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UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON AT TACOMA

PIERCE COUNTY,

Plaintiff,

No.

v.

COMPLAINT

PURDUE PHARMA, L.P.; PURDUE  
PHARMA, INC.; THE PURDUE FREDERICK  
COMPANY, INC.; ENDO HEALTH  
SOLUTIONS INC.; ENDO  
PHARMACEUTICALS, INC.; JANSSEN  
PHARMACEUTICALS, INC.; JOHNSON &  
JOHNSON; and JOHN AND JANE DOES 1  
THROUGH 100, INCLUSIVE,

Defendants.

COMPLAINT

**KELLER ROHRBACK L.L.P.**

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Seattle, WA 98101-3052  
TELEPHONE: (206) 623-1900  
FACSIMILE: (206) 623-3384

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**I. INTRODUCTION**

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

4 2. Since 2000, more than 300,000 Americans have lost their lives to an opioid  
5 overdose, more than five times as many American lives as were lost in the entire Vietnam War.  
6 On any given day, 145 people will die from opioid overdoses in the United States. Opioid  
7 overdose is now the leading cause of death for Americans between the ages of 25 and 60.

8 3. The opioid crisis has become a public health emergency of unprecedented levels.  
9 Plaintiff Pierce County, one of the largest counties in Washington State with more than 860,000  
10 residents, has been deeply affected by the crisis. Opioids have reshaped daily reality for Pierce  
11 County in numerous ways, including increased and intensified emergency medical responses to  
12 overdoses; increased drug-related offenses affecting law enforcement, jails, and courts;  
13 additional resources spent on community and social programs; higher workers' compensation  
14 costs for prescription opioids and opioid-related claims; and prevalent drug use throughout  
15 Pierce County including in streets, buses, and parks.

16 4. Pierce County has been working to confront the emergency caused by  
17 Defendants' reckless promotion of prescription opioids. In May 2017, Pierce County convened  
18 an Opioid Use Task Force, a multidisciplinary group of 25 leaders from various sectors and  
19 communities, to address the opioid-use public health crisis in Pierce County through strategies  
20 that target prevention, treatment, and recovery.

21 5. But even as Pierce County marshals considerable resources and expert knowledge  
22 to respond to this crisis with forward-thinking solutions, fully addressing the opioid crisis also  
23 necessitates looking back and requiring those responsible to pay for their conduct and to abate  
24 the nuisance and harms they have created in Pierce County. The opioid epidemic is no accident.

1 On the contrary, it is the foreseeable consequence of Defendants' reckless promotion of potent  
2 opioids for chronic pain while deliberately downplaying the significant risks of addiction and  
3 overdose.

4 6. Defendant Purdue set the stage for the opioid epidemic, through the production  
5 and promotion of its blockbuster drug, OxyContin. Purdue introduced a drug with a narcotic  
6 payload many times higher than that of previous prescription painkillers, while executing a  
7 sophisticated, multi-pronged marketing campaign to change prescribers' perception of the risk of  
8 opioid addiction and to portray opioids as effective treatment for chronic pain. Purdue pushed its  
9 message of opioids as a low-risk panacea on doctors and the public through every available  
10 avenue, including through lobbying efforts, direct marketing, front groups, key opinion leaders,  
11 unbranded advertising, and hundreds of sales representatives who visited doctors and clinics on a  
12 regular basis.  
13

14 7. As sales of OxyContin and Purdue's profits surged, Defendants Endo and Janssen  
15 added additional prescription opioids, aggressive sales tactics, and dubious marketing claims of  
16 their own to the deepening crisis. They paid hundreds of millions of dollars to market and  
17 promote the drugs, notwithstanding their dangers, and pushed bought-and-paid-for "science"  
18 supporting the safety and efficacy of opioids that lacked any basis in fact or reality. Obscured  
19 from the marketing was the fact that prescription opioids are not much different than heroin—  
20 indeed on a molecular level, they are virtually indistinguishable.  
21

22 8. Defendants' efforts were remarkably successful: since the mid-1990s, opioids  
23 have become the most prescribed class of drugs in America. Between 1991 and 2011, opioid  
24 prescriptions in the U.S. tripled from 76 million to 219 million per year.<sup>1</sup> In 2016, health care  
25  
26

---

<sup>1</sup> Nora D. Volkow, MD, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, Appearing before the Senate Caucus on International Narcotics Control, NIH National Institute on Drug Abuse (May 14, 2014),

1 providers wrote more than 289 million prescriptions for opioid pain medication, enough for  
2 every adult in the United States to have more than one bottle of pills.<sup>2</sup> In terms of annual sales,  
3 the increase has been ten-fold; before the FDA approved OxyContin in 1995, annual opioid sales  
4 hovered around \$1 billion. By 2015, they increased to almost \$10 billion. By 2020, revenues are  
5 projected to grow to \$18 billion.<sup>3</sup>

6  
7 9. But Defendants' profits have come at a steep price. Opioids are now the leading  
8 cause of accidental death in the U.S., surpassing deaths caused by car accidents. Opioid overdose  
9 deaths (which include prescription opioids as well as heroin) have risen steadily every year, from  
10 approximately 4,030 in 1999, to 15,597 in 2009, to over 33,000 in 2015. In 2016, that toll  
11 climbed to 53,000.<sup>4</sup> As shown in the graph below, the recent surge in opioid-related deaths  
12 involves prescription opioids, heroin, and other synthetic opioids. More than half of all opioid  
13 overdose deaths involve a prescription opioid like those manufactured by Defendants,<sup>5</sup> and the  
14 increase in overdoses from non-prescription opioids is directly attributable to Defendants'  
15 success in expanding the market for opioids of any kind.  
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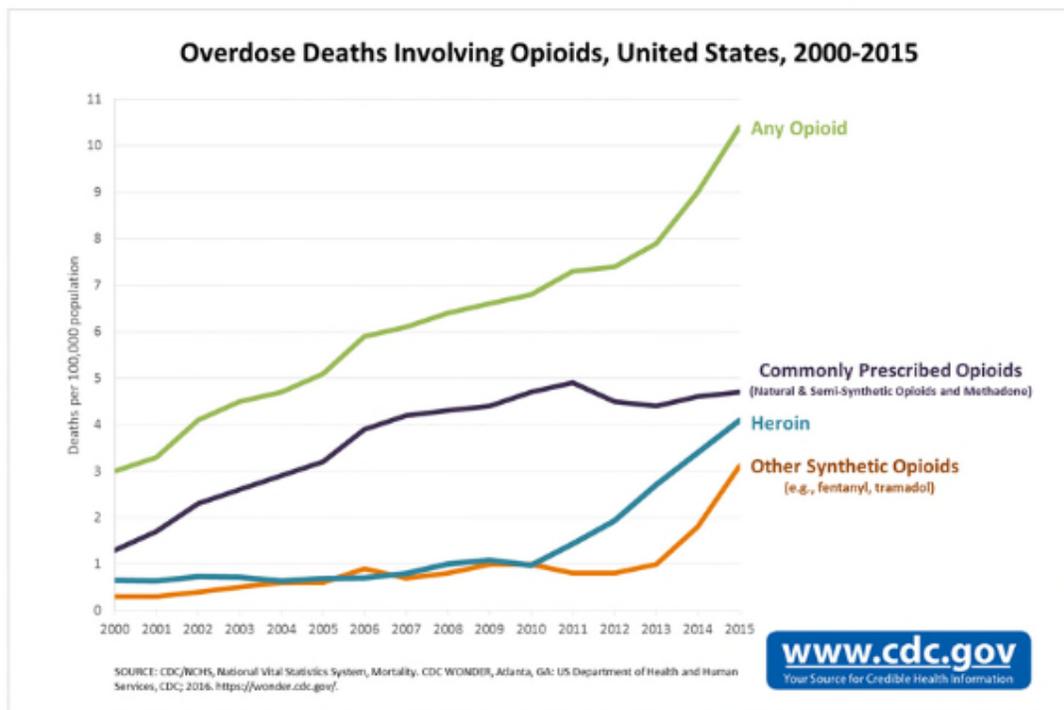
23 <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

24 <sup>2</sup> *Prevalence of Opioid Misuse*, BupPractice, <https://www.buppractice.com/node/15576> (last visited Jan. 31, 2018).

25 <sup>3</sup> *Report: Opioid pain sales to hit \$18.4B in the U.S. by 2020*, CenterWatch (July 17, 2017),  
<https://www.centerwatch.com/news-online/2017/07/17/report-opioid-pain-sales-hit-18-4b-u-s-2020/#more-31534>.

26 <sup>4</sup> *Overdose Death Rates*, NIH National Institute on Drug Abuse, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (revised Jan. 2017).

<sup>5</sup> *Understanding the Epidemic*, Centers for Disease Control and Prevention,  
<https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated Aug. 30, 2017).



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

18 11. Just as it has nationally, the opioid epidemic in Pierce County has exacted a grim  
19 toll. From 2012 to 2016, 423 residents of Pierce County have died from opioid-related  
20 overdoses,<sup>6</sup> including eighty-one deaths in 2016 alone.<sup>7</sup> The rate of opioid-related overdose  
21 deaths in Pierce County during this time period was higher than the state average.  
22  
23  
24

25 <sup>6</sup> *Opioid-related Deaths in Washington State, 2006-2016*, Washington State Department of Health (May 2017),  
26 <https://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf>.

<sup>7</sup> Matt Driscoll, *Noah's story shows why the region's desperate fight against opioids is worth waging*, The News  
Tribune (Jan. 26, 2018, 7:00am), <http://www.thenewstribune.com/news/local/news-columns-blogs/matt-driscoll/article196749979.html>.

1 12. Since 2007, the number of people admitted into treatment programs for  
2 prescription opioids and heroin in Pierce County has more than doubled. In addition, first-time  
3 opioid treatment admissions tripled from 2002 to 2015, with the biggest spike among people  
4 ages eighteen to twenty-nine.<sup>8</sup>

5  
6 13. Faced with the effects of opioid-related overdoses, deaths, and crime, Pierce  
7 County declared a “State of Opioid Crisis” in August 2017, in a letter signed by all seven  
8 members of the County Council to Washington Governor Jay Inslee.

9 14. Beyond the human cost, the CDC recently estimated that the total economic  
10 burden of prescription opioid abuse costs the United States \$78.5 billion per year, which includes  
11 increased costs for health care and addiction treatment, increased strains on human services and  
12 criminal justice systems, and substantial losses in workforce productivity.<sup>9</sup>

13  
14 15. But even these estimates are conservative. The Council of Economic Advisers—  
15 the primary advisor to the Executive Office of the President—recently issued a report stating that  
16 it “estimates that in 2015, the economic cost of the opioid crisis was \$504.0 billion, or 2.8  
17 percent of GDP that year. This is over six times larger than the most recently estimated economic  
18 cost of the epidemic.”<sup>10</sup> Whatever the final tally, there is no doubt that this crisis has had a  
19 profound economic impact.

20  
21 16. Defendants orchestrated this crisis. Despite knowing about the true hazards of  
22 their products, Defendants misleadingly advertised their opioids as safe and effective for treating  
23 chronic pain and pushed hundreds of millions of pills into the marketplace for consumption.

24  
25 <sup>8</sup> *Id.*

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

<sup>10</sup> *The Underestimated Cost of the Opioid Crisis*, The Council of Economic Advisers (Nov. 2017),  
<https://static.politico.com/1d/33/4822776641cfbac67f9bc7dbd9c8/the-underestimated-cost-of-the-opioid-crisis-embargoed.pdf>.

1 Through their sophisticated and well-orchestrated campaign, Defendants touted the purported  
2 benefits of opioids to treat pain and downplayed the risks of addiction. Moreover, even as the  
3 deadly toll of prescription opioid use became apparent to Defendants in years following  
4 OxyContin’s launch, Defendants persisted in aggressively selling prescription opioids and spent  
5 hundreds of millions of dollars promoting and marketing opioids.  
6

7 17. Defendants consistently, deliberately, and recklessly made and continue to make  
8 false and misleading statements—including to doctors and patients in Pierce County—regarding,  
9 among other things, the low risk of addiction to opioids, opioids’ efficacy for chronic pain and  
10 ability to improve patients’ quality of life with long-term use, the lack of risk associated with  
11 higher dosages of opioids, the need to prescribe more opioids to treat withdrawal symptoms, and  
12 that risk-mitigation strategies and abuse-deterrent technologies allow doctors to safely prescribe  
13 opioids.  
14

15 18. Because of Defendants’ misconduct, Pierce County is experiencing a severe  
16 public health crisis and has suffered significant economic damages, including but not limited to  
17 increased costs related to public health, opioid-related crimes and emergencies, health care,  
18 criminal justice, and public safety. Pierce County has incurred substantial costs in responding to  
19 the crisis and will continue to do so in the future.  
20

21 19. Accordingly, Pierce County brings this action to hold Defendants liable for their  
22 misrepresentations regarding the benefits and risks of opioids, conduct that (i) violates the  
23 Washington Consumer Protection Act, RCW 19.86 *et seq.*, (ii) constitutes a public nuisance  
24 under Washington law, (iii) constitutes negligence and gross negligence under Washington law,  
25 (iv) has unjustly enriched Defendants; and (v) violates the Racketeer Influenced and Corrupt  
26 Organizations Act (“RICO”), 18 U.S.C. §1961, *et seq.*

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**II. PARTIES**

**Pierce County**

20. Plaintiff Pierce County (“Plaintiff” or “Pierce County” or “County”) is a Washington County organized and existing under the laws of the State of Washington, RCW 36.01 *et seq.*

**Purdue**

21. Defendant Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Defendant Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Defendant The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut. Collectively, these entities are referred to as “Purdue.”

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

23. Purdue manufactures, promotes, sells, markets, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States, including in Pierce County.

24. Purdue generates substantial sales revenue from its opioids. For example, OxyContin is Purdue’s best-selling opioid, and since 2009, Purdue has generated between \$2 and \$3 billion annually in sales of OxyContin, one of the primary prescription opioids available in the painkiller market.

**Endo**

25. 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.”

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

3           27.     Endo manufacturers, promotes, sells, markets, and distributes opioids such as  
4 Percocet, Opana, and Opana ER in the United States, including in Pierce County.

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

8  
9           **Janssen**

10          29.     Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its  
11 principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of  
12 Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in  
13 New Brunswick, New Jersey. Collectively, these entities are referred to as “Janssen.”

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

16          31.     Johnson & Johnson is the only company that owns more than 10% of Janssen  
17 Pharmaceuticals, Inc., and corresponds with the FDA regarding the drugs manufactured by  
18 Janssen Pharmaceuticals, Inc. Johnson & Johnson also paid prescribers to speak about opioids  
19 manufactured by Janssen Pharmaceuticals, Inc. In short, Johnson & Johnson controls the sale and  
20 development of the drugs manufactured by Janssen Pharmaceuticals, Inc.  
21

22          32.     Janssen manufacturers, promotes, sells, markets, and distributes opioids such as  
23 Duragesic, Nucynta, and Nucynta ER in the United States, including in Pierce County. Janssen  
24 stopped manufacturing Nucynta and Nucynta ER in 2015.  
25  
26

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

4 **John and Jane Does 1-100, inclusive**

5 34. In addition to Defendants, the true names, roles, and/or capacities in the  
6 wrongdoing alleged herein of Defendants named John and Jane Does 1 through 100, inclusive,  
7 are currently unknown to Plaintiff, and thus, are named as Defendants under fictitious names as  
8 permitted by the rules of this Court. Plaintiff will amend this complaint and identify their true  
9 identities and their involvement in the wrongdoing at issue, as well as the specific causes of  
10 action asserted against them when they become known.  
11

12 **III. JURISDICTION AND VENUE**

13 35. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332. The  
14 Court also has federal question subject matter jurisdiction arising out of Plaintiff's RICO claims  
15 pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1961, *et seq.*  
16

17 36. Venue in this Court is proper under 28 U.S.C. § 1391(b).

18 **IV. FACTUAL ALLEGATIONS**

19 **A. Making an Old Drug New Again**

20 **1. A history and background of opioids in medicine**

21 37. Opioids, including natural, synthetic, and semi-synthetic opioids, are a class of  
22 drugs generally used to treat pain. Opioids produce multiple effects on the human body, the most  
23 significant of which are analgesia, euphoria, and respiratory depression. In addition, opioids  
24 cause sedation and constipation.  
25

26 38. 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 can develop a

1 tolerance to the analgesic and euphoric effects, there is no corresponding tolerance to respiratory  
2 depression. Increasing the opioid dose will increasingly depress the respiratory system until, at  
3 some point, breathing stops. This is why the risk of opioid overdose is so high, and why many of  
4 those who overdose simply go to sleep and never wake up.

5  
6 39. Natural opioids are derived from the opium poppy and have been used since  
7 antiquity, going as far back as 3400 B.C. The opium poppy contains various opium alkaloids,  
8 three of which are used in the pharmaceutical industry: morphine, codeine, and thebaine.

9 40. In the 1500s, a European alchemist developed a tincture of opium called  
10 laudanum, which became popular in Victorian England. Laudanum contains almost all of the  
11 opioid alkaloids and is still available by prescription today. English chemists first isolated the  
12 morphine and codeine alkaloids in the early 1800s, and Merck began marketing morphine  
13 commercially in 1827. Heroin, first synthesized from morphine in 1874, was marketed  
14 commercially by the Bayer Pharmaceutical Company beginning in 1898.

15  
16 41. Opioids provided relief from acute pain and were also useful in treating diarrhea,  
17 but there was a problem: they were highly addictive. For a time, morphine was used to treat  
18 opium addiction; later, heroin was marketed as a safe alternative to morphine. In 1916, three  
19 years after Bayer stopped mass-producing heroin because of its dangers, German chemists  
20 synthesized oxycodone from thebaine, with the hope that its different alkaloid source might  
21 mean it could provide the benefits of morphine and heroin without the drawbacks.

22  
23 42. But each opiate was just as addictive as the one before it, and eventually the issue  
24 of opioid addiction—affecting, in particular, Civil War veterans treated for pain and “genteel  
25  
26

1 ladies”<sup>11</sup> who were prescribed opiates by their doctors for various ailments—could not be  
2 ignored. The nation’s first Opium Commissioner, Hamilton Wright, remarked in 1911, “The  
3 habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of  
4 victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who  
5 prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in  
6 the United States.”<sup>12</sup>

8 43. Concerns over opioid addiction led to national legislation and international  
9 agreements regulating narcotics: the International Opium Convention, signed at the Hague in  
10 1912, and, in the U.S., the Harrison Narcotics Tax Act of 1914. Opioids were no longer marketed  
11 as cure-alls, and instead were relegated to the treatment of acute pain.

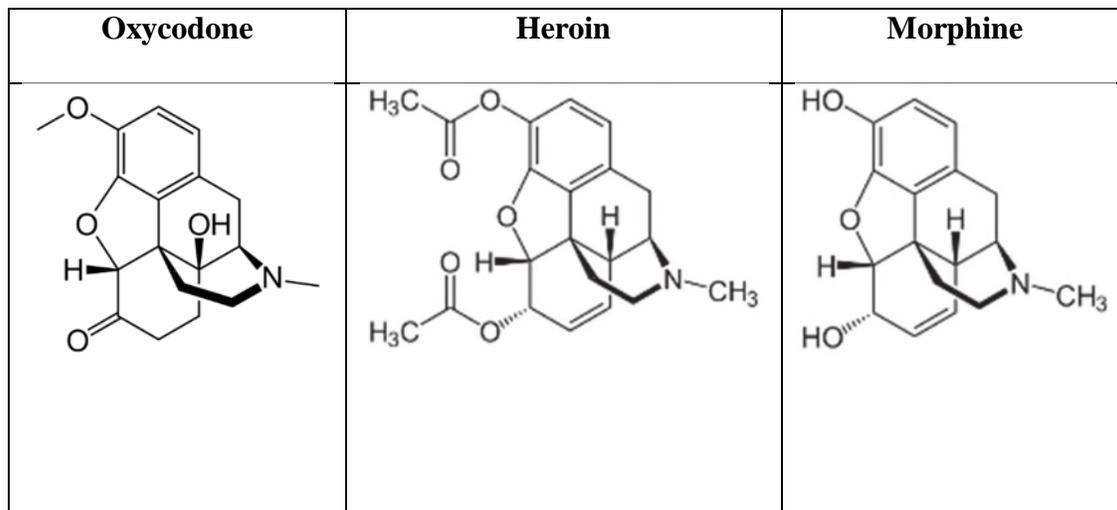
12 44. Throughout the twentieth century, pharmaceutical companies continued to  
13 develop prescription opioids, but these opioids were generally produced in combination with  
14 other drugs, with relatively low opioid content. For example, Percodan, produced by Defendant  
15 Endo since 1950, is oxycodone and aspirin, and contains just under 5 mg of oxycodone.  
16 Percocet, manufactured by Endo since 1971, is the combination of oxycodone and  
17 acetaminophen, with dosage strengths delivering between 2.5 mg and 10 mg of oxycodone.  
18 Vicodin, a combination of hydrocodone and acetaminophen, was introduced in the U.S. in 1978  
19 and is sold in strengths of 5 mg, 7.5 mg, and 10 mg of hydrocodone. Defendant Janssen also  
20 manufactured a drug with 5 mg of oxycodone and 500 mg of acetaminophen, called Tylox, from  
21 1984 to 2012.  
22  
23  
24  
25

26 <sup>11</sup> Nick Miroff, *From Teddy Roosevelt to Trump: How drug companies triggered an opioid crisis a century ago*, The 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](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).

<sup>12</sup> *Id.*

1 45. In contrast, OxyContin, the product with the dubious honor of the starring role in  
 2 the opioid epidemic, is pure oxycodone. Purdue initially made it available in the following  
 3 dosage strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. In other  
 4 words, the weakest OxyContin delivers as much narcotic as the strongest Percocet, and some  
 5 OxyContin tablets delivered sixteen times as much as that.  
 6

7 46. Prescription opioids are essentially pharmaceutical heroin; they are synthesized  
 8 from the same plant, have similar molecular structures, and bind to the same receptors in the  
 9 human brain. It is no wonder then that there is a straight line between prescription opioid abuse  
 10 and heroin addiction. Indeed, studies show that over 80% of new heroin addicts between 2008  
 11 and 2010 started with prescription opioids.<sup>13</sup>  
 12



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 22 47. Medical professionals describe the strength of various opioids in terms of  
 23 “morphine milligram equivalents” (“MME”). According to the CDC, dosages at or above 50  
 24  
 25  
 26

<sup>13</sup> Jones CM, *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>.

1 MME/day double the risk of overdose compared to 20 MME/day, and one study found that  
2 patients who died of opioid overdose were prescribed an average of 98 MME/day.

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

7  
8 49. As journalist Barry Meier wrote in his 2003 book *Pain Killer: A "Wonder"*  
9 *Drug's Trail of Addiction and Death*, "In terms of narcotic firepower, OxyContin was a nuclear  
10 weapon."<sup>14</sup>

11 50. Fentanyl, an even more potent and more recent arrival in the opioid tale, is a  
12 synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First  
13 developed in 1959, fentanyl is showing up more and more often in the market for opioids created  
14 by Defendants' promotion, with particularly lethal consequences.

15  
16 **2. The Sackler family pioneered the integration of advertising and medicine.**

17 51. Given the history of opioid use in the U.S. and the medical profession's resulting  
18 wariness, the commercial success of Defendants' prescription opioids would not have been  
19 possible without a fundamental shift in prescribers' perception of the risks and benefits of long-  
20 term opioid use.

21 52. As it turned out, Purdue was uniquely positioned to execute just such a maneuver,  
22 thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of  
23 Purdue and one of the wealthiest families in America, surpassing the wealth of storied families  
24  
25  
26

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<sup>14</sup> Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (Rodale 2003).

1 like the Rockefellers, the Mellons, and the Busches.<sup>15</sup> Because of Purdue and, in particular,  
2 OxyContin, the Sacklers' net worth was \$13 billion as of 2016. Today, all nine members of the  
3 Purdue board are family members, and all of the company's profits go to Sackler family trusts  
4 and entities.<sup>16</sup> Yet the Sacklers have avoided publicly associating themselves with Purdue, letting  
5 others serve as the spokespeople for the company.  
6

7 53. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small  
8 patent-medicine company called the Purdue Frederick Company in 1952. While all three  
9 brothers were accomplished psychiatrists, it was Arthur, the oldest, who directed the Sackler  
10 story, treating his brothers more as his protégés than colleagues, putting them both through  
11 medical school and essentially dictating their paths. It was Arthur who created the Sackler  
12 family's wealth, and it was Arthur who created the pharmaceutical advertising industry as we  
13 know it—laying the groundwork for the OxyContin promotion that would make the Sacklers  
14 billionaires.  
15

16 54. Arthur Sackler was both a psychiatrist and a marketing executive, and, by many  
17 accounts, a brilliant and driven man. He pursued two careers simultaneously, as a psychiatrist at  
18 Creedmoor State Hospital in New York and the president of an advertising agency called  
19 William Douglas McAdams. Arthur pioneered both print advertising in medical journals and  
20 promotion through physician “education” in the form of seminars and continuing medical  
21 education courses. He understood intuitively the persuasive power of recommendations from  
22 fellow physicians, and did not hesitate to manipulate information when necessary. For example,  
23  
24

25  
26 <sup>15</sup> 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/#382ab3275e02>.

<sup>16</sup> 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/>.

1 one promotional brochure produced by his firm for Pfizer showed business cards of physicians  
2 from various cities as if they were testimonials for the drug, but when a journalist tried to contact  
3 these doctors, he discovered that they did not exist.<sup>17</sup>

4  
5 55. It was Arthur who, in the 1960s, made Valium into the first \$100-million drug, so  
6 popular it became known as “Mother’s Little Helper.” His expertise as a psychiatrist was key to  
7 his success; as his biography in the Medical Advertising Hall of Fame notes, it “enabled him to  
8 position different indications for Roche’s Librium and Valium—to distinguish for the physician  
9 the complexities of anxiety and psychic tension.”<sup>18</sup> When Arthur’s client, Roche, developed  
10 Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for  
11 treatment of anxiety. So Arthur invented a condition he called “psychic tension”—essentially  
12 stress—and pitched Valium as the solution.<sup>19</sup> The campaign, for which Arthur was compensated  
13 based on volume of pills sold,<sup>20</sup> was a remarkable success.

14  
15 56. Arthur’s entrepreneurial drive led him to create not only the advertising for his  
16 clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper  
17 called the *Medical Tribune*, which he distributed for free to doctors nationwide. Arthur also  
18 conceived a company now called IMS Health Holdings Inc., which monitors prescribing  
19 practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies  
20 like Defendants, who utilize it to tailor their sales pitches to individual physicians.

21  
22 57. Even as he expanded his business dealings, Arthur was adept at hiding his  
23 involvement in them. When, during a 1962 Senate hearing about deceptive pharmaceutical

24  
25 <sup>17</sup> Meier, *supra* note 14, at 204.

26 <sup>18</sup> *MAHF Inductees, Arthur M. Sackler*, Medical Advertising Hall of Fame, <https://www.mahf.com/mahf-inductees/>  
(last visited Jan. 31, 2018).

<sup>19</sup> Meier, *supra* note 14, 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>.

<sup>20</sup> WBUR On Point interview, *supra* note 19.

1 advertising, he was asked about a public relations company called Medical and Science  
2 Communications Associates, which distributed marketing from drug companies disguised as  
3 news articles, Arthur was able to truthfully testify that he never was an officer for nor had any  
4 stock in that company. But the company's sole shareholder was his then-wife. Around the same  
5 time, Arthur also successfully evaded an investigative journalist's attempt to link the Sacklers to  
6 a company called MD Publications, which had funneled payments from drug companies to an  
7 FDA official named Henry Welch, who was forced to resign when the scandal broke.<sup>21</sup> Arthur  
8 had set up such an opaque and layered business structure that his connection to MD Publications  
9 was only revealed decades later when his heirs were fighting over his estate.  
10

11 58. Arthur Sackler did not hesitate to manipulate information to his advantage. His  
12 legacy is a corporate culture that prioritizes profits over people. In fact, in 2007, federal  
13 prosecutors conducting a criminal investigation of Purdue's fraudulent advertising of OxyContin  
14 found a "corporate culture that allowed this product to be misbranded with the intent to defraud  
15 and mislead."<sup>22</sup> Court documents from the prosecution state that "certain Purdue supervisors and  
16 employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less  
17 addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal  
18 than other pain medications . . ."<sup>23</sup> Half a century after Arthur Sackler wedded advertising and  
19 medicine, Purdue employees were following his playbook, putting product sales over patient  
20 safety.  
21  
22  
23  
24

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25 <sup>21</sup> Meier, *supra* note 14, at 210-14.

26 <sup>22</sup> Naomi Spencer, *OxyContin manufacturer reaches \$600 million plea deal over false marketing practices*, World Socialist Web Site (May 19, 2007), <http://www.wsws.org/en/articles/2007/05/oxy-m19.html>.

<sup>23</sup> Agreed Statement of Facts, *U.S. v. The Purdue Frederick Company, Inc., et al.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

1           **3. Purdue and the development of OxyContin**

2           59. After the Sackler brothers acquired the Purdue Frederick Company in 1952,  
3 Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable  
4 business. As an advertising executive, Arthur was not involved, on paper at least, in running  
5 Purdue because that would have been a conflict of interest. Raymond became Purdue's head  
6 executive while Mortimer ran Purdue's UK affiliate.  
7

8           60. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer  
9 that had developed a sustained-release technology suitable for morphine. Purdue marketed this  
10 extended-release morphine as MS Contin. It quickly became Purdue's best seller. As the patent  
11 expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time,  
12 Raymond's oldest son, Richard Sackler, who was also a trained physician, became more  
13 involved in the management of the company. Richard had grand ambitions for the company;  
14 according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I  
15 mean *really* big."<sup>24</sup> Richard believed Purdue should develop another use for its "Contin" timed-  
16 release system.  
17

18           61. In 1990, Purdue's VP of clinical research, Robert Kaiko, sent a memo to Richard  
19 and other executives recommending that the company work on a pill containing oxycodone. At  
20 the time, oxycodone was perceived as less potent than morphine, largely because it was most  
21 commonly prescribed as Percocet, the relatively weak oxycodone-acetaminophen combination  
22 pill. MS Contin was not only approaching patent expiration but had always been limited by the  
23 stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was  
24 sometimes mistakenly called "oxycodone," which also contributed to the perception of relatively  
25  
26

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<sup>24</sup> 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/>.

1 lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its  
2 advantage when it eventually pled guilty to criminal charges of “misbranding” in 2007, admitting  
3 that it was “well aware of the incorrect view held by many physicians that oxycodone was  
4 weaker than morphine” and “did not want to do anything ‘to make physicians think that  
5 oxycodone was stronger or equal to morphine’ or to ‘take any steps . . . that would affect the  
6 unique position that OxyContin’” held among physicians.<sup>25</sup>

8 62. For Purdue and OxyContin to be “*really big*,” Purdue needed to both distance its  
9 new product from the traditional view of narcotic addiction risk, and broaden the drug’s uses  
10 beyond cancer pain and hospice care. A marketing memo sent to Purdue’s top sales executives in  
11 March 1995 recommended that if Purdue could show that the risk of abuse was lower with  
12 OxyContin than with traditional immediate-release narcotics, sales would increase.<sup>26</sup> As  
13 discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue  
14 from making that claim regardless.

16 63. Despite the fact that there has been little or no change in the amount of pain  
17 reported in the U.S. over the last twenty years, Purdue recognized an enormous untapped market  
18 for its new drug. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the  
19 Early Show, a CBS morning talk program, “There are 50 million patients in this country who  
20 have chronic pain that’s not being managed appropriately every single day. OxyContin is one of  
21 the choices that doctors have available to them to treat that.”<sup>27</sup>

23 64. In pursuit of these 50 million potential customers, Purdue poured resources into  
24 OxyContin’s sales force and advertising. The graph below shows how promotional spending in  
25

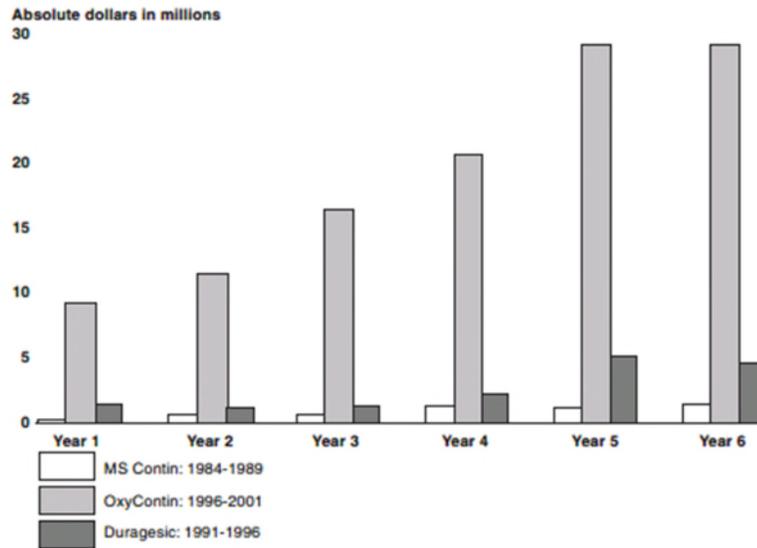
26 <sup>25</sup> *U.S. v. The Purdue Frederick Company, Inc., et al.*, *supra* note 23.

<sup>26</sup> Meier, *supra* note 14, at 269.

<sup>27</sup> *Id.* at 156.

1 the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin or  
 2 Defendant Janssen's spending on Duragesic:<sup>28</sup>

3  
 4 **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.

16 65. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such  
 17 a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners. Today,  
 18 one in every five patients who present themselves to physicians' offices with non-cancer pain  
 19 symptoms or pain-related diagnoses (including acute and chronic pain) receives an opioid  
 20 prescription.<sup>29</sup>

22 66. Purdue has generated estimated sales of more than \$35 billion from opioids since  
 23 1996, while raking in more than \$3 billion in 2015 alone. Remarkably, its opioid sales continued

25  
 26 <sup>28</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office Report to Congressional Requesters at 22 (Dec. 2003), <http://www.gao.gov/new.items/d04110.pdf>.

<sup>29</sup> 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*, Centers for Disease Control and Prevention (Mar. 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

1 to climb even after a period of media attention and government inquiries regarding OxyContin  
2 abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue  
3 proved itself skilled at evading full responsibility and continuing to sell through the controversy.  
4 The company's annual opioid sales of \$3 billion in 2015 represent a four-fold increase from its  
5 2006 sales of \$800 million.  
6

7 67. One might imagine that Richard Sackler's ambitions have been realized. But in  
8 the best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits.  
9 Under the name of Mundipharma, the Sacklers are looking to new markets for their opioids—  
10 employing the exact same playbook in South America, China, and India as they did in the United  
11 States.  
12

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

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

24 Internal documents revealed in court proceedings now tell us that since the early  
25 development of OxyContin, Purdue was aware of the high risk of addiction it  
26 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 overdose

1 deaths, Mundipharma now aggressively markets OxyContin internationally. In  
 2 fact, Mundipharma uses many of the same tactics that caused the opioid epidemic  
 3 to flourish in the U.S., though now in countries with far fewer resources to devote  
 to the fallout.<sup>30</sup>

4 69. Purdue's pivot to untapped markets, after extracting substantial profits from  
 5 entities like Pierce County and leaving them to address the damage, underscores that its actions  
 6 have been knowing, intentional, and motivated by profits throughout this entire tragic story.

## 7 **B. The Booming Business of Addiction**

### 8 **1. Other Defendants seized the opioid opportunity.**

9 70. Purdue created a market in which the prescription of powerful opioids for a range  
 10 of common aches and pains was not only acceptable but encouraged—but it was not alone.  
 11 Defendants Endo and Janssen, each of which already produced and sold prescription opioids,  
 12 both positioned themselves to take advantage of the opportunity Purdue created, developing both  
 13 branded and generic opioids to compete with OxyContin while misrepresenting the safety and  
 14 efficacy of their products.  
 15

16 71. Endo, which for decades had sold Percocet and Percodan, both containing  
 17 relatively low doses of oxycodone, moved quickly to develop a generic version of extended-  
 18 release oxycodone to compete with OxyContin, receiving tentative FDA approval for its generic  
 19 version in 2002. As Endo stated in its 2003 Form 10-K, it was the first to file an application with  
 20 the FDA for bioequivalent versions of the 10, 20, and 40 mg strengths of OxyContin, which  
 21 potentially entitled it to 180 days of generic marketing exclusivity—“a significant advantage.”<sup>31</sup>  
 22 Purdue responded by suing Endo for patent infringement, litigating its claims through a full trial  
 23  
 24

25 \_\_\_\_\_  
 26 <sup>30</sup> Letter to Dr. Margaret Chan, World Health Organization (May 3, 2017),  
[http://katherineclark.house.gov/\\_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf](http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf).

<sup>31</sup> Endo Pharmaceuticals Holdings, Inc. 2003 Form 10-K at 4, [http://media.corporate-ir.net/media\\_files/irol/12/123046/reports/10K\\_123103.pdf](http://media.corporate-ir.net/media_files/irol/12/123046/reports/10K_123103.pdf) (last visited Jan. 31, 2018).

1 and a Federal Circuit appeal—unsuccessfully. As the trial court found, and the appellate court  
2 affirmed, Purdue obtained the oxycodone patents it was fighting to enforce through “inequitable  
3 conduct”—namely, suggesting that its patent applications were supported by clinical data when  
4 in fact they were based on an employee’s “insight and not scientific proof.”<sup>32</sup> Endo began selling  
5 its generic extended-release oxycodone in 2005.  
6

7 72. At the same time as Endo was battling Purdue over generic OxyContin—and as  
8 the U.S. was battling increasingly widespread opioid abuse—Endo was working on getting  
9 another branded prescription opioid on the market. In 2002, Endo submitted applications to the  
10 FDA for both immediate-release and extended-release tablets of oxymorphone, branded as  
11 Opana and Opana ER.  
12

13 73. Like oxycodone, oxymorphone is not a new drug; it was first synthesized in  
14 Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name  
15 Numorphan, in injectable, suppository, and oral tablet forms. But the oral tablets proved highly  
16 susceptible to abuse. Called “blues” after the light blue color of the 10 mg pills, Numorphan  
17 provoked, according to some users, a more euphoric high than heroin, and even had its moment  
18 in the limelight as the focus of the movie *Drugstore Cowboy*. As the National Institute on Drug  
19 Abuse observed in its 1974 report, “Drugs and Addict Lifestyle,” Numorphan was extremely  
20 popular among addicts for its quick and sustained effect.<sup>33</sup> Endo withdrew oral Numorphan from  
21 the market in 1979, reportedly for “commercial reasons.”<sup>34</sup>  
22

23 74. Two decades later, however, as communities around the U.S. were first sounding  
24 the alarm about prescription opioids and Purdue executives were being called to testify before  
25

26 <sup>32</sup> *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1131 (Fed. Cir. 2006).

<sup>33</sup> John Fauber and Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015),  
<https://www.medpagetoday.com/psychiatry/addictions/51448>.

<sup>34</sup> *Id.*

1 Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted  
2 off a product it had previously shelved after widespread abuse, and pushed it into the  
3 marketplace with a new trade name and a potent extended-release formulation.

4 75. The clinical trials submitted with Endo's first application for approval of Opana  
5 were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be  
6 revived with naloxone. Endo then submitted new "enriched enrollment" clinical trials, in which  
7 trial subjects who do not respond to the drug are excluded from the trial, and obtained approval.  
8 Endo began marketing Opana and Opana ER in 2006.  
9

10 76. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017,  
11 the FDA sought removal of Opana ER. In its press release, the FDA indicated that "the agency is  
12 seeking removal based on its concern that the benefits of the drug may no longer outweigh its  
13 risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain  
14 medication from sale due to the public health consequences of abuse."<sup>35</sup> On July 6, 2017, Endo  
15 agreed to withdraw Opana ER from the market.<sup>36</sup>  
16

17 77. Janssen, which already marketed the Duragesic (fentanyl) patch, developed a new  
18 opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate  
19 to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of  
20 chronic pain in 2011.  
21

22 78. Defendants have reaped enormous profits from the addiction crisis they spawned.  
23 For example, Opana ER alone generated more than \$1 billion in revenue for Endo in 2010 and  
24  
25

26 <sup>35</sup> Press Release, U.S. Food & Drug Administration, *FDA requests removal of Opana ER for risks related to abuse*  
(June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

<sup>36</sup> *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>.

1 again in 2013. Janssen earned more than \$1 billion in sales of Duragesic in 2009, and Nucynta  
2 and Nucynta ER accounted for \$172 million in sales in 2014.

3 **2. Pill Mills and overprescribing doctors also placed their financial interests**  
4 **ahead of their patients' interests.**

5 79. Prescription opioid manufacturers were not the only ones to recognize an  
6 economic opportunity. Around the country, including in Pierce County, certain doctors or pain  
7 clinics ended up doing brisk business dispensing opioid prescriptions. As Dr. Andrew Kolodny,  
8 cofounder of Physicians for Responsible Opioid Prescribing, observed, this business model  
9 meant doctors would “have a practice of patients who’ll never miss an appointment and who pay  
10 in cash.”<sup>37</sup>

11  
12 80. Moreover, Defendants’ sales incentives rewarded sales representatives who  
13 happened to have pill mills within their territories, enticing those representatives to look the  
14 other way even when their in-person visits to such clinics should have raised numerous red flags.  
15 In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin.  
16 People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA’s  
17 diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the  
18 doctors. But Purdue’s sales representative for that territory, Eric Wilson, continued to promote  
19 OxyContin sales at the clinic. He reportedly told another local physician that this clinic  
20 accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue’s  
21 top-ranked sales representative.<sup>38</sup> In response to news stories about this clinic, Purdue issued a  
22 statement, declaring that “if a doctor is intent on prescribing our medication inappropriately,  
23 such activity would continue regardless of whether we contacted the doctor or not.”<sup>39</sup>  
24  
25

26 <sup>37</sup> Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* 314 (Bloomsbury Press 2015).

<sup>38</sup> Meier, *supra* note 14, at 298-300.

<sup>39</sup> *Id.*

1           81.       Whenever examples of opioid diversion and abuse have drawn media attention,  
2 Defendants have consistently blamed “bad actors.” For example, in 2001, during a Congressional  
3 hearing, Purdue’s attorney Howard Udell answered pointed questions about how it was that  
4 Purdue could utilize IMS Health data to assess their marketing efforts but not notice a  
5 particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell  
6 asserted that Purdue was “fooled” by the “bad actor” doctor: “The picture that is painted in the  
7 newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this  
8 community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He  
9 fooled the DEA. He fooled local law enforcement. He fooled us.”<sup>40</sup>

11           82.       But given the closeness with which Defendants monitored prescribing patterns  
12 through IMS Health data, it is highly improbable that they were “fooled.” In fact, a local  
13 pharmacist had noticed the volume of prescriptions coming from Paolino’s clinic and alerted  
14 authorities. Purdue had the prescribing data from the clinic and alerted no one. Rather, it appears  
15 Purdue and other Defendants used the IMS Health data to target pill mills and sell more pills.  
16 Indeed, a Purdue executive referred to Purdue’s tracking system and database as a “gold mine”  
17 and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

19           83.       Sales representatives making in-person visits to such clinics were likewise not  
20 fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives  
21 alike, Defendants and their employees turned a collective blind eye, allowing certain clinics to  
22 dispense staggering quantities of potent opioids and feigning surprise when the most egregious  
23 examples eventually made the nightly news.

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<sup>40</sup> *Id.* at 179.

1           **3.     Widespread prescription opioid use broadened the market for heroin and**  
 2           **fentanyl.**

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

7           85.     In his book *Dreamland: The True Tale of America's Opiate Epidemic*, journalist  
 8 Sam Quinones summarized the easy entrance of black tar heroin in a market primed by  
 9 prescription opioids:  
 10

11           His black tar, once it came to an area where OxyContin had already tenderized the  
 12 terrain, sold not to tapped-out junkies but to younger kids, many from the suburbs,  
 13 most of whom had money and all of whom were white. Their transition from Oxy  
 14 to heroin, he saw, was a natural and easy one. Oxy addicts began by sucking on  
 15 and dissolving the pills' timed-release coating. They were left with 40 or 80 mg of  
 16 pure oxycodone. At first, addicts crushed the pills and snorted the powder. As  
 17 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.<sup>41</sup>

18           86.     In a study examining the relationship between the abuse of prescription opioids  
 19 and heroin, researchers found that 75% of those who began their opioid abuse in the 2000s  
 20 reported that their first opioid was a prescription drug.<sup>42</sup> As the graph below illustrates,  
 21 prescription opioids replaced heroin as the first opioid of abuse beginning in the 1990s.  
 22  
 23  
 24  
 25

26 <sup>41</sup> Quinones, *supra* note 37, at 165-66.

<sup>42</sup> 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>.



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

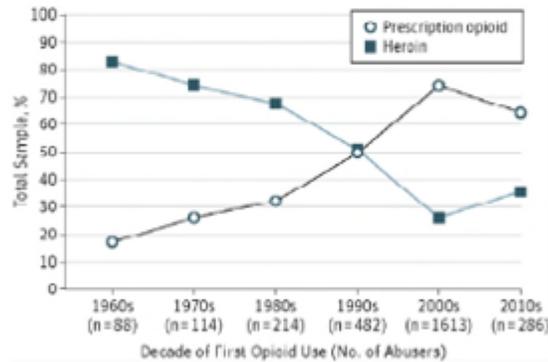


Figure Legend:

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.

87. 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.

88. 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.

1 89. From 2002 to 2016, fatal overdoses related to heroin in the U.S. increased by  
2 **533%**—from 2,089 deaths in 2002 to 13,219 deaths in 2016.<sup>43</sup>

3 90. Along with heroin use, fentanyl use is on the rise, as a result of America's  
4 expanded appetite for opiates. But fentanyl, as noted above, is fifty times more potent than  
5 heroin, and overdosing is all too easy. Fentanyl is expected to cause over 20,000 overdoses in  
6 2017.<sup>44</sup>

7 91. As Dr. Caleb Banta-Green, senior research scientist at the University of  
8 Washington's Alcohol and Drug Abuse Institute, told The Seattle Times in August 2017, "The  
9 bottom line is opioid addiction is the overall driver of deaths. People will use whatever opioid  
10 they can get. It's just that which one they're buying is changing a bit."<sup>45</sup>

### 11 **C. Defendants Promoted Prescription Opioids Through Several Channels.**

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

17 93. Defendants disseminated their deceptive statements about opioids through several  
18 channels.<sup>46</sup> First, Defendants aggressively and persistently pushed opioids through sales  
19 representatives. Second, Defendants funded third-party organizations that appeared to be neutral  
20  
21  
22  
23

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24 <sup>43</sup> Niall McCarthy, *U.S. Heroin Deaths Have Increased 533% Since 2002*, Forbes (Sept. 11, 2017, 8:26am),  
25 [https://www.forbes.com/sites/niallmccarthy/2017/09/11/u-s-heroin-deaths-have-increased-533-since-2002-  
26 infographic/#13ab9a531abc](https://www.forbes.com/sites/niallmccarthy/2017/09/11/u-s-heroin-deaths-have-increased-533-since-2002-infographic/#13ab9a531abc).

<sup>44</sup> *Id.*

<sup>45</sup> *Opioids: The Leading Cause of Drug Deaths in Seattle Area*, University of Washington School of Public Health  
(Aug. 25, 2017), [http://sph.washington.edu/news/article.asp?content\\_ID=8595](http://sph.washington.edu/news/article.asp?content_ID=8595).

<sup>46</sup> The specific misrepresentations and omissions are discussed below in Section D.

1 but which served as additional marketing departments for drug companies. Third, Defendants  
2 utilized prominent physicians as paid spokespeople—“Key Opinion Leaders”—to take  
3 advantage of doctors’ respect for and reliance on the recommendations of their peers. Finally,  
4 Defendants also used print and online advertising, including unbranded advertising, which is not  
5 reviewed by the FDA.

6  
7 94. Defendants spent substantial sums and resources in making these  
8 communications. For example, Purdue spent more than \$200 million marketing OxyContin in  
9 2001 alone.<sup>47</sup>

10 **1. Defendants aggressively deployed sales representatives to push their**  
11 **products.**

12 95. Defendants communicated to prescribers directly in the form of in-person visits  
13 and communications from sales representatives.

14 96. Defendants’ tactics through their sales representatives—also known as  
15 “detailers”—were particularly aggressive. In 2014, Defendants collectively spent well over \$100  
16 million on detailing branded opioids to doctors.

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

20 98. When Purdue launched OxyContin in 1996, its 300-plus sales force had a total  
21 physician call list of approximately 33,400 to 44,500. By 2000, nearly 700 representatives had a  
22 total call list of approximately 70,500 to 94,000 physicians. Each sales representative was  
23 expected to make about thirty-five physician visits per week and typically called on each  
24  
25

26  

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<sup>47</sup> *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 physician every three to four weeks, while each hospital sales representative was expected to  
2 make about fifty physician visits per week and call on each facility every four weeks.<sup>48</sup>

3 99. One of Purdue's early training memos compared doctor visits to "firing at a  
4 target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim  
5 and what you want to hit!"<sup>49</sup> According to the memo, the target is physician resistance based on  
6 concern about addiction: "The physician wants pain relief for these patients without addicting  
7 them to an opioid."<sup>50</sup>

8 100. To hit that target, Purdue sales representatives were taught to say, "The delivery  
9 system is believed to reduce the abuse liability of the drug."<sup>51</sup> But as one sales representative told  
10 a reporter, "I found out pretty fast that it wasn't true."<sup>52</sup> In 2002, former Purdue sales manager  
11 William Gergely told a Florida state investigator that sales representatives were instructed to say  
12 that OxyContin was "virtually non-addicting" and "non-habit-forming."<sup>53</sup>

13 101. As Shelby Sherman, a Purdue sales representative from 1974 to 1998, told a  
14 reporter regarding OxyContin promotion, "It was sell, sell, sell. We were directed to lie. Why  
15 mince words about it?"<sup>54</sup>

16 102. Defendants utilized lucrative bonus systems to encourage their sales  
17 representatives to stick to the script and increase opioid sales in their territories. Purdue paid \$40  
18

19  
20  
21  
22 <sup>48</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 28, at 20.

<sup>49</sup> Meier, *supra* note 14, at 102.

<sup>50</sup> *Id.*

<sup>51</sup> Patrick Radden Keefe, *The Family That Built an Empire of Pain*, *The New Yorker* (Oct. 30, 2017),  
23 <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>; see also Meier, *supra*  
24 note 14, at 102 ("Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of  
25 the drug.").

<sup>52</sup> Keefe, *supra* note 51.

<sup>53</sup> Fred Schulte and Nancy McVicar, *Oxycontin Was Touted As Virtually Nonaddictive, Newly Released State  
26 Records Show*, *Sun Sentinel* (Mar. 6, 2003), [http://articles.sun-sentinel.com/2003-03-06/news/0303051301\\_1\\_purdue-pharma-oxycontin-william-gergely](http://articles.sun-sentinel.com/2003-03-06/news/0303051301_1_purdue-pharma-oxycontin-william-gergely).

<sup>54</sup> Glazek, *supra* note 24.

1 million in sales incentive bonuses to its sales representatives in 2001 alone, with annual bonuses  
2 ranging from \$15,000 to nearly \$240,000.<sup>55</sup> The training memo described above, in keeping with  
3 a Wizard of Oz theme, reminded sales representatives: “A pot of gold awaits you ‘Over the  
4 Rainbow’!”<sup>56</sup>

5  
6 103. As noted above, Defendants have also spent substantial sums to purchase,  
7 manipulate, and analyze prescription data available from IMS Health, which allows them to track  
8 initial prescribing and refill practices by individual doctors, and in turn to customize their  
9 communications with each doctor. Defendants’ use of this marketing data was a cornerstone of  
10 their marketing plan,<sup>57</sup> and continues to this day.

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

17 105. Furthermore, Defendants knew or should have known the doctors they targeted  
18 were often poorly equipped to treat or manage pain comprehensively, as they often had limited  
19 resources or time to address behavioral or cognitive aspects of pain treatment or to conduct the  
20 necessary research themselves to determine whether opioids were as beneficial as Defendants  
21 claimed. In fact, the majority of doctors and dentists who prescribe opioids are not pain  
22 specialists. For example, a 2014 study conducted by pharmacy benefit manager Express Scripts  
23  
24  
25

26 <sup>55</sup> Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*,  
99(2) Am J Public Health 221-27 (Feb. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/>.

<sup>56</sup> Meier, *supra* note 14, at 103.

<sup>57</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 55.

1 reviewing narcotic prescription data from 2011 to 2012 concluded that of the more than 500,000  
2 prescribers of opioids during that time period, *only* 385 were identified as pain specialists.<sup>58</sup>

3 106. When Defendants presented these doctors with sophisticated marketing material  
4 and apparently scientific articles that touted opioids' ability to easily and safely treat pain, many  
5 of these doctors began to view opioids as an efficient and effective way to treat their patients.  
6

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

11 It went something like this. "Doctor, what is the highest dose of OxyContin you  
12 have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain  
13 score is still high you can increase the dose 100% to 40mg Q12h, will you do  
14 that?" "Okay." "Doctor, what if that patient then came back and said their pain  
15 score was still high, did you know that you could increase the OxyContin dose to  
16 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do  
17 agree that you would at least Rx the 40mg dose, right?" "Yes."

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

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

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<sup>58</sup> *A Nation in Pain*, Express Scripts (Dec. 9, 2014), <http://lab.express-scripts.com/lab/publications/a-nation-in-pain>.

1 109. Defendants applied this combination of intense competitive pressure and lucrative  
2 financial incentives because they knew that sales representatives, with their frequent in-person  
3 visits with prescribers, were incredibly effective. In fact, manufacturers' internal documents  
4 reveal that they considered sales representatives their "most valuable resource."  
5

6 **2. Defendants bankrolled seemingly independent "front groups" to promote  
7 opioid use and fight restrictions on opioids.**

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

15 111. Defendants spent significant financial resources contributing to and working with  
16 these various front groups to increase the number of opioid prescriptions written.

17 112. The most prominent front group utilized by Defendants was the **American Pain  
18 Foundation** (APF), which received more than \$10 million from opioid drug manufacturers,  
19 including Defendants, from 2007 through 2012. Purdue contributed \$1.7 million and Endo also  
20 contributed substantial sums to the APF.<sup>59</sup>

21 113. Throughout its existence, APF's operating budget was almost entirely comprised  
22 of contributions from prescription opioid manufacturers. For instance, nearly 90% of APF's \$5  
23 million annual budget in 2010 came from "donations" from some of the Defendants, and by  
24  
25  
26

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<sup>59</sup>Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011, 9:15am),  
<https://www.propublica.org/article/the-champion-of-painkillers>.

1 2011, APF was entirely dependent on grants from drug manufacturers, including from Purdue  
2 and Endo. Not only did Defendants control APF's purse strings, APF's board of directors was  
3 comprised of doctors who were on Defendants' payrolls, either as consultants or speakers at  
4 medical events.<sup>60</sup>

5  
6 114. Although holding itself out as an independent advocacy group promoting patient  
7 well-being, APF consistently lobbied against federal and state proposals to limit opioid use.

8 115. Another prominent front group was the **American Academy of Pain Medicine**  
9 (AAPM), which has received over \$2.2 million in funding since 2009 from opioid drug  
10 manufacturers, including Defendants. Like APF, AAPM presented itself as an independent and  
11 non-biased advocacy group representing physicians practicing in the field of pain medicine, but  
12 in fact was just another mouthpiece Defendants used to push opioids on doctors and patients.<sup>61</sup>

13  
14 116. Both the APF and the AAPM published treatment guidelines and sponsored and  
15 hosted medical education programs that touted the benefits of opioids to treat chronic pain while  
16 minimizing and trivializing their risks. The treatment guidelines the front groups published—  
17 many of which are discussed in detail below—were particularly important to Defendants in  
18 ensuring widespread acceptance for opioid therapy to treat chronic pain. Defendants realized,  
19 just as the CDC has, that such treatment guidelines can “change prescribing practices,” because  
20 they appear to be unbiased sources of evidence-based information, even when they are in reality  
21 marketing materials.

22  
23 117. For instance, the AAPM, in conjunction with the **American Pain Society** (APS),  
24 issued comprehensive guidelines in 2009 titled “Guideline for the Use of Chronic Opioid

25  
26 <sup>60</sup> *Id.*

<sup>61</sup> 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>.

1 Therapy in Chronic Noncancer Pain – Evidence Review” (“2009 Guidelines”). The 2009  
2 Guidelines promoted opioids as “safe and effective” for treating chronic pain, despite  
3 acknowledging limited evidence to support this statement. Unsurprisingly, Defendants have  
4 widely referenced and promoted these guidelines, issued by front groups Defendants funded and  
5 controlled. These 2009 Guidelines are still available online today.<sup>62</sup>

6  
7 118. In addition, Defendants participated in the **Pain Care Forum**, a coalition of drug  
8 makers, trade groups, and nonprofit organizations. From 2006 to 2015, participants in the Pain  
9 Care Forum spent over \$740 million lobbying in the nation’s capital and in all fifty statehouses  
10 on an array of issues, including opioid-related measures. The collective spending on lobbying  
11 and campaigns amounts to more than two hundred times the \$4 million spent during the same  
12 period by the handful of groups that work to warn the public about the dangers of opioids and  
13 lobby for restrictions on painkillers.<sup>63</sup>

14  
15 119. Defendants have also targeted specific groups to encourage opioid prescribing  
16 practices. One such group, a University of Wisconsin-based organization known as the **Pain &**  
17 **Policy Studies Group**, received \$2.5 million from pharmaceutical companies to promote opioid  
18 use and discourage the passing of regulations against opioid use in medical practice. The Pain &  
19 Policy Studies Group wields considerable influence over the nation’s medical schools as well as  
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25 <sup>62</sup> *Clinical Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, American Pain Society,  
26 <http://americanpainsociety.org/uploads/education/guidelines/chronic-opioid-therapy-cnccp.pdf> (last visited Jan. 31,  
2018).

<sup>63</sup> Matthew Perrone and Ben Wieder, *Pro-painkiller echo chamber shaped policy amid drug epidemic*, AP News  
(Sept. 19, 2016), <https://apnews.com/3d257452c24a410f98e8e5a4d9d448a7/pro-painkiller-echo-chamber-shaped-policy-amid-drug>.

1 within the medical field in general.<sup>64</sup> Purdue was the largest contributor to the Pain & Policy  
2 Studies Group, paying approximately \$1.6 million between 1999 and 2010.<sup>65</sup>

3           120. The **Federation of State Medical Boards** (FSMB) of the United States is a  
4 national non-profit organization that represents the seventy-state medical and osteopathic boards  
5 of the United States and its territories and co-sponsors the United States Medical Licensing  
6 Examination. Beginning in 1997, FSMB developed model policy guidelines around the treatment  
7 of pain, including opioid use. The original initiative was funded by the Robert Wood Johnson  
8 Foundation, but subsequently AAPM, APS, the University of Wisconsin Pain & Policy, and the  
9 American Society of Law, Medicine, & Ethics all made financial contributions to the project.  
10

11           121. FSMB's 2004 Model Policy encourages state medical boards "to evaluate their  
12 state pain policies, rules, and regulations to identify *any regulatory restrictions or barriers that*  
13 *may impede the effective use of opioids to relieve pain.*"<sup>66</sup>  
14

15           122. One of the most significant barriers to convincing doctors that opioids were safe  
16 to prescribe to their patients for long-term treatment of chronic pain was the fact that many of  
17 those patients would, in fact, become addicted to opioids. If patients began showing up at their  
18 doctors' offices with obvious signs of addiction, the doctors would, of course, become concerned  
19 and likely stop prescribing opioids. And, doctors might stop believing Defendants' claims that  
20 addiction risk was low.  
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22  
23

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24 <sup>64</sup> *The Role of Pharmaceutical Companies in the Opioid Epidemic*, Addictions.com,  
25 <https://www.addictions.com/opiate/the-role-of-pharmaceutical-companies-in-the-opioid-epidemic/> (last visited  
Jan. 31, 2018).

26 <sup>65</sup> John Fauber, *UW group ends drug firm funds*, Journal Sentinel (Apr. 20, 2011),  
<http://archive.jsonline.com/watchdog/watchdogreports/120331689.html>.

<sup>66</sup> *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, Federation of State Medical Boards  
of the United States, Inc. (May 2004),  
<http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/model04.pdf>.

1           123. To overcome this hurdle, Defendants promoted a concept called  
2 “pseudoaddiction.” Defendants told doctors that when their patients appeared to be addicted to  
3 opioids—for example, asking for more and higher doses of opioids, increasing doses themselves,  
4 or claiming to have lost prescriptions in order to get more opioids—this was not actual addiction.  
5 Rather, Defendants told doctors what appeared to be classic signs of addiction were actually just  
6 signs of undertreated pain. The solution to this “pseudoaddiction”: more opioids. Instead of  
7 warning doctors of the risk of addiction and helping patients to wean themselves off of powerful  
8 opioids and deal with their actual addiction, Defendants pushed even more dangerous drugs onto  
9 patients.  
10

11           124. The FSMB’s Model Policy gave a scientific veneer to this fictional and overstated  
12 concept. The Policy defines “pseudoaddiction” as “[t]he iatrogenic syndrome resulting from the  
13 misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are  
14 commonly seen with addiction” and states that these behaviors “resolve upon institution of  
15 effective analgesic therapy.”<sup>67</sup>  
16

17           125. In May 2012, Senate Finance Committee Chairman Max Baucus and senior  
18 Committee member Chuck Grassley initiated an investigation into the connections of Defendants  
19 with medical groups and physicians who have advocated increased opioid use.<sup>68</sup> In addition to  
20 the three manufacturers, the senators sent letters to APF, APS, AAPM, FSMB, the University of  
21 Wisconsin Pain & Policy Studies Group, the Joint Commission on Accreditation of Healthcare  
22 Organization, and the Center for Practical Bioethics, requesting from each “a detailed account of  
23 all payments/transfers received from corporations and any related corporate entities and  
24

25 \_\_\_\_\_  
26 <sup>67</sup> *Id.*

<sup>68</sup> *Baucus, Grassley Seek Answers about Opioid Manufacturers’ Ties to Medical Groups*, United States Senate Committee on Finance (May 8, 2012), <https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medical-groups>.

1 individuals that develop, manufacture, produce, market, or promote the use of opioid-based  
2 drugs from 1997 to the present.”<sup>69</sup>

3 126. On the same day as the senators’ investigation began, APF announced that it  
4 would “cease to exist, effective immediately.”<sup>70</sup>

5  
6 **3. “It was pseudoscience”: Defendants paid prominent physicians to promote  
7 their products.**

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

14 128. Defendants also identified doctors to serve as speakers or attend all-expense-paid  
15 trips to programs with speakers.<sup>71</sup> Defendants used these trips and programs—many of them  
16 lavish affairs—to incentivize the use of opioids while downplaying their risks, bombarding  
17 doctors with messages about the safety and efficacy of opioids for treating long-term pain.  
18 Although often couched in scientific certainty, Defendants’ messages were false and misleading,  
19 and helped to ensure that millions of Americans would be exposed to the profound risks of these  
20 drugs.  
21

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<sup>69</sup> Letter from United States Senate Committee on Finance to American Pain Foundation (May 8, 2012),  
25 <https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Foundation2.pdf>.

26 <sup>70</sup> 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>.

<sup>71</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 55.

1 129. It is well documented that this type of pharmaceutical company symposium  
2 influences physicians' prescribing, even though physicians who attend such symposia believe  
3 that such enticements do not alter their prescribing patterns.<sup>72</sup> For example, doctors who were  
4 invited to these all-expenses-paid weekends in resort locations like Boca Raton, Florida, and  
5 Scottsdale, Arizona, wrote twice as many prescriptions as those who did not attend.<sup>73</sup>  
6

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

11 131. One of the most prominent KOLs for Defendants' opioids was Dr. Russell  
12 Portenoy. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential.  
13 Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described  
14 him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is  
15 Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs  
16 have been letting patients suffer; nobody really gets addicted; it's been studied.'"<sup>74</sup>  
17

18 132. As one organizer of CME seminars, who worked with Portenoy and Purdue,  
19 pointed out, "had Portenoy not had Purdue's money behind him, he would have published some  
20 papers, made some speeches, and his influence would have been minor. With Purdue's millions  
21 behind him, his message, which dovetailed with their marketing plans, was hugely magnified."<sup>75</sup>  
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23  
24

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25 <sup>72</sup> *Id.*

26 <sup>73</sup> Harriet Ryan, Lisa Girion and Scott Glover, *OxyContin goes global — "We're only just getting started"*, Los Angeles Times (Dec. 18, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part3/>.

<sup>74</sup> Quinones, *supra* note 37, at 314.

<sup>75</sup> *Id.* at 136.

1           133. In recent years, some of Defendants' KOLs have conceded that many of their past  
 2 claims in support of opioid use lacked evidence or support in the scientific literature.<sup>76</sup> Dr.  
 3 Portenoy himself specifically admitted that he overstated the drugs' benefits and glossed over  
 4 their risks, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that  
 5 weren't true."<sup>77</sup> He mused, "Did I teach about pain management, specifically about opioid  
 6 therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did .  
 7 . . We didn't know then what we know now."<sup>78</sup>

9           134. Dr. Portenoy did not need "the standards of 2012" to discern evidence-based  
 10 science from baseless claims, however. When interviewed by journalist Barry Meier for his 2003  
 11 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to  
 12 have always to live with that one."<sup>79</sup>

14           135. Dr. Portenoy was perhaps the most prominent KOL for prescription opioids, but  
 15 he was far from the only one. In fact, Dr. Portenoy and a doctor named Perry Fine co-wrote *A*  
 16 *Clinical Guide to Opioid Analgesia*, which contained statements that conflict with the CDC's  
 17 2016 findings, such as the following examples regarding respiratory depression and addiction:

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

21           Overall, the literature provides evidence that the outcomes of drug abuse and  
 22 addiction are rare among patients who receive opioids for a short period (ie, for  
 23

24 <sup>76</sup> See, e.g., John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012),  
 25 [http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-  
 139609053.html/](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).

26 <sup>77</sup> Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17,  
 2012, 11:36am), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

<sup>78</sup> *Id.*

<sup>79</sup> Meier, *supra* note 14, at 277.

1 acute pain) and among those with no history of abuse who receive long-term  
2 therapy for medical indications.<sup>80</sup>

3 136. Dr. Fine is a Professor of Anesthesiology at the University of Utah School of  
4 Medicine's Pain Research Center. He has served on Purdue's advisory board, provided medical  
5 legal consulting for Janssen, and participated in CME activities for Endo, along with serving in  
6 these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid  
7 Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that  
8 group from 2011 to 2013, and was also on the board of directors of APF.<sup>81</sup>

9  
10 137. In 2011, he and Dr. Scott Fishman, discussed below, published a letter in *JAMA*  
11 called "Reducing Opioid Abuse and Diversion," which emphasized the importance of  
12 maintaining patient access to opioids.<sup>82</sup> The editors of *JAMA* found that both doctors had  
13 provided incomplete financial disclosures and made them submit corrections listing all of their  
14 ties to the prescription painkiller industry.<sup>83</sup>

15 138. Dr. Fine also failed to provide full disclosures as required by his employer, the  
16 University of Utah. For example, Dr. Fine told the university that he had received under \$5,000  
17 in 2010 from Johnson & Johnson for providing "educational" services, but Johnson & Johnson's  
18 website states that the company paid him \$32,017 for consulting, promotional talks, meals and  
19 travel that year.<sup>84</sup>

20  
21  
22  
23 <sup>80</sup> 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>.

24 <sup>81</sup> Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*,  
306 (13) *JAMA* 1445 (Sept. 20, 2011), [https://jamanetwork.com/journals/jama/article-  
25 abstract/1104464?redirect=true](https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true).

26 <sup>82</sup> 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>.

<sup>83</sup> *Incomplete Financial Disclosures in: Reducing Opioid Abuse and Diversion*, 306 (13) *JAMA* 1446 (Oct. 5,  
2011), <https://jamanetwork.com/journals/jama/fullarticle/1104453>.

<sup>84</sup> Weber and Ornstein, *supra* note 61.

1           139. In 2012, along with other KOLs, Dr. Fine was investigated for his ties to drug  
2 companies as part of the Senate investigation of front groups described above. When Marianne  
3 Skolek, a reporter for the online news outlet Salem-News.com and a critic of opioid overuse,  
4 wrote an article about him and another KOL being investigated, Dr. Fine fired back, sending a  
5 letter to her editor accusing her of poor journalism and saying that she had lost whatever  
6 credibility she may have had. He criticized her for linking him to Purdue, writing, “I have never  
7 had anything to do with Oxycontin development, sales, marketing or promotion; I have never  
8 been a Purdue Pharma speaker”—neglecting to mention, of course, that he served on Purdue’s  
9 advisory board, as the *JAMA* editors had previously forced him to disclose.<sup>85</sup>

11           140. Another Utah physician, Dr. Lynn Webster, was the director of Lifetree Clinical  
12 Research & Pain Clinic in Salt Lake City from 1990 to 2010, and in 2013 was the president of  
13 AAPM (one of the front groups discussed above). Dr. Webster developed a five-question survey  
14 he called the Opioid Risk Tool, which he asserted would “predict accurately which individuals  
15 may develop aberrant behaviors when prescribed opioids for chronic pain.”<sup>86</sup> He published  
16 books titled *The Painful Truth: What Chronic Pain Is Really Like and Why It Matters to Each of*  
17 *Us* and *Avoiding Opioid Abuse While Managing Pain*.

19           141. Dr. Webster and the Lifetree Clinic were investigated by the DEA for  
20 overprescribing opioids after twenty patients died from overdoses. In keeping with the opioid  
21 industry’s promotional messages, Dr. Webster apparently believed the solution to patients’  
22 tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.  
23 Tina Webb, a Lifetree patient who overdosed in 2007, was taking as many as thirty-two pain  
24

25 \_\_\_\_\_  
26 <sup>85</sup> 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-fole-ms.php>.

<sup>86</sup> 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>.

1 pills a day in the year before she died, all while under doctor supervision.<sup>87</sup> Carol Ann Bosley,  
2 who sought treatment for pain at Lifetree after a serious car accident and multiple spine  
3 surgeries, quickly became addicted to opioids and was prescribed increasing quantities of pills; at  
4 the time of her death, she was on seven different medications totaling approximately 600 pills a  
5 month.<sup>88</sup> Another woman, who sought treatment from Lifetree for chronic low back pain and  
6 headaches, died at age forty-two after Lifetree clinicians increased her prescriptions to fourteen  
7 different drugs, including multiple opioids, for a total of 1,158 pills a month.<sup>89</sup>

9 142. By these numbers, Lifetree resembles the pill mills and “bad actors” that  
10 Defendants blame for opioid overuse. But Dr. Webster was an integral part of Defendants’  
11 marketing campaigns, a respected pain specialist who authored numerous CMEs sponsored by  
12 Endo and Purdue. And Defendants promoted his Opioid Risk Tool and similar screening  
13 questionnaires as measures that allow powerful opioids to be prescribed for chronic pain.  
14

15 143. Even in the face of patients’ deaths, Dr. Webster continues to promote a pro-  
16 opioid agenda, even asserting that alternatives to opioids are risky because “[i]t’s not hard to  
17 overdose on NSAIDs or acetaminophen.”<sup>90</sup> He argued on his website in 2015 that DEA  
18 restrictions on the accessibility of hydrocodone harm patients, and in 2017 tweeted in response to  
19  
20  
21  
22

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23 <sup>87</sup> Jesse Hyde and Daphne Chen, *The untold story of how Utah doctors and Big Pharma helped drive the national*  
24 *opioid epidemic*, Deseret News (Oct. 26, 2017, 12:01am), <https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html>.

25 <sup>88</sup> 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>.

26 <sup>89</sup> *Id.*

<sup>90</sup> *APF releases opioid medication safety module*, Drug Topics (May 10, 2011),  
<http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-news/apf-releases-opioid-medication-safety-module>.

1 CVS Caremark’s announcement that it will limit opioid prescriptions that “CVS Caremark’s new  
2 opioid policy is wrong, and it won’t stop illegal drugs.”<sup>91</sup>

3 144. Another prominent KOL is Dr. Scott M. Fishman, the Chief of the Department of  
4 Pain Medicine at University of California, Davis. He has served as president of APF and AAPM,  
5 and a consultant and a speaker for Purdue, in addition to providing the company grant and  
6 research support. He also has had financial relationships with Endo and Janssen. He wrote a  
7 book for the FSMB called *Responsible Opioid Use: A Physician’s Guide*, which was distributed  
8 to over 165,000 physicians in the U.S.  
9

10 145. Dr. Fishman and Dr. Fine, along with Dr. Seddon Savage, published an editorial  
11 in the Seattle Times in 2010, arguing that Washington legislation proposed to combat  
12 prescription opioid abuse would harm patients, in particular by requiring chronic pain patients to  
13 consult with a pain specialist before receiving a prescription for a moderate to high dose of an  
14 opioid.<sup>92</sup>  
15

16 146. These KOLs and others—respected specialists in pain medicine—proved to be  
17 highly effective spokespeople for Defendants.  
18

19 **4. Defendants used “unbranded” advertising as a platform for their  
20 misrepresentations about opioids.**

21 147. Defendants also aggressively promoted opioids through “unbranded advertising”  
22 to generally tout the benefits of opioids without specifically naming a particular brand of opioid.  
23 A trick often used by pharmaceutical companies, unbranded marketing is not typically reviewed  
24 by the FDA, giving the pharmaceutical companies considerable leeway to make sweeping claims  
25

26 <sup>91</sup> @LynnRWebsterMD, Twitter (Dec. 7, 2017, 1:45pm),  
<https://twitter.com/LynnRWebsterMD/status/938887130545360898>.

<sup>92</sup> Perry G. Fine, Scott M. Fishman, and Seddon R. Savage, *Bill to combat prescription abuse really will harm patients in pain*, The Seattle Times (Mar. 16, 2010, 4:39pm),  
[http://old.seattletimes.com/html/opinion/2011361572\\_guest17fine.html](http://old.seattletimes.com/html/opinion/2011361572_guest17fine.html).

1 about types of drugs. Conversely, branded marketing, which identifies and promotes a specific  
2 drug, is subject to FDA review for consistency with the drug's label and adequate presentation of  
3 risk and benefits.

4 148. By engaging in unbranded advertising, Defendants were and are able to avoid  
5 FDA review and issue general statements to the public including that opioids improve function,  
6 that addiction usually does not occur, and that withdrawal can easily be managed.  
7

8 149. Through the various marketing channels described above—all of which  
9 Defendants controlled, funded, and facilitated, and for which they are legally responsible—  
10 Defendants made false or misleading statements about opioids despite the lack of scientific  
11 evidence to support their claims, while omitting the true risk of addiction and death.  
12

13 **D. Specific Misrepresentations Made by Defendants.**

14 150. All Defendants have made and/or continue to make false or misleading claims in  
15 the following areas: (1) the low risk of addiction to opioids, (2) opioids' efficacy for chronic pain  
16 and ability to improve patients' quality of life with long-term use, (3) the lack of risk associated  
17 with higher dosages of opioids, (4) the need to prescribe more opioids to treat withdrawal  
18 symptoms, and (5) that risk-mitigation strategies and abuse-deterrent technologies allow doctors  
19 to safely prescribe opioids for chronic use. These illustrative but non-exhaustive categories of  
20 Defendants' misrepresentations about opioids are described in detail below.  
21

22 **1. Defendants falsely claimed that the risk of opioid abuse and addiction was low.**

23 151. Collectively, Defendants have made a series of false and misleading statements  
24 about the low risk of addiction to opioids over the past twenty years. Defendants have also failed  
25 to take sufficient remedial measures to correct its false and misleading statements.  
26

1           152. Defendants knew that many physicians were hesitant to prescribe opioids other  
2 than for acute or cancer-related pain because of concerns about addiction. Because of this  
3 general perception, sales messaging about the low risk of addiction was a fundamental  
4 prerequisite misrepresentation.

5  
6           153. Purdue launched OxyContin in 1996 with the statement that OxyContin's  
7 patented continuous-release mechanism "is believed to reduce the abuse liability." This  
8 statement, which appeared in OxyContin's label and which sales representatives were taught to  
9 repeat verbatim, was unsupported by any studies, and was patently false. The continuous-release  
10 mechanism was simple to override, and the drug correspondingly easy to abuse. This fact was  
11 known, or should have been known, to Purdue prior to its launch of OxyContin, because people  
12 had been circumventing the same continuous-release mechanism for years with MS Contin,  
13 which in fact commanded a high street price because of the dose of pure narcotic it delivered. In  
14 addition, with respect to OxyContin, Purdue researchers notified company executives, including  
15 Raymond and Richard Sackler, by email that patients in their clinical trials were abusing the drug  
16 despite the timed-release mechanism.<sup>93</sup>

17  
18           154. In 2007, as noted above, Purdue pleaded guilty to misbranding a drug, a felony  
19 under the Food, Drug, and Cosmetic Act. 21 U.S.C. § 331(a)(2). As part of its guilty plea,  
20 Purdue agreed that certain Purdue supervisors and employees had, "with the intent to defraud or  
21 mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and  
22 diversion, and less likely to cause tolerance and withdrawal than other pain medications" in the  
23 following ways:

24  
25           Trained PURDUE sales representatives and told some health care providers that it  
26           was more difficult to extract the oxycodone from an OxyContin tablet for the

---

<sup>93</sup> WBUR On Point interview, *supra* note 19.

1 purpose of intravenous abuse, although PURDUE’s own study showed that a drug  
2 abuser could extract approximately 68% of the oxycodone from a single 10mg  
3 OxyContin tablet by crushing the tablet, stirring it in water, and drawing the  
4 solution through cotton into a syringe;

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

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

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

14 Told certain health care providers that OxyContin did not cause a “buzz” or  
15 euphoria, caused less euphoria, had less addiction potential, had less abuse  
16 potential, was less likely to be diverted than immediate-release opioids, and could  
17 be used to “weed out” addicts and drug seekers.<sup>94</sup>

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

25 156. When it launched OxyContin, Purdue knew it would need data to overcome  
26 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 other Defendants)

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<sup>94</sup> *U.S. v. The Purdue Frederick Company, Inc., et al.*, *supra* note 23. *See also*, Plea Agreement, *U.S. v. The Purdue Frederick Company, Inc., et al.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

1 found this “research” in the form of a one-paragraph letter to the editor published in the *New*  
 2 *England Journal of Medicine* (NEJM) in 1980.

3 157. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of  
 4 addiction “rare” for patients treated with opioids.<sup>95</sup> They had analyzed a database of hospitalized  
 5 patients who were given opioids in a controlled setting to ease suffering from acute pain. These  
 6 patients were not given long-term opioid prescriptions or provided opioids to administer to  
 7 themselves at home, nor was it known how frequently or infrequently and in what doses the  
 8 patients were given their narcotics. Rather, it appears the patients were treated with opioids for  
 9 short periods of time under in-hospital doctor supervision.  
 10

11  
 12 **ADDICTION RARE IN PATIENTS TREATED  
 WITH NARCOTICS**

13 *To the Editor:* Recently, we examined our current files to deter-  
 14 mine the incidence of narcotic addiction in 39,946 hospitalized  
 15 medical patients<sup>1</sup> who were monitored consecutively. Although  
 16 there were 11,882 patients who received at least one narcotic pre-  
 17 paration, there were only four cases of reasonably well documented  
 addiction in patients who had no history of addiction. The addic-  
 tion was considered major in only one instance. The drugs im-  
 18 plicated were meperidine in two patients,<sup>2</sup> Percodan in one, and  
 hydromorphone in one. We conclude that despite widespread use of  
 narcotic drugs in hospitals, the development of addiction is rare in  
 19 medical patients with no history of addiction.

20 JANE PORTER  
 21 HERSHEL JICK, M.D.  
 Boston Collaborative Drug  
 Surveillance Program  
 22 Waltham, MA 02154 Boston University Medical Center

- 23 1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D.  
 Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.  
 24 2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical  
 25 patients. *J Clin Pharmacol*. 1978; 18:180-8.  
 26

27 158. As Dr. Jick explained to a journalist years later, he submitted the statistics to  
 28 NEJM as a letter because the data were not robust enough to be published as a study, and that

<sup>95</sup> Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *N Engl J Med*. 123  
 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

1 one could not conclude anything about long-term use of opioids from his figures.<sup>96</sup> Dr. Jick also  
2 recalled that no one from drug companies or patient advocacy groups contacted him for more  
3 information about the data.<sup>97</sup>

4  
5 159. Nonetheless, Defendants regularly invoked this letter as proof of the low  
6 addiction risk in connection with taking opioids despite its obvious shortcomings. Defendants'  
7 egregious misrepresentations based on this letter included claims that *less than one percent* of  
8 opioid users become addicted.

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

14  
15 [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and  
16 uncritically cited as evidence that addiction was rare with long-term opioid therapy. We  
17 believe that this citation pattern contributed to the North American opioid crisis by  
18 helping to shape a narrative that allayed prescribers' concerns about the risk of addiction  
19 associated with long-term opioid therapy . . .<sup>98</sup>

20 161. Unfortunately, by the time of this analysis and the CDC's findings in 2016, the  
21 damage had already been done. "It's difficult to overstate the role of this letter," said Dr. David  
22 Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that  
23 helped the opiate manufacturers convince front-line doctors that addiction is not a concern."<sup>99</sup>

24 <sup>96</sup> Meier, *supra* note 14, at 174.

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

26 <sup>98</sup> 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>.

<sup>99</sup> *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017),  
<https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

1 162. Defendants successfully manipulated the 1980 Porter and Jick letter as the  
2 “evidence” supporting their fundamental misrepresentation that the risk of opioid addiction was  
3 low when opioids were prescribed to treat pain. For example, in its 1996 press release  
4 announcing the release of OxyContin, Purdue advertised that the “fear of addiction is  
5 exaggerated” and quoted the chairman of the American Pain Society Quality of Care Committee,  
6 who claimed that “there is very little risk of addiction from the proper uses of these [opioid]  
7 drugs for pain relief.”<sup>100</sup>

8  
9 PR Newswire

10  
11 **May** 31, 1996, Friday - 15:47 Eastern Time

12 **NEW HOPE FOR MILLIONS OF AMERICANS SUFFERING FROM**  
13 **PERSISTENT**

14 **The fear of addiction is exaggerated.**

15 One cause of patient resistance to appropriate pain treatment – the  
16 fear of addiction – is largely unfounded. According to Dr. Max,  
17 “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.”

18 Paul D. Goldenheim, M.D., Vice President of **Purdue Pharma** L.P. in  
19 Norwalk, Connecticut, agrees with this assessment. “Proper use of  
20 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.”

21 163. Dr. Portenoy, the Purdue KOL mentioned previously, also stated in a promotional  
22 video from the 1990s that “the likelihood that the treatment of pain using an opioid drug which is  
23 prescribed by a doctor will lead to addiction is extremely low.”<sup>101</sup>

24  
25  
26 <sup>100</sup> Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting  
OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm),  
<http://documents.latimes.com/oxycontin-press-release-1996/>.

<sup>101</sup> Catan and Perez, *supra* note 77.



10 164. Purdue also specifically used the Porter and Jick letter in its 1998 promotional  
11 video “I got my life back,” in which Dr. Alan Spanos says “In fact, the rate of addiction amongst  
12 pain patients who are treated by doctors *is much less than 1%*.”<sup>102</sup>



22 165. The Porter and Jick letter was also used on Purdue’s “Partners Against Pain”  
23 website, which was available in the early 2000s, where Purdue claimed that the addiction risk  
24 with OxyContin was very low.<sup>103</sup>

25  
26  

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<sup>102</sup> Our Amazing World, *Purdue Pharma OxyContin Commercial*, <https://www.youtube.com/watch?v=Er78Dj5hyeI>  
(last visited Jan. 31, 2018) (emphasis added).

<sup>103</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 55.

1 166. The Porter and Jick letter was used frequently in literature given to prescribing  
2 physicians and to patients who were prescribed OxyContin.<sup>104</sup>

3 167. In addition to the Porter and Jick letter, Defendants exaggerated the significance  
4 of a study published in 1986 regarding cancer patients treated with opioids. Conducted by Dr.  
5 Portenoy and another pain specialist, Dr. Kathleen Foley, the study involved only 38 patients,  
6 who were treated for non-malignant cancer pain with low doses of opioids (the majority were  
7 given less than 20 MME/day, the equivalent of only 13 mg of oxycodone).<sup>105</sup> Of these 38  
8 patients, only two developed problems with opioid abuse, and Dr. Portenoy and Dr. Foley  
9 concluded that “opioid maintenance therapy can be a safe, salutary and more humane alternative  
10 to the options of surgery or no treatment in those patients with intractable non-malignant pain  
11 and no history of drug abuse . . .”<sup>106</sup> Notwithstanding the small sample size, low doses of opioids  
12 involved, and the fact that all the patients were cancer patients, Defendants used this study as  
13 “evidence” that high doses of opioids were safe for the treatment of chronic non-cancer pain.  
14

15 168. Defendants’ repeated misrepresentations about the low risk of opioid addiction  
16 were so effective that this concept became part of the conventional wisdom. Dr. Nathaniel Katz,  
17 a pain specialist, recalls learning in medical school that previous fears about addiction were  
18 misguided, and that doctors should feel free to allow their patients the pain relief that opioids can  
19 provide. He did not question this until one of his patients died from an overdose. Then, he  
20 searched the medical literature for evidence of the safety and efficacy of opioid treatment for  
21 chronic pain. “There’s not a shred of research on the issue. All these so-called experts in pain are  
22  
23  
24

25 <sup>104</sup> Art Van Zee, M.D., *The OxyContin Abuse Problem: Spotlight on Purdue Pharma’s Marketing* (Aug. 22, 2001),  
26 <https://web.archive.org/web/20170212210143/https://www.fda.gov/ohrms/dockets/dockets/01n0256/c000297-A.pdf>.

<sup>105</sup> 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>.

<sup>106</sup> *Id.*

1 dedicated and have been training me that opioids aren't as addictive as we thought. But what is  
2 that based on? It was based on nothing."<sup>107</sup>

3 169. At a hearing before the House of Representatives' Subcommittee on Oversight  
4 and Investigations of the Committee on Energy and Commerce in August 2001, Purdue  
5 continued to emphasize "legitimate" treatment, dismissing cases of overdose and death as  
6 something that would not befall "legitimate" patients: "Virtually all of these reports involve  
7 people who are abusing the medication, not patients with legitimate medical needs under the  
8 treatment of a healthcare professional."<sup>108</sup>

10 170. Purdue spun this baseless "legitimate use" distinction out even further in a patient  
11 brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a  
12 Partner Against Pain." In response to the question, "Aren't opioid pain medications like  
13 OxyContin Tablets 'addicting'? Even my family is concerned about this," Purdue claimed that  
14 there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:  
15

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

19 171. Similarly, Dr. David Haddox, Senior Medical Director for Purdue, cavalierly  
20 stated, "[w]hen this medicine is used appropriately to treat pain under a doctor's care, it is not  
21 only effective, it is safe."<sup>109</sup> He went so far as to compare OxyContin to celery, because even  
22 celery would be harmful if injected: "If I gave you a stalk of celery and you ate that, it would be  
23

24  
25 <sup>107</sup> Quinones, *supra* note 37, at 188-89.

26 <sup>108</sup> *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/html/CHRG-107hhrg75754.htm>.

<sup>109</sup> Roger Alford, *Deadly OxyContin abuse expected to spread in the U.S.*, *Charleston Gazette*, Feb. 9, 2001.

1 healthy for you. But if you put it in a blender and tried to shoot it into your veins, it would not be  
2 good.”<sup>110</sup>

3 172. Purdue sales representatives also repeated these misstatements regarding the low  
4 risk for addiction to doctors across the country.<sup>111</sup> Its sales representatives targeted primary care  
5 physicians in particular, downplaying the risk of addiction and, as one doctor observed,  
6 “promot[ing] among primary care physicians a more liberal use of opioids.”<sup>112</sup>

7 173. Purdue sales representatives were instructed to “distinguish between iatrogenic  
8 addiction (<1% of patients) and substance abusers/diversion (about 10 percent of the population  
9 abuse something: weed; cocaine; heroin; alcohol; valium; etc.).”<sup>113</sup>

10 174. Purdue also marketed OxyContin for a wide variety of conditions and to doctors  
11 who were not adequately trained in pain management.<sup>114</sup>

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

14  
15  
16 Concerns about abuse, addiction, and diversion should not prevent the proper management of pain.  
17 The development of addiction to opioid analgesics in properly managed patients with pain has been  
18 reported to be rare. However, data are not available to establish the true incidence of addiction in  
19 chronic pain patients.

20 176. Although Purdue has acknowledged it has made some misrepresentations about  
21 the safety of its opioids,<sup>115</sup> it has done nothing to address the ongoing harms of their  
22 misrepresentations; in fact, it continues to make those misrepresentations today.

23 <sup>110</sup> *Id.*

24 <sup>111</sup> Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, *The New York Times* (May 10, 2007),  
<http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

25 <sup>112</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 55.

26 <sup>113</sup> Meier, *supra* note 14, at 269.

<sup>114</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 28.

<sup>115</sup> 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

1 177. Defendant Endo also made dubious claims about the low risk of addiction. For  
 2 instance, it sponsored a website, PainKnowledge.com, on which in 2009 it claimed that “[p]eople  
 3 who take opioids as prescribed usually do not become addicted.”<sup>116</sup> The website has since been  
 4 taken down.

5 178. In another website, PainAction.com—which is still currently available today—  
 6 Endo also claimed that “most chronic pain patients do not become addicted to the opioid  
 7 medications that are prescribed for them.”<sup>117</sup>

8 179. In a pamphlet titled “Understanding Your Pain: Taking Oral Opioid Analgesics,”  
 9 Endo assured patients that addiction is something that happens to people who take opioids for  
 10 reasons other than pain relief, “such as unbearable emotional problems”<sup>118</sup>:  
 11

12 Some questions you may have are:

13 *Is it wrong to take opioids for pain?*

- 14 ♦ No. Pain relief is an important medical  
 15 reason to take opioids as prescribed  
 16 by your doctor. Addicts take opioids  
 17 for other reasons, such as unbearable  
 18 emotional problems. Taking opioids as  
 19 prescribed for pain relief is not addiction.

20  
 21  
 22  
 23 were inconsistent with the F.D.A.-approved prescribing information for OxyContin and the express warnings it  
 24 contained about risks associated with the medicine. The statements also violated written company policies  
 25 requiring adherence to the prescribing information.”

25 <sup>116</sup> German Lopez, *US officials are starting to treat opioid companies like Big Tobacco—and suing them*, Vox  
 26 (Aug. 9, 2017, 3:53pm), <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits>.

<sup>117</sup> *Opioid medication and addiction*, Pain Action (Aug. 17, 2017), <https://www.painaction.com/opioid-medication-addiction/>.

<sup>118</sup> *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004),  
[http://www.thblack.com/links/RSD/Understand\\_Pain\\_Opioid\\_Analgesics.pdf](http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf).

1 *How can I be sure I'm not addicted?*

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

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

16 181. In its currently active website, PrescribeResponsibly.com, Defendant Janssen  
17 states that concerns about opioid addiction are “overestimated” and that “true addiction occurs  
18 only in a small percentage of patients.”<sup>119</sup>

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<sup>119</sup> Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly,  
<http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

# 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.<sup>15,16</sup> By the same token, patients report similar concerns about developing an addiction to opioid analgesics.<sup>17</sup> 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 analgesic therapy.<sup>18</sup>



182. 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.<sup>120</sup>

<sup>120</sup> Molly Huff, *Finding Relief: Pain Management for Older Adults*, Centers for Pain Management (Mar. 9, 2011), <http://www.managepaintoday.com/news/-Finding-Relief-Pain-Management-for-Older-Adults>.

1 183. Janssen also approved and distributed a patient education guide in 2009 that  
2 attempted to counter the “myth” that opioids are addictive, claiming that “[m]any studies show  
3 that opioids are rarely addictive when used properly for the management of chronic pain.”<sup>121</sup>

4 184. In addition, all three Defendants used third parties and front groups to further their  
5 false and misleading statements about the safety of opioids.

6 185. For example, in testimony for the Hearing to Examine the Effects of the Painkiller  
7 OxyContin, Focusing on Risks and Benefits, in front of the Senate Health, Education, Labor and  
8 Pensions Committee in February 2002, Dr. John D. Giglio, Executive Director of the APF, the  
9 organization which, as described above, received the majority of its funding from opioid  
10 manufacturers, including Purdue, stated that “opioids are safe and effective, and only in rare  
11 cases lead to addiction.”<sup>122</sup> Along with Dr. Giglio’s testimony, the APF submitted a short  
12 background sheet on “the scope of the undertreatment of pain in the U.S.,” which asserted that  
13 “opioids are often the best” treatment for pain that hasn’t responded to other techniques, but that  
14 patients and many doctors “lack even basic knowledge about these options and fear that powerful  
15 pain drugs will [c]ause addiction.” According to the APF, “most studies show that less than 1%  
16 of patients become addicted, which is medically different from becoming physically  
17 dependent.”<sup>123</sup>

18 186. The APF further backed up Purdue in an amicus curiae brief filed in an Ohio  
19 appeals court in December 2002, in which it claimed that “medical leaders have come to  
20  
21  
22  
23  
24

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25 <sup>121</sup> Lopez, *supra* note 116.

26 <sup>122</sup> *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>.

<sup>123</sup> *Id.*

1 understand that the small risk of abuse does not justify the withholding of these highly effective  
2 analgesics from chronic pain patients.”<sup>124</sup>

3 187. In a 2007 publication titled “Treatment Options: A Guide for People Living with  
4 Pain,” APF downplayed the risk of addiction and argued that concern about this risk should not  
5 prevent people from taking opioids: “Restricting access to the most effective medications for  
6 treating pain is not the solution to drug abuse or addiction.”<sup>125</sup> APF also tried to normalize the  
7 dangers of opioids by listing opioids as one of several “[c]ommon drugs that can cause physical  
8 dependence,” including steroids, certain heart medications, and caffeine.<sup>126</sup>

9  
10 188. Defendants’ repeated statements about the low risk of addiction when taking  
11 opioids as prescribed for chronic pain were blatantly false and were made with reckless disregard  
12 for the potential consequences.

13  
14 **2. Defendants falsely claimed that opioids were proven effective for chronic  
15 pain and would improve quality of life.**

16 189. Not only did Defendants falsely claim that the risk of addiction to prescription  
17 opioids was low, Defendants represented that there was a significant upside to long-term opioid  
18 use, including that opioids could restore function and improve quality of life.<sup>127</sup>

19 190. Such claims were viewed as a critical part of Defendants’ marketing strategies.  
20 An internal Purdue report from 2001 noted the lack of data supporting improvement in quality of  
21 life with OxyContin treatment:

22  
23  
24 <sup>124</sup> Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio  
25 Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA  
26 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>.

<sup>125</sup> *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation,  
<https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last visited Jan. 31, 2018).

<sup>126</sup> *Id.*

<sup>127</sup> 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.

1 Janssen has been stressing decreased side effects, especially constipation, as well  
2 as patient quality of life, as supported by patient rating compared to sustained  
3 release morphine... We do not have such data to support OxyContin promotion. . .  
4 . In addition, Janssen has been using the “life uninterrupted” message in  
5 promotion of Duragesic for non-cancer pain, stressing that Duragesic “helps  
6 patients think less about their pain.” This is a competitive advantage based on our  
7 inability to make any quality of life claims.<sup>128</sup>

8 191. Despite the lack of data supporting improvement in quality of life, Purdue ran a  
9 full-page ad for OxyContin in the Journal of the American Medical Association in 2002,  
10 proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside  
11 his grandson.<sup>129</sup> This ad earned a warning letter from the FDA, which admonished, “It is  
12 particularly disturbing that your November ad would tout ‘Life With Relief’ yet fail to warn that  
13 patients can die from taking OxyContin.”<sup>130</sup>

14 192. Purdue also consistently tried to steer any concern away from addiction, and focus  
15 on its false claims that opioids were effective and safe for dealing with chronic pain. At a hearing  
16 before the House of Representatives’ Subcommittee on Oversight and Investigations of the  
17 Committee on Energy and Commerce in August 2001, Michael Friedman, Executive Vice  
18 President and Chief Operating Officer of Purdue, testified that “even the most vocal critics of  
19 opioid therapy concede the value of OxyContin in the legitimate treatment of pain,” and that  
20 “OxyContin has proven itself an effective weapon in the fight against pain, returning many  
21 patients to their families, to their work, and to their ability to enjoy life.”<sup>131</sup>

22 193. Purdue sponsored the development and distribution of an APF guide in 2011  
23 which claimed that “multiple clinical studies have shown that opioids are effective in improving  
24

25 <sup>128</sup> Meier, *supra* note 14, at 281.

26 <sup>129</sup> *Id.* at 280.

<sup>130</sup> Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, The Wall Street Journal (Jan. 23, 2003, 12:01am), <https://www.wsj.com/articles/SB1043259665976915824>.

<sup>131</sup> *Oxycontin: Its Use and Abuse*, *supra* note 108.

1 daily function, psychological health, and health-related quality of life for chronic pain patients.”

2 This guide is still available today.

3 194. Purdue also ran a series of advertisements of OxyContin in 2012 in medical  
4 journals titled “Pain vignettes,” which were styled as case studies of patients with persistent pain  
5 conditions and for whom OxyContin was recommended to improve their function.  
6

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

10 196. Endo’s advertisements for Opana ER claimed that use of the drug for chronic pain  
11 allowed patients to perform demanding tasks like construction and portrayed Opana ER users as  
12 healthy and unimpaired.  
13

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

18 198. Endo further sponsored a series of CME programs through NIPC which claimed  
19 that chronic opioid therapy has been “shown to reduce pain and depressive symptoms and  
20 cognitive functioning.”  
21

22 199. Through PainKnowledge.org, Endo also supported and sponsored guidelines that  
23 stated, among other things, that “Opioid Medications are a powerful and often highly effective  
24 tool in treating pain,” and that “they can help restore comfort, function, and quality of life.”<sup>132</sup>  
25

26  

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<sup>132</sup>*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](https://www.mainequalitycounts.org/image_upload/Opioid%20Informed%20Consent%20Formatted_1_23_2008.pdf).

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

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

8           202. Furthermore, sales representatives for Purdue, Endo, and Janssen communicated  
9 and continue to communicate the message that opioids will improve patients’ function, without  
10 appropriate disclaimers.

11           203. Defendants’ statements regarding opioids’ ability to improve function and quality  
12 of life are false and misleading. As the CDC’s 2016 Guidelines confirm, not a single study  
13 supports these claims.

14           204. In fact, to date, there have been no long-term studies that demonstrate that opioids  
15 are effective for treating long-term or chronic pain. Instead, reliable sources of information,  
16 including from the CDC in 2016, indicate that there is “[n]o evidence” to show “a long-term  
17 benefit of opioids in pain and function versus no opioids for chronic pain.”<sup>133</sup> By contrast,  
18 significant research has demonstrated the colossal dangers of opioids. The CDC, for example,  
19 concluded that “[e]xtensive evidence shows the possible harms of opioids (including opioid use  
20 disorder, overdose, and motor vehicle injury)” and that “[o]pioid pain medication use presents  
21 serious risks, including overdose and opioid use disorder.”<sup>134</sup>  
22  
23  
24  
25  
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<sup>133</sup> Dowell, et al., *supra* note 29.

<sup>134</sup> *Id.*

1           **3. Defendants falsely claimed doctors and patients could increase opioid usage**  
2           **indefinitely without added risk.**

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

11           206. Twelve-hour dosing is a significant marketing advantage for any medication,  
12 because patient compliance is improved when a medication only needs to be taken twice a day.  
13 For prescription painkillers, the 12-hour dosing is even more significant because shorter-acting  
14 painkillers did not allow patients to get a full night's sleep before the medication wore off. A  
15 Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is  
16 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'"   
17 and further that "[t]he convenience of q12h dosing was emphasized as the most important  
18 benefit."<sup>135</sup>

19           207. Purdue executives therefore maintained the messaging of 12-hour dosing even  
20 when many reports surfaced that OxyContin did not last 12 hours. Instead of acknowledging a  
21 need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills.  
22

23           208. For example, in a 1996 sales strategy memo from a Purdue regional manager, the  
24 manager emphasized that representatives should "convinc[e] the physician that there is no need"  
25  
26

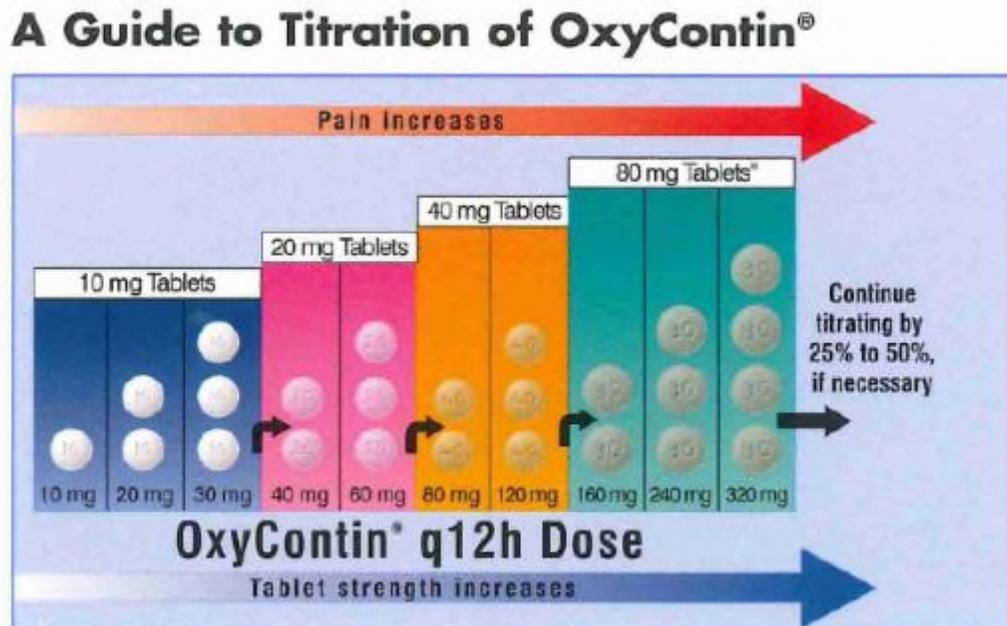
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<sup>135</sup> *OxyContin launch*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/oxycontin-launch-1995/>.

1 for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and  
 2 instead the solution is prescribing higher doses. The manager directed representatives to discuss  
 3 with physicians that there is “no[] upward limit” for dosing and ask “if there are any reservations  
 4 in using a dose of 240mg-320mg of OxyContin.”<sup>136</sup>

5  
 6 209. As doctors began prescribing OxyContin at shorter intervals in the late 1990s,  
 7 Purdue directed its sales representatives to “refocus” physicians on 12-hour dosing. One sales  
 8 manager instructed her team that anything shorter “needs to be nipped in the bud. NOW!!”<sup>137</sup>

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



26 <sup>136</sup> Sales manager on 12-hour dosing, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/sales-manager-on-12-hour-dosing-1996/>.

<sup>137</sup> Harriet Ryan, Lisa Girion, and Scott Glover, ‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

1           211. In a 2004 response letter to the FDA, Purdue tried to address concerns that  
2 patients who took OxyContin more frequently than 12 hours would be at greater risk of side  
3 effects or adverse reactions. Purdue contended that the peak plasma concentrations of oxycodone  
4 would not increase with more frequent dosing, and therefore no adjustments to the package  
5 labeling or 12-hour dosing regimen were needed.<sup>138</sup> But these claims were false, and Purdue’s  
6 suggestion that there was no upper limit or risk associated with increased dosage was incredibly  
7 misleading.  
8

9           212. Suggesting that it recognized the danger of its misrepresentations of no dose  
10 ceiling, Purdue discontinued the OxyContin 160 mg tablet in 2007 and stated that this step was  
11 taken “to reduce the risk of overdose accompanying the abuse of this dosage strength.”<sup>139</sup>  
12

13           213. But still Purdue and the other Defendants worked hard to protect their story. In  
14 March 2007, Dr. Gary Franklin, Medical Director for the Washington State Department of Labor  
15 & Industries, published the *Interagency Guideline on Opioid Dosing for Chronic Non-Cancer*  
16 *Pain*. Developed in collaboration with providers in Washington State who had extensive  
17 experience in the evaluation and treatment of patients with chronic pain, the guideline  
18 recommended a maximum daily dose of opioids to protect patients.  
19

20           214. In response, Purdue sent correspondence to Dr. Franklin specifically indicating,  
21 among other things, that “limiting access to opioids for persons with chronic pain is not the  
22 answer” and that the “safety and efficacy of OxyContin doses greater than 40 mg every 12 hours  
23 in patients with chronic nonmalignant pain” was well established. Purdue even went so far as to  
24

25 \_\_\_\_\_  
26 <sup>138</sup> *Purdue Response to FDA, 2004*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/purdue-response-fda-2004/>.

<sup>139</sup> *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).

1 represent to Dr. Franklin that even if opioid treatment produces significant adverse effects in a  
2 patient, “this does not preclude a trial of another opioid.”

3 215. In 2010, Purdue published a Risk Evaluation and Mitigation Strategy (“REMS”)  
4 for OxyContin, but even the REMS does not address concerns with increasing dosage, and  
5 instead advises prescribers that “dose adjustments may be made every 1-2 days”; “it is most  
6 appropriate to increase the q12h dose”; the “total daily dose can usually be increased by 25% to  
7 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under  
8 control, then resume upward titration.”<sup>140</sup>

9  
10 216. In 2012, APF claimed on its website that there was no “ceiling dose” for opioids  
11 for chronic pain.<sup>141</sup> APF also made this claim in a guide sponsored by Purdue, which is still  
12 available online.

13  
14 217. Accordingly, Purdue continued to represent both publicly and privately that  
15 increased opioid usage was safe and did not present additional risk at higher doses.

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

18 219. In the “Understanding Your Pain” pamphlet discussed above, Endo assures opioid  
19 users that concern about developing tolerance to the drugs’ pain-relieving effect is “not a  
20 problem,” and that “[t]he dose can be increased” and “[y]ou won’t ‘run out’ of pain relief.”<sup>142</sup>

21  
22  
23  
24 <sup>140</sup> *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P.,  
25 <https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf> (last modified Nov. 2010).

26 <sup>141</sup> Noah Nesin, M.D., FAAFP, *Responsible Opioid Prescribing*, PCHC  
[https://www.mainequalitycounts.org/image\\_upload/Keynote-%20Managing%20Chronic%20Pain%20and%20Opioids\\_Nesin.pdf](https://www.mainequalitycounts.org/image_upload/Keynote-%20Managing%20Chronic%20Pain%20and%20Opioids_Nesin.pdf) (last visited Jan. 31, 2018).

<sup>142</sup> *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004),  
[http://www.thblack.com/links/RSD/Understand\\_Pain\\_Opioid\\_Analgesics.pdf](http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf).

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**Understanding Your Pain**

**Taking Oral Opioid Analgesics**

This brochure was developed by  
Margo McCallery, 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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**How can the use of opioids be safe?**

- 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 the medicine if my pain went away? If your answer is no, you are taking opioids for the right reasons—to reduce 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?**

Some patients with chronic pain worry about this, but it is not a problem.

- The dose can be increased or other medications can be added.
- The opioid is not of your own.

**WHAT CAN I DO ABOUT SIDE EFFECTS?**

Talk to your doctor, nurse, or pharmacist about the side effects of opioids. If they occur, remember that most opioid side effects can be treated or prevented.

**Constipation**

- Graduation from opioids to any other drug, 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® suppositories or suppositories and Senokot® tablets. Ask your pharmacist about less expensive generic forms.

**Nausea or vomiting (sickness)**

- 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.
- Non-drug 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 drowsiness would be normal when you start taking an opioid, but after a few days the drowsiness usually goes away.

220. 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.

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

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

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

9 223. One way that Defendants worked to obstruct appropriate responses to opioid  
10 addiction was to push a concept called “pseudoaddiction.” Dr. David Haddox—who later  
11 became a Senior Medical Director for Purdue—published a study in 1989 coining the term,  
12 which he characterized as “the iatrogenic syndrome of abnormal behavior developing as a direct  
13 consequence of inadequate pain management.”<sup>143</sup> (“Iatrogenic” describes a condition induced by  
14 medical treatment.) In other words, he claimed that people on prescription opioids who exhibited  
15 classic signs of addiction—“abnormal behavior”—were not addicted, but rather simply suffering  
16 from under-treatment of their pain. His solution for pseudoaddiction? More opioids.

17 224. Although this concept was formed based on a single case study, it proved to be a  
18 favorite trope in the Defendants’ marketing schemes. For example, using this study, Purdue  
19 informed doctors and patients that signs of addiction are actually the signs of under-treated pain  
20 which should be treated with even more opioids. Purdue reassured doctors and patients, telling  
21 them that “chronic pain has been historically undertreated.”<sup>144</sup>  
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<sup>143</sup> 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>.

<sup>144</sup> *Oxycontin: Its Use and Abuse*, *supra* note 108.

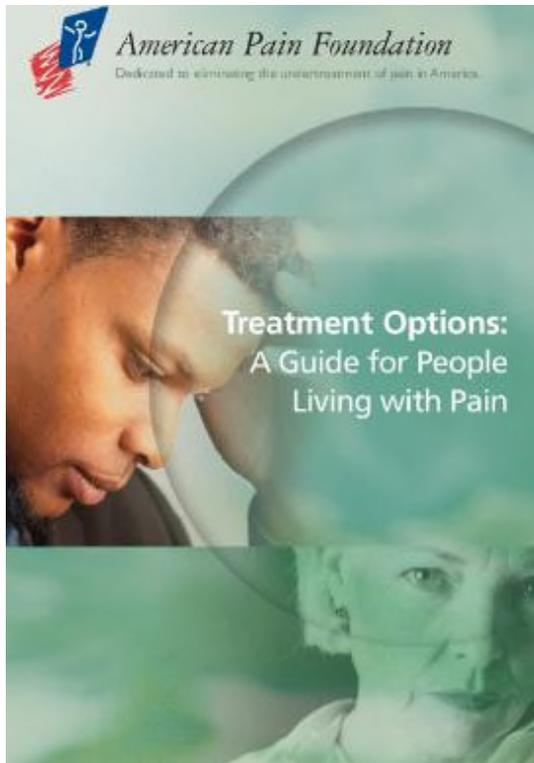
1           225. Defendants continued to spread the concept of pseudoaddiction through the APF,  
2 which even went so far as to compare opioid addicts to coffee drinkers. In a 2002 court filing,  
3 APF wrote that “[m]any pain patients (like daily coffee drinkers) claim they are ‘addicted’ when  
4 they experience withdrawal symptoms associated with physical dependence as they decrease  
5 their dose. But unlike actual addicts, such individuals, if they resume their opioid use, will only  
6 take enough medication to alleviate their pain . . .”<sup>145</sup>

8           226. In a 2007 publication titled “Treatment Options: A Guide for People Living with  
9 Pain,” the APF claimed: “*Physical dependence is normal*; any patient who is taking an opioid on  
10 a regular basis for a few days should be assumed to be physically dependent. This does **NOT**  
11 mean you are addicted.”<sup>146</sup> In this same publication, when describing behaviors of addiction, the  
12 APF again used the idea of pseudoaddiction, claiming that people who are not substance abusers  
13 may also engage in behaviors that mirror those of actual addicts.  
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<sup>145</sup> APF Brief Amici Curiae, *supra* note 124, at 10-11.

<sup>146</sup> *Treatment Options: A Guide for People Living with Pain*, *supra* note 125.



**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 concentrating. 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 long time 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.

227. 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.”<sup>147</sup>

228. 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.

229. 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.

<sup>147</sup> *OxyContin Risk Evaluation and Mitigation Strategy*, supra note 140.

1 230. A 2001 paper which was authored by a doctor affiliated with Janssen stated that  
2 “[m]any patients presenting to a doctor’s office asking for pain medications are accused of drug  
3 seeking. In reality, most of these patients may be undertreated for their pain syndrome.”<sup>148</sup>

4 231. In 2009, on a website it sponsored, Janssen stated that pseudoaddiction is different  
5 from true addiction “because such behaviors can be resolved with effective pain  
6 management.”<sup>149</sup>

7 232. Indeed, on its currently active website PrescribeResponsibly.com, Janssen defines  
8 pseudoaddiction as “a syndrome that causes patients to seek additional medications due to  
9 inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately,  
10 the inappropriate behavior ceases.”<sup>150</sup>

## 13 What a Prescriber Should 14 Know Before Writing the 15 First Prescription



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23 <sup>148</sup> 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),

24 <http://www.med.uottawa.ca/courses/totalpain/pdf/doc-34.pdf>.

25 <sup>149</sup> 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/](https://consumerist.com/2017/05/31/ohio-makers-of-oxycontin-percocet-other-opioids-helped-fuel-drug-epidemic-by-misleading-doctors-patients/).

26 <sup>150</sup> 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*,  
<http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction> (last modified July 2,  
2015).

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**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.<sup>25</sup>



233. 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 addicting drugs.

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

234. Even when 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, 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.

235. 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. Purdue stressed

1 that all patients should be screened for their risk of abuse or addiction, and that such screening  
2 could curb the incidence of addiction.<sup>151</sup>

3           236. The APF also proclaimed in a 2007 booklet, sponsored in part by Purdue, that  
4 “[p]eople with the disease of addiction may abuse their medications, engaging in unacceptable  
5 behaviors like increasing the dose without permission or obtaining the opioid from multiple  
6 sources, among other things. Opioids get into the hands of drug dealers and persons with an  
7 addictive disease as a result of pharmacy theft, forged prescriptions, Internet sales, and even  
8 from other people with pain. It is a problem in our society that needs to be addressed through  
9 many different approaches.”<sup>152</sup>

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11           237. On its current website for OxyContin,<sup>153</sup> Purdue acknowledges that certain  
12 patients have higher risk of opioid addiction based on history of substance abuse or mental  
13 illness—a statement which, even if accurate, obscures the significant risk of addiction for all  
14 patients, including those without such a history, and comports with statements it has recently  
15 made that it is “bad apple” patients, and not the opioids, that are arguably the source of the  
16 opioid crisis:  
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<sup>151</sup> *Oxycontin Risk Evaluation and Mitigation Strategy*, *supra* note 140.

<sup>152</sup> *Treatment Options: A Guide for People Living with Pain*, *supra* note 125.

<sup>153</sup> OxyContin, <https://www.oxycontin.com/index.html> (last visited Jan. 31, 2018).

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

18 238. Additionally, on its current website, Purdue refers to publicly available tools that  
 19 can assist with prescribing compliance, such as patient-prescriber agreements and risk  
 20 assessments.<sup>154</sup>

21 239. Purdue continues to downplay the severity of addiction and withdrawal and  
 22 claims that dependence can easily be overcome by strategies such as adhering to a tapering  
 23 schedule to successfully stop opioid treatment. On the current website for OxyContin, it instructs  
 24 that “[w]hen discontinuing OxyContin, gradually taper the dosage. Do not abruptly discontinue  
 25 OxyContin.”<sup>155</sup> And on the current OxyContin Medication Guide, Purdue also states that one  
 26 should “taper the dosage gradually.”<sup>156</sup> 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

<sup>154</sup> *ER/LA Opioid Analgesics REMS*, Purdue, <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/remis/> (last visited Jan. 31, 2018).

<sup>155</sup> Oxycontin.com, *supra* note 153.

<sup>156</sup> *OxyContin Full Prescribing Information*, Purdue Pharma LP, <http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o> (last visited Jan. 31, 2018).

1 suggestion that tapering is sufficient in the context of chronic use of potent opioids is misleading  
2 and dangerous, and sets patients up for withdrawal and addiction.

3 240. In its “Dear Healthcare Professional” letter in 2010, Purdue instructed doctors to  
4 gradually taper someone off of OxyContin to prevent signs and symptoms of withdrawal in  
5 patients who were physically dependent.<sup>157</sup> Nowhere does Purdue warn doctors or patients that  
6 tapering may be inadequate to safely end opioid treatment and avoid addiction.  
7

8 241. Endo also suggests that risk-mitigation strategies enable the safe prescription of  
9 opioids. In its currently active website, Opana.com, Endo states that assessment tools should be  
10 used to assess addiction risk, but that “[t]he potential for these risks should not, however, prevent  
11 proper management of pain in any given patient.”<sup>158</sup>  
12

13 242. On the same website, Endo makes similar statements about tapering, stating  
14 “[w]hen discontinuing OPANA ER, gradually taper the dosage.”<sup>159</sup>

15 243. Janssen states on its currently active website, PrescribeResponsibly.com, that the  
16 risk of opioid addiction “can usually be managed” through tools such as “opioid agreements”  
17 between patients and doctors.<sup>160</sup>

18 244. Each Defendant’s statements about tapering misleadingly implied that gradual  
19 tapering would be sufficient to alleviate any risk of withdrawal or addiction while taking opioids.  
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21 245. Defendants have also made and continue to make false and misleading statements  
22 about the purported abuse-deterrent properties of their opioid pills to suggest these reformulated  
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26 <sup>157</sup> *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 140.

<sup>158</sup> Opana ER, <http://www.opana.com> (last visited Jan. 31, 2018).

<sup>159</sup> *Id.*

<sup>160</sup> Heit & Gourlay, *supra* note 150.

1 pills are not susceptible to abuse. In so doing, Defendants have increased their profits by selling  
2 more pills for substantially higher prices.

3 246. For instance, since at least 2001, Purdue has contended that “abuse resistant  
4 products can reduce the incidence of abuse.”<sup>161</sup> Its current website touts abuse-deterrent  
5 properties by saying they “can make a difference.”<sup>162</sup>  
6

7 247. On August 17, 2015, Purdue announced the launch of a new website, “Team  
8 Against Opioid Abuse,” which it said was “designed to help healthcare professionals and  
9 laypeople alike learn about different abuse-deterrent technologies and how they can help in the  
10 reduction of misuse and abuse of opioids.”<sup>163</sup> This website appears to no longer be active.

11 248. A 2013 study which was authored by at least two doctors who at one time  
12 worked for Purdue stated that “[a]buse-deterrent formulations of opioid analgesics can reduce  
13 abuse.”<sup>164</sup> In another study from 2016 with at least one Purdue doctor as an author, the authors  
14 claimed that abuse decreased by as much as 99% in some situations after abuse-deterrent  
15 formulations were introduced.<sup>165</sup>  
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21 <sup>161</sup> *Oxycontin: Its Use and Abuse*, *supra* note 108.

22 <sup>162</sup> *Opioids with Abuse-Deterrent Properties*, Purdue, <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/> (last visited Jan. 31, 2018).

23 <sup>163</sup> *Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com*, Purdue (Aug. 17, 2015),  
24 <http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/>.

25 <sup>164</sup> Paul M. Coplan, Hrishikesh Kale, Lauren Sandstrom, Craig Landau, and Howard D. Chilcoat, *Changes in  
26 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/>.

<sup>165</sup> 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>.

1 249. Interestingly, one report found that the original safety label for OxyContin, which  
2 instructed patients not to crush the tablets because it would have a rapid release effect, may have  
3 inadvertently given opioid users ideas for techniques to get high from these drugs.<sup>166</sup>

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

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

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

14 The postmarketing investigations are inconclusive, and even if one were to treat available  
15 data as a reliable indicator of abuse rates, one of these investigations also suggests the  
16 troubling possibility that a higher percentage of reformulated Opana ER abuse is via  
injection than was the case with the original formulation.<sup>167</sup>

17 251. Despite the FDA's determination that the evidence did not support Endo's claims  
18 of abuse-deterrence, Endo advertised its reformulated pills as "crush resistant" and directed its  
19 sales representatives to represent the same to doctors. Endo improperly marketed Opana ER as  
20 crush-resistant, when Endo's own studies showed that the pill could be crushed and ground. In  
21 2016, Endo reached an agreement with the Attorney General of the State of New York that  
22 required Endo to discontinue making such statements.<sup>168</sup>

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25 <sup>166</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 28.

26 <sup>167</sup> *FDA Statement: Original Opana ER Relisting Determination*, U.S. Food & Drug Administration (May 10,  
2013), [https://wayback.archive-  
it.org/7993/20171102214123/https://www.fda.gov/Drugs/DrugSafety/ucm351357.htm](https://wayback.archive-it.org/7993/20171102214123/https://www.fda.gov/Drugs/DrugSafety/ucm351357.htm).

<sup>168</sup> 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* (Mar. 3, 2016),

1           252. Defendants’ assertions that their reformulated pills could curb abuse were false  
2 and misleading, as the CDC’s 2016 Guideline, discussed below, confirm.

3           253. Ultimately, even if a physician prescribes opioids after screening for abuse risk,  
4 advising a patient to taper, and selecting brand-name, abuse-deterrent formulations, chronic  
5 opioid use still comes with significant risks of addiction and abuse. Defendants’ statements to the  
6 contrary were designed to create a false sense of security and assure physicians that they could  
7 safely prescribe potent narcotics to their patients.  
8

9 **E. The Falseness of Defendants’ Claims Is Brought into Stark Relief by the Work of**  
10 **the Washington Department of Labor and Industries.**

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

15           255. One place where this evidence surfaced is the Washington State Department of  
16 Labor and Industries (“L&I”). The Department of L&I runs the state’s workers’ compensation  
17 program, which covers all employees in the state, other than those who work for large companies  
18 and government entities. In 2000, L&I’s new chief pharmacist, Jaymie Mai, noticed an increase  
19 in prescription of opioids for chronic pain, approximately 50 to 100 cases a month.<sup>169</sup> It was then  
20 that she discovered some of these same workers were dying from opioid overdoses. That workers  
21 suffered back pain or sprained knees on the job was nothing new, but workers dying from their  
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<https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals>.

<sup>169</sup> Quinones, *supra* note 37, at 203.

1 pain medication was assuredly not. Mai reported what she was seeing to L&I's Medical Director,  
2 Dr. Gary Franklin.<sup>170</sup>

3 256. In addition to being L&I's Medical Director, Dr. Franklin is a research professor  
4 at the University of Washington in the departments of Environmental Health, Neurology, and  
5 Health Services. Alarmed by Mai's finding, Dr. Franklin and Mai undertook a thorough analysis  
6 of all recorded deaths in the state's workers' comp system. In 2005, they published their findings  
7 in the American Journal of Industrial Medicine.<sup>171</sup>

9 257. Their research showed that the total number of opioid prescriptions paid for by  
10 the Workers' Compensation Program tripled between 1996 and 2006.<sup>172</sup> Not only did the number  
11 of prescriptions balloon, so too did the doses; from 1996 to 2002 the mean daily morphine  
12 equivalent dose ("MED") nearly doubled, and remained that way through 2006.<sup>173</sup> As injured  
13 Washington workers were given more prescriptions of more higher doses of opioids the rates of  
14 opioid overdoses among that population jumped, from zero in 1996 to more than twenty in 2005.  
15 And in 2009, over thirty people receiving opioid prescriptions through the Workers'  
16 Compensation Program died of an opioid overdose.<sup>174</sup>

18 258. Armed with these alarming statistics, Dr. Franklin, in conjunction with other  
19 doctors in Washington, set out to limit the doses of opioids prescribed through the workers'  
20 compensation program. As part of that effort, in 2007 the Agency Medical Directors Group  
21

22  
23 <sup>170</sup> *Id.*

24 <sup>171</sup> 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).

25 <sup>172</sup> 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  
26 Opioid Dosing and Mortality Curves: Impact of the Washington State Opioid Dosing Guideline*, 55 Am J Ind Med  
325, 327 (2012).

<sup>173</sup> *Id.* at 327-28.

<sup>174</sup> *Id.* at 328.

1 launched an Interagency Guideline on Opioid Dosing, aimed at reducing the numbers of opioid  
2 overdoses. Through this, and other related efforts, both the rates of opioid prescriptions and the  
3 sizes of doses have declined in Washington, beginning in 2009. As opioid prescriptions rates for  
4 injured workers have declined, so too has the death rate among this population.<sup>175</sup>

5  
6 259. Dr. Franklin's research not only demonstrated the dangers of prescription opioids,  
7 but also showed that the use of opioids to treat pain after an injury actually prevents or slows a  
8 patient's recovery.

9 260. In a study he published in 2008, Dr. Franklin looked at Washington State  
10 employees who had suffered a low back injury on the job, and compared the impact of opioid  
11 prescriptions on the outcomes for these workers.

12 261. The results of his study were striking: after controlling for numerous variables,  
13 Dr. Franklin's research showed that if an injured worker was prescribed opioids soon after the  
14 injury, high doses of opioids, or opioids for more than week, the employee was far more likely to  
15 experience negative health outcomes than the same employee who was not prescribed opioids in  
16 these manners.

17  
18 262. For example, the study showed that, after adjusting for the baseline covariates,  
19 injured workers who received a prescription opioid for more than seven days during the first six  
20 weeks after the injury were 2.2 times more likely to remained disabled a year later than workers  
21 with similar injuries who received no opioids at all. Similarly, those who received two  
22 prescriptions of opioids for the injury were 1.8 times more likely to remain disabled a year after  
23 their injury than workers who received no opioids at all. Those receiving daily doses higher than  
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<sup>175</sup> *Id.*

1 150 MED more than doubled the likelihood of disability a year later, relative to workers who  
2 received no opioids.<sup>176</sup>

3 263. The results of this study are troubling: not only do prescription opioids present  
4 significant risks of addiction and overdose, but they also appear to hinder patient recovery after  
5 an injury.

6  
7 264. This dynamic presents problems for employers, too, who bear significant costs  
8 when their employees do not recover quickly from workplace injuries. Employers are left  
9 without their labor force, and may be responsible for paying for the injured employee's disability  
10 for long periods of time.

11 **F. The 2016 CDC Guidelines and Other Recent Studies Confirm That Defendants'**  
12 **Statements About the Risks and Benefits of Opioids are Patently False.**

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

16 266. The CDC issued its *Guideline for Prescribing Opioids for Chronic Pain* on March  
17 15, 2016 (the "2016 CDC Guideline" or "Guideline").<sup>177</sup> The 2016 CDC Guideline, approved by  
18 the FDA, "provides recommendations for primary care clinicians who are prescribing opioids for  
19 chronic pain outside of active cancer treatment, palliative care, and end-of-life care." The  
20 Guideline also assesses the risks and harms associated with opioid use.

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22 267. The 2016 CDC Guideline is the result of a thorough and extensive process by the  
23 CDC. The CDC issued the Guideline after it "obtained input from experts, stakeholders, the  
24

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26 <sup>176</sup> 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.

<sup>177</sup> Dowell, et al., *supra* note 29.

1 public, peer reviewers, and a federally chartered advisory committee.” The recommendations in  
2 the 2016 CDC Guideline were further made “on the basis of a systematic review of the best  
3 available evidence . . .”

4 268. The CDC went through an extensive and detailed process to solicit expert  
5 opinions for the Guideline:  
6

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

19 269. The 2016 Guideline was also peer-reviewed pursuant to “the final information  
20 quality bulletin for peer review.” Specifically, the Guideline describes the following independent  
21 peer-review process:  
22

23 [P]eer review requirements applied to this guideline because it provides influential  
24 scientific information that could have a clear and substantial impact on public- and  
25 private-sector decisions. Three experts independently reviewed the guideline to determine  
26 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.

1           270. The findings in the 2016 CDC Guideline both confirmed the existing body of  
2 scientific evidence regarding the questionable efficacy of opioid use and contradicted  
3 Defendants' statements about opioids.

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

13           272. The Guideline also concludes that there is “[n]o evidence” to show “a long-term  
14 benefit of opioids in pain and function versus no opioids for chronic pain . . .” Furthermore, the  
15 Guideline indicates that “continuing opioid therapy for 3 months substantially increases the risk  
16 of opioid use disorder.” Indeed, the Guideline indicates that “[p]atients who do not experience  
17 clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with  
18 longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in  
19 order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids”  
20 because the patient is “not receiving a clear benefit.” These findings flatly contradict claims  
21 made by the Defendants that there are minimal or no adverse impacts of long-term opioid use, or  
22 that long-term opioid use could actually improve or restore a patient’s function.  
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1           273. In support of these statements about the lack of long-term benefits of opioid use,  
2 the CDC concluded that “[a]lthough opioids can reduce pain during short-term use, the clinical  
3 evidence review found insufficient evidence to determine whether pain relief is sustained and  
4 whether function or quality of life improves with long-term opioid therapy.” The CDC further  
5 found that “evidence is limited or insufficient for improved pain or function with long-term use  
6 of opioids for several chronic pain conditions for which opioids are commonly prescribed, such  
7 as low back pain, headache, and fibromyalgia.”

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

19           275. The 2016 CDC Guideline also contradicts statements made by Defendants that  
20 there are reliable risk-mitigation tactics to reduce the risk of addiction. For instance, the  
21 Guideline indicates that available risk screening tools “show insufficient accuracy for  
22 classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that  
23 doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid  
24 therapy.”  
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1           276. Finally, the 2016 CDC Guideline states that “[n]o studies” support the notion that  
 2 “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,”  
 3 noting that the technologies—even when they work—“do not prevent opioid abuse through oral  
 4 intake, the most common route of opioid abuse, and can still be abused by nonoral routes.” In  
 5 particular, the CDC found as follows:

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

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

13           277. Notably, in addition to the findings made by the CDC in 2016, the Washington  
 14 State Agency Medical Directors’ Group (AMDG)—a collaboration among several Washington  
 15 State Agencies—published its *Interagency Guideline on Prescribing Opioids for Pain* in 2015.  
 16 The AMDG came to many of the same conclusions as the CDC did. For example, the AMDG  
 17 found that “there is little evidence to support long term efficacy of [chronic opioid analgesic  
 18 therapy, or “COAT”] in improving function and pain, [but] there is ample evidence of its risk for  
 19 harm . . .”<sup>178</sup>

20  
 21           278. In addition, as discussed above, in contrast to Defendants’ statements that the  
 22 1980 Porter and Jick letter provided evidence of the low risk of opioid addiction in pain patients,  
 23 the NEJM recently published a letter largely debunking the use of the Porter and Jick letter as  
 24 evidence for such a claim.<sup>179</sup> The researchers demonstrated how the Porter and Jick letter was  
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 178 *Interagency Guideline on Prescribing Opioids for Pain*, Agency Medical Directors’ Group (June 2015),  
<http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf>.

179 Leung, et al., *supra* note 98.

1 irresponsibly cited and, in some cases, “grossly misrepresented,” when in fact it did not provide  
 2 evidence supporting the broad claim of low addiction risk for all patients prescribed opioids for  
 3 pain. As noted above, Dr. Jick reviewed only files of patients administered opioids in a hospital  
 4 setting, rather than patients sent home with a prescription for opioids to treat chronic pain.

5  
 6 279. The authors of the 2017 letter described their methodology as follows:

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

14 We identified 608 citations of the index publication and noted a sizable increase after the  
 15 introduction of OxyContin (a long-acting formulation of oxycodone) in 1995 . . . **Of the  
 16 articles that included a reference to the 1980 letter, the authors of 439 (72.2%) cited  
 17 it as evidence that addiction was rare in patients treated with opioids. Of the 608  
 18 articles, the authors of 491 articles (80.8%) did not note that the patients who were  
 19 described in the letter were hospitalized at the time they received the prescription,  
 20 whereas some authors grossly misrepresented the conclusions of the letter . . . Of  
 21 note, affirmational citations have become much less common in recent years. In contrast  
 22 to the 1980 correspondence, 11 stand-alone letters that were published  
 23 contemporaneously by the Journal were cited a median of 11 times.**<sup>180</sup>

24  
 25 280. The researchers provided examples of quotes from articles citing the 1980 letter,  
 26 and noted several shortcomings and inaccuracies with the quotations. For instance, the  
 27 researchers concluded that these quotations (i) “overstate[] conclusions of the index publication,”  
 28 (ii) do[] not accurately specify its study population,” and (iii) did not adequately address  
 29 “[I]mitizations to generalizability.”<sup>181</sup>

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<sup>180</sup> *Id.* (emphasis added).

<sup>181</sup> 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 N Engl J Med 2194-95 (June 1, 2017), [http://www.nejm.org/doi/suppl/10.1056/NEJMc1700150/suppl\\_file/nejmc1700150\\_appendix.pdf](http://www.nejm.org/doi/suppl/10.1056/NEJMc1700150/suppl_file/nejmc1700150_appendix.pdf).

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>Onco Targets 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(6):718-39.	Incorrectly identifies the index study population as cancer patients; does not otherwise address limitations to generalizability.

281. 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.<sup>182</sup>

<sup>182</sup> Leung, et al., *supra* note 98.

1           282. These researchers' careful analysis demonstrates the falsity of Defendants' claim  
2 that this 1980 letter was evidence of a low risk of addiction in opioid-treated patients. By casting  
3 this letter as evidence of low risk of addiction, Defendants played fast and loose with the truth,  
4 with blatant disregard for the consequences of their misrepresentations.  
5

6 **G. Sales Representatives Knew or Should Have Known their Representations**  
7 **Regarding the Safety and Efficacy of Prescription Opioids in Pierce County Were**  
8 **False and Misleading.**

9           283. As discussed above, sales representatives also played a key role in promoting  
10 Defendants' opioids. These sales representatives routinely visited physicians, nurses,  
11 pharmacists, and others in the medical community to deliver Defendants' messages about the  
12 safety and efficacy of opioids. In face-to-face meetings, sales representatives would urge doctors  
13 to prescribe opioids to their patients for a wide range of ailments, making the same types of  
14 misrepresentations Defendants made, as detailed above.

15           284. But these sales representatives were not simple conduits of information, merely  
16 passing on what they believed to be good scientific information to doctors. Instead, the sales  
17 representatives knew, or should have known, that they were making false and misleading  
18 statements and providing untrue information to doctors and others about opioids.

19           285. Former sales representative Steven May, who worked for Purdue from 1999 to  
20 2005, explained to a journalist how he and his coworkers were trained to overcome doctors'  
21 objections to prescribing opioids. The most common objection he heard about prescribing  
22 OxyContin was that "it's just too addictive."<sup>183</sup> May memorized this line from the drug's label:  
23 "The delivery system is believed to reduce the abuse liability of the drug." He repeated that line  
24  
25

26  

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<sup>183</sup> David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe),  
The New Yorker (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

1 to doctors even though he “found out pretty fast that it wasn’t true.”<sup>184</sup> He and his coworkers  
2 learned quickly that people were figuring out how to remove the time-releasing coating, but they  
3 continued making this misrepresentation until Purdue was forced to remove it from the drug’s  
4 label. In addition, May explained, he and his coworkers were trained to “refocus” doctors on  
5 “legitimate” pain patients, and to represent that “legitimate” patients would not become addicted.  
6 In addition, they were trained to say that the 12-hour dosing made the extended-release opioids  
7 less “habit-forming” than painkillers that need to be taken every four hours. Defendants knew or  
8 should have known that such statements were false and misleading, yet they continued to make  
9 them.  
10

11           286. Sales representatives also quickly learned that the prescription opioids they were  
12 promoting were dangerous. For example, May had only been at Purdue for two months when he  
13 found out that a doctor he was calling on had just lost a family member to an OxyContin  
14 overdose.<sup>185</sup> And as another sales representative wrote on a public forum:  
15

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

23           287. Sales representatives knew or should have known the potential consequences of  
24 pushing potent doses of opioids for chronic pain and other common indications.  
25

26           288. These sales representatives targeted their efforts at local doctors, such as, for  
example, Dr. Frank Li, the former medical director of several pain clinics (including one in  
Tacoma) who eventually had his medical license suspended for improperly prescribing opioids.

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<sup>184</sup> Keefe, *supra* note 51.

<sup>185</sup> Remnick, *supra* note 183.

1 Indeed, during detailers' frequent visits to Dr. Li, they often noted circumstances that should  
2 have led them to discontinue sales calls and report Dr. Li and his staff to the appropriate  
3 authorities. Instead, they continued to target him for detailing visits that incited him to prescribe  
4 even more opioids, with disastrous consequences for public health.

5  
6 289. In addition, detailers told providers at Dr. Li's clinic that the Washington State  
7 opioid prescription guidelines were wrong and overly conservative, including those related to  
8 calculating the relative strength of different brands of opioids. These detailers often urged Dr.  
9 Li's staff to give patients more opioids, and particular brands of opioids, even when this was  
10 incorrect or conflicted with Washington State guidelines or other medical information.

11  
12 290. Purdue's sales call notes also repeatedly reference how busy Dr. Li and his staff  
13 were—which, combined with the exceptionally high number of opioid prescriptions written by  
14 Dr. Li, should have been another red flag that OxyContin and other opioids were likely being  
15 abused.

16  
17 291. Defendants' sales representatives also provided health care providers in Pierce  
18 County with pamphlets, visual aids, and other marketing materials designed to increase the rate  
19 of opioids prescribed to patients. These sales representatives knew the doctors they visited relied  
20 on the information they provided, and that the doctors had minimal time or resources to  
21 investigate the materials' veracity independently.

22  
23 292. Sales representatives were also given bonuses when doctors whom they had  
24 detailed wrote prescriptions for their company's drug. Because of this incentive system, sales  
25 representatives stood to gain significant bonuses if they had a pill mill in their sales region.<sup>186</sup>

26  

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<sup>186</sup> Indeed, Defendants often helped their sales representatives find and target such pill mills. As recently as 2016, Purdue commissioned a marketing study to help target Washington prescribers and spread its deceptive message regarding opioids, and on information and belief, utilized its sale representatives to carry out these strategies.

1 Sales representatives could be sure that doctors and nurses at pill mills would be particularly  
 2 receptive to their messages and incentives, and receive “credit” for the many prescriptions these  
 3 pill mills wrote.

4 **H. Pierce County Has Been Directly Affected by the Opioid Epidemic Caused By**  
 5 **Defendants.**

6 293. Pierce County is one of the most populous counties in Washington State, with  
 7 approximately 861,312 residents.<sup>187</sup>

8 294. Much like the rest of the United States, Pierce County has felt the profound  
 9 consequences of this epidemic. As a direct result of Defendants’ aggressive marketing scheme,  
 10 Pierce County has suffered significant and ongoing harms—harms that will continue well into  
 11 the future. Each day that Defendants continue to evade responsibility for the epidemic they  
 12 caused, the County must continue allocating substantial resources to address it.

13 295. Opioid use has reached crisis levels in Pierce County. Between 2005 and 2014,  
 14 there were 704 fatal opioid overdoses in Pierce County.<sup>188</sup> The overall trend is that the number of  
 15 opioid-related deaths in Pierce County continues to climb. For example, from 2008 to 2010,  
 16 there were 156 opioid-related deaths in Pierce County,<sup>189</sup> while from 2012 to 2016, that number  
 17 rose to 423.<sup>190</sup>

18 296. Treatment admissions for prescription opioids have also increased significantly in  
 19 the last decade. For example, in 1999, Pierce County had twenty-six treatment admissions for  
 20  
 21  
 22  
 23

24 <sup>187</sup> *Quick Facts: Pierce County, Washington*, United States Census Bureau,  
 25 <https://www.census.gov/quickfacts/fact/table/piercecountywashington,US/PST045216> (last visited Jan. 31, 2018).

26 <sup>188</sup> Tacoma-Pierce County Health Department, *Pierce County Hit Hard by Heroin and Prescription Painkiller Use*,  
 The Suburban Times (July 12, 2016), <https://thesubtimes.com/2016/07/12/pierce-county-hit-hard-by-heroin-and-prescription-painkiller-use/> (citing report from University of Washington’s Alcohol and Drug Abuse Institute).

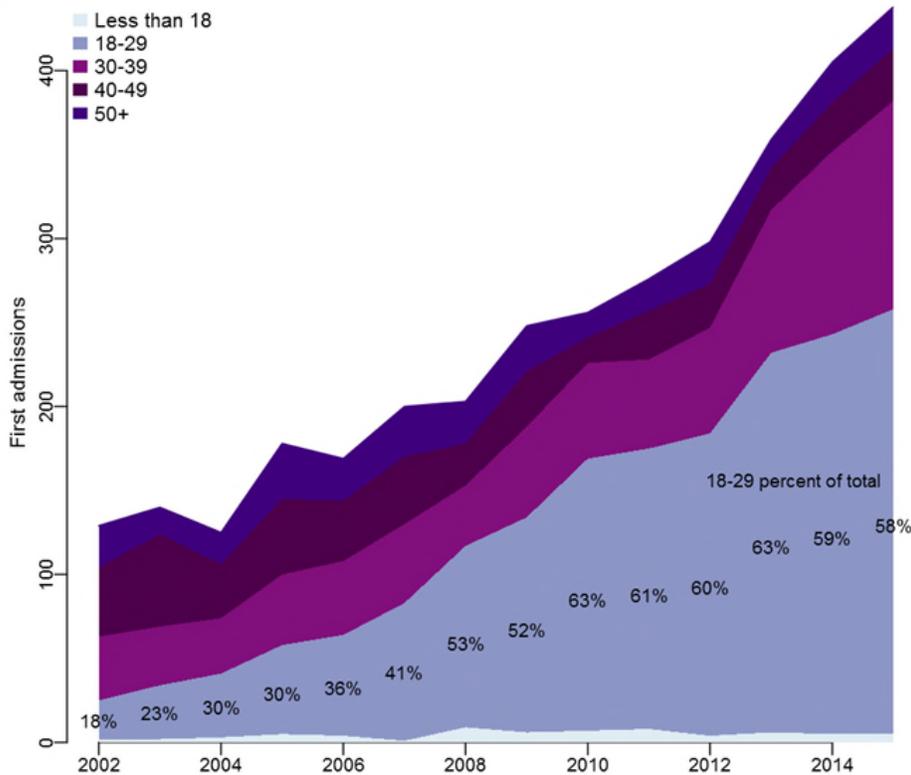
<sup>189</sup> *Prescription Opiates and Heroin – Pierce County*, University of Washington Alcohol & Drug Abuse Institute,  
[http://adai.uw.edu/wastate/opiates/pierce\\_opiates\\_2010.pdf](http://adai.uw.edu/wastate/opiates/pierce_opiates_2010.pdf) (last visited Jan. 31, 2018).

<sup>190</sup> *Opioid-related Deaths in Washington State, 2006-2016*, *supra* note 6.

1 prescription opioids. By 2010, the number of prescription opioid admissions rose to 510.<sup>191</sup>  
 2 Similarly, the number of people entering treatment for any opioid rose at a dramatic rate.  
 3 Between 2002-2004 and 2011-2013, publicly funded treatment admissions involving any opioid  
 4 grew 152.6%.<sup>192</sup> Overall, from 2002 to 2015, there were 3,424 first-time admissions for opioid  
 5 addiction in Pierce County.<sup>193</sup>

7 297. The graph below shows how first-time admissions to treatment in Pierce County  
 8 with any opioid as the primary drug of choice have tripled from 2002 to 2015. This increase is  
 9 driven primarily by those ages eighteen to twenty-nine.<sup>194</sup>

10 *Figure 4. First time admissions to treatment with any opioid as the primary drug of choice*



191 *Prescription Opiates and Heroin – Pierce County*, *supra* note 189.

192 *Opioid Trends Across Washington State*, University of Washington Alcohol and Drug Abuse Institute (Apr. 2015), <http://ada.i.uw.edu/pubs/infobriefs/ADAI-IB-2015-01.pdf>.

193 *Id.*; See also, *Pierce County Hit Hard by Heroin and Prescription Painkiller Use*, *supra* note 188.

194 *Opioid Trends in Pierce County*, prepared by the Alcohol and Drug Abuse Institute, University of Washington, and commissioned by Tacoma-Pierce County Health Department (Feb. 23, 2017).

1           298. From 2008 onward, over half of those entering treatment for the first time were  
2 young adults. The growing number of young adults seeking treatment corresponds to rates of  
3 misuse of opioids among adolescents in Pierce County. Between 2006 and 2014, 5-10% of tenth  
4 graders in Pierce County reported using painkillers to get high within the last month.<sup>195</sup>

5  
6           299. As observed in a report commissioned by the Tacoma-Pierce County Health  
7 Department, it is possible that approximately 25% of these youth who use misuse prescription-  
8 type-opioids will eventually develop opioid use disorder, based on evidence that 25% of those  
9 who try heroin develop opioid use disorder, and the fact that heroin and prescription opioids are  
10 chemical equivalents.<sup>196</sup> Thus, “a substantial minority of those who misuse prescription-type  
11 opioids may develop opioid use disorder and in turn need recovery supports (social,  
12 psychological, and/or medicine) for the rest of their life.”<sup>197</sup>

13  
14           300. Underlying these data on opioid misuse, overdoses, and treatment admissions is  
15 the fact that the rate of opioid prescriptions in Pierce County exploded in the early 2000s. While  
16 the number of opioid prescriptions has tapered off in recent years, the data indicate that millions  
17 of prescription opioids flooded Pierce County during the last two decades.

18           301. As is true around the country, the increase in prescription opioid use in Pierce  
19 County was followed closely by an increase in heroin use. Many individuals using prescription  
20 opioids turned to heroin when they could no longer obtain those prescriptions.

21  
22           302. The below graph shows rates of opioid-related deaths in Pierce County.<sup>198</sup> While  
23 deaths attributable to any opioid appear to have leveled off over the last several years in Pierce  
24

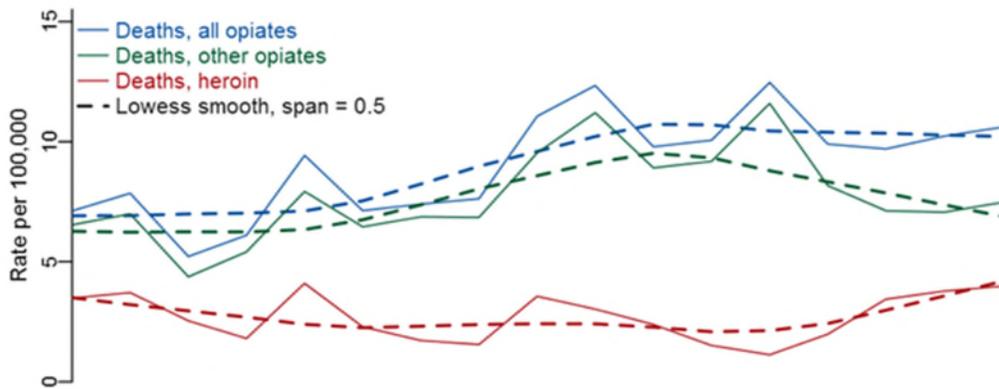
25  
26 \_\_\_\_\_  
<sup>195</sup> *Id.*

<sup>196</sup> *Id.*

<sup>197</sup> *Id.*

<sup>198</sup> *Opioid Trends in Pierce County, supra* note 194.

1 County, the overall trend reflects an increase in heroin-involved deaths—a trend similar to  
 2 Washington State as a whole.



3  
 4  
 5  
 6  
 7  
 8  
 9  
 10 303. Increased heroin use is also behind a recent rise in police evidence testing cases  
 11 and drug overdose deaths.<sup>199</sup> Correspondingly, treatment admissions in Pierce County for heroin  
 12 and first admissions for heroin have risen precipitously since 2013.

13  
 14 304. Furthermore, a 2015 survey of seventy-seven syringe-exchange participants in  
 15 Pierce County found that heroin was the most common primary drug used (74%), and most  
 16 heroin users (57%) reported that they were “hooked on” prescription-type opioids before they  
 17 began using heroin.<sup>200</sup> Twenty-two percent of those surveyed reported having an overdose in the  
 18 previous year and 40% reported witnessing an overdose. Seventy-seven percent of those  
 19 surveyed reported interest in “getting help to stop or reduce” their drug use.  
 20

21 305. Pierce County also has a number of opioid addiction clinics and opioid treatment  
 22 programs (OTPs) that dispense methadone and buprenorphine.<sup>201</sup> Like methadone,  
 23 buprenorphine is a proven opioid-use-disorder medication that cuts the odds of dying in half  
 24

25 <sup>199</sup> *Id.*

26 <sup>200</sup> *Id.*

<sup>201</sup> *Methadone and Buprenorphine Clinics in Pierce County*, WA, Clermont Counseling,  
<http://www.clermontcounseling.org/methadone-buprenorphine-clinics/Pierce-county-WA/programs.html> (last  
 visited Jan. 31, 2018).

1 compared to no treatment or counseling only. OTPs can provide buprenorphine, but—unlike  
2 methadone—it can also be prescribed by a physician in an office-based setting and obtained at a  
3 pharmacy. Treatment capacity for buprenorphine is limited and far exceeded by demand.

4  
5 306. In addition to these clinics and OTPs, Pierce County also has resources for opioid  
6 rehabilitation. For example, the Pierce County Alliance, established in 1994 in cooperation with  
7 Pierce County Superior Court, the County Prosecutor, and the Department of Assigned Counsel,  
8 provides court supervised drug treatment services for eligible, non-violent offenders.<sup>202</sup> In  
9 addition to mental health, alcoholism and dual-diagnosis treatment, the Pierce County Alliance  
10 focuses on opiate addiction and supporting individuals recovering from opioid addiction. The  
11 Pierce County Alliance treats individuals suffering from addiction to illegal opioids like heroin,  
12 as well as prescription drugs like oxycodone. The center combines physical and emotional  
13 support to help stop addiction. The rehab services include Medication-Assisted Treatment with  
14 medications like buprenorphine and naloxone. The Pierce County Alliance offers both inpatient  
15 and outpatient services.  
16

17 307. Pierce County also has eighteen locations throughout the County, primarily at law  
18 enforcement sites, and at two pharmacies, that are drug-take-back sites.<sup>203</sup> These drug-take-back  
19 sites are essential in providing a safe, convenient, and responsible way to dispose of prescription  
20 opioids and minimize the potential for abuse and diversion.  
21

22 308. In addition, the Tacoma Needle Exchange Program provides access to sterile  
23 syringes and other injecting equipment in Pierce County. The Tacoma Needle Exchange  
24 Program provides new, sterile syringes and clean injection equipment for people who use drugs  
25

26 <sup>202</sup> *Pierce County Alliance*, Rehab.com, <https://www.rehab.com/pierce-county-alliance/6182570-r> (last visited Jan. 31, 2018).

<sup>203</sup> Take Back Your Meds, <http://www.takebackyourmeds.org/22679-2/> (last visited Jan. 31, 2018).

1 by injection. The program also provides referrals to social, health, and welfare services including  
2 opioid abuse prevention and naloxone distribution. While the Tacoma Needle Exchange Program  
3 serves individuals who use a variety of drugs, a substantial percentage of participants use  
4 opioids.

5  
6 309. Pierce County has also invested resources into efforts that, it hopes, will bring an  
7 end to the opioid epidemic here. As noted above, Pierce County convened an Opioid Use Task  
8 Force (“Task Force”) in May of 2017, bringing together a group of twenty-five leaders from  
9 various sectors of the community, representing multiple disciplines, such as community based  
10 organizations (including syringe exchange and homeless shelters), public health, social service  
11 agencies, hospitals, law enforcement, criminal justice, emergency departments, treatment  
12 providers, and others working together to expand the region’s capacity for treatment and  
13 prevention capacity. The Task Force is a collaboration of efforts established under the  
14 Washington Prescription Drug Overdose (PDO)/Substance Abuse and Mental Health Services  
15 Administration (SAMSHA) Grant, the Pierce County Accountable Community of Health, and  
16 the Pierce County Health and Human Services Committee. The purpose of the Task Force is to  
17 prevent and reduce opioid-related morbidity and mortality through strategies that target  
18 prevention, treatment, and recovery supports.  
19

20  
21 310. The Task Force charter indicates that the Task Force is striving to develop  
22 measures that address opioid-related deaths, non-fatal overdoses involving prescription opioids,  
23 substance use disorder treatment penetration, new opioid users that become chronic users,  
24 patients on high-dose chronic opioid therapy, patients with concurrent sedatives prescriptions,  
25 and Medication Assisted Therapy (MAT) with both buprenorphine and methadone.  
26

1           311. The Task Force strategy includes developing a regional Opioid Working Plan that  
2 addresses opioid prevention, treatment, and overdose prevention.<sup>204</sup> A Task Force project  
3 includes developing a sustainability strategy for funding syringe exchange supplies and  
4 improving awareness of the Good Samaritan law. The common goal is to work together to  
5 reduce the impact of the opioid use public health crisis.  
6

7           312. As these circumstances reflect, Pierce County has devoted enormous resources in  
8 dealing with this epidemic, and has been saddled with enormous financial and economic costs as  
9 a direct result of Defendants' misconduct.

10           313. Furthermore, Pierce County is served by an array of different departments,  
11 agencies, and offices, which provide essential services to the County's residents. The costs  
12 incurred by the following departments provide an illustrative but non-exhaustive picture of the  
13 many ways in which Pierce County is impacted by the crisis caused by Defendants.  
14

15           **1. The Department of Human Services has incurred enormous costs in dealing**  
16           **with the crisis caused by Defendants.**

17           314. Pierce County's Department of Human Services (PCHS) is responsible for  
18 services to the most vulnerable citizens in Pierce County. PCHS and the people and communities  
19 it serves are also at the center of the opioid crisis. PCHS provides the County some of the most  
20 critical services to address, mitigate, and potentially reverse the opioid epidemic.

21           315. PCHS manages a wide range of programs and services to assist the County's most  
22 vulnerable residents and strengthen its communities. These include services for aging and  
23 disability resources, career and employment, developmental disabilities, housing assistance,  
24

25  
26  

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<sup>204</sup> *Opioid Task Force*, Pierce County ACH (June 2017), <http://www.piercecountyach.org/wp-content/uploads/2017/05/June2017-Opioid-Task-Force-Presentation.pdf>.

1 behavioral health (mental health and substance use disorder) prevention and treatment, veterans'  
2 services, and youth and community development services.

3 316. PCHS also works to ensure all of Pierce County has equitable access to  
4 community-based services. Providers in Pierce County contract through the Optum Pierce  
5 Behavioral Health Organization (BHO), which in turn contracts with local service providers.  
6 Optum Pierce BHO provides crisis services to the entire Pierce County population and partners  
7 with providers to offer services, programs, and resources for mental health and substance abuse  
8 disorders to Medicaid members in the Pierce County public behavioral health system.  
9

10 **a. Community Health Services**

11 317. Optum Pierce BHO spends considerable resources providing substance-use  
12 disorder services. It contracts with several agencies to provide outpatient services to adults,  
13 including: Asian Counseling, Consejo, Greater Lakes, MDC, Multicare, Northwest Integrated  
14 Health, Olalla, Pierce County Alliance, Pioneer, Prosperity, and SeaMar. Optum Pierce BHO's  
15 annual funding for outpatient services is approximately \$8 million. Optum Pierce BHO also  
16 contracts with Olalla, Prosperity, SeaMar, and Pioneer to provide residential services in Pierce  
17 County, with annual funding of approximately \$3.9 million. Optum Pierce BHO also allocates  
18 over half a million dollars to outpatient services for youth clientele.  
19

20 318. Considerable resources are also devoted specifically to opioid treatment services.  
21 Optum Pierce BHO contracts with Tacoma Pierce County Department of Health and Northwest  
22 Integrated Health to provide methadone clinics. BHO also contracts with the Tacoma Needle  
23 Exchange Program, described in detail above and managed by the Point Defiance AIDS Project,  
24 to offer for community outreach, education, and referrals to health and social services. Optum  
25 Pierce BHO spends nearly \$6 million annually on these services.  
26

1 319. Optum Pierce BHO also provides outpatient and residential services for mental  
2 health treatment as well as crisis services which include the following: Mobile Crisis Teams,  
3 Crisis Triage and Stabilization Facility, Crisis Line Support, Substance Use Detoxification  
4 Facility, and Acute Mental Health Inpatient Treatment Services, Mental-Health Post-  
5 Hospitalization, and Peers in Emergency Rooms.

6  
7 320. Optum Pierce BHO also contracts to provide six adult Residential Treatment  
8 Facilities (RTF) specific to substance abuse, and three RTFs for youth to treat substance abuse.  
9 The RTFs are operated by MDC, Prosperity, SeaMar, Olalla Recovery Centers, Pioneer, and  
10 Lakeside-Milam.

11 321. As explained in further detail below, homelessness is also a significant issue in  
12 Pierce County, and a significant percentage of the County's homeless population is addicted to  
13 prescription opioids and/or heroin. PCHS obviously expends significant resources in serving this  
14 segment of the County's homeless population.

15  
16 **b. Justice-Involved Services**

17 322. Optum Pierce BHO also allocates resources to therapeutic courts in Pierce  
18 County. BHO contracts with Pierce County Superior Court and Greater Lakes to operate a felony  
19 mental health court. BHO contracts with Pierce County Superior Court and the Pierce County  
20 Alliance to fund the Adult Drug Court, and Family Drug Court. Services are also devoted to  
21 Pierce County Jail (contractors Greater Lakes and Pierce County Alliance) as well as the  
22 Department of Corrections for Substance Use Disorder and Outpatient Services (contractor  
23 Pierce County Alliance).

24  
25 323. BHO also contracts with Catholic Community Services to provide homeless  
26 outreach services; annual funding estimates are nearly \$350,000. Because of the link between the

1 opioid crisis and homelessness, discussed below, these funds are spent in part to address the  
2 consequences of Defendants' conduct.

3 **2. Emergency Management Services has borne substantial costs as a result of**  
4 **the opioid epidemic.**

5 324. Pierce County's Emergency Management Services (EMS) provides essential  
6 emergency medical and life-saving services to the County and in an area spanning 1,806 square  
7 miles. Any time residents of Pierce County call 9-1-1 for an emergency, they use EMS which  
8 partners with fire departments, paramedic agencies, dispatch centers, and hospitals.

9  
10 325. EMS is at the front line of the opioid crisis, as they are the first responders to  
11 overdoses, deaths, and injuries related to opioid abuse. Both in terms of responding to these  
12 emergencies and in training and preparing for them, EMS has incurred substantial costs as a  
13 result of Defendants' conduct.

14 326. In most cases, a paramedic or Emergency Medical Technician (EMT) responding  
15 to a 9-1-1 call about an opioid overdose will administer naloxone—a costly medication used to  
16 block and reverse the effects of an opioid overdose. Naloxone reverses opioid overdoses by  
17 binding to opioid receptors and thereby blocking the effects of the opioid substance, including  
18 respiratory depression. If naloxone is administered in time, it will restore the patient's airway  
19 reflexes, respiratory drive, and level of consciousness. Naloxone is expensive, and EMS spends  
20 considerable sums purchasing and distributing naloxone to its EMTs and fire departments, and  
21 will continue to do so well into the foreseeable future.

22  
23 327. In 2011, Pierce County EMS responded to 116 overdoses where naloxone was  
24 administered. In 2017, that number rose to 167 responses. Each time EMS responds to an  
25 overdose call where naloxone is administered, EMS must devote significant personnel resources;  
26

1 for example, medic, emergency vehicles (ladder and engine), dispatch, and command are all  
2 involved.

3 328. The annual cost of responding to overdoses in 2011 was approximately  
4 \$53,808.72. In 2017, County EMS spent \$80,718.99 on responses to overdoses with naloxone  
5 administration alone.

6  
7 329. Over 500 staff hours per year are devoted to overdose responses. Notably, when  
8 EMS responds to an overdose, it places emergency response units out of service for other  
9 emergencies in the community.

10 330. In addition to the financial costs, the opioid epidemic has also affected the first  
11 responders themselves. The Assistant Chief of EMS in Pierce County indicated that “running  
12 into these types of incidents day after day is demoralizing” and no doubt adds to the “burnout”  
13 type symptoms for their EMTs and paramedics.

14  
15 331. Overdoses are not the only opioid-related health emergencies to which EMS must  
16 respond. For example, opioids have helped to drive a wave of new health problems that EMS  
17 must deal with. Many of these health problems, including infections and infectious diseases, fall  
18 outside the typical emergencies for which EMS was designed to respond or address. As a result,  
19 opioids have had subtler effects on EMS and its budget.

20  
21 332. Accordingly, EMS has shouldered and continues to shoulder a burden on its  
22 resources in responding to the opioid crisis caused by Defendants.

23 **3. The Pierce County Sheriff’s Department also devotes significant resources to**  
24 **handle the consequences of the opioid epidemic.**

25 333. The Pierce County Sheriff’s Department (PCSD) provides law enforcement, jail,  
26 court security, and civil processing services to all areas of unincorporated Pierce County and the  
contract cities of Edgewood and University Place. PCSD ensures the safety of the entire County

1 through its approximately 300 commissioned officers who serve unincorporated areas, 6  
2 commissioned officers in the City of Edgewood and 16 commissioned officers in the City of  
3 University Place, 309 commissioned corrections officers, and 61 civilian employees.

4           334. PCSD expends enormous resources fulfilling its critical missions. A significant  
5 portion of these resources are devoted to addressing and responding to the crisis caused by  
6 Defendants. The astounding and devastating rise of opioids—both “legal” and illegal—has  
7 profoundly affected public safety issues in the County, and the PCSD’s work and resources.  
8

9           335. For example, the opioid epidemic has forced PCSD to expend significant  
10 resources fighting drug trafficking in the County. In addition, crimes associated with illicit drug  
11 use, including violent and property crimes, have grown significantly. And the number of people  
12 involved in drug-related activities has reached new levels.  
13

14           336. Not only has drug use increased in the County, drug trafficking is now more  
15 complex. Pills and heroin arrive in the County through large, difficult-to-untangle networks that  
16 stretch across state lines. Combatting this rise in drug trafficking has forced the County to put  
17 more officers in the community and assign more detectives to investigate these drug cases.  
18

19           337. Because many of the sources of illegal opioids in Pierce County come from large  
20 criminal networks, PCSD has spent considerable time and effort coordinating law enforcement  
21 efforts with other jurisdictions.

22           338. PCSD deputies also are equipped with naloxone—which as described herein is a  
23 costly medication utilized to reverse an opioid overdose—and the County has incurred  
24 significant costs to ensure this life-saving drug is available to its deputies.  
25  
26

1           **4. The Pierce County Prosecuting Attorney’s Office and Pierce County District**  
2           **and Superior Courts have incurred substantial costs in responding to the**  
3           **epidemic caused by Defendants.**

4           339. The Pierce County Prosecuting Attorney’s Office (PAO) represents the County in  
5 both criminal and civil matters. It employs over 200 people, more than 115 of whom are  
6 attorneys.

7           340. The Criminal Division represents the state and the county in criminal matters in  
8 Pierce County District and Superior Courts, the state and federal courts of appeal, and the  
9 Washington and U.S. Supreme Courts. The Criminal Division, the largest division at the PAO, is  
10 responsible for prosecuting all felonies in Pierce County and all misdemeanors in unincorporated  
11 areas of Pierce County, including crimes related to opioids.

12           341. The Civil Division of the PAO provides legal advice to county officials and  
13 represents the County’s interest in court.

14           342. The Family Support Division is also an integral part of the federal and state child  
15 support system. This division represents the Division of Child Support, a Department of Social  
16 and Health Services (DSHS) agency, and works with child support agencies throughout  
17 Washington State, the United States, and abroad to establish and enforce child support and to  
18 protect the best interests of children.

19           343. The opioid epidemic has had a deep impact on the PAO. The opioid problem in  
20 Pierce County has been ongoing and persistent and is reflected in the criminal cases in the PAO.

21           344. In 2015, 191 opioid cases were referred to the drug unit and 171 opioid cases  
22 were charged in the Drug Unit. In 2015, 10.87% of the total cases in the Drug Unit were opioid-  
23 related, and the estimated total staff costs for Drug Unit cases associated with opioids were  
24 \$172,083.33.  
25  
26

1           345. In 2016, there were 574 opiate related referrals in the Drug Unit, and 585 opioid-  
2 related cases were charged. Notably, cases can be charged that were initially referred in a  
3 different year. In 2016, the percentage of charged Drug Unit cases that were opioid-related rose  
4 to 49.91%, with an approximate staff costs for those cases of \$864,505.25. The quick rise in the  
5 percentage of opioid-related drug cases is indicative of the opioid problem in Pierce County.  
6

7           346. In the Drug Unit specifically, there were 443 opioid-related referrals and 464  
8 opioid-related charged cases. In 2017, the number of charged opioid-related cases remained at  
9 49% of total Drug Unit cases, with an associated cost of prosecution for those cases of  
10 \$783,955.72.

11           347. The numerical change in charged drug cases as a percentage of total crimes,  
12 however, does not reflect the entire picture. In some of these cases, opioids are directly involved  
13 in the illegal activity; for example, the PAO routinely prosecutes people who sell heroin or  
14 prescription opioids on the illegal market. Yet opioids play a role in other cases, too, even when  
15 the charges are not related to controlled substances violations. Many of these cases are time  
16 intensive and cost the PAO significant resources to prosecute.  
17

18           348. The criminal impact is broader than the simple drug possession or destruction  
19 case. For example, many cases charged in other PAO units (Robbery, Gang, Elder Abuse,  
20 Domestic Violence, Property/ID Theft, Special Assault, Murder/Manslaughter, and the Vehicular  
21 unit) involved drugs, including opioids. Opioid consumption gone awry, or acts committed to  
22 fuel illicit drug use, are frequently at the heart of many violent and non-violent crimes. For  
23 example, an individual charged with identity theft (non-violent property crime) may be convicted  
24 of theft when the underlying motivation was fueling his or her drug addiction, or someone may  
25 be convicted of an assault when he or she also had heroin on his or her person.  
26

1 349. The Civil and Family Support Divisions, too, have not been immune to the  
2 impacts of the opioid epidemic. And the Family Support Division's work becomes more  
3 complex when parents are addicted to opioids.

4 350. In addition, PAO has made efforts to provide alternatives to prosecution and an  
5 opportunity for substance use disorder treatment, to non-violent eligible defendants.  
6

7 351. The rise in cases handled by the PAO has also had an obvious impact on the  
8 County's court system. The Courts have had to process and handle more cases involving opioid-  
9 related crimes.

10 352. The PAO and District and Superior Courts have engaged in efforts to provide  
11 alternatives to felony prosecution for possession of controlled substance charges. In 2016, the  
12 PAO, along with the Pierce County Superior and District Courts, formed the Drug Abuse  
13 Reduction Team (DART). DART is a two-year deferred sentencing program designed to help  
14 individuals who would otherwise be charged with felony possession of a controlled substance,  
15 who are willing to remain sober, change their lifestyle, actively participate in treatment, and  
16 engage in monitoring by probation. After the filing of felony charges, DART participant cases  
17 are refiled into District Court and resolved as a gross misdemeanor charge (solicitation to possess  
18 a controlled substance); if the defendant appears in District Court and pleads guilty, the felony  
19 case is dismissed and the defendant is admitted into the District Court DART program.  
20

21 353. If the participant successfully completes the two-year DART deferred sentencing  
22 program, the misdemeanor is dismissed and there are no convictions on their record arising from  
23 that offense. This program has directly impacted District Court case filings. The prosecuting  
24 attorney's district court unit has prioritized processing DART cases and monitoring compliance  
25 as a top priority.  
26

1 354. Pierce County also has a Drug Court that was established in 1994 through  
2 collaboration between Superior Court, the Prosecutor's Office, the Department of Assigned  
3 Counsel and the Pierce County Alliance. The program is an alternative to imprisonment and  
4 provides court supervised drug and alcohol treatment services for non-violent felony offenders.  
5

6 **5. Defendants' conduct has increased Pierce County's health care costs.**

7 355. Defendants' misrepresentations regarding the purported safety and efficacy of  
8 opioids have also substantially increased the County's health care costs. Pierce County provides  
9 health insurance to 2,900 employees and their dependents. The County offers a self-insured  
10 medical program, which means that when anyone covered by this health insurance program visits  
11 a doctor or fills a prescription or otherwise incurs covered health-related costs—including, for  
12 example, opioid-related medical claims—the County pays for those costs directly.  
13

14 356. Pierce County, like other entities and corporations across the country who are  
15 self-insured, has incurred significant costs for prescription opioids. For example, across the  
16 United States, people who are prescribed opioid painkillers cost health insurers approximately  
17 \$16,000 more than those who do not have such prescriptions.<sup>205</sup> Those costs, including those  
18 borne by the County, would have been avoided had Defendants not hidden the truth about the  
19 risks and benefits of opioids.  
20

21 357. Pierce County has also incurred opioid-related costs in administering its own  
22 workers' compensation program.

23 358. Had Defendants told the truth about the risks and benefits of opioids, Pierce  
24 County would not have had to pay for these drugs or the costs associated with opioid-related  
25 claims.  
26

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<sup>205</sup> *The Impact of the Opioid Crisis on the Healthcare System: A Study of Privately Billed Services*, FAIR Health  
(Sept. 2016), [http://www.khi.org/assets/uploads/news/14560/the\\_impact\\_of\\_the\\_opioid\\_crisis.pdf](http://www.khi.org/assets/uploads/news/14560/the_impact_of_the_opioid_crisis.pdf).

1           **6. The opioid epidemic has also contributed to the homelessness crisis in Pierce**  
2           **County.**

3           359. Another particularly visible effect of the opioid epidemic in Pierce County is the  
4 growing homeless population.

5           360. The 2016 Homeless Point-in-Time Count indicated that there were 1,762  
6 homeless persons in Pierce County, a 37% increase from 2015.<sup>206</sup> Forty-six percent more people  
7 were unsheltered or living somewhere not meant for human habitation. In 2017, those numbers  
8 decreased slightly; the Point-in-Time Count indicated that 1,321 people were homeless.<sup>207</sup>

9           361. Notwithstanding fluctuations in the numbers, homelessness is a persistent  
10 problem in Pierce County. In the last five years, unsheltered homelessness (i.e., sleeping outside  
11 or in places not meant for human habitation) increased by 157%. This statistic is consistent with  
12 what has been observed in the County—more encampments and people sleeping on sidewalks  
13 and in door steps. In Pierce County, and across the state, there are increases in unsheltered  
14 homelessness; even where total homelessness has declined, unsheltered homelessness has  
15 increased.

16           362. The number of people who are chronically homeless—i.e., homeless for longer  
17 than one year—has increased 97% over the last five years.

18           363. Although the causes of homelessness are multi-faceted and complex, substance  
19 abuse is both a contributing cause and result of homelessness. In Pierce County, the rise in  
20 homelessness is linked to the opioid epidemic. In fact, recent surveys in Tacoma estimated that at  
21 least 50% of its homeless population is addicted to opioids. In addition, a significant portion of  
22  
23  
24

25  
26 <sup>206</sup> 2016 Homeless Point In Time Count Results, Pierce County, <http://co.pierce.wa.us/DocumentCenter/View/41015>  
(last visited Jan. 31, 2018).

<sup>207</sup> Homelessness 2017, Pierce County, <http://co.pierce.wa.us/DocumentCenter/View/58187> (last visited Jan. 31,  
2018).

1 the calls received by Pierce County EMS relates to opioid-related emergencies from the  
2 County's homeless population.

3 364. Prescription opioids have not only helped to fuel homelessness, but have also  
4 made it immeasurably more difficult for Pierce County to address. For example, mental health  
5 services are critical for many in the homeless population, but opioid use and addiction can make  
6 it more difficult to provide effective mental health treatment. Opioids provide a way to self-  
7 medicate and avoid getting the treatment that might lead to long-term success and more positive  
8 outcomes. Whether opioid addiction was a contributing cause or a result of homelessness, opioid  
9 addictions now prevent many individuals from regaining permanent housing.

10 365. Additionally, while the leading cause of death among homeless Americans used  
11 to be HIV, it is now drug overdose. A study published in *JAMA Internal Medicine* found that  
12 overdoses were the leading cause of death among individuals experiencing homelessness in the  
13 Boston area. Of the overdose deaths, 81% involved opioids.<sup>208</sup>

14  
15  
16 **7. Individual stories of Pierce County residents demonstrate the devastating**  
17 **impacts of opioids.**

18 366. A resident of Fircrest in Pierce County recently wrote a letter to Pierce County  
19 regarding the opioid epidemic. She shared that after a 2007 surgery she was “almost instantly  
20 addicted to the pain medication [she] was sent home with.” She took them several times a day for  
21 three months until she was “cut off.” She described going into withdrawals and then looking for  
22 more pain medication. For eight years, she struggled with her addiction. In 2015, she began  
23 taking Suboxone, a combination of buprenorphine and naloxone designed to treat narcotic  
24 withdrawal symptoms.  
25

26  

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<sup>208</sup> Travis P. Baggett, MD, MPH, Stephen W. Hwang, MD, MPH, James J. O’Connell, MD, et al., *Mortality Among Homeless Adults in Boston, Shifts in Causes of Death Over a 15-Year Period*, 173 (3) *JAMA Intern Med.* 189-95 (2013), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1556797#qundefined>.

1           367. But Suboxone and similar opioid-addiction treatments such as methadone do not  
2 “cure” opioid addiction; they are themselves opioids. Some individuals in recovery may stay on  
3 Suboxone or other maintenance medications for the rest of their lives. As the Fircrest resident  
4 indicated, “now, here I am a little over 2 years later still addicted to suboxone . . . All I have done  
5 is switched one for another.”  
6

7           368. Her addiction negatively affected multiple aspects of her life; she has spent  
8 thousands of dollars on prescriptions and doctor bills, has had her vehicle impounded, and almost  
9 lost her marriage and family.

10           369. Her story is an example of how individuals become addicted to opioids through  
11 lawfully prescribed medications, following routine medical procedures. What it also  
12 demonstrates, however, is how difficult it is to fully recover from opioid addiction, even when  
13 actively undergoing treatment for it. Opioid addiction casts a long shadow, affecting individuals’  
14 lives, families, and communities for years.  
15

16           370. Another all-too-familiar story of how the opioid epidemic has affected individual  
17 lives in Pierce County was recently highlighted in the Tacoma News Tribune, as a thirty-four-  
18 year-old Pierce County man shared his story of addiction and recovery with the newspaper. His  
19 addiction began with abusing prescription pain pills during adolescence, and he then “moved  
20 from crushing and snorting OxyContin to smoking the powerful pain medication. When money  
21 got tight, his tolerance high and obtaining the pills on the street increasingly difficult, he  
22 graduated to shooting heroin—crossing a line he always told himself he wouldn’t.”<sup>209</sup>  
23  
24  
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26

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<sup>209</sup> Driscoll, *supra* note 7.

1 371. As a result of his addiction, he committed crimes, was homeless, and “betrayed  
2 everyone who would give him their trust.”<sup>210</sup> He “spent years living in cheap hotel rooms,  
3 stealing and dealing drugs to afford the heroin he needed to ‘get well.’”<sup>211</sup>  
4

5 372. In 2014, his older brother died in an incident the family believes was an  
6 addiction-related suicide. The medical examiner’s account described “multiple blunt force  
7 injuries” after the brother crashed his car, climbed over a barrier, and fell twenty-seven feet onto  
8 the pavement. The brothers had a history of prescription opioid abuse together. The thirty-four-  
9 year-old also acknowledged introducing his brother to methamphetamine.

10 373. His grief and guilt following his brother’s suicide propelled him further into  
11 addiction. Then he himself almost died, exactly one year after his brother’s death, when he  
12 overdosed on heroin. That near-fatal experience, along with his mother’s urging and the threat of  
13 prison hanging over his head, compelled him to seek help. Today, he is enrolled in community  
14 college and working as a behavioral health technician at a recovery center. He also launched an  
15 online support community, “Can’t Go Back,” ten months after getting clean. The online group,  
16 which provides support and inspiration for individuals in recovery, has since grown to over 2,500  
17 members.  
18

19 374. He describes the ongoing work of recovery as a book that is “never closed,”  
20 adding that “freedom from active addiction is never owned, it’s rented. And the rent is due every  
21 day.”<sup>212</sup> His story and the Fircrest resident’s story reflect the experiences of many others in  
22 Pierce County. Even for those fortunate enough to survive the opioid epidemic, there are  
23 enormous personal and societal costs associated with survival and recovery.  
24  
25

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26 <sup>210</sup> *Id.*

<sup>211</sup> *Id.*

<sup>212</sup> *Id.*

1 **I. No Federal Agency Action, Including by the FDA, Can Provide the Relief Pierce**  
2 **County Seeks Here.**

3 375. The injuries Pierce County has suffered and will continue to suffer cannot be  
4 addressed by agency or regulatory action. There are no rules the FDA could make or actions the  
5 agency could take that would provide Pierce County the relief it seeks in this litigation.

6 376. Even if prescription opioids were entirely banned today, thousands of Pierce  
7 County residents, and millions of Americans, would remain addicted to opioids. Overdoses will  
8 continue. The County will respond to related medical emergencies and administer naloxone. The  
9 Sheriff's Department will spend extraordinary resources combatting illegal opioid sales, and the  
10 Prosecuting Attorney's Office and Pierce County courts will remain burdened with opioid-  
11 related crimes. Social services and public health efforts will be stretched thin.

12 377. Regulatory action would do nothing to compensate the County for the money and  
13 resources it has already expended addressing the impacts of the opioid epidemic. Only this  
14 litigation has the ability to provide the County with the relief it seeks.

15 378. Furthermore, the costs Pierce County has incurred in responding to the homeless  
16 crises and in rendering public services described above are recoverable pursuant to the causes of  
17 actions raised by the County. Defendants' misconduct alleged herein is not a series of isolated  
18 incidents, but instead the result of a sophisticated and complex marketing scheme over the course  
19 of more than twenty years that has caused a substantial and long-term burden on the municipal  
20 services provided by the County. In addition, the public nuisance created by Defendants and the  
21 County's requested relief in seeking abatement further compels Defendants to reimburse and  
22 compensate Pierce County for substantial costs they have spent addressing the crisis caused by  
23 Defendants.  
24  
25  
26

1 **V. CLAIMS FOR RELIEF**

2 **COUNT ONE — VIOLATIONS OF THE WASHINGTON CONSUMER PROTECTION**  
3 **ACT, RCW 19.86, ET SEQ.**

4 379. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
5 fully set forth herein.

6 380. The Washington Consumer Protection Act is codified at RCW 19.86 *et seq.*  
7 (CPA). The CPA establishes a comprehensive framework for redressing the violations of  
8 applicable law, and municipalities of Washington State like Pierce County can enforce the CPA  
9 and recover damages. RCW 19.86.090. The conduct at issue in this case falls within the scope of  
10 the CPA.

11 381. The CPA prohibits unfair methods of competition and unfair or deceptive acts or  
12 practices in the conduct of any trade or commerce. Defendants engaged and continue to engage  
13 in the same pattern of unfair methods of competition, and unfair and/or deceptive conduct  
14 pursuant to a common practice of misleading the public regarding the purported benefits and  
15 risks of opioids.

16 382. Defendants, at all times relevant to this Complaint, directly and/or through their  
17 control of third parties, violated the CPA by making unfair and/or deceptive representations  
18 about the use of opioids to treat chronic and non-cancer pain, including to physicians and  
19 consumers in Pierce County. Each Defendant also omitted or concealed material facts and failed  
20 to correct prior misrepresentations and omissions about the purported benefits and risks of  
21 opioids. In addition, each Defendant's silence regarding the full risks of opioid use constitutes  
22 deceptive conduct prohibited by the CPA.

23 383. These unfair methods of competition and unfair and/or deceptive acts or practices  
24 in the conduct of trade or commerce were reasonably calculated to deceive Pierce County and its  
25  
26

1 consumers, and did in fact deceive the County and its consumers. Each Defendant's  
2 misrepresentations, concealments, and omissions continue to this day.

3 384. Pierce County has paid money for health care costs associated with prescription  
4 opioids for chronic pain. The County has also paid significant sums of money treating those  
5 covered by its health insurance for other opioid-related health costs. The Defendants'  
6 misrepresentations have further caused the County to spend substantial sums of money on  
7 increased law enforcement, emergency services, social services, public safety, and other human  
8 services in Pierce County, as described above.

9  
10 385. But for these unfair methods of competition and unfair and/or deceptive acts or  
11 practices in the conduct of trade or commerce, Pierce County would not have incurred the  
12 substantial payments to Defendants for harmful drugs with limited, if any, benefit, or the massive  
13 costs related to the epidemic caused by Defendants, as fully described above.

14  
15 386. Logic, common sense, justice, policy, and precedent indicate Defendants' unfair  
16 and deceptive conduct has caused the damage and harm complained of herein. Defendants knew  
17 or reasonably should have known that their statements regarding the risks and benefits of opioids  
18 were false and misleading, and that their statements were causing harm from their continued  
19 production and marketing of opioids. Thus, the harm caused by Defendants' unfair and deceptive  
20 conduct to Pierce County was reasonably foreseeable, including the financial and economic  
21 losses incurred by the County.

22  
23 387. Furthermore, Pierce County brings this cause of action in its sovereign capacity  
24 for the benefit of the State of Washington. The CPA expressly authorizes local governments to  
25 enforce its provisions and to recover damages for violations of the CPA, and this action is  
26 brought to promote the public welfare of the state and for the common good of the state.

1 388. As a direct and proximate cause of each Defendant’s unfair and deceptive  
2 conduct, (i) Pierce County has sustained and will continue to sustain injuries, and (ii) pursuant to  
3 RCW 19.86.090, Pierce County is entitled to actual and treble damages in amounts to be  
4 determined at trial, attorneys’ fees and costs, and all other relief available under the CPA.

5 389. The Court should also grant injunctive relief enjoining Defendants from future  
6 violations of the CPA. Defendants’ actions, as complained of herein, constitute unfair  
7 competition or unfair, deceptive, or fraudulent acts or practices in violation of the CPA.  
8

9 **COUNT TWO — PUBLIC NUISANCE**

10 390. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
11 fully set forth herein.

12 391. Pursuant to RCW 7.48.010, an actionable nuisance is defined as, *inter alia*,  
13 “whatever is injurious to health or indecent or offensive to the senses . . .”  
14

15 392. Pursuant to RCW 7.48.130, “A public nuisance is one which affects equally the  
16 rights of an entire community or neighborhood, although the extent of the damage may be  
17 unequal.”

18 393. Pursuant to Pierce County Code, Chapter 8.08.040(A), “A public nuisance  
19 consists of performing an unlawful act, or omitting to perform a duty, or permitting an action or  
20 condition to occur or exist which . . . [u]nreasonably annoys, injures, or endangers the comfort,  
21 repose, health, or safety of others.” The County can also assess civil penalties for these violations  
22 “in an amount up to \$1,000 for each violation” pursuant to Pierce County Code Chapter  
23 8.08.090(A).  
24

25 394. Pierce County and its residents have a right to be free from conduct that  
26 endangers their health and safety. Yet Defendants have engaged in conduct which endangers or  
injures the health and safety of the residents of the County by their production, promotion,

1 distribution, and marketing of opioids for use by residents of Pierce County and in a manner that  
2 substantially interferes with the welfare of Pierce County.

3 395. Each Defendant has created or assisted in the creation of a condition that is  
4 injurious to the health and safety of Pierce County and its residents, and interferes with the  
5 comfortable enjoyment of life and property of entire communities and/or neighborhoods in the  
6 County.  
7

8 396. Defendants' conduct has directly caused deaths, serious injuries, and a severe  
9 disruption of the public peace, order and safety, including fueling the homeless and heroin crises  
10 facing the County described herein. Defendants' conduct is ongoing and continues to produce  
11 permanent and long-lasting damage.  
12

13 397. The health and safety of the residents of Pierce County, including those who use,  
14 have used, or will use opioids, as well as those affected by users of opioids, are matters of  
15 substantial public interest and of legitimate concern to the County's citizens and its residents.  
16

17 398. Defendants' conduct has impacted and continues to impact a substantial number  
18 of people within Pierce County and is likely to continue causing significant harm to patients with  
19 chronic pain who are being prescribed and take opioids, their families, and their communities.  
20

21 399. But for Defendants' actions, opioid use and ultimately its misuse and abuse would  
22 not be as widespread as it is today, and the massive epidemic of opioid abuse that currently exists  
23 would have been averted.

24 400. Logic, common sense, justice, policy, and precedent indicate Defendants' unfair  
25 and deceptive conduct has caused the damage and harm complained of herein. Defendants knew  
26 or reasonably should have known that their statements regarding the risks and benefits of opioids  
were false and misleading, and that their false and misleading statements were causing harm

1 from their continued production and marketing of opioids. Thus, the public nuisance caused by  
2 Defendants to Pierce County was reasonably foreseeable, including the financial and economic  
3 losses incurred by the County.

4 401. Furthermore, Pierce County brings this cause of action in its sovereign capacity  
5 for the benefit of the State of Washington. The applicable RCW with respect to a public nuisance  
6 expressly prohibits the conduct complained of herein, and this action is brought to promote the  
7 public welfare of the state and for the common good of the state.

8 402. In addition, engaging in any business in defiance of a law regulating or  
9 prohibiting the same is a nuisance per se under Washington law. Each Defendant's conduct  
10 described herein of deceptively marketing opioids violates RCW 7.48.010 and therefore  
11 constitutes a nuisance per se.  
12

13 403. As a direct and proximate cause of Defendants' conduct creating or assisting in  
14 the creation of a public nuisance, Pierce County, its community, and its residents have sustained  
15 and will continue to sustain substantial injuries.  
16

17 404. Pursuant to RCW 7.48.020 and Pierce County Code, Chapter 8.08.080, Pierce  
18 County requests an order providing for abatement of the public nuisance that each Defendant has  
19 created or assisted in the creation of, and enjoining Defendants from future violations of RCW  
20 7.48.010 and Pierce County Code, Chapter 8.08.040(A).  
21

22 405. Pierce County also seeks the maximum statutory and civil penalties permitted by  
23 law as a result of the public nuisance created by Defendants.

24 **COUNT THREE — NEGLIGENCE**

25 406. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
26 fully set forth herein.



1 413. As set forth above, each Defendant owed a duty of care to Pierce County,  
2 including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-  
3 prescription of opioids.

4 414. In violation of this duty, each Defendant failed to take reasonable steps to prevent  
5 the misuse, abuse, and over-prescription of opioids in Pierce County by misrepresenting the risks  
6 and benefits associated with opioids.

7 415. In addition, each Defendant knew or should have known, and/or recklessly  
8 disregarded, that the opioids they manufactured, promoted, and distributed were being used for  
9 unintended uses.

10 416. For instance, Defendants failed to exercise slight care to Pierce County by, *inter*  
11 *alia*, failing to take appropriate action to stop opioids from being used for unintended purposes.  
12 Furthermore, despite each Defendant's actual or constructive knowledge of the wide  
13 proliferation and dissemination of opioids in Pierce County, Defendants took no action to  
14 prevent the abuse and diversion of their pharmaceutical drugs. In fact, Defendants promoted and  
15 actively targeted doctors and their patients in Pierce County through training their sales  
16 representatives to encourage doctors to prescribe more prescription opioids.

17 417. Defendants' misrepresentations further include falsely claiming that the risk of  
18 opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids  
19 was appropriate when patients presented symptoms of addiction, falsely claiming that risk-  
20 mitigation strategies could safely address concerns about addiction, falsely claiming that doctors  
21 and patients could increase opioid usage indefinitely without added risk, deceptively marketing  
22 that purported abuse-deterrent technology could curb misuse and addiction, and falsely claiming  
23 that long-term opioid use could actually restore function and improve a patient's quality of life.  
24  
25  
26

1 Each of these misrepresentations made by Defendants violated the duty of care to Pierce County,  
2 and in a manner that is substantially and appreciably greater than ordinary negligence.

3 418. As a direct and proximate cause of each Defendant's gross negligence, Pierce  
4 County has suffered and will continue to suffer harm, and is entitled to damages in an amount  
5 determined at trial.  
6

7 **COUNT FIVE — UNJUST ENRICHMENT**

8 419. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
9 fully set forth herein.

10 420. Each Defendant was required to take reasonable steps to prevent the misuse,  
11 abuse, and over-prescription of opioids.

12 421. Rather than prevent or mitigate the wide proliferation of opioids into Pierce  
13 County, each Defendant instead chose to place its monetary interests first and each Defendant  
14 profited immensely from supplying prescription opioids to Pierce County.  
15

16 422. Each Defendant also failed to maintain effective controls against the unintended  
17 and illegal use of their prescription opioids, again choosing instead to place its monetary interests  
18 first.

19 423. Each Defendant therefore received a benefit from the sale of prescription opioids  
20 to and in Pierce County, and these Defendants have been unjustly enriched at the expense of  
21 Pierce County.  
22

23 424. As a result, Pierce County is entitled to damages on its unjust enrichment claim in  
24 an amount to be proven at trial.  
25  
26

1 **COUNT SIX — VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT**  
2 **ORGANIZATIONS ACT (“RICO”), 18 U.S.C. § 1961, *ET SEQ.***

3 425. Plaintiff hereby incorporates by reference the allegations contained in the  
4 preceding paragraphs of this complaint.

5 426. This claim is brought by Pierce County against each Defendant for actual  
6 damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C.  
7 § 1961, *et seq.*

8 427. At all relevant times, each Defendant is and has been a “person” within the  
9 meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, “a legal or  
10 beneficial interest in property.”

11 428. Plaintiff is a “person,” as that term is defined in 18 U.S.C. § 1961(3), and has  
12 standing to sue as it was and is injured in its business and/or property as a result of the  
13 Defendants’ wrongful conduct described herein.

14 429. Section 1962(c) makes it “unlawful for any person employed by or associated  
15 with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce,  
16 to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through  
17 a pattern of racketeering activity . . . ” 18 U.S.C. § 1962(c).

18 430. Section 1962(d) makes it unlawful for “any person to conspire to violate” Section  
19 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

20 431. Each Defendant conducted the affairs of an enterprise through a pattern of  
21 racketeering activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

1 **A. Description of the Defendants’ Enterprise**

2 432. RICO defines an enterprise as “any individual, partnership, corporation,  
3 association, or other legal entity, and any union or group of individuals associated in fact  
4 although not a legal entity.” 18 U.S.C. § 1961(4).

5 433. Under 18 U.S.C. § 1961(4) a RICO “enterprise” may be an association-in-fact  
6 that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among  
7 those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise’s  
8 purpose. *See Boyle v. United States*, 556 U.S. 938, 946 (2009).

9 434. Defendants formed such an association-in-fact enterprise—referred to herein as  
10 “the Enterprise.”

11 435. The Enterprise consists of Defendants, Front Groups, and KOLs. In particular, the  
12 Enterprise consists of (a) Defendant Purdue, including its employees and agents, (b) Defendant  
13 Endo, including its employees and agents, and (c) Defendant Janssen, including its employees  
14 and agents (collectively, the “Defendants”); certain Front Groups described above, including but  
15 not limited to (a) the American Pain Foundation, including its employees and agents, (b) the  
16 American Academy of Pain Medicine, including its employees and agents, and (c) the American  
17 Pain Society, including its employees and agents (collectively, the “Front Groups”); and certain  
18 key opinion leaders, including but not limited to (a) Dr. Russell Portenoy, and (b) Kathleen Foley  
19 (collectively, the “KOLs”).

20 436. Alternatively, each of the above-named Defendants and Front Groups constitutes  
21 a single legal entity “enterprise” within the meaning of 18 U.S.C. § 1961(4), through which the  
22 members of the enterprise conducted a pattern of racketeering activity. The separate legal status  
23 of each member of the Enterprise facilitated the fraudulent scheme and provided a hoped-for  
24 shield from liability for Defendants and their co-conspirators.

1 437. Alternatively, each of Defendants, together with the Front Groups and the KOLs,  
2 constitute three separate, associated-in-fact Enterprises within the meaning of 18 U.S.C. §  
3 1961(4).

4 438. The Enterprise is an ongoing and continuing business organization consisting of  
5 “persons” within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic  
6 links for a common purpose: to sell pharmaceutical drugs, specifically opioids, that have little or  
7 no demonstrated efficacy for the pain they are purported to treat in the majority of persons that  
8 obtain prescriptions for them.

9  
10 439. To accomplish this purpose, the Enterprise engaged in a sophisticated, well-  
11 developed, and fraudulent marketing scheme designed to increase the prescription rate for  
12 Defendants’ opioid medications and popularize the misunderstanding that the risk of addiction to  
13 prescription opioids is low when used to treat chronic pain (the “Scheme”).  
14

15 **B. The Enterprise Sought to Fraudulently Increase Defendants’ Profits and Revenues**

16 440. At all relevant times, each Defendant was aware of the conduct of the Enterprise,  
17 was a knowing and willing participant in that conduct, and reaped profits from that conduct in  
18 the form of increased sales and prescriptions of their opioid medications while the Front Groups  
19 and KOLs received direct payments from Defendants in exchange their role in the Enterprise,  
20 and to advance the Enterprise’s fraudulent marketing scheme.

21 441. The Enterprise engaged in, and its activities affected, interstate and foreign  
22 commerce because it involved commercial activities across state boundaries, including but not  
23 limited to: (1) the marketing, promotion, and advertisement of Defendants’ opioid medication;  
24 (2) the advocacy at the state and federal level for change in the law governing the use and  
25 prescription of Defendants’ opioid medication; (3) the issuance of prescriptions and prescription  
26

1 guidelines for Defendants' opioid medication; and (4) the issuance of fees, bills, and statements  
2 demanding payment for prescriptions of Defendants' opioid medications.

3 442. The persons engaged in the Enterprise are systematically linked through  
4 contractual relationships, financial ties, and continuing coordination of activities, as spearheaded  
5 by Defendants. Each Defendant funded and directed the operations of the KOLs and the Front  
6 Groups; in fact, the board of directors of each of the Front Groups are and were full of doctors  
7 who were on the Defendants' payrolls, either as consultants or speakers at medical events.  
8 Moreover, each Defendant coordinated and, at times, co-funded their activities in furtherance of  
9 the goals of the Enterprise. This coordination can also be inferred through the consistent  
10 misrepresentations described below.  
11

12 443. There is regular communication between each Defendant, each of the Front  
13 Groups, and each KOL in which information regarding Defendants' opioid medication and the  
14 Defendants' marketing and education scheme to increase prescription rates for those medications  
15 is shared. Typically, this communication occurred, and continues to occur, through the use of the  
16 wires and the mail in which Defendants, the Front Groups, and the KOL share information  
17 regarding the operation of the Enterprise.  
18

19 444. The Enterprise functioned as a continuing unit for the purposes of executing the  
20 Scheme and when issues arose during the Scheme, each member of the Enterprise agreed to take  
21 actions to hide the Scheme and the existence of the Enterprise.  
22

23 445. Each Defendant participated in the operation and management of the Enterprise  
24 by directing its affairs as described herein.  
25  
26

1           446. While Defendants participated in, and are members of, the Enterprise, they have  
2 an existence separate from the Enterprise, including distinct legal statuses, affairs, offices and  
3 roles, officers, directors, employees, and individual personhood.

4           447. Each Defendant orchestrated the affairs of the Enterprise and exerted substantial  
5 control over the Enterprise by, at least: (1) making misleading statements about the purported  
6 benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of  
7 telephonic and electronic communications, CME programs, medical journals, advertisements,  
8 and websites; (2) employing sales representatives or detailers to promote the use of opioid  
9 medications; (3) purchasing and utilizing sophisticated marketing data (e.g., IMS data) to  
10 coordinate and refine the Scheme; (4) employing doctors to serve as speakers at or attend all-  
11 expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (5)  
12 funding, controlling, and operating the Front Groups to target doctors, patients, and lawmakers  
13 and provide a veneer of legitimacy to Defendants' Scheme; (6) retaining KOLs to promote the  
14 use of their opioid medicines; and (7) concealing the true nature of their relationship with the  
15 other members of the Enterprise, including the Front Groups and the KOLs.

16           448. In addition to the above described actions taken in furtherance of the Enterprise,  
17 Defendant Purdue specifically orchestrated the affairs of the Enterprise by: (1) making a number  
18 of misleading statements described herein; (2) funding, controlling, and operating the Front  
19 Groups, including the American Pain Foundation and the Pain & Policy Studies Group; (3)  
20 participating in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit  
21 organizations that, collectively, spent hundreds of millions of dollars lobbying against opioid-  
22 related measures; (4) retaining KOLs, including Dr. Russell Portenoy and Kathleen Foley to tout  
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25  
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1 the benefits of opioid medicines; and (5) concealing the true nature of its relationship with the  
2 other members of the Scheme, and the Enterprise, including the Front Groups and the KOLs.

3 449. In addition to the above-described actions taken in furtherance of the Enterprise,  
4 Defendant Endo specifically orchestrated the affairs of the Enterprise by: (1) making a number of  
5 misleading statements described herein; (2) sponsoring a 2009 National Initiative on Pain  
6 Control CME program which promoted the concept of pseudoaddiction; (3) funding, controlling,  
7 and operating the Front Groups, including the American Pain Foundation and the Pain & Policy  
8 Studies Group; (3) sponsoring a series of CME programs which claimed that opioid therapy has  
9 been shown to reduce pain and depressive symptoms; (4) supporting and sponsoring guidelines  
10 indicating that opioid medications are effective and can restore patients' quality of life; (5)  
11 participating in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit  
12 organizations that, collectively, spent hundreds of millions of dollars lobbying against opioid-  
13 related measures; (6) retaining KOLs, including Dr. Russell Portenoy and Kathleen Foley to tout  
14 the benefits of opioid medicines; and (7) concealing the true nature of its relationship with the  
15 other members of the Scheme and the Enterprise, including the Front Groups and the KOLs.

16 17 18 450. In addition to the above described actions taken in furtherance of the Enterprise,  
19 Defendant Janssen specifically orchestrated the affairs of the Enterprise by: (1) making a number  
20 of misleading statements described herein; (2) funding, controlling, and operating Front Groups,  
21 including the Pain & Policy Studies Group; (3) supporting and sponsoring guidelines indicating  
22 that opioid medications are effective and can restore patients' quality of life; (4) sponsoring,  
23 funding, and editing a website which features an interview indicating that opioid medications can  
24 improve patients' function; (5) participating in the Pain Care Forum, a coalition of drug makers,  
25 trade groups, and nonprofit organizations that, collectively, spent hundreds of millions of dollars  
26

1 lobbying against opioid-related measures; (6) retaining KOLs, including Dr. Russell Portenoy  
2 and Kathleen Foley to tout the benefits of opioid medicines; and (7) concealing the true nature of  
3 its relationship with the other members of the Enterprise, including the Front Groups and the  
4 KOLs.

5  
6 451. The Front Groups orchestrated the affairs of the Enterprise and exerted substantial  
7 control over the Enterprise by, at least: (1) making misleading statements about the purported  
8 benefits, efficacy, and low risks of opioids described herein; (2) holding themselves out as  
9 independent advocacy groups, when in fact their operating budgets are entirely comprised of  
10 contributions from opioid drug manufacturers; (3) lobbying against federal and state proposals to  
11 limit opioid use; (4) publishing treatment guidelines that advised the prescription of opioids; (5)  
12 engaging in ‘unbranded’ advertisement for opioid medicines; (6) hosting medical education  
13 programs that touted the benefits of opioids to treat chronic pain while minimizing and  
14 trivializing their risks; and (7) concealing the true nature of their relationship with the other  
15 members of the Enterprise.  
16

17 452. In addition to the above described actions taken in furtherance of the Enterprise,  
18 the American Pain Foundation specifically orchestrated the affairs of the Enterprise and exerted  
19 substantial control over the Enterprise by, at least: (1) making a number of public statements,  
20 detailed herein, advocating for the prescription of opioids; (2) holding itself out to be an  
21 independent and scientific body despite maintaining an operating budget comprised almost  
22 entirely of donations from Defendants, including Purdue and Endo; (3) consistently lobbying  
23 against federal and state proposals to limit opioid use; (4) publishing treatment guidelines which  
24 encouraged the prescription of opioid medicines including the 2009 “Guideline for the Use of  
25  
26

1 Chronic Opioid Therapy in Chronic Noncancer Pain-Evidence Review””; and (5) sponsoring  
2 medical education programs advocating for the prescription of opioid medicines.

3 453. In addition to the above described actions taken in furtherance of the Enterprise,  
4 the American Academy of Pain Medicine specifically orchestrated the affairs of the Enterprise  
5 and exerted substantial control over the Enterprise by, at least: (1) making a number of public  
6 statements, detailed herein, advocating for the prescription of opioids; (2) holding itself out to be  
7 an independent and scientific body despite maintaining an operating budget comprised almost  
8 entirely of donations from Defendants; (3) consistently lobbying against federal and state  
9 proposals to limit opioid use; (4) publishing treatment guidelines which encouraged the  
10 prescription of opioid medicines; and (5) sponsoring medical education programs advocating for  
11 the prescription of opioid medicines.  
12

13 14 454. In addition to the above described actions taken in furtherance of the Enterprise,  
15 the American Pain Society specifically orchestrated the affairs of the Enterprise and exerted  
16 substantial control over the Enterprise by, at least: (1) making a number of public statements,  
17 detailed herein, advocating for the prescription of opioid medications; (2) holding itself out to be  
18 an independent and scientific body despite maintaining an operating budget comprised almost  
19 entirely of donations from Defendants; and (3) publishing treatment guidelines which  
20 encouraged the prescription of opioid medicines including the 2009 “Guideline for the Use of  
21 Chronic Opioid Therapy in Chronic Noncancer Pain-Evidence Review.”  
22

23 455. The KOLs orchestrated the affairs of the Enterprise and exerted substantial  
24 control over the Enterprise by, at least: (1) making misleading statements about the purported  
25 benefits, efficacy, and low risks of opioids; (2) holding themselves out as independent, when in  
26

1 fact there are systematically linked to and funded by opioid drug manufacturers; and (3)  
2 concealing the true nature of their relationship with the other members of the Enterprise.

3 456. Without the willing participation of each member of the Enterprise, the Scheme  
4 and the Enterprise's common course of conduct would not have been successful.

5 457. The members of the Enterprise directed and controlled the ongoing organization  
6 necessary to implement the Scheme at meetings and through communications of which Plaintiff  
7 cannot fully know at present, because such information lies in the Defendants' and others' hands.

8  
9 **C. Predicate Acts: Mail and Wire Fraud**

10 458. To carry out, or attempt to carry out, the scheme to defraud, the members of the  
11 Enterprise, each of whom is a person associated-in-fact with the Enterprise, did knowingly  
12 conduct or participate, directly or indirectly, in the affairs of the Enterprise through a pattern of  
13 racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and  
14 employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud)  
15 and § 1343 (wire fraud).

16  
17 459. Specifically, the members of the Enterprise have committed, conspired to commit,  
18 and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity  
19 (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

20 460. The multiple acts of racketeering activity which the members of the Enterprise  
21 committed, or aided or abetted in the commission of, were related to each other, posed a threat of  
22 continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

23 461. The racketeering activity was made possible by the Enterprise's regular use of the  
24 facilities, services, distribution channels, and employees of the Enterprise.

25 462. The members of the Enterprise participated in the Scheme by using mail,  
26 telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

1 463. The members of the Enterprise used, directed the use of, and/or caused to be used,  
2 thousands of interstate mail and wire communications in service of their Scheme through  
3 common misrepresentations, concealments, and material omissions.

4 464. In devising and executing the illegal Scheme, the members of the Enterprise  
5 devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiff and the  
6 public to obtain money by means of materially false or fraudulent pretenses, representations,  
7 promises, or omissions of material facts.

8 465. For the purpose of executing the illegal Scheme, the members of the Enterprise  
9 committed these racketeering acts, which number in the thousands, intentionally and knowingly  
10 with the specific intent to advance the illegal Scheme.

11 466. The Enterprise's predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but  
12 are not limited to:

13  
14  
15 A. Mail Fraud: The members of the Enterprise violated 18 U.S.C. § 1341 by  
16 sending or receiving, or by causing to be sent and/or received, fraudulent materials  
17 via U.S. mail or commercial interstate carriers for the purpose of selling drugs,  
18 specifically opioids, that have little or no demonstrated efficacy for the pain they  
19 are purported to treat in the majority of persons prescribed them.

20 B. Wire Fraud: The members of the Enterprise violated 18 U.S.C. § 1343 by  
21 transmitting and/or receiving, or by causing to be transmitted and/or received,  
22 fraudulent materials by wire for the purpose of selling drugs, specifically opioids,  
23 that have little or no demonstrated efficacy for the pain they are purported to treat  
24 in the majority of persons prescribed them.

25 467. Defendant Purdue's false or misleading use of the mails and wires include, but are  
26 not limited to: (1) a May 31, 1996 press release announcing the release of OxyContin and  
indicating that the fear of its addictive properties is exaggerated; (2) a 1990 promotional video in  
which Dr. Portenoy, a paid Purdue KOL, understated the risk of opioid addiction; (3) a 1998  
promotion video which erroneously cited a 1980 NEJM letter in support of the use of opioids to

1 treat chronic pain; (4) statements made on its 2000 “Partners Against Pain” website which  
2 claimed that the addiction risk of OxyContin was very low; (5) literature distributed to  
3 physicians which erroneously cited a 1980 NEJM letter in support of the use of opioids to treat  
4 chronic pain; (6) August 2001 statements to Congress by Purdue Executive Vice President and  
5 Chief Operating Officer Michael Friedman regarding the value of OxyContin in treating chronic  
6 pain; (7) a patient brochure entitled “A Guide to Your New Pain Medicine and How to Become a  
7 Partner Against Pain” indicating that OxyContin is non-addicting; (8) a 2001 statement by Senior  
8 Medical Director for Purdue, Dr. David Haddox, indicating that the ‘legitimate’ use of  
9 OxyContin would not result in addiction; (9) multiple communications by Purdue’s sales  
10 representatives regarding the low risk of addiction associated with opioids; (10) statements  
11 included in promotional materials for opioids distributed to doctors via the mail and wires; (11)  
12 statements in a 2003 Patient Information Guide distributed by Purdue indicating that addiction to  
13 opioid analgesics in properly managed patients with pain has been reported to be rare; (12)  
14 telephonic and electronic communications to doctors and patients indicating that signs of  
15 addiction in the case of opioid use are likely only the signs of under-treated pain; (13) statements  
16 in Purdue’s Risk Evaluation and Mitigation Strategy for OxyContin indicating that drug-seeking  
17 behavior on the part of opioid patients may, in fact, be pain-relief seeking behavior; (14)  
18 statements made on Purdue’s website and in a 2010 “Dear Healthcare Professional” letter  
19 indicating that opioid dependence can be addressed by dosing methods such as tapering; (15)  
20 statements included in a 1996 sales strategy memo indicating that there is no ceiling dose for  
21 opioids for chronic pain; (16) statements on its website that abuse-resistant products can prevent  
22 opioid addiction; (17) statements made in a 2012 series of advertisements for OxyContin  
23 indicating that long-term opioid use improves patients’ function and quality of life; (18)  
24  
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1 statements made in advertising and a 2007 book indicating that pain relief from opioids improve  
2 patients' function and quality of life; (19) telephonic and electronic communications by its sales  
3 representatives indicating that opioids will improve patients' function; and (20) electronic and  
4 telephonic communications concealing its relationship with the other members of the Enterprise.

5  
6 468. Defendant Endo Pharmaceuticals, Inc. also made false or misleading claims in  
7 violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made,  
8 beginning in at least 2009, on an Endo-sponsored website, PainKnowledge.com, indicating that  
9 patients who take opioids as prescribed usually do not become addicted; (2) statements made on  
10 another Endo-sponsored website, PainAction.com, indicating that most chronic pain patients do  
11 not become addicted to opioid medications; (3) statements in pamphlets and publications  
12 described by Endo indicating that most people who take opioids for pain relief do not develop an  
13 addiction; (4) statements made on the Endo-run website, Opana.com, indicating that opioid use  
14 does not result in addiction; (5) statements made on the Endo-run website, Opana.com,  
15 indicating that opioid dependence can be addressed by dosing methods such as tapering; (6)  
16 statements made on its website, PainKnowledge.com, that opioid dosages could be increased  
17 indefinitely; (7) statements made in a publication entitled "Understanding Your Pain: Taking  
18 Oral Opioid Analgesics" suggesting that opioid doses can be increased indefinitely; (8)  
19 electronic and telephonic communications to its sales representatives indicating that the formula  
20 for its medicines is 'crush resistant;' (9) statements made in advertisements and a 2007 book  
21 indicating that pain relief from opioids improves patients' function and quality of life; (10)  
22 telephonic and electronic communications by its sales representatives indicating that opioids will  
23 improve patients' function; and (11) telephonic and electronic communications concealing its  
24 relationship with the other members of the Enterprise.  
25  
26

1           469. Defendant Janssen made false or misleading claims in violation of 18 U.S.C. §  
2 1341 and § 1343 including but not limited to: (1) statements on its website,  
3 PrescribeResponsibly.com, indicating that concerns about opioid addiction are overestimated; (2)  
4 statements in a 2009 patient education guide claiming that opioids are rarely addictive when used  
5 properly; (3) statements included on a 2009 Janssen-sponsored website promoting the concept of  
6 opioid pseudoaddiction; (4) statements on its website, PrescribeResponsibly.com, advocating the  
7 concept of opioid pseudoaddiction; (5) statements on its website, PrescribeResponsibly.com,  
8 indicating that opioid addiction can be managed; (6) statements in its 2009 patient education  
9 guide indicating the risks associated with limiting the dosages of pain medicines; (7) telephonic  
10 and electronic communications by its sales representatives indicating that opioids will improve  
11 patients' function; and (8) telephonic and electronic communications concealing its relationship  
12 with the other members of the Enterprise.  
13  
14

15           470. The American Academic of Pain Medicine made false or misleading claims in  
16 violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made in a  
17 2009 patient education video entitled "Finding Relief: Pain Management for Older Adults"  
18 indicating the opioids are rarely addictive; and (2) telephonic and electronic communications  
19 concealing its relationship with the other members of the Enterprise.  
20

21           471. The American Pain Society Quality of Care Committee made a number of false or  
22 misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) a  
23 May 31, 1996 press release in which the organization claimed there is very little risk of addiction  
24 from the proper use of drugs for pain relief; and (2) telephonic and electronic communications  
25 concealing its relationship with the other members of the Enterprise.  
26

1           472.    The American Pain Foundation (“APF”) made a number of false and misleading  
2 claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements  
3 made by an APF Executive Director to Congress indicating that opioids only rarely lead to  
4 addiction; (2) statements made in a 2002 amicus curiae brief filed with an Ohio appeals court  
5 claiming that the risk of abuse does not justify restricting opioid prescriptions for the treatment  
6 of chronic pain; (3) statements made in a 2007 publication entitled “Treatment Options: A Guide  
7 for People Living with Pain” indicating that the risks of addiction associated with opioid  
8 prescriptions have been overstated; (4) statements made in a 2002 court filing indicating that  
9 opioid users are not ‘actual addicts;’ (5) statements made in a 2007 publication entitled  
10 “Treatment Options: A Guide for People Living with Pain” indicating that even physical  
11 dependence on opioids does not constitute addiction; (6) claims on its website that there is no  
12 ceiling dose for opioids for chronic pain; (7) statements included in a 2011 guide indicating that  
13 opioids can improve daily function; and (8) telephonic and electronic communications  
14 concealing its relationship with the other members of the Enterprise.  
15

16  
17           473.    The KOLs, including Russell Portenoy and Kathleen Foley, made a number of  
18 misleading statements in the mail and wires in violation of 18 U.S.C. § 1341 and § 1343,  
19 described above, including statements made by Dr. Portenoy in a promotional video indicating  
20 that the likelihood of addiction to opioid medications is extremely low. Indeed, Dr. Portenoy has  
21 since admitted that his statements about the safety and efficacy of opioids were false.  
22

23           474.    The mail and wire transmissions described herein were made in furtherance of  
24 Defendants’ Scheme and common course of conduct designed to sell drugs that have little or no  
25 demonstrated efficacy for the pain they are purported to treat in the majority of persons  
26 prescribed them; increase the prescription rate for opioid medications; and popularize the

1 misunderstanding that the risk of addiction to prescription opioids is low when used to treat  
2 chronic pain.

3 475. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate  
4 wire facilities have been deliberately hidden, and cannot be alleged without access to  
5 Defendants' books and records. However, Plaintiff has described the types of predicate acts of  
6 mail and/or wire fraud, including certain specific fraudulent statements and specific dates upon  
7 which, through the mail and wires, Defendants engaged in fraudulent activity in furtherance of  
8 the Scheme.

9  
10 476. The members of the Enterprise have not undertaken the practices described herein  
11 in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. §  
12 1962(d), the members of the Enterprise conspired to violate 18 U.S.C. § 1962(c), as described  
13 herein. Various other persons, firms, and corporations, including third-party entities and  
14 individuals not named as defendants in this Complaint, have participated as co-conspirators with  
15 Defendants and the members of the Enterprise in these offenses and have performed acts in  
16 furtherance of the conspiracy to increase or maintain revenue, increase market share, and/or  
17 minimize losses for the Defendants and their named and unnamed co-conspirators throughout the  
18 illegal scheme and common course of conduct.

19  
20 477. The members of the Enterprise aided and abetted others in the violations of the  
21 above laws.

22  
23 478. To achieve their common goals, the members of the Enterprise hid from Plaintiff  
24 and the public: (1) the fraudulent nature of Defendants' marketing scheme; (2) the fraudulent  
25 nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of  
26

1 and risk of addiction associated with Defendants' opioid medications; and (3) the true nature of  
2 the relationship between the members of the Enterprise.

3 479. Defendants and each member of the Enterprise, with knowledge and intent,  
4 agreed to the overall objectives of the Scheme and participated in the common course of conduct.  
5 Indeed, for the conspiracy to succeed, each of the members of the Enterprise and their co-  
6 conspirators had to agree to conceal their fraudulent scheme.  
7

8 480. The members of the Enterprise knew, and intended that, Plaintiff and the public  
9 would rely on the material misrepresentations and omissions made by them and suffer damages  
10 and a result.

11 481. As described herein, the members of the Enterprise engaged in a pattern of related  
12 and continuous predicate acts for years. The predicate acts constituted a variety of unlawful  
13 activities, each conducted with the common purpose of obtaining significant monies and  
14 revenues from Plaintiff and the public based on their misrepresentations and omissions.  
15

16 482. The predicate acts also had the same or similar results, participants, victims, and  
17 methods of commission.

18 483. The predicate acts were related and not isolated events.

19 484. The true purposes of Defendants' Scheme were necessarily revealed to each  
20 member of the Enterprise. Nevertheless, the members of the Enterprise continued to disseminate  
21 misrepresentations regarding the nature of Defendants' opioid medications and the functioning  
22 of the Scheme.  
23

24 485. Defendants' fraudulent concealment was material to Plaintiff and the public. Had  
25 the members of the Enterprise disclosed the true nature of the Defendants' opioid medications,  
26

1 Plaintiff would not have acted as it did, including relying on Defendants' misrepresentations to  
2 their detriment.

3 486. The pattern of racketeering activity described above is currently ongoing and  
4 open-ended, and threatens to continue indefinitely unless this Court enjoins the racketeering  
5 activity.  
6

7 **D. Pierce County Has Been Damaged by Defendants' RICO Violations**

8 487. By reason of, and as a result of the conduct of the Enterprise and, in particular, its  
9 pattern of racketeering activity, Pierce County, its community, and the public have been injured  
10 in their business and/or property in multiple ways, including but not limited to increased health  
11 care costs, increased human services costs, costs related to dealing with opioid-related crimes  
12 and emergencies, and other public safety costs, as fully described above.  
13

14 488. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and  
15 proximately caused injuries and damages to Pierce County, its community, and the public, and  
16 the County is entitled to bring this action for three times its actual damages, as well as  
17 injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. § 1964(c).  
18

19 **PRAYER FOR RELIEF**

20 WHEREFORE, Plaintiff Pierce County respectfully requests the Court order the  
21 following relief:

- 22 A. An Order that the conduct alleged herein violates the Washington CPA;  
23 B. An Order that Plaintiff is entitled to treble damages pursuant to the Washington  
24 CPA;  
25 C. An Order that the conduct alleged herein constitutes a public nuisance, including  
26 under RCW 7.48 *et seq.*, Pierce County Code, Chapter 8.08.040(A), and under Washington law;  
D. An Order that Defendants abate the public nuisance that they caused;

1 E. An Order that Defendants are liable for civil and statutory penalties to the fullest  
2 extent permissible under Washington law for the public nuisance they caused;

3 F. An Order that Defendants are negligent under Washington law;

4 G. An Order that Defendants are grossly negligent under Washington law;

5 H. An Order that Defendants have been unjustly enriched at Plaintiff's expense  
6 under Washington law;

7 I. An Order that Defendants' conduct constitutes violations of the Racketeer  
8 Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, *et seq.*;

9 J. An Order that Plaintiff is entitled to recover all measure of damages permissible  
10 under the statutes identified herein and under common law;

11 K. An Order that Defendants are enjoined from the practices described herein;

12 L. An Order that judgment be entered against Defendants in favor of Plaintiff;

13 M. An Order that Plaintiff is entitled to attorneys' fees and costs pursuant to any  
14 applicable provision of law, including but not limited to under the Washington CPA; and

15 N. An Order awarding any other and further relief deemed just and proper, including  
16 pre-judgment and post-judgment interest on the above amounts.

17  
18  
19 **JURY TRIAL DEMAND**

20 Plaintiff demands a trial by jury on all claims and of all issues so triable.

21 DATED this 1st day of February, 2018.  
22  
23  
24  
25  
26

1 **PIERCE COUNTY**

**KELLER ROHRBACK L.L.P.**

2  
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4 By /s/ Michelle Luna-Green  
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By /s/ Gretchen Freeman Cappio  
By /s/ David J. Ko  
By /s/ Daniel P. Mensher  
By /s/ Alison S. Gaffney  
Lynn Lincoln Sarko, WSBA #16569  
Derek W. Loeser, WSBA #24274  
Gretchen Freeman Cappio, WSBA #29576  
David J. Ko, WSBA #38299  
Daniel P. Mensher, WSBA #47719  
Alison S. Gaffney, WSBA #45565  
Erika M. Keech, WSBA #45988  
(admission pending)  
1201 Third Avenue, Suite 3200  
Seattle, WA 98101  
Phone: 206-623-1900  
Fax: 206-623-3384

*Attorneys for Plaintiff*

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Pierce County

(b) County of Residence of First Listed Plaintiff Pierce (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) Keller Rohrback L.L.P. Pierce County Prosecuting Attorney's Office 1201 Third Avenue, Suite 3200 9655 Tacoma Avenue South, Suite 310 Seattle, WA 98101 - 206-623-1900 Tacoma, WA 98402 - 253-798-6380

DEFENDANTS

Purdue Pharma, L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Janssen Pharmaceuticals, Inc.; Johnson & Johnson; and John and Jane Does 1 Through 100, Inclusive

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship: Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation.

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Large table with categories: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District (specify)
6 Multidistrict Litigation - Transfer
8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 18 U.S.C. Section 1961, et seq. Brief description of cause: Plaintiff alleges violations of the Washington CPA and RICO, other causes of action under WA law.

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Honorable Richardo S. Martinez DOCKET NUMBER USDC WD WA 3:17-cv-5737

DATE SIGNATURE OF ATTORNEY OF RECORD s/Derek W. Loeser

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

## INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

### Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.  
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.  
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.  
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.  
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.  
 Original Proceedings. (1) Cases which originate in the United States district courts.  
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.  
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.  
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.  
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.  
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.  
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.  
**PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.  
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.  
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.
- Date and Attorney Signature.** Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Washington

Pierce County

Plaintiff(s)

v.

Purdue Pharma, L. P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Janssen Pharmaceuticals, Inc; Johnson & Johnson; and John and Jane Does 1 through 100, inclusive.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Purdue Pharma, L. P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Janssen Pharmaceuticals, Inc; Johnson & Johnson; and John and Jane Does 1 through 100, inclusive.

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Derek W. Loeser
Keller Rohrback L.L.P.
1201 Third Avenue, Suite 3200
Seattle, WA 98101

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_ .

I personally served the summons on the individual at *(place)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* \_\_\_\_\_ , who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_ ; or

I returned the summons unexecuted because \_\_\_\_\_ ; or

Other *(specify)*:

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_ 0.00 \_\_\_\_\_ .

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc: