identifies the index study population as cancer patients; does not otherwise address limitations to generalizability.

²³⁶ Supplementary Appendix to Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 *New Eng. J. Med.* 2194-95 (June 1, 2017), <https://www.nejm.org/doi/full/10.1056/NEJMc1700150>.

427. Based on this review, the researchers concluded as follows:

[W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy. In 2007, the manufacturer of OxyContin and three senior executives pleaded guilty to federal criminal charges that they misled regulators, doctors, and patients about the risk of addiction associated with the drug. Our findings highlight the potential consequences of inaccurate citation and underscore the need for diligence when citing previously published studies.²³⁷

428. These researchers' careful analysis demonstrates the falsity of Defendants' claim that this 1980 letter was evidence of a low risk of addiction in opioid-treated patients. By casting this letter as evidence of low risk of addiction, Defendants played fast and loose with the truth, with blatant disregard for the consequences of their misrepresentations.

H. The Opioid Crisis Has Been Especially Devastating to Native American Communities

429. While the opioid epidemic has not spared any community in the United States, Native American communities have been particularly devastated by the crisis. As the National Congress of American Indians explained in a resolution calling for increased resources to combat opioid abuse and addiction in Indian Country, "drug trafficking, prescription drug abuse and the resulting heroin and opioid epidemics have plagued

²³⁷ Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N. Engl. J. Med. 2194-95 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article>.

Native American communities throughout Indian Country, causing countless deaths of many young people from overdoses and suicide[.]”²³⁸ This epidemic “poses a direct threat to Native citizens and the future of Indian Country[.]”²³⁹

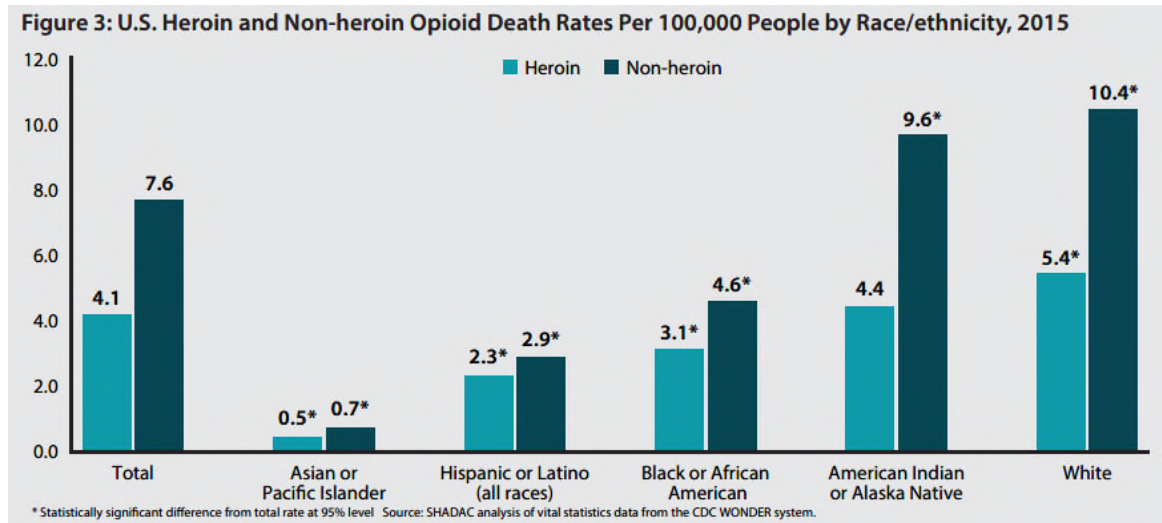
430. Despite the perception that white Americans have been hardest hit by the opioid epidemic, opioid overdoses have consistently claimed Native American lives at rates higher than or equal to those of whites. As stated above, an analysis of data from 1999 to 2009 showed that the incidence of prescription opioid overdoses for Native Americans was slightly higher than the incidence rate for whites, and the same was true in 2014.

431. In 2015, both Native Americans and whites experienced opioid overdoses at much higher rates than other groups, as shown in the below graph, which compares heroin and non-heroin opioid death rates across ethnic groups.²⁴⁰

²³⁸ *In Support of Increasing Resources in Native American Communities to Combat Heroin and Opioid Abuse and Addiction in Indian Country*, Nat’l. Congress of Am. Indians, Resolution # PHX-16-027 (2016), <http://www.ncai.org/resources/resolutions/in-support-of-increasing-resources-in-native-american-communities-to-combat-heroin-and-opioid-abuse-and-addiction-in-indian-country>.

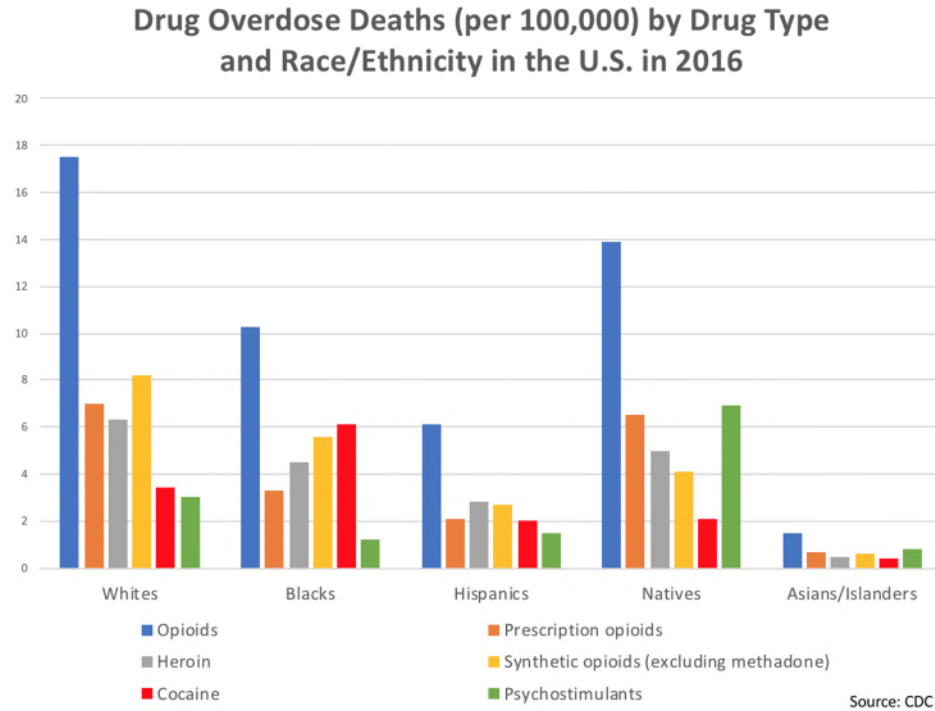
²³⁹ *Id.*

²⁴⁰ *The Opioid Epidemic: National Trends in Opioid-Related Overdose Deaths from 2000 to 2015*, State Health Access Data Assistance Ctr. (June 2017), <http://www.shadac.org/sites/default/files/publications/US%20opioid%20brief%202017%20web.pdf>.



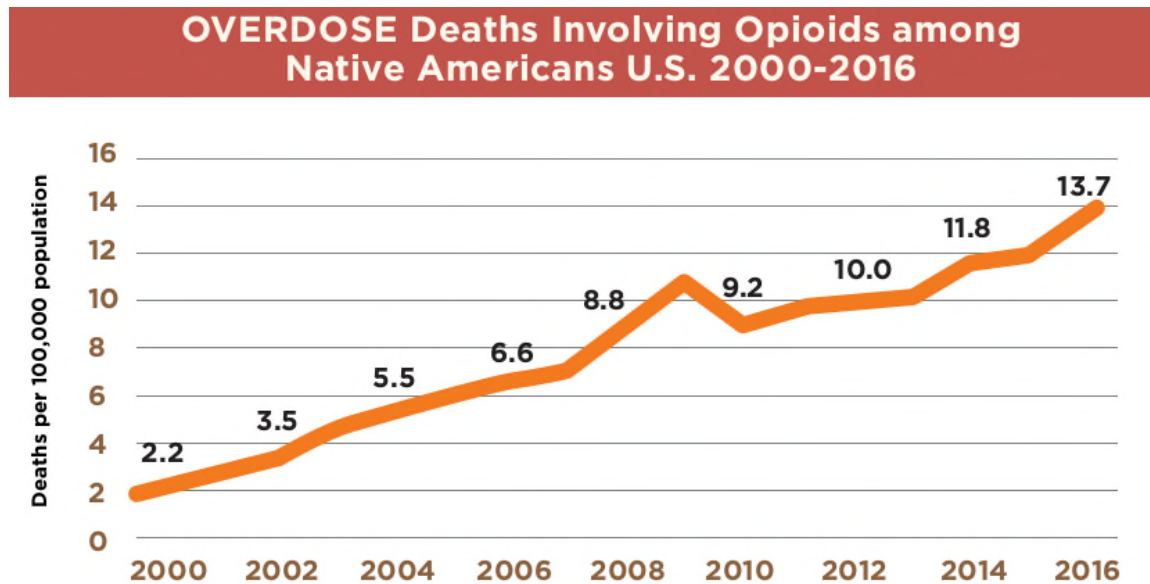
432. In 2016, whites and Native Americans died as a result of prescription opioid overdoses at roughly the same rate, while whites had higher rates of overdose from synthetic opioids such as fentanyl.²⁴¹

²⁴¹ Alex Berezwow, *White Overdose Deaths 50% Higher Than Blacks, 167% Higher Than Hispanics*, Am. Council on Sci. and Health (Apr. 5, 2018), <https://www.acsh.org/news/2018/04/05/white-overdose-deaths-50-higher-blacks-167-higher-hispanics-12804>.

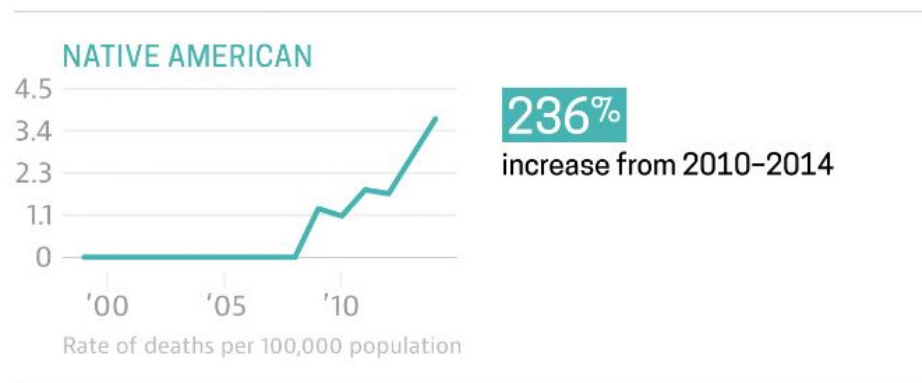


433. Since the Marketing Defendants began aggressively promoting the widespread use of prescription opioids in the late 1990s, the rate of opioid overdoses among Native Americans has grown every year.²⁴²

²⁴² *The Opioid Crisis Impact on Native American Communities*, Albuquerque Area Sw. Tribal Epidemiology Ctr., <https://tribalepicenters.org/wp-content/uploads/2018/03/AASTE-ocpioids-fact-sheet.pdf> (last visited May 16, 2018).



434. As the graph below illustrates, heroin only began to factor into this overdose rate in recent years. From 2010 to 2014, the death rate from heroin overdoses among Native Americans increased by 236%.²⁴³



435. As high as these reported overdose rates are, it is likely that they represent underreporting. The CDC has acknowledged that because of the misclassification of race

²⁴³ Dan Nolan and Chris Amico, *How Bad is the Opioid Epidemic?*, Frontline (Feb. 23, 2016), <https://www.pbs.org/wgbh/frontline/article/how-bad-is-the-opioid-epidemic/> (headings revised for clarity).

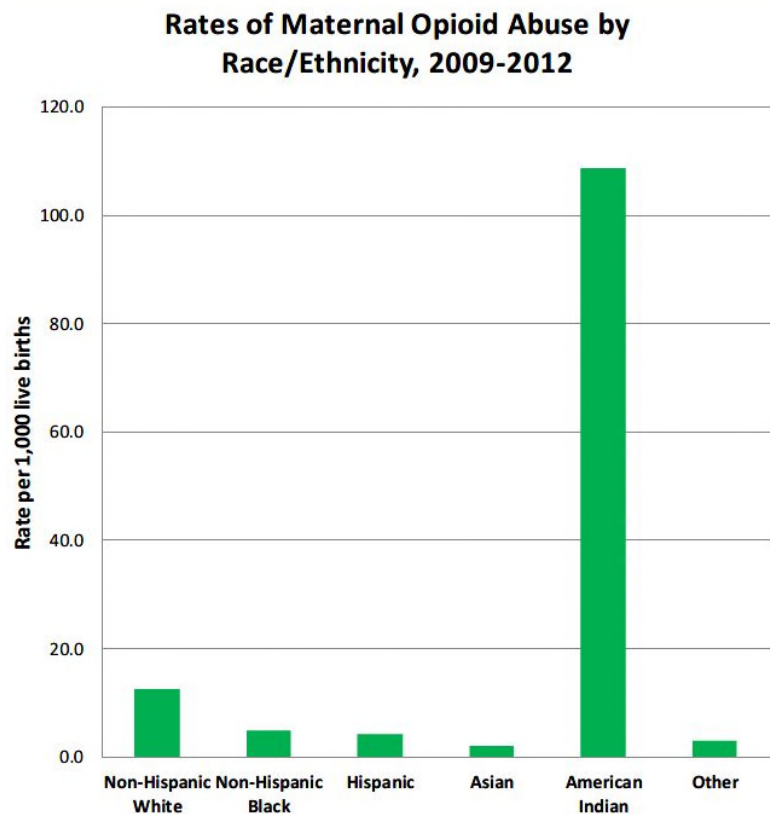
listed on death certificates, the actual numbers for deaths of Native Americans might be underestimated by up to 35%.²⁴⁴

The opioid epidemic has multi-generational impacts on tribal communities. The rate of Native American infants born dependent on opioids has climbed steeply in recent years. As discussed above, when a woman uses opioids while pregnant, her child may suffer from Neonatal Abstinence Syndrome (“NAS”)—opioid withdrawal upon birth. Infants suffering from NAS require extensive care, which in some instances includes carefully tapered doses of the opioid morphine to counteract the symptoms of withdrawal.²⁴⁵ Particularly among Native Americans, the use of opioids during pregnancy has skyrocketed. Between 2009 and 2012, more than one in ten Native American women were diagnosed with opioid dependency or abuse during pregnancy—8.7 times the rate among non-Hispanic white women.²⁴⁶

²⁴⁴ *Morbidity and Mortality Weekly Report — Illicit Drug Use, Illicit Drug Use Disorders, and Drug Overdose Deaths in Metropolitan and Nonmetropolitan Areas — United States*, Ctrs. for Disease Control and Prevention (Oct. 20, 2017), <https://www.cdc.gov/mmwr/volumes/66/ss/pdfs/ss6619.pdf>.

²⁴⁵ See *Neonatal Abstinence Syndrome: Indian Health Service (IHS) Best Practices Guidelines*, Indian Health Serv., https://www.ihs.gov/odm/includes/themes/responsive2017/display_objects/documents/NAS-Guidelines-Recommendation.pdf.

²⁴⁶ Jennifer DuPuis, *The Opioid Crisis in Indian Country – Part One*, Nat’l. Indian Health Board, <https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last visited Mar. 12, 2020).



436. In addition, as discussed above, tribes bear the responsibility and expense of caring for children whose parents are addicted to opioids. The number of Native American children who must be separated from their parents has increased dramatically due to the opioid epidemic, outstripping the number of tribal members who are able to take in children in need of placement. As a result, tribal children frequently must be separated not only from their families, but from their tribes and culture.²⁴⁷

²⁴⁷ Paige Winfield Cunningham, *The Health 202: Opioid company blames government for Native American crisis*, Wash. Post (Apr. 2, 2018), https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2018/04/02/the-health-202-opioid-company-blames-government-for-native-american-crisis/5abd0fae30fb042a378a2f42/?utm_term=.cfadc1346cbc; Justin Wingerter, *Creeks, fearful of 'losing children from the tribe forever,' sue opioid makers and distributors*, Oklahoman (Apr. 4, 2018, 12:44pm),

437. Native American adolescents have also been disproportionately affected by the epidemic. A survey from the National Institute on Drug Abuse found that from 2009 to 2012, Native American students' annual use of heroin and OxyContin was two to three times higher than the national average.²⁴⁸ According to CDC data from 2012, the reported rate of non-medical use of prescription opioids among Native American adolescents was twice as high as that of white adolescents and three times as high as African American adolescents.²⁴⁹

438. Tribes also must shoulder the costs of treating tribal members who are addicted to opioids, as well as addressing the ripple effects of addiction on those tribal members' families and communities. This includes, for some tribes, providing medication-assisted treatment ("MAT"), counseling, and culturally appropriate services.

439. Fighting opioid addiction and abuse on a community level, however, is extremely expensive. Moreover, because they are sovereign nations, tribes are not systematically included in statewide public-health initiatives such as prevention and interventions funded through opioid crisis grants, leaving tribal governments to bear the economic burdens of responding to the crisis to an even greater degree than non-tribal

<http://newsok.com/article/5589586/creeks-fearful-of-losing-children-from-the-tribe-forever-sue-opioid-makers-and-distributors>.

²⁴⁸ *Native Americans hit hard by opioid epidemic*, CBS News (Sept. 21, 2016, 12:48pm), <https://www.cbsnews.com/news/native-americans-hit-hard-by-opioid-epidemic/>.

²⁴⁹ *IHS Grapples with Pervasive Prescription Opioid Misuse in Tribal Areas*, U.S. Med. (Jan. 10, 2012), <http://www.usmedicine.com/clinical-topics/addiction/ihs-grapples-with-pervasive-prescription-opioid-misuse-in-tribal-areas/>.

jurisdictions.²⁵⁰ As the Affiliated Tribes of Northwest Indians declared in January 2018, the opioid epidemic is “one of the most dangerous epidemics Indian Country has ever seen,” and combatting it means that “tribes have allocated more precious government resources than ever to various areas of tribal government from law enforcement, to tribal court and justice services, to medical treatment, to rehabilitation, to social services, to prevention and education[.]”²⁵¹

440. The opioid epidemic has affected virtually every other function of tribal government as well. Tribal departments that maintain tribal lands now must contend with increasing amounts of used hypodermic needles—hazardous refuse of the opioid crisis. Law enforcement agencies of some tribes now carry naloxone in light of the number of opioid overdoses that they encounter. Tribal courts are often overwhelmed with criminal cases of unlawful possession of opioids or other opioid-related crimes, such as theft committed to purchase opioids. And among all tribal departments, there is a significant loss of worker productivity due to opioid dependence or abuse.

²⁵⁰ *Addressing the Opioid Epidemic in American Indian and Alaska Native Communities*, Nat’l. Indian Health Board, <https://www.nihb.org/docs/09182017/Opioids%20One%20pager.PDF> (last visited May 16, 2018).

²⁵¹ *Support for Tribal Nations Taking on Big Pharma to Combat the Opioid Epidemic in Indian Country*, Affiliated Tribes of Northwest Indians, Res. #18-01 (2018), <http://www.ncai.org/resources/resolutions/support-for-tribal-nations-taking-on-pharmaceutical-companies-to-combat-the-opioid-epidemic-in-indian-country>.

I. The Hopi Tribe Has Been Directly Affected by the Opioid Epidemic Caused by Defendants.

441. Plaintiff Hopi Tribe, whose Reservation is located in Navajo and Coconino Counties in northeastern part of the State of Arizona, has approximately 14,617 registered tribal members. Approximately 9,227 people live on the Reservation.

442. Like other sovereign Indian nations, the Tribe has felt the profound consequences of the opioid epidemic. As a direct result of Defendants' aggressive marketing scheme and efforts to increase the excessive distribution of prescription opioids, the Tribe has suffered significant and ongoing harms—harms that will continue well into the future. Each day that Defendants continue to evade responsibility for the epidemic they caused, the Tribe must continue allocating resources to address it.

443. Opioid use has reached crisis levels across the country and throughout the State of Arizona, and the Hopi Reservation is not immune to these broader trends. Arizona has the twelfth highest drug overdose mortality rate in the United States.²⁵² Four in ten adults in Arizona know someone who has been addicted to opioids.²⁵³ One in seven know someone who fatally overdosed.²⁵⁴ Between June 15, 2017, and January 31, 2019,

²⁵² *Prescription Drug Overdose Prevention*, Navajo Cty. Ariz., <http://www.navajocountyaz.gov/Departments/Public-Health-Services/Programs-and-Services/Prescription-Drug-Overdose-Prevention> (last visited Mar. 7, 2019).

²⁵³ Lily Altavena, *Poll examines opioids in Arizona*, Mohave Valley Daily News (Apr. 16, 2017), http://www.mohavedailynews.com/news/poll-examines-opioids-in-arizona/article_16c6c628-2279-11e7-9975-7fe51b52700f.html.

²⁵⁴ *Id.*

there were 17,186 suspected opioid overdoses across Arizona, with 2,348 fatalities.²⁵⁵ Of these fatal overdoses, 280 occurred in Navajo County, one of the two counties where the Hopi Reservation is located.²⁵⁶

444. In Coconino County, the other county where the Hopi Reservation is located, there was an 285% overall increase in the number of emergency room visits and hospitalizations related to opioid use between 2010 and 2016.²⁵⁷ The percent increase in the rate of visits related to opioids was most dramatic among the Native American and Alaska Native population from 2011 to 2015. The increase in opioid-related visits for white non-Hispanic men was 147%, compared with a 653% increase among Native American/Alaska Native men.²⁵⁸ One in four hospital visits primarily caused by drugs were related to opioids.²⁵⁹ Kelly Donohue, the Chief Clinical Officer at The Guidance Center in Northern Arizona, said that the increase in the number of clients coming in seeking treatment for opioid-use disorder in Coconino County has been “dramatic.”²⁶⁰

²⁵⁵ *Opioid Epidemic*, Ariz. Dept. of Health Serv., <https://www.azdhs.gov/prevention/womens-childrens-health/injury-prevention/opioid-prevention/index.php> (last visited Mar. 7, 2019).

²⁵⁶ *Id.*

²⁵⁷ *Opioid Poisoning and Abuse among Coconino County Residents* at 6, Coconino Cty. Pub. Health Serv. Dist. (June 2017), <https://www.coconino.az.gov/DocumentCenter/View/17695/Opioid-Report-6-9-17->.

²⁵⁸ *Id.* at 8.

²⁵⁹ Kimberly Nelson, Tom Carr, Mary Peoples, *Fighting the Opioid Epidemic*, ICMA Conference (Sept. 2018), https://icma.org/sites/default/files/Opioid%20Session_Master.pdf.

²⁶⁰ Emery Cowan, *Opioid epidemic brings unique challenges, even in Coconino County*, Ariz. Daily Sun (Jun. 3, 2018), https://azdailysun.com/news/local/opioid-epidemic-brings-unique-challenges-even-in-coconino-county/article_2fbd37de-80f3-563d-afae-1e5779daefe7.htm.

445. No segment of the population of these counties, including the Hopi people living on the Reservation, is immune to the opioid epidemic. Youth populations are also significantly affected. In Navajo County, 5.6% of the youth population reports prescription drug misuse.²⁶¹ Not only does this represent a tragedy for families and the community, it puts real and direct strains on the government and related service providers. For example, the average emergency department poisoning visit costs \$4,769.²⁶²

446. Agencies across these two counties and the Reservation are spending time and resources to raise awareness about opioid-use disorder and avoid fatal opioid overdoses. For example, Hopi Law Enforcement Services trains its officers to administer naloxone to reverse opioid overdoses. While IHS currently provides naloxone to Hopi Law Enforcement Services, that emergency treatment previously was provided by the Tribe.

447. Although not all Distributor Defendants supply prescription opioids directly to the Tribe, they all contributed to the opioid crisis by distributing opioids to areas surrounding the Reservation. Similarly, the Retail Pharmacy Defendants dispensed opioids in areas surrounding the Reservation. Once opioids are diverted into the illicit market, they do not stay put. Drug traffickers use couriers or other methods to move prescription opioids across state, national, and tribal borders alike. In one example, the

²⁶¹ *Prescription Drug Overdose Prevention*, Navajo Cty. Ariz., <http://www.navajocountyaz.gov/Departments/Public-Health-Services/Programs-and-Services/Prescription-Drug-Overdose-Prevention> (last visited Mar. 7, 2019).

²⁶² *Id.*

Drug Enforcement Administration charged a trafficking ring with transporting oxycodone, hydromorphone, hydrocodone, and methadone, as well as heroin and methamphetamine, from major cities in Minnesota, Wisconsin, Illinois, and Michigan to the Red Lake and White Earth Indian Reservations in Minnesota and to Native American communities in North Dakota.²⁶³ As this example illustrates, prescription opioids diverted into illicit markets travel across tribal borders. By continuing to distribute or dispense excessive quantities of prescription opioids even where diversion was known or suspected, each Distributor Defendant and Retail Pharmacy Defendant contributed to the opioid epidemic.

448. In addition, in Arizona in particular, illicit drug smuggling has increased in relation to the demand for opioids created by Defendants. The Tohono O’odham Nation Reservation has become one of the busiest drug-smuggling corridors in North America.²⁶⁴ In March 2019, the U.S. Department of the Interior’s Joint Task Force to Combat Opioids in Indian Country seized approximately 30,000 fentanyl pills along with other drugs, as part of a Bureau of Indian Affairs Drug Enforcement joint investigation into trafficking of fentanyl from Mexico into the U.S. through the Tohono O’odham Nation.²⁶⁵

²⁶⁴ Dan Harris et al., *On tribal land along US-Mexico border, drug and human smuggling corrupts an ancient culture*, ABC News (May 16, 2019), <https://abcnews.go.com/US/tribal-land-us-mexico-border-drug-human-smuggling/story?id=63064992>.

²⁶⁵ *30,000 Fentanyl pills trafficked by Mexican drug cartel seized by Interior Department Law Enforcement Task Force on Opioids*, U.S. Dep’t. of the Interior (Mar. 15, 2019),

449. Studies have shown higher rates of substance use, and specifically use of OxyContin, among Native American students on reservations.²⁶⁶ Defendants have contributed to these rates, and there is a great need for culturally appropriate opioid-use disorder interventions and treatment for Native American youth.

450. The Hopi Tribe has been working to confront the consequences of Defendants' reckless promotion and distribution of prescription opioids. The costs described in the following sections are illustrative but not exhaustive examples of the significant burden the opioid crisis has imposed on the Tribe.

1. The Tribe's police department has incurred costs related to the epidemic caused by Defendants.

451. The Tribe's police department, Hopi Resource Enforcement Services (HRES) has incurred costs as a result of the opioid epidemic. The Tribe has spent time and resources training officers to use naloxone to reverse opioid overdoses. Tribal police have responded to calls from the high school on the Reservation when teenagers were caught with opioids suspected to have been stolen from family members.

452. HRES resources that are being spent combating the issues associated with the opioid epidemic inevitably means that fewer resources are being put towards the prevention and investigation of other public safety matters.

<https://www.doi.gov/pressreleases/30000-fentanyl-pills-trafficked-mexican-drug-cartel-seized-interior-department-law>.

²⁶⁶ *Higher rate of substance use among Native American youth on reservations*, Nat'l. Inst. On Drug Abuse (May 31, 2018), <https://www.drugabuse.gov/news-events/news-releases/2018/05/higher-rate-substance-use-among-native-american-youth-reservations>.

2. The Tribe has expended resources on social services related to the epidemic caused by Defendants.

453. To protect vulnerable members of the community, including children and elders, the Tribe dedicates considerable resources to social services. The Tribe's social services are underfunded, however, and further strained by the impacts of the opioid crisis on the community. For example, a social services employee has spent time educating the community about the dangers of prescription opioids as a member of a prescription-drug task force. She explained that at the peak of the crisis, people were seen waiting outside of pharmacies on the Reservation, seeking to purchase opioids from patients to whom they had been prescribed. Some tribal members reported that they carried their prescribed opioids with them at all times because opioids previously had been stolen from the members' homes. To address this issue, Indian Health Services (IHS) worked with the Tribe to set up drug lockboxes in homes to reduce theft of prescription drugs. The resources that IHS has put toward opioid abatement in different forms could have been spent on other Tribal needs if not for the crisis created by Defendants.

3. The Tribe's Behavioral Health Services department is expending time and resources to educate the community about the opioid epidemic and better track its effects.

454. Because there is not enough funding for services within the Tribe, staff at the Tribe's Behavioral Health Services department have spent time applying for grants that can be used to provide education and awareness regarding the opioid epidemic. For example, the Tribe recently applied for and received a grant through the Substance Abuse and Mental Health Services Administration (SAMHSA) to develop a surveillance system

to accurately collect data about opioid use and to increase the community's awareness of the opioid crisis.²⁶⁷ Because these efforts are grant-funded, the Tribe will need further funding to support them in the future.

J. No Federal Agency Action, Including by the FDA, Can Provide the Relief the Tribe Seeks Here.

455. The injuries the Tribe has suffered and will continue to suffer cannot be addressed by agency or regulatory action. There are no rules the FDA could make or actions the agency could take that would provide the Tribe the relief it seeks in this litigation.

456. Even if prescription opioids were entirely banned today or only used for the intended purpose, millions of Americans, including tribal members and other Reservation residents, would remain affected by the opioid epidemic.

457. Regulatory action would do nothing to compensate the Tribe for the money and resources it has already expended addressing the impacts of the opioid epidemic and the resources it will need in the future. Only this litigation has the ability to provide the Tribe with the relief it seeks.

458. Furthermore, the costs the Tribe has incurred in responding to the opioid crisis and in rendering public services described above are recoverable pursuant to the causes of actions raised by the Tribe. Defendants' misconduct alleged herein is not a series of isolated incidents, but instead the result of a sophisticated and complex

²⁶⁷ Award TI082585-01: *San Carlos Apache Healthcare Corporation*, Substance Abuse and Mental Health Serv. Admin., <https://www.samhsa.gov/grants/awards/2019/TI-19-012> (last viewed Feb. 26, 2020).

marketing scheme over the course of more than twenty years that has caused a substantial and long-term burden on the municipal services provided by the Tribe. In addition, the public nuisance created by Defendants and the Tribe’s requested relief in seeking abatement further compels Defendants to reimburse and compensate the Tribe for the substantial resources it has expended to address the opioid crisis.

V. CLAIMS FOR RELIEF

COUNT ONE — VIOLATIONS OF THE ARIZONA CONSUMER FRAUD ACT, A.R.S. § 44-1521 *ET SEQ.*

459. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

460. The Arizona Consumer Fraud Act is codified at A.R.S. §44-1521 *et seq.* (CFA). The CFA establishes a comprehensive framework for redressing the violations of applicable law. The conduct at issue in this case falls within the scope of the CFA.

461. The CFA prohibits the “use or employment ... of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise....” Ariz. Rev. Stat. Ann. § 44-1522. Defendants have engaged in and continue to engage in the same pattern of unfair methods of competition, and unfair and/or deceptive conduct pursuant to a common practice of misleading the public regarding the purported benefits and risks of opioids.

462. The Marketing Defendants, at all times relevant to this Complaint, directly and/or through their control of third parties, violated the CFA by making deceptive and misleading representations to physicians and consumers about the safety and effectiveness of chronic and continuous use of opioids. Each of these Defendants also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the purported benefits and risks of opioids.

463. All Defendants, at all times relevant to this Complaint, directly and/or through their control of third parties, violated the CFA by making deceptive and misleading representations about their compliance with their obligations to maintain effective controls against diversion of prescription opioids and to report suspicious orders in connection with the sale of opioids. All Defendants concealed the extent of their opioid sales and distribution in order to avoid the issuance of restrictive quotas and manipulated the political process to shield themselves from enforcement actions that would have stopped shipments of opioids.

464. Defendants' misconduct has caused the Tribe to spend money on law enforcement, social services, and other human services, as described above.

465. But for these unfair methods of competition and unfair and/or deceptive acts or practices in the conduct of trade or commerce, the Tribe would not have incurred the significant costs related to the epidemic caused by Defendants above.

466. Defendants marketed and supplied opioids and are ultimately responsible for the unreasonable and unconscionable amount of pills on and around the Reservation. Marketing Defendants knew or reasonably should have known that their statements

regarding the risks and benefits of opioids were false and misleading, and that their statements were causing harm from their continued production and marketing of opioids. All Defendants knew or reasonably should have known that their deceptive conduct regarding the sufficiency of their controls over opioid distribution was misleading and that the proliferation of prescription opioids was causing damage to the Tribe. Thus, the harms caused by Defendants' unfair and deceptive conduct to the Tribe were reasonably foreseeable, including the financial and economic losses incurred by the Tribe.

COUNT TWO — PUBLIC NUISANCE

467. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this complaint.

468. Under Arizona criminal law, “[i]t is a public nuisance . . . for anything . . . [t]o be injurious to health . . . that interferes with the comfortable enjoyment of life or property by an entire community or neighborhood or by a considerable number of persons.” A.R.S. § 13-2917(A).

469. Arizona tort law is to the same effect. Any conduct which unreasonably and significantly interferes with the public health, safety, peace, comfort, or convenience is a public nuisance.

470. A nuisance per se is any act or omission, which is of itself hurtful to the health, tranquility, or morals, or outrages the decency, of the community. A nuisance per se is not permissible or excusable under any circumstances. When anything is a nuisance per se, all that is necessary to establish the right of the public authorities to demand the proper remedy is to prove the act which, as a matter of law, constitutes the nuisance.

471. As set forth above, the Marketing Defendants' actions and omissions include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid doses indefinitely without added risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these actions and omissions unreasonably and significantly interfered with the public health, safety, peace, comfort and convenience on and around the Reservation.

472. As set forth above, the Manufacturing Defendants filled orders for, and Distributor Defendants distributed, and the Retail Pharmacy Defendants dispensed enormous quantities of potent narcotics that far exceeded quantities that could reasonably be expected to be for legitimate medical use. Despite knowing the risk of diversion, all Defendants failed to adequately monitor, report, and halt orders that were suspicious by nature of their frequency and volume. These acts significantly interfered with the public health, safety, peace, comfort and convenience on and around the Reservation.

473. The Tribe demands all the relief to which it is entitled, including damages in an amount to be determined at trial and an order of this Court abating, enjoining, and preventing the acts and omissions constituting the public nuisance described above.

COUNT THREE — NEGLIGENCE

474. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

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

476. Each Defendant owed a duty of care to Plaintiff, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

477. In violation of this duty, Defendants failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids by misrepresenting the risks and benefits associated with opioids and by distributing dangerous quantities of opioids.

478. As set forth above, Marketing Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid doses indefinitely without added risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these misrepresentations made by Defendants violated the duty of care to the Tribe.

479. The Manufacturing Defendants negligently filled orders for, and the Distributor Defendants negligently distributed enormous quantities of potent narcotics

and failed to report such orders and distributions. Distributor Defendants violated their duty of care by moving these dangerous products into and around the Reservation in such quantities, facilitating diversion, misuse, and abuse of opioids. The Retail Pharmacy Defendants had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. The Retail Pharmacy Defendants also had the duty to look for red flags of diversion on the patient, prescriber, and store levels, and to refuse to fill and to report prescriptions suggestive of potential diversion. By failing to do so, they violated their duty of care as retailers of dangerous narcotics.

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

COUNT FOUR — WANTON NEGLIGENCE

481. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

482. Defendants' conduct constitutes aggravated negligence. Defendants had actual or constructive knowledge of the danger of excessive promotion and supply of powerful opioids and that harm from that danger was not only possible but probable. Defendants consciously failed to act to avoid this danger.

483. Each Defendant knew or had reason to know that opioids were highly addictive, and that grave harm would result from the misuse, abuse, or over-prescription

of opioids, but consciously misrepresented the risks and benefits associated with opioids and facilitated the distribution of dangerous quantities of opioids.

484. As set forth above, Marketing Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid doses indefinitely without added risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these misrepresentations were made with disregard for the inevitable harm of misuse, abuse, or over-prescription of opioids.

485. The Manufacturing Defendants negligently filled orders for, and the Distributor Defendants distributed enormous quantities of potent narcotics and failed to report such orders and distributions with disregard for the inevitable harm of these actions. Despite the probability of grave harm as a result, Distributor Defendants moved these dangerous products into and/or around the Reservation in such quantities, facilitating diversion, misuse, and abuse of opioids. Despite their knowledge of the grave risk of harm from diverted opioids, the Retail Pharmacy Defendants ignored red flags of diversion and emphasized volume and speed of prescription transactions—even though these transactions were for dangerous and highly addictive drugs with a high rate of fatal overdoses.

486. As a proximate cause of Defendants' wanton conduct, Plaintiff has suffered and will continue to suffer harm, and is entitled to damages in an amount determined at trial, including but not limited to compensatory and punitive damages.

COUNT FIVE — UNJUST ENRICHMENT

487. Each Defendant was required to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

488. Rather than prevent or mitigate the wide proliferation of opioids into the Tribe, each Defendant instead chose to place its monetary interests first and each Defendant profited from prescription opioids sold on and/or around the Reservation.

489. Each Defendant also failed to maintain effective controls against the unintended and illegal use of the prescription opioids it manufactured or distributed, again choosing instead to place its monetary interests first.

490. Each Defendant therefore received a benefit from the sale and distribution of prescription opioids on and around the Reservation, and these Defendants have been unjustly enriched at the expense of the Tribe.

491. As a result, the Tribe is entitled to damages on its unjust enrichment claim in an amount to be proven at trial.

COUNT SIX — VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, *ET SEQ.*

492. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this complaint.

493. This claim is brought by Plaintiff against each Defendant for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1961, *et seq.*

494. At all relevant times, each Defendant is and has been a “person” within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, “a legal or beneficial interest in property.”

495. The Tribe has standing to sue as it was and is injured in its business and/or property as a result of the Defendants’ wrongful conduct described herein. 18 U.S.C. §§ 1961(3), 1964.

496. Section 1962(c) makes it “unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity . . . ” 18 U.S.C. § 1962(c).

497. Section 1962(d) makes it unlawful for “any person to conspire to violate” Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

498. Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

A. Description of the Defendants’ Enterprises.

499. RICO defines an enterprise as “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4).

500. Under 18 U.S.C. § 1961(4) a RICO “enterprise” may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise’s purpose. *See Boyle v. United States*, 556 U.S. 938, 946 (2009).

501. Defendants formed two such association-in-fact enterprises—referred to herein as “the Opioid Marketing Enterprise” and “the Opioid Supply Chain Enterprise.”

502. The Opioid Marketing Enterprise consists of Defendants Endo, Janssen, Teva, Actavis, and Mallinckrodt, Front Groups, and KOLs. In particular, the Opioid Marketing Enterprise consists of (a) Defendant Endo, including its employees and agents, (b) Defendant Janssen, including its employees and agents, (c) Defendant Teva, including its employees and agents, (d) Defendant Actavis, including its employees and agents, and (e) Defendant Mallinckrodt, including its employees and agents (collectively, “Marketing Defendants”); certain front groups described above, including but not limited to (a) the American Pain Foundation, including its employees and agents, (b) the American Academy of Pain Medicine, including its employees and agents, and (c) the American Pain Society, including its employees and agents (collectively, the “Front Groups”); and certain Key Opinion Leaders, including but not limited to (a) Dr. Russell Portenoy, (b) Dr. Perry Fine, (c) Dr. Lynn Webster, and (d) Dr. Scott Fishman (collectively, the “KOLs”). The entities in the Opioid Marketing Enterprise acted in concert to create demand for prescription opioids.

503. Alternatively, each of the above-named Marketing Defendants and Front Groups constitutes a single legal entity “enterprise” within the meaning of 18 U.S.C. §

1961(4), through which the members of the enterprise conducted a pattern of racketeering activity. The separate legal status of each member of the Enterprise facilitated the fraudulent scheme and provided a hoped-for shield from liability for Defendants and their co-conspirators.

504. Alternatively, each of the Marketing Defendants, together with the Distributor Defendants, the Front Groups, and the KOLs, constitute separate, associated-in-fact Enterprises within the meaning of 18 U.S.C. § 1961(4).

505. The Opioid Supply Chain Enterprise consists of all Defendants. In particular, the Opioid Supply Chain Enterprise consists of (a) Defendant Endo, including its employees and agents, (b) Defendant Janssen, including its employees and agents, (c) Defendant Teva, including its employees and agents, (d) Defendant Actavis, including its employees and agents, (e) Defendant Mallinckrodt, including its employees and agents, (f) Defendant Mylan, including its employees and agents, (g) Defendant West-Ward, including its employees and agents, (h) Defendant KVK, including its employees and agents, (i) Defendant Sandoz USA, including its employees and agents, (j) Defendant Amneal, including its employees and agents, (k) Defendant AmerisourceBergen, including its employees and agents, (l) Defendant Cardinal Health, including its employees and agents, (m) Defendant McKesson, including its employees and agents, (n) Defendant Walgreens, including its employees and agents, (o) Defendant Walmart, Inc., including its employees and agents, and (p) Defendant CVS, including its employees and agents (collectively, “Defendants”).

506. The CSA and its implementing regulations require all manufacturers and distributors of controlled substances, including opioids, to maintain a system to identify and report suspicious orders, including orders of unusual size or frequency, or orders deviating from a normal pattern, and maintain effective controls against diversion of controlled substances. *See* 21 U.S.C. § 823; 21 C.F.R. §1301.74(b). All Defendants—manufacturers, distributors, and pharmacies alike—are required to become “registrants” under the CSA, 21 U.S.C. § 823(a)-(b), and its implementing regulations, which provide that “[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance. . . shall obtain a registration[.]” 21 C.F.R. § 1301.11(a). Defendants’ duties as registrants include reporting suspicious orders of controlled substances, which are defined as including “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

507. The Manufacturing Defendants carried out the Opioid Supply Chain Enterprise by incentivizing and supplying suspicious sales of opioids, despite their knowledge that their opioids were being diverted to illicit use, and by failing to notify the DEA of such suspicious orders as required by law. The Distributor Defendants and, in their capacity as distributors of opioids to their own retail locations, the Retail Pharmacy Defendants carried out the Opioid Supply Chain Enterprise by failing to maintain effective controls against diversion, intentionally evading their obligation to report suspicious orders to the DEA, and conspiring to prevent limits on the prescription opioids they were oversupplying to communities like Plaintiff’s.

508. The Opioid Marketing Enterprise is an ongoing and continuing business organization consisting of “persons” within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to sell highly addictive opioids for treatment of chronic pain while knowing that opioids have little or no demonstrated efficacy for such pain and have significant risk of addiction, overdose, and death.

509. The Opioid Supply Chain Enterprise is an ongoing and continuing business organization consisting of “persons” within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to distribute highly addictive opioids in quantities that far exceeded amounts that could reasonably be considered medically necessary.

510. To accomplish these purposes, the Opioid Marketing Enterprise engaged in a sophisticated, well-developed, and fraudulent marketing scheme designed to increase the prescription rate for Defendants’ opioid medications (the “Marketing Scheme”), and the Opioid Supply Chain Enterprise carried out a scheme to systematically disregard, avoid, or frustrate the monitoring and reporting requirements intended to prevent the widespread distribution of dangerous controlled substances (the “Diversion Scheme”). The Marketing Scheme and the Diversion Scheme are collectively referred to as the “Schemes.” Together, Defendants engaged in these broad Schemes with the overarching purposes of materially expanding prescription opioid use by altering the medical community’s opioid prescribing practices through repeated fraudulent statements and

misrepresentations and materially expanding prescription opioid supply by avoiding monitoring requirements and actively seeking higher quotas.

B. The Enterprises Sought to Fraudulently Increase Defendants' Profits and Revenues

511. At all relevant times, each Defendant was aware of the conduct of the Enterprises, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales and distribution of prescription opioids. In addition, the Front Groups and KOLs received direct payments from the Marketing Defendants in exchange for their role in the Opioid Marketing Enterprise, and to advance the Opioid Marketing Enterprise's fraudulent marketing scheme.

512. The Enterprises engaged in, and their activities affected, interstate and foreign commerce because they involved commercial activities across state boundaries, including but not limited to: (1) the marketing, promotion, and distribution of prescription opioids; (2) advocacy at the state and federal level for change in the law governing the use and prescription of prescription opioids; (3) the issuance of prescriptions and prescription guidelines for opioids; (4) the issuance of fees, bills, and statements demanding payment for prescriptions of opioids; (5) payments, rebates, and chargebacks between Defendants; and (6) the creation of documents, reports, and communications related to Defendants' reporting requirements under the CSA and its implementing regulations.

513. The persons engaged in the Enterprises are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as

spearheaded by Defendants. With respect to the Opioid Marketing Enterprise, each Marketing Defendant funded and directed the operations of the KOLs and the Front Groups; in fact, the board of directors of each of the Front Groups are and were full of doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. Moreover, each Marketing Defendant coordinated and, at times, co-funded their activities in furtherance of the goals of the Enterprise. This coordination can also be inferred through the consistent misrepresentations described below. With respect to the Opioid Supply Chain Enterprise, Defendants were financially linked through a system of payments, rebates, and chargebacks.

514. In the Opioid Marketing Enterprise, there is regular communication between each Marketing Defendant, each of the Front Groups, and each KOL in which information regarding the Defendants' scheme to increase opioid prescriptions is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Marketing Defendants, the Front Groups, and the KOL share information regarding the operation of the Opioid Marketing Enterprise.

515. In the Opioid Supply Chain Enterprise, there is regular communication between each Defendant in which information regarding the Defendants' scheme to oversupply opioids and avoid restrictive regulations or quotas is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants share information regarding the operation of the Opioid Supply Chain Enterprise.

516. The Enterprises functioned as continuing units for the purposes of executing the Schemes, and when issues arose during the Schemes, each member of the Enterprises agreed to take actions to hide the Schemes and the existence of the Enterprises.

517. Each Defendant participated in the operation and management of the Enterprises by directing its affairs as described herein.

518. While Defendants participate in, and are members of, the Enterprises, they have an existence separate from the Enterprises, including distinct legal statuses, affairs, offices and roles, officers, directors, employees, and individual personhood.

519. Each Marketing Defendant orchestrated the affairs of the Opioid Marketing Enterprise and exerted substantial control over the Opioid Marketing Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME programs, medical journals, advertisements, and websites; (2) employing sales representatives to promote the use of opioid medications; (3) purchasing and utilizing sophisticated marketing data (e.g., IMS data) to coordinate and refine the Marketing Scheme; (4) employing doctors to serve as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (5) funding, controlling, and operating the Front Groups, including the American Pain Foundation and the Pain & Policy Studies Group; (6) sponsoring CME programs that claimed that opioid therapy has been shown to reduce pain and depressive symptoms; (7) supporting and sponsoring guidelines indicating that opioid medications

are effective and can restore patients' quality of life; (8) retaining KOLs to promote the use of opioids; and (9) concealing the true nature of their relationships with the other members of the Marketing Scheme, and the Opioid Marketing Enterprise, including the Front Groups and the KOLs.

520. The Front Groups orchestrated the affairs of the Opioid Marketing Enterprise and exerted substantial control over the Opioid Marketing Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids described herein; (2) holding themselves out as independent advocacy groups, when in fact their operating budgets are entirely comprised of contributions from opioid drug manufacturers; (3) publishing treatment guidelines that advised the prescription of opioids; (4) sponsoring medical education programs that touted the benefits of opioids to treat chronic pain while minimizing and trivializing their risks; and (5) concealing the true nature of their relationship with the other members of the Opioid Marketing Enterprise.

521. The KOLs orchestrated the affairs of the Opioid Marketing Enterprise and exerted substantial control over the Opioid Marketing Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids; (2) holding themselves out as independent, when in fact they are systematically linked to and funded by opioid drug manufacturers; and (3) concealing the true nature of their relationship with the other members of the Opioid Marketing Enterprise.

522. Without the willing participation of each member of the Opioid Marketing Enterprise, the Marketing Scheme and the Opioid Marketing Enterprise's common course of conduct would not have been successful.

523. Each Distributor Defendant and, in their capacity as distributors of opioids to their own retail locations, each Retail Pharmacy Defendant orchestrated the affairs of the Opioid Supply Chain Enterprise and exerted substantial control over the Opioid Supply Chain Enterprise by, at least: (1) refusing or failing to identify, investigate, or report suspicious orders of opioids to the DEA; (2) providing the Manufacturing Defendants with data regarding their prescription opioid sales, including purchase orders and ship notices; (3) accepting payments from the Manufacturing Defendants in the form of rebates and/or chargebacks; (4) filling suspicious orders for prescription opioids despite having identified them as suspicious and knowing opioids were being diverted into the illicit drug market; (5) working with other members of the Enterprise through groups like the Healthcare Distribution Alliance and the Pain Care Forum to ensure the free flow of opioids, including by supporting limits on the DEA's ability to use immediate suspension orders; and (6) concealing the true nature of their relationships with the other members of the Opioid Supply Chain Enterprise.

524. Each Manufacturing Defendant orchestrated the affairs of the Opioid Supply Chain Enterprise and exerted substantial control over the Opioid Supply Chain Enterprise by, at least: (1) refusing or failing to identify, investigate, or report suspicious orders of opioids to the DEA; (2) obtaining from the Distributor Defendants data regarding their prescription opioid sales, including purchase orders and ship notices; (3)

providing payments to the Distributor Defendants in the form of rebates and/or chargebacks; (4) working with other members of the Opioid Supply Chain Enterprise through groups like the Healthcare Distribution Alliance to ensure the free flow of opioids, including by supporting limits on the DEA's ability to use immediate suspension orders; and (5) concealing the true nature of their relationships with the other members of the Opioid Supply Chain Enterprise.

525. Without the willing participation of each member of the Opioid Supply Chain Enterprise, the Diversion Scheme and the Opioid Supply Chain Enterprise's common course of conduct would not have been successful.

C. Predicate Acts: Mail and Wire Fraud

526. To carry out, or attempt to carry out, the Schemes, the members of the Enterprises, each of whom is a person associated-in-fact with the Enterprises, did knowingly conduct or participate in, directly or indirectly, the affairs of the Enterprises through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

527. Specifically, the members of the Enterprises have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

528. The multiple acts of racketeering activity which the members of the Enterprises committed, or aided or abetted in the commission of, were related to each

other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.”

529. The racketeering activity was made possible by the Enterprises’ regular use of the facilities, services, distribution channels, and employees of the Enterprises.

530. The members of the Enterprises participated in the Schemes by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

531. The members of the Enterprises used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their Schemes through common misrepresentations, concealments, and material omissions.

532. In devising and executing the illegal Schemes, the members of the Enterprises devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiff and the public to obtain money by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

533. For the purpose of executing the illegal Schemes, the members of the Enterprises committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal Schemes.

534. The Enterprises’ predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

A. Mail Fraud: The members of the Enterprises violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling and distributing excessive quantities of highly addictive opioids.

B. Wire Fraud: The members of the Enterprises violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling and distributing excessive quantities of highly addictive opioids.

535. The Marketing Defendants falsely and misleadingly used the mails and wires in violation of 18 U.S.C. § 1341 and § 1343. Illustrative and non-exhaustive examples include the following: Purdue's (1) May 31, 1996 press release announcing the release of OxyContin and indicating that the fear of OxyContin's addictive properties was exaggerated; (2) 1990 promotional video in which Dr. Portenoy, a paid Purdue KOL, understated the risk of opioid addiction; (3) 1998 promotional video which misleadingly cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (4) statements made on its 2000 "Partners Against Pain" website which claimed that the addiction risk of OxyContin was very low; (5) literature distributed to physicians which misleadingly cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (6) August 2001 statements to Congress by Purdue Executive Vice President and Chief Operating Officer Michael Friedman regarding the value of OxyContin in treating chronic pain; (7) patient brochure entitled "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain" indicating that OxyContin is non-addicting; (8) 2001 statement by Senior Medical Director for Purdue, Dr. David Haddox, indicating that the 'legitimate' use of OxyContin would not result in addiction; (9) multiple sales representatives' communications regarding the low risk of addiction associated with opioids; (10) statements included in promotional materials for opioids distributed to doctors via the mail and wires; (11) statements in a 2003 Patient Information Guide

distributed by Purdue indicating that addiction to opioid analgesics in properly managed patients with pain has been reported to be rare; (12) telephonic and electronic communications to doctors and patients indicating that signs of addiction in the case of opioid use are likely only the signs of under-treated pain; (13) statements in Purdue's Risk Evaluation and Mitigation Strategy for OxyContin indicating that drug-seeking behavior on the part of opioid patients may, in fact, be pain-relief seeking behavior; (14) statements made on Purdue's website and in a 2010 "Dear Healthcare Professional" letter indicating that opioid dependence can be addressed by dosing methods such as tapering; (15) statements included in a 1996 sales strategy memo indicating that there is no ceiling dose for opioids for chronic pain; (16) statements on its website that abuse-resistant products can prevent opioid addiction; (17) statements made in a 2012 series of advertisements for OxyContin indicating that long-term opioid use improves patients' function and quality of life; (18) statements made in advertising and a 2007 book indicating that pain relief from opioids improve patients' function and quality of life; (19) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function; and (20) electronic and telephonic communications concealing its relationship with the other members of the Enterprises.

536. Defendant Endo Pharmaceuticals, Inc. also made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made, beginning in at least 2009, on an Endo-sponsored website, PainKnowledge.com, indicating that patients who take opioids as prescribed usually do not become addicted; (2) statements made on another Endo-sponsored website, PainAction.com, indicating that

most chronic pain patients do not become addicted to opioid medications; (3) statements in pamphlets and publications described by Endo indicating that most people who take opioids for pain relief do not develop an addiction; (4) statements made on the Endo-run website, Opana.com, indicating that opioid use does not result in addiction; (5) statements made on the Endo-run website, Opana.com, indicating that opioid dependence can be addressed by dosing methods such as tapering; (6) statements made on its website, PainKnowledge.com, that opioid dosages could be increased indefinitely; (7) statements made in a publication entitled “Understanding Your Pain: Taking Oral Opioid Analgesics” suggesting that opioid doses can be increased indefinitely; (8) electronic and telephonic communications to its sales representatives indicating that the formula for its medicines is ‘crush resistant;’ (9) statements made in advertisements and a 2007 book indicating that pain relief from opioids improves patients’ function and quality of life; (10) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients’ function; and (11) telephonic and electronic communications concealing its relationship with the other members of the Enterprises.

537. Defendant Janssen made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements on its website, PrescribeResponsibly.com, indicating that concerns about opioid addiction are overestimated; (2) statements in a 2009 patient education guide claiming that opioids are rarely addictive when used properly; (3) statements included on a 2009 Janssen-sponsored website promoting the concept of opioid pseudoaddiction; (4) statements on its website, PrescribeResponsibly.com, advocating the concept of opioid pseudoaddiction;

(5) statements on its website, PrescribeResponsibly.com, indicating that opioid addiction can be managed; (6) statements in its 2009 patient education guide indicating the risks associated with limiting the dosages of pain medicines; (7) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function; and (8) telephonic and electronic communications concealing its relationship with the other members of the Enterprises.

538. The American Academy of Pain Medicine made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made in a 2009 patient education video entitled "Finding Relief: Pain Management for Older Adults" indicating the opioids are rarely addictive; and (2) telephonic and electronic communications concealing its relationship with the other members of the Opioid Marketing Enterprise.

539. The American Pain Society Quality of Care Committee made a number of false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) a May 31, 1996 press release in which the organization claimed there is very little risk of addiction from the proper use of drugs for pain relief; and (2) telephonic and electronic communications concealing its relationship with the other members of the Opioid Marketing Enterprise.

540. The American Pain Foundation ("APF") made a number of false and misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made by an APF Executive Director to Congress indicating that opioids only rarely lead to addiction; (2) statements made in a 2002 amicus curiae brief filed with

an Ohio appeals court claiming that the risk of abuse does not justify restricting opioid prescriptions for the treatment of chronic pain; (3) statements made in a 2007 publication entitled “Treatment Options: A Guide for People Living with Pain” indicating that the risks of addiction associated with opioid prescriptions have been overstated; (4) statements made in a 2002 court filing indicating that opioid users are not “actual addicts;” (5) statements made in a 2007 publication entitled “Treatment Options: A Guide for People Living with Pain” indicating that even physical dependence on opioids does not constitute addiction; (6) claims on its website that there is no ceiling dose for opioids for chronic pain; (7) statements included in a 2011 guide indicating that opioids can improve daily function; and (8) telephonic and electronic communications concealing its relationship with the other members of the Opioid Marketing Enterprise.

541. The KOLs, including Drs. Russell Portenoy, Perry Fine, Scott Fishman, and Lynn Webster, made a number of misleading statements in the mail and wires in violation of 18 U.S.C. § 1341 and § 1343, described above, including statements made by Dr. Portenoy in a promotional video indicating that the likelihood of addiction to opioid medications is extremely low. Indeed, Dr. Portenoy has since admitted that his statements about the safety and efficacy of opioids were false.

542. The Manufacturing Defendants, Distributor Defendants, and Retail Pharmacy Defendants falsely and misleadingly used the mails and wires in violation of 18 U.S.C. § 1341 and § 1343. Illustrative and non-exhaustive examples include the following: (1) the transmission of documents and communications regarding the sale, shipment, and delivery of excessive quantities of prescription opioids, including invoices

and shipping records; (2) the transmission of documents and communications regarding their requests for higher aggregate production quotas, individual manufacturing quotas, and procurement quotas; (3) the transmission of reports to the DEA that did not disclose suspicious orders as required by law; (4) the transmission of documents and communications regarding payments, rebates, and chargebacks; (5) the transmission of the actual payments, rebates, and chargebacks themselves; (6) correspondence between Defendants and their representatives in front groups and trade organizations regarding efforts to curtail restrictions on opioids and hobble DEA enforcement actions; (7) the submission of false and misleading certifications required annually under various agreements between Defendants and federal regulators; and (8) the shipment of vast quantities of highly addictive opioids. Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

543. In addition, the Distributor Defendants and Retail Pharmacy Defendants misrepresented their compliance with laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion into the illicit market. At the same time, the Distributor Defendants and Retail Pharmacy Defendants misrepresented the effectiveness of their monitoring programs, their ability to detect suspicious orders, their commitment to preventing diversion of prescription opioids, and their compliance with regulations regarding the identification and reporting of suspicious orders of prescription opioids.

544. The mail and wire transmissions described herein were made in furtherance of Defendants' Schemes and common course of conduct designed to sell drugs that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them; increase the prescription rate for opioid medications; and popularize the misunderstanding that the risk of addiction to prescription opioids is low when used to treat chronic pain, and to deceive regulators and the public regarding Defendants' compliance with their obligations to identify and report suspicious orders of prescription opioids, while Defendants intentionally enabled millions of prescription opioids to be deposited into communities across the United States, including on and around the Reservation. Defendants' scheme and common course of conduct was intended to increase or maintain high quotas for the manufacture and distribution of prescription opioids and their corresponding high profits for all Defendants.

545. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of predicate acts of mail and/or wire fraud, including certain specific fraudulent statements and specific dates upon which, through the mail and wires, Defendants engaged in fraudulent activity in furtherance of the Schemes.

546. The members of the Enterprises have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the members of the Enterprises conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms, and corporations,

including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with Defendants and the members of the Enterprises in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenue, increase market share, and/or minimize losses for the Defendants and their named and unnamed co-conspirators throughout the illegal scheme and common course of conduct.

547. The members of the Enterprises aided and abetted others in the violations of the above laws.

548. To achieve their common goals, the members of the Enterprises hid from Plaintiff and the public: (1) the fraudulent nature of the Marketing Defendants' marketing scheme; (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of and risk of addiction associated with prescription opioids; (3) the fraudulent nature of the Distributor Defendants' and Retail Pharmacy Defendants' representations regarding their compliance with requirements to maintain effective controls against diversion and report suspicious orders of opioids; and (4) the true nature of the relationship between the members of the Enterprises.

549. Defendants and each member of the Enterprises, with knowledge and intent, agreed to the overall objectives of the Schemes and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprises and their co-conspirators had to agree to conceal their fraudulent scheme.

550. The members of the Enterprises knew, and intended that, Plaintiff and the public would rely on the material misrepresentations and omissions made by them and suffer damages as a result.

551. As described herein, the members of the Enterprises engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiff and the public based on their misrepresentations and omissions.

552. The predicate acts also had the same or similar results, participants, victims, and methods of commission.

553. The predicate acts were related and not isolated events.

554. The true purposes of Defendants' Schemes were necessarily revealed to each member of the Enterprises. Nevertheless, the members of the Enterprises continued to disseminate misrepresentations regarding the nature of prescription opioids and the functioning of the Schemes.

555. Defendants' fraudulent concealment was material to Plaintiff and the public. Had the members of the Enterprises disclosed the true nature of prescription opioids and their excessive distribution, Plaintiff would not have acted as it did or incurred the substantial costs in responding to the crisis caused by Defendants' conduct.

556. The pattern of racketeering activity described above is currently ongoing and open-ended, and threatens to continue indefinitely unless this Court enjoins the racketeering activity.

D. The Tribe Has Been Damaged by Defendants' RICO Violations

557. By reason of, and as a result of the conduct of the Enterprises and, in particular, their patterns of racketeering activity, the Tribe has been injured in its business and/or property in multiple ways, including but not limited to increased social services costs, costs related to dealing with opioid-related crimes, and other public safety costs, as fully described above. The Tribe will continue incurring these substantial costs well into the future. The Marketing Defendants' deceptive marketing scheme changed the way physicians prescribe opioids, and together with their systemic undermining of quotas and institutional controls as well as the failure to monitor for suspicious orders or red flags of diversion by both the Manufacturing, Distributor, and Retail Pharmacy Defendants, Defendants achieved an enormous increase in the number of opioids sold and distributed across the country and on and around the Reservation.

558. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and proximately caused injuries and damages to the Tribe, its community, and the public, and the Tribe is entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

COUNT SEVEN — PUNITIVE DAMAGES

559. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this complaint.

560. Defendants acted to serve their own interests, having reason to know, and consciously disregarding, a substantial risk that their conduct might significantly injure the rights of others.

561. Plaintiff is entitled to recover punitive damages in an amount sufficient to punish Defendants for their wrongful conduct and deter others from engaging in similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Hopi Tribe respectfully requests the Court order the following relief:

- A. An Order that the conduct alleged herein violates the Arizona CFA;
- B. An Order that Plaintiff is entitled to damages pursuant to the Arizona CFA;
- C. An Order that Defendants are negligent under Arizona law;
- D. An Order that Defendants are wantonly negligent under Arizona law;
- E. An Order that Representative Defendants have been unjustly enriched at Plaintiff's expense under Arizona law;
- F. An Order that Defendants' conduct constitutes violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, *et seq.*;
- G. An Order that Plaintiff is entitled to treble damages pursuant to RICO;
- H. An Order that Plaintiff is entitled to recover all measure of damages permissible under the statutes identified herein and under common law;
- I. An Order that Plaintiff is entitled to punitive damages;
- J. An Order that Defendants are enjoined from the practices described herein;

K. An Order that judgment be entered against Defendants in favor of Plaintiff;

L. An Order that Plaintiff is entitled to attorneys' fees and costs pursuant to any applicable provision of law; and

M. An Order awarding any other and further relief deemed just and proper, including pre-judgment and post-judgment interest on the above amounts.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all claims and of all issues so triable.

DATED this 19th day of June, 2020.

KELLER ROHRBACK L.L.P.

By: /s/ Ron Kilgard

Ron Kilgard, No. 005902
Gary Gotto, No. 007401
3101 North Central Avenue, Suite 1400
Phoenix, AZ 85012
Phone: (602) 248-0088
Fax: (602) 248-2822
rkilgard@kellerrohrback.com
ggotto@kellerrohrback.com

Lynn L. Sarko
Derek W. Loeser
Gretchen Freeman Cappio
David J. Ko
Daniel P. Mensher
Alison S. Gaffney
1201 Third Avenue, Suite 3200
Seattle, WA 98101
Phone: (206) 623-1900
Fax: (206) 623-3384
lsarko@kellerrohrback.com
dloeser@kellerrohrback.com
gcappio@kellerrohrback.com
dko@kellerrohrback.com

dmensher@kellerrohrback.com
agaffney@kellerrohrback.com

Attorneys for Plaintiff Hopi Tribe

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Civil Cover Sheet

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the District of Arizona.

The completed cover sheet must be printed directly to PDF and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff(s): Hopi Tribe

Defendant(s): Endo Health Solutions, Inc. ; Endo Pharmaceuticals, Inc. ; Par Pharmaceutical, Inc. ; Par Pharmaceutical Companies, Inc. ; Janssen Pharmaceuticals, Inc. ; Johnson & Johnson ; Teva Pharmaceuticals Industries, Ltd. ; Teva Pharmaceuticals USA, Inc. ; Cephalon, Inc. ; Allergan PLC f/k/a Actavis PLC ; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. ; Watson Laboratories, Inc. ; Actavis LLC ; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc ; Mallinckrodt PLC ; Mallinckrodt, LLC ; SpecGX LLC ; Mylan Pharmaceuticals, Inc. ; West-Ward Pharmaceuticals Corp. ; Hikma Pharmaceuticals PLC ; KVK-Tech, Inc. ; Sandoz, Inc. ; Amneal Pharmaceuticals, LLC ; Amneal Pharmaceuticals, Inc. ; Impax Generics ; Impax Laboratories, Inc. ; Cardinal Health, Inc. ; McKesson Corporation ; AmerisourceBergen Drug Corporation ; Walgreens Boots Alliance Inc. a/k/a Walgreen Co. ; Walmart, Inc. ; CVS Health Corporation ; CVS Pharmacy, Inc. ; John and Jane Does 1 through 100

County of Residence: Navajo

County of Residence: Outside the State of Arizona

County Where Claim For Relief Arose: Navajo

Plaintiff's Atty(s):

Defendant's Atty(s):

Ron Kilgard (Hopi Tribe)

Keller Rohrback LLP
3101 North Central Avenue, Suite 1400
Phoenix, Arizona 85012
(602) 248-0088

Gary Gotto (Hopi Tribe)
Keller Rohrback LLP
3101 North Central Avenue, Suite 1400
Phoenix, Arkansas 85012
(602) 248-0088

II. Basis of Jurisdiction: **3. Federal Question (U.S. not a party)**

III. Citizenship of Principal
Parties (Diversity Cases Only)

Plaintiff:- N/A
Defendant:- N/A

IV. Origin : **1. Original Proceeding**

V. Nature of Suit: **470 RICO**

VI.Cause of Action: **Violation of 18 U.S.C. § 1961, deceptive marketing of opioids.**

VII. Requested in Complaint

Class Action: **No**
Dollar Demand:
Jury Demand: **Yes**

VIII. This case **IS RELATED** to Case Number **1:17-md-02804-DAP, N. Dist. of Ohio** assigned to Judge **Dan A. Polster.**

Signature: s/ Ron Kilgard

Date: 6/19/2020

If any of this information is incorrect, please go back to the Civil Cover Sheet Input form using the *Back* button in your browser and change it. Once correct, save this form as a PDF and include it as an attachment to your case opening documents.