UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT TACOMA

CITY OF TACOMA,

Plaintiff,

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,

Defendants.

No. 3:17-cv-5737

COMPLAINT

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I. INTRODUCTION

1. The United States is currently experiencing an epidemic and crisis unlike any it has seen before—the misuse, abuse, and over-prescription of opioids.

2. Since the mid-1990s, sales of opioids have increased almost ten-fold, revenues for the pharmaceutical companies that manufacture these drugs have skyrocketed, and opioids have become the most prescribed class of drugs in America. In 2016 alone, health care providers wrote more than 289 million prescriptions for opioid pain medication, enough for *every adult in the United States* to have more than one bottle of pills.[1]

3. As a result of the flood of opioids into this country, cities like Tacoma have had to deal with the crippling effects of widespread opioid addiction. The Centers for Disease Control and Prevention ("CDC") recently estimated that the total economic burden of prescription opioid abuse costs the United States $78.5 billion per year, which includes significantly increased costs for health care and addiction treatment, and dramatic increases in strains on human services and criminal justice systems, as well as substantial losses in work force productivity.[2]

4. The cost in human lives is even more staggering. Today, opioids are the leading cause of accidental deaths in the country, surpassing deaths caused by car accidents. And exposure to these dangerous drugs comes through purportedly legitimate prescriptions written by doctors and dentists, making this an epidemic like no other.

5. Defendants, drug manufacturers of opioids, represented to physicians and the public that opioids were safe and effectively treated pain, with a low risk for addiction. But for

[1] *Prevalence of Opioid Misuse*, BupPractice, https://www.buppractice.com/node/15576 (last visited Sept. 7, 2017).
[2] *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.

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many of those prescribed opioids, the consequences have been severe. Every day more than 1,000 people are admitted to emergency rooms across the country because of opioid-related abuse. Naloxone, a costly medication used to block and reverse the effects of an opioid overdose, is now routinely carried by law enforcement and EMTs. And individuals addicted to opioids, but without a prescription or the resources to obtain them, have turned to heroin, sparking another crisis directly related to the widespread abuse of opioids.

6. The epidemic is not a coincidence. Instead, it is the direct result of a sophisticated and well-developed marketing scheme by Defendants to sell drugs that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons who receive prescriptions for them. Despite minimal or arguably no scientific evidence indicating that opioids offer any long-term benefit in treating chronic pain, Defendants misleadingly advertised their opioids as a panacea and pushed hundreds of millions of pills into the marketplace for consumption, fueling a crisis of unprecedented levels.

7. In fact, to date, there have been no long-term studies that demonstrate that opioids are effective for treating long-term or chronic pain. Instead, reliable sources of information, including from the CDC last year, indicate that there is "*[n]o evidence*" to show "a long-term benefit of opioids in pain and function versus no opioids for chronic pain."[3] By contrast, significant research has demonstrated the colossal dangers of opioids. The CDC, for example, concluded that "[e]xtensive evidence shows the possible harms of opioids (including opioid use

[3] 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.

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disorder, overdose, and motor vehicle injury)" and that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder."[4]

8. This crisis arose because Defendants told physicians and the public, through a well-orchestrated marketing campaign, that the risk of addiction to prescription opioids was low when opioids were prescribed to treat chronic pain. In support of this claim, Defendants misrepresented research and manipulated data to make opioids appear safe. For instance, Defendants widely invoked a one-paragraph letter-to-the-editor published in the New England Journal of Medicine ("NEJM") in 1980 that declared the incidence of addiction was "rare" for patients treated with opioids.[5]

9. Defendants used this letter to promote opioids as safe treatment for chronic pain, even though the letter's authors examined only the files of patients administered opioids to treat acute pain in a hospital under doctor supervision.[6] Despite knowing the very limited scope of the study, Defendants regularly utilized and cited this letter as proof of the low addiction risk in connection with taking opioids. Defendants' egregious misrepresentations based on this letter included claims that *less than one percent* of opioid users become addicted.

10. Defendants' marketing campaign worked. Their reliance on this letter and other sources of information that were false and misleading (as described in more detail below) ultimately resulted in a well-documented and substantial increase in prescription rates of opioids. But on June 1, 2017, the NEJM published another letter calling attention to the way the one-

[4] *Id.*
[5] 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.
[6] *Id.*

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paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . .[7]

Unfortunately, by the time of this analysis and the CDC's findings last year, the damage had already been done. Defendants successfully manipulated the 1980 letter as the "evidence" supporting their fundamental misrepresentation that the risk of opioid addiction was low when opioids were prescribed to treat pain.

11. References to this letter were just one small part of the tidal wave of false and misleading statements made by Defendants over the last 20 years, including statements that continue to this day, regarding the purported benefits and minimal risks of opioids.

12. Defendants spent substantial sums of money promoting and marketing opioids to doctors, patients, and the public, including through direct marketing, front groups, key opinion leaders, medical journals, and unbranded advertising. Through their well-orchestrated campaign, Defendants were able to convey a message that touted the purported benefits of opioids to treat pain and downplayed the risks of addiction related to opioid use.

13. Furthermore, Defendants consistently, deliberately, and recklessly made false and misleading statements—including to doctors and patients in Tacoma— regarding, *inter alia*, the low risk of addiction to opioids, the need to prescribe more opioids to treat pain, risk-mitigation

[7] 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.

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strategies to safely prescribe opioids, the lack of risk associated with higher dosages of opioids, the benefits of abuse-deterrent technology to curb abuse, and that long-term opioid use improved patients' function and quality of life.

14. Defendants profited handsomely from this campaign, generating billions of dollars in sales. Annual prescription opioid sales have consistently approached more than $10 billion in recent years. Indeed, despite making up only 4.6% of the world's population, Americans consume 80% of the world's opioid supply, including 99% percent of the global hydrocodone supply.

15. In short, Defendants made and continue to make false and misleading statements about the benefits and risks of opioids, and did so through a well-funded marketing and advertising scheme to doctors, patients, and the public—including to doctors and patients in the City of Tacoma—despite knowing that there was little to no evidence to support their claims. As a result of these false and misleading statements, Tacoma has suffered significant economic damages, including but not limited to increased health care costs it bears as a self-insured city, health services costs, costs related to responding to and dealing with opioid-related crimes and emergencies—most notably borne by the Tacoma Police and Fire Departments—and other significant public safety costs, as described in more detail below.

16. Accordingly, the City of Tacoma brings this action to hold Defendants liable for their deliberate misrepresentation regarding the benefits and risks of using opioids to treat pain—conduct that (i) violates the Washington Consumer Protection Act, RCW 19.86 *et seq.*, (ii) constitutes a public nuisance under Washington law, (iii) constitutes negligence under Washington law, and (iv) violates the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, *et seq.*

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II. PARTIES

Tacoma

17. Plaintiff City of Tacoma ("City" or "Tacoma" or "Plaintiff") is located in Pierce County, Washington. Tacoma is incorporated as a first-class city pursuant to RCW 35.22 *et seq.*, as it has a population of ten thousand or more inhabitants and has adopted a charter in accordance with Article XI, section 10 of the State of Washington's constitution.

Purdue

18. 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 principle place of business in Stamford, Connecticut. Collectively, these entities are referred to as "Purdue."

19. 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.

20. 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 the City of Tacoma.

21. OxyContin, Butrans, and Hysingla ER are Schedule II and III opioids first approved in 1995, 2010, and 2014, respectively.

22. 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.

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Endo

23. 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."

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

25. Endo manufacturers, promotes, sells, markets, and distributes opioids such as Percocet, Opana, and Opana ER in the United States, including in the City of Tacoma.

26. Opana and Opana ER are Schedule II opioids first approved in 2006.

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

28. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that "the agency is seeking removal based on its concern that the benefits of the drug may no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse."[8] On July 6, 2017, Endo agreed to withdraw Opana ER from the market.[9]

Janssen

29. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of

[8] 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.

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

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Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Collectively, these entities are referred to as "Janssen."

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

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

32. Janssen manufacturers, promotes, sells, markets, and distributes opioids such as Duragesic, Nucynta, and Nucynta ER in the United States, including in the City of Tacoma. Janssen stopped manufacturing Nucynta and Nucynta ER in 2015.

33. Duragesic and Nucynta ER are Schedule II opioids first approved in 1990 and 2011 respectively.

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

John and Jane Does 1-100, inclusive

35. The true names, roles, and/or capacities in the wrongdoing alleged herein of Defendants named John and Jane Does 1 through 100, inclusive, are currently unknown to Plaintiff, and thus, are named as Defendants under fictitious names as permitted by the rules of this Court. Plaintiff will amend this complaint and identify their true identities and their

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involvement in the wrongdoing at issue, as well as the specific causes of action asserted against them, if and when they become known.

III. JURISDICTION AND VENUE

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

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

IV. FACTUAL ALLEGATIONS

A. Opioids are causing unprecedented harm.

38. Opioids are a class of drugs generally used to treat pain. They are derived in whole or in part from the opium poppy, the same substance from which morphine and heroin are made. Some opioids are also completely synthetic, but nevertheless contain the same properties as morphine and heroin.

39. As such, the term opioid is often used to refer to the entire family of opioids, including natural, synthetic, and semi-synthetic. The latter two categories of opioids are the focus of this complaint, and include drugs manufactured by Defendants.

40. Despite being one of the world's oldest known drugs, opioids have seen a dramatic rise to prominence in the last twenty years and are today commonly prescribed for pain. In fact, one in every five patients who present themselves to physicians' offices with non-cancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receives an opioid prescription.[10]

[10] *See supra* note 3.

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41. Over that same time period, opioid prescription sales have skyrocketed. Before the FDA approved OxyContin—which as described above is manufactured by Purdue—annual opioid sales hovered around $1 billion. By 2015, they increased nearly ten-fold to almost $10 billion:[11]

42. Increased revenues from opioids are the direct result of increased use of these drugs. As stated above, in 2016 alone, health care providers wrote more than 289 million prescriptions for opioid pain medication, enough for *every adult in the United States* to have at least one bottle of pills.[12]

[11] David Crow, *Drugmakers hooked on $10bn opioid habit*, Financial Times (Aug. 10, 2016), https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95?mhq5j=e1.

[12] *See supra* note 1.

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43. Between 1991 and 2011, prescriptions of opioids in the U.S. tripled from 76 million to 219 million per year.[13] Along with that increase in volume, the potency of prescription opioids also increased. By 2002, one in six opioid users were being prescribed drugs more powerful than morphine; by 2012 the ratio had doubled to one in three.[14]

44. The increase in prescriptions coincided with a well-developed, deceptive, and misleading marketing and advertising campaign by Defendants which significantly downplayed the risks and grossly exaggerated the benefits of the drugs.

45. Studies have shown that prescription opioids are simply ineffective tools in managing anything but end-of-life pain or acute pain over very short periods. Even though there are limited situations in which opioid use might be proper, the drugs have potential to cause incredible harm. Patients can quickly become addicted to opioids, despite Defendants' misleading statements that such addiction would not or could not happen. Sadly, because of Defendants' misleading statements and marketing, millions of Americans have become hooked on these deadly opioids.

46. Defendants aggressively and relentlessly pushed to expand the use of their drugs, despite the fact that there has been little or no change in the amount of pain reported in the U.S. over the last twenty years. In fact, the majority of doctors and dentists who prescribe opioids are not pain specialists. For example, a 2014 study conducted by pharmacy benefit manager Express Scripts reviewing narcotic prescription data from 2011-2012 concluded that of the more than half

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[13] 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), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

[14] *America's opioid epidemic is worsening*, the Economist (Mar. 6, 2017), https://www.economist.com/blogs/graphicdetail/2017/03/daily-chart-3.

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million prescribers of opioids during that time period, *only 385* were identified as pain specialists.[15]

47. There is no controversy that the increase in prescriptions of opioids to treat pain is causing an epidemic in this country. For instance, from 1999 to 2015, the rate of opioid-related overdose deaths increased every year. In 1999, opioid overdose deaths totaled approximately 4,030. In 2009, this number rose to 15,597. By 2015, that number rose to more than 33,000, nearly equal to the number of deaths from car crashes. The 33,000 opioid-related deaths in 2015 represented approximately 63% of the more than 52,000 deaths caused by all drug overdoses.[16]

48. In total, *more than 183,000 deaths* from prescription opioids have been reported in the United States since 1999, and more than half of all opioid overdose deaths involve a prescription opioid, like those manufactured by Defendants.[17] In fact, in 2015, this opioid epidemic accounts for an average of 10.3 deaths per 100,000 people. Someone in the U.S. dies from an overdose of a prescription opioid every sixteen minutes, according to the CDC.

49. To place these numbers in perspective, approximately 58,000 U.S. soldiers died in the Vietnam War, nearly 55,000 Americans died of car crashes at the peak of such deaths in 1972, more than 43,000 died due to HIV/AIDS during that epidemic's peak in 1995, and nearly 40,000 died of guns during the peak of firearm deaths in 1993.[18]

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[15] *A Nation in Pain*, Express Scripts (Dec. 9, 2014), http://lab.express-scripts.com/lab/publications/a-nation-in-pain.

[16] *Overdose Death Rates*, NIH National Institute on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (revised Jan. 2017).

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

[18] German Lopez, *Drug overdose deaths skyrocketed in 2016 — and traditional opioid painkillers weren't the cause*, Vox (Sept. 5, 2017), https://www.vox.com/platform/amp/policy-and-politics/2017/9/5/16255040/opioid-epidemic-overdose-death-2016.

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50. Further, in 2014, the most recent year for which this data is available, there were an astonishing 1.27 million emergency room visits or inpatient stays for opioid-related issues.[19] This is a dramatic increase over the approximately 366,000 emergency department visits related to the misuse or abuse of narcotic pain relievers in 2011.[20] By comparison, in 2011 these visits averaged 1,150 *per day*. In 2014, the average had climbed to nearly 3,500 visits per day.

51. The direct harm caused by Defendants blanketing the country with opioids is staggering—indeed, it has been referred to as "the worst man-made epidemic in modern medical history."[21]

52. The impact does not stop with prescription pills. As a direct result of opioid abuse, individuals who have become addicted to painkillers—but cannot afford their increased costs or are unable to secure a prescription—have turned to cheaper, more potent, and dangerous alternatives, primarily heroin, fueling another crisis in this country directly attributable to opioid abuse.

53. The dramatic rise of this crisis is illustrated by the fact that 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.

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[19] Audrey J. Weiss, Ph.D., et al., *Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014*, HCUP Statistical Brief #224 (June 2017), https://www.hcup-us.ahrq.gov/reports/statbriefs/sb224-Patient-Characteristics-Opioid-Hospital-Stays-ED-Visits-by-State.pdf.

[20] Elizabeth H. Crane, Ph.D., *Emergency Department Visits Involving Narcotic Pain Relievers*, Substance Abuse and Mental Health Services Administration (Nov. 5, 2017), https://www.samhsa.gov/data/sites/default/files/report_2083/ShortReport-2083.html.

[21] Gary Franklin, M.D., *Warning: This Drug May Kill You*, HBO, http://www.hbo.com/documentaries/warning-this-drug-may-kill-you/video/how-did-we-get-here.html?autoplay=true (last visited Sept. 7, 2017).

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54. Heroin is not only more available but also more affordable. In fact, today, the average street value of a gram of heroin in Tacoma is approximately $300, whereas in the late 1990s and early 2000s, the average cost was approximately $1,800 per gram.

55. In 2016, the NEJM published an article examining the relationship between opioids and heroin use. The article concluded that "75% of [heroin] users initiated opioid use with prescription opioids."[22] This study draws a direct line between Defendants' deceptive marketing of opioids and the subsequent heroin epidemic in the United States, including in Tacoma.

56. The economic impact of the opioid crisis is devastating. The CDC recently estimated that the total economic burden of prescription opioid abuse costs the United States $78.5 billion per year, which includes costs of health care, lost productivity, addiction treatment, and criminal justice involvement.[23] One quarter of these costs are borne by the public sector, including by municipalities like the City of Tacoma.[24]

57. As the director of the CDC recently stated: "America is awash in opioids; urgent action is critical."[25]

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[22] Wilson M. Compton, M.D., M.P.E., Christopher M. Jones, Pharm.D., M.P.H., and Grant T. Baldwin, Ph.D., M.P.H., 374 N Engl J Med 154-63 (Jan. 14, 2106), http://www.nejm.org/doi/full/10.1056/NEJMra1508490#ref41.

[23] *See supra* note 2.

[24] Wolters Kluwer Health: Lippincott Williams and Wilkins, *Costs of US prescription opioid epidemic estimated at $78.5 billion*, *Science Daily* (Sept. 14, 2016), https://www.sciencedaily.com/releases/2016/09/160914105756.htm.

[25] Thomas Frieden, M.D., CDC Chief Frieden: How to end America's growing opioid epidemic, FOX News (Dec. 17, 2016), http://www.foxnews.com/opinion/2016/12/17/exclusive-cdc-chief-frieden-how-to-end-americas-growing-opioid-epidemic.html.

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B. Defendants made and continue to make false and misleading statements about opioids through various channels.

58. Despite having knowledge of the profound and devastating impact of opioids on the American public, Defendants have made and continue to make misleading statements about the purported benefits, efficacy, and low risks of opioids—statements that Defendants have failed to completely correct. There is little doubt that today's opiate epidemic stems from aggressive marketing tactics used by pharmaceutical companies over the past two decades. Indeed, a spokesperson for the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), testified before Congress that "aggressive marketing by pharmaceutical companies" is a cause of the opioid abuse problem.[26]

59. Defendants effectuated their deceptive marketing campaign by convincing doctors, patients, and the public, among others, that the benefits of using opioids to treat chronic pain outweighed any risks or dangers, and that opioids could be safely used by most patients. They did this despite knowing that the evidence suggesting opioids could be effectively used to treat long-term, chronic pain was and continues to be very weak, while the evidence to suggest opioids cause substantial harm was and continues to be very strong.

60. In particular, Defendants disseminated this false and misleading information through three primary channels.[27]

61. **First**, Defendants communicated to doctors directly in the form of in-person visits and communications from sales representatives, continuing medical education programs, medical journals, advertisements, and websites.

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[26] *See supra* note 13.

[27] Through these three avenues, Defendants made six specific categories of false and misleading statements about opioids, discussed in further detail below.

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62. Defendants spent substantial sums and resources in making these communications. For example, Purdue spent more than $200 million marketing OxyContin alone in 2001.[28]

63. Defendants' tactics through their sales representatives—also known as "detailers"—were particularly aggressive. In 2014, Defendants collectively spent well over $100 million on detailing branded opioids to doctors.

64. Defendants implemented lucrative bonus systems to encourage sales representatives to increase opioid sales in their territories, resulting in numerous repeat visits to physicians with high rates of opioid prescriptions, as well as a multifaceted information campaign targeting these physicians. For example, Purdue paid $40 million in sales incentive bonuses to its sales representatives in 2001, with annual bonuses ranging from $15,000 to nearly $240,000.[29] In fact, from 1996 to 2000, Purdue increased its internal sales force from 318 sales representatives to 671, and its total physician call list from approximately 33,400 to 44,500 to approximately 70,500 to 94,000 physicians.[30]

65. Defendants have also spent substantial sums to purchase, manipulate, and analyze sophisticated data available from IMS Health Holdings, Inc.—a company that collects healthcare information including prescription data—to track the rates of initial prescribing and renewals by individual doctors, which in turn allows Defendants to customize their communications with each doctor. Defendants' use of this sophisticated marketing data was a cornerstone of their

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[28] Mike Mariani, *How the American opiate epidemic was started by one pharmaceutical company*, The Week (Mar. 4, 2015), http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company.
[29] 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/.
[30] *Id.*

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marketing plan.[31] Defendants, knowing full well how effective their detailing is, continue this data analysis to this day.

66. Defendants also identified doctors to serve as speakers or attend all-expense-paid trips to programs with speakers.[32] Defendants used these trips and programs—many of them quite lavish affairs—to incentivize the use of opioids while downplaying their risks, bombarding doctors with messages about the safety and efficacy of opioids for treating long-term pain. Although often couched in a veneer of scientific certainty, Defendants' messages were false and misleading, and helped to ensure that millions of Americans would be exposed to the profound risks of these drugs.

67. It is well documented that this type of pharmaceutical company symposium influences physicians' prescribing, even though physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.[33] For example, doctors who were invited to these all-expenses-paid weekends in resort locations like Boca Raton, Florida, and Scottsdale, Arizona, wrote twice as many prescriptions as those who did not attend.[34]

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

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[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] 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/.

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tactics were so aggressive that in some offices, doctors considered hiring or designating employees to coordinate the various social activities to which the sales representatives consistently and almost daily invited these doctors.

69. Furthermore, Defendants knew or should have known the doctors they targeted were often poorly equipped to treat or manage pain comprehensibly, as they often had limited resources or time to address behavioral or cognitive aspects of pain treatment or to conduct the necessary research themselves to determine whether opioids were as beneficial as Defendants claimed. When Defendants presented these doctors with the marketing material that touted opioids' ability to easily and safely treat pain, many of these doctors began to view opioids as an efficient and effective way to treat their patients.

70. These doctors, however, conducted limited due diligence of their own, and instead relied on Defendants' so-called evidence-based claims. Defendants knew or should have known that these doctors did not often have time to conduct their own research into the efficacy and risks of pharmaceuticals, and often rely heavily on materials provided by the drug companies.

71. **Second**, Defendants funded, controlled, and operated third-party organizations that communicated to doctors, patients, and the public the benefits of opioids to treat chronic pain. These organizations—also known as "Front Groups"—gave off the impression they were independent and unbiased. These Front Groups published prescribing guidelines, unbranded materials, and other programs that promoted opioid treatment as a way to address patients' chronic pain. The Front Groups targeted doctors, patients, and lawmakers, all in coordinated efforts to promote opioid prescriptions.

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72. There is absolutely no dispute that Defendants spent significant financial resources contributing to and working with these various Front Groups to increase the number of opioid prescriptions written.

73. The most prominent Front Group utilized by Defendants was the American Pain Foundation ("APF"), which received more than $10 million from opioid drug manufacturers, including Defendants, from 2007 through 2012. Purdue contributed $1.7 million and Endo also contributed substantial sums to the APF.[35]

74. Throughout its existence, APF's operating budget was almost entirely comprised of contributions from opioid drug manufacturers. For instance, nearly 90% of APF's $5 million annual budget came from "donations" from some of the Defendants, and by 2011, APF was entirely dependent on grants from Defendants, including from Purdue and Endo. Not only did Defendants control APF's purse strings, its board of directors was full of doctors who were on Defendants' payrolls, either as consultants or speakers at medical events.[36]

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

76. Another prominent Front Group was the American Academy of Pain Medicine ("AAPM"), which has received over $2.2 million in funding since 2009 from opioid drug manufacturers, including Defendants. Like APF, AAPM held itself as an independent and non-

[35] Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011), https://www.propublica.org/article/the-champion-of-painkillers.

[36] *Id.*

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biased advocacy group representing physicians practicing in the field of pain medicine, but in fact was just another mouthpiece Defendants used to push opioids on doctors and patients.[37]

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

78. For instance, the AAPM, in conjunction with the American Pain Society ("APS"), issued comprehensive guidelines in 2009 titled "Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain – Evidence Review" ("2009 Guidelines"). The 2009 Guidelines promoted opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence to support this statement. Unsurprisingly, Defendants have widely referenced and promoted these guidelines, issued by Front Groups they funded and controlled. These 2009 Guidelines are still available online today.[38]

79. In addition, Defendants participated in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit organizations. From 2006 to 2015, participants in the Pain

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

[38] *Clinical Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, American Pain Society, http://americanpainsociety.org/uploads/education/guidelines/chronic-opioid-therapy-cncp.pdf (last visited Sept. 7, 2017).

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Care Forum spent over $740 million lobbying in the nation's capital and in all fifty statehouses on an array of issues, including opioid-related measures. The collective spending on lobbying and campaigns amounts to more than two hundred times the $4 million spent during the same period by the handful of groups that work to warn the public about the dangers of opioids and lobby for restrictions on painkillers.[39]

80. Defendants have also targeted specific groups to encourage opioid prescribing practices. One such group, a University of Wisconsin-based organization known as the Pain & Policy Studies Group, received $2.5 million from pharmaceutical companies to promote opioid use and discourage the passing of regulations against opioid use in medical practice. The Pain & Policy Studies Group wields considerable influence over the nation's medical schools as well as within the medical field in general.[40] Purdue was the largest contributor to the Pain & Policy Studies Group, paying approximately $1.6 million between 1999 and 2010.[41]

81. Through these third-party organizations, Defendants also engaged in unbranded advertising to generally tout the benefits of opioids without specifically naming a particular brand of opioid. Unbranded marketing does not refer to a specific drug, but promotes a type of treatment generally, and unbranded materials are not typically reviewed by the FDA. Conversely, branded marketing, which identifies and promotes a specific drug, is subject to FDA

[39] 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.

[40] *The Role of Pharmaceutical Companies in the Opioid Epidemic*, Addictions.com, https://www.addictions.com/opiate/the-role-of-pharmaceutical-companies-in-the-opioid-epidemic/ (last visited Sept. 7, 2017).

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

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review, must be consistent with its label and supported by substantial scientific evidence, and must not include false or misleading statements or material omissions.

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

83. **Third**, Defendants retained highly credentialed medical professionals to promote the purported benefits and minimal risks of opioids. These medical professionals are also known as "Key Opinions Leaders" or "KOLs."

84. Defendants paid substantial amounts to KOLs to present at Continuing Medical Education ("CME") seminars and conferences, and to serve on their advisory boards and on the boards of third-party organizations described above.

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

86. Two key KOLs were Russell Portenoy and Kathleen Foley. Defendants utilized both individuals repeatedly and consistently for several years to tout the benefits and minimize the risks of opioids.

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87. In recent years, some of Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.[42] In fact, Dr. Portenoy specifically admitted that he overstated the drugs' benefits and glossed over their risks, claiming: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . . We didn't know then what we know now."[43]

88. While such acknowledgments of past misstatements and misrepresentations are important to correct the tidal wave of misinformation that Defendants are responsible for, they have been insufficient to undo the harm the past statements created or alter the opioid addictions that resulted from these misrepresentations. And although some of the KOLs have acknowledged their past misstatements, many of them continue to appear nationwide, including in the City of Tacoma, and their dangerous and false messages live on.

89. Through these three primary channels—all of which Defendants controlled, funded, and facilitated, and for which they are legally responsible—Defendants ultimately made false or misleading statements about opioids despite the lack of scientific evidence to support their claims.

90. Specifically, Defendants have made and/or continue to make false or misleading claims in six primary areas: (1) the low risk of addiction to opioids, (2) the need to prescribe more opioids to treat pain, (3) risk-mitigation strategies to safely prescribe opioids, including

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[42] *See, e.g.*, John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 19, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/ (finding that a key Endo KOL acknowledged that opioid marketing went too far).

[43] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

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tapering, (4) the lack of risk associated with higher dosages of opioids, (5) the benefits of abuse-deterrent technology to curb abuse, and (6) that long-term opioid use improves patient function and quality of life. These illustrative but non-exhaustive categories of Defendants' misrepresentations about opioids are described in detail below.

1. Defendants falsely claimed that the risk of opioid addiction was low.

91. Each Defendant has made a series of false and misleading statements about the low risk of addiction to opioids over the past twenty years. Each Defendant has also failed to take sufficient remedial measures to correct its false and misleading statements.

92. One of the primary and specific claims made by Defendants was that addiction was actually rare in patients treated with opioids. In support of this statement, Defendants cited the 1980 NEJM letter which stated that the "development of addiction is rare in medical patients with no history of addiction."[44] Though the letter's authors stated that they examined the files of 11,882 patients, no analysis was included in the letter.

93. In addition, the study referenced in the letter analyzed a database of hospitalized patients who were given doses of opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions, nor were they given opioids to administer to themselves at home; rather they were treated with opioids under in-hospital doctor supervision.

94. Defendants nevertheless used the letter to tout the purportedly low risk of addiction to the drugs, generally. For example, in its 1996 press release announcing the release of OxyContin, Purdue advertised that the "fear of addiction is exaggerated" and quoted the

[44] *See supra* note 5.

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chairman of the American Pain Society Quality of Care Committee, who claimed that "there is very little risk of addiction from the proper uses of these [opioid] drugs for pain relief."[45]

PR Newswire

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

NEW HOPE FOR MILLIONS OF AMERICANS SUFFERING FROM PERSISTENT

The fear of addiction is exaggerated.

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

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

95. Dr. Portenoy, a paid Purdue KOL as mentioned previously, also stated in a promotional video from the 1990s that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[46]

[45] 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), http://documents.latimes.com/oxycontin-press-release-1996/.

[46] *See supra* note 43.

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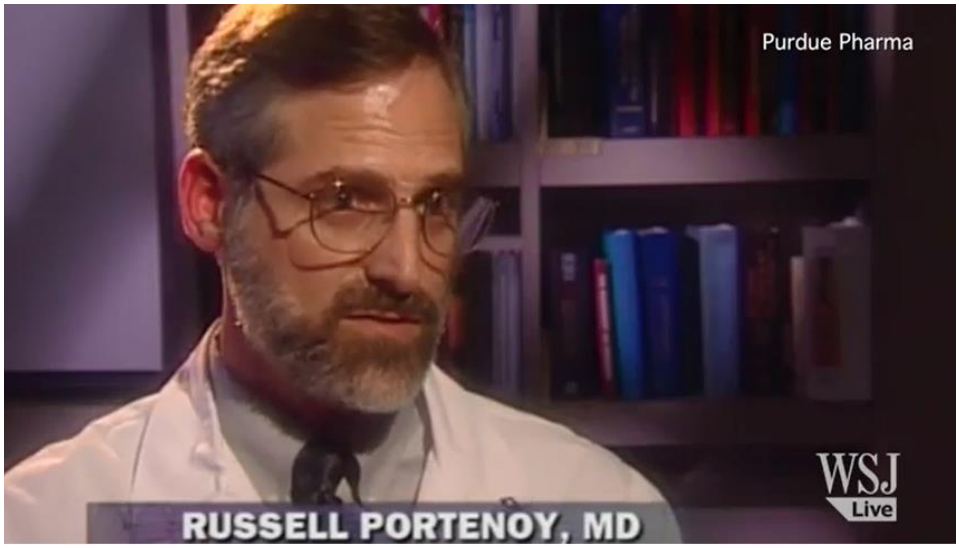

96. Purdue also specifically used the 1980 NEJM letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos says "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*."[47]

[47] Our Amazing World, *Purdue Pharma OxyContin Commercial*, https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited Sept. 7, 2017) (emphasis added).

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97. The 1980 NEJM letter was also used on Purdue's "Partners Against Pain" website, which was available in the early 2000s, where Purdue claimed that the addiction risk with OxyContin was very low.[48]

98. The 1980 NEJM letter was used frequently in literature given to physicians, and in literature given to patients who were prescribed OxyContin.[49]

99. Additionally, Dr. Portenoy used the 1980 NEJM letter as a source in his landmark 1986 paper on the chronic use of opioids, which was based on just 38 patients, all of whom were cancer patients.[50] Because only two of the 38 patients examined became addicted, Portenoy concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse . . ."[51]

100. Purdue also consistently tried to steer any concern away from addiction, and focus on its false claims that opioids were effective and safe for dealing with chronic pain. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Michael Friedman, Executive Vice President and Chief Operating Officer of Purdue, testified that "even the most vocal critics of opioid therapy concede the value of OxyContin in the legitimate treatment of pain," and that

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[48] *See supra* note 29.

[49] Art Van Zee, M.D., *The OxyContin Abuse Problem: Spotlight on Purdue Pharma's Marketing* (Aug. 22, 2001), https://www.fda.gov/ohrms/dockets/dockets/01n0256/c000297-A.pdf.

[50] Russel 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://fellowiki.wikispaces.com/file/view/PAIN+CHRONIC+USE+OF+OPIOIDS.pdf.

[51] *Id.*

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"OxyContin has proven itself an effective weapon in the fight against pain, returning many patients to their families, to their work, and to their ability to enjoy life."[52]

101. At this same hearing, Purdue continued to emphasize "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[53]

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

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

103. Similarly, a Senior Medical Director for Purdue, Dr. David Haddox, cavalierly stated, "[w]hen this medicine is used appropriately to treat pain under a doctor's care, it is not only effective, it is safe."[54] He went so far as to compare OxyContin to celery, because even celery would be harmful if injected: "If I gave you a stalk of celery and you ate that, it would be

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[52] *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.

[53] *Id.*

[54] Roger Alford, *Deadly OxyContin abuse expected to spread in the U.S.*, Charleston Gazette, Feb. 9, 2001.

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healthy for you. But if you put it in a blender and tried to shoot it into your veins, it would not be good."[55]

104. Purdue sales representatives also repeated these misstatements regarding the low risk for addiction to doctors across the country.[56] Its sales representatives targeted primary care physicians in particular, downplaying the risk of addiction and, as one doctor observed, "promot[ing] among primary care physicians a more liberal use of opioids."[57] Purdue also marketed OxyContin for a wide variety of conditions and to doctors who were not adequately trained in pain management.[58]

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

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

106. Although Purdue has acknowledged it has made some misrepresentations about the safety of its opioids,[59] it has done nothing to address the ongoing harms of their misrepresentations; in fact, it continues to make those misrepresentations today.

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[55] *Id.*

[56] 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.

[57] *See supra* note 29.

[58] *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office Report to Congressional Requesters (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.

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

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107. Defendant Endo also made dubious claims about the low risk of addiction. For instance, it sponsored a website, PainKnowledge.com, on which in 2009 it claimed that "[p]eople who take opioids as prescribed usually do not become addicted."[60] The website has since been taken down.

108. In another website, PainAction.com—which is still currently available today—Endo also claimed that "most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."[61]

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

110. In its currently active website, PrescribeResponsibly.com, Defendant Janssen states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[62]

[60] German Lopez, *US officials are starting to treat opioid companies like Big Tobacco—and suing them*, Vox (Aug. 9, 2017), https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits.

[61] *Opioid medication and addiction*, Pain Action (Aug. 17, 2017), https://www.painaction.com/opioid-medication-addiction/.

[62] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last modified Jul. 2, 2015).

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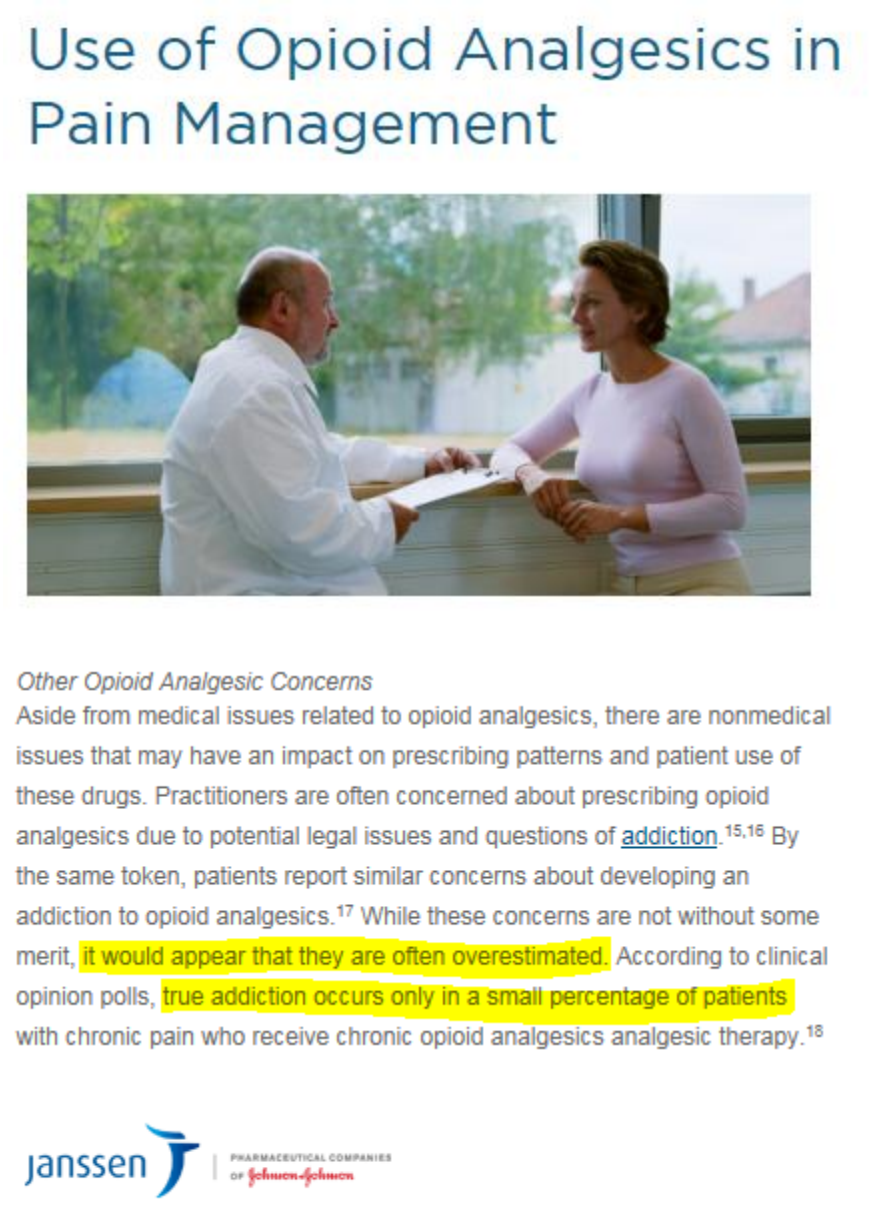
Use of Opioid Analgesics in Pain Management

Other Opioid Analgesic Concerns

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

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

111. 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.[63]

[63] 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.

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112. Janssen also approved and distributed a patient education guide in 2009 that attempted to counter the "myth" that opioids are addictive, claiming that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."[64]

113. In addition, all three Defendants used third parties and Front Groups to further their false and misleading statements about the safety of opioids.

114. For example, in testimony for the Hearing to Examine the Effects of the Painkiller OxyContin, Focusing on Risks and Benefits, in front of the Senate Health, Education, Labor and Pensions Committee in February 2002, Dr. John D. Giglio, Executive Director of the APF, the organization which, as described above, received the majority of its funding from opioid manufacturers, including Purdue, stated that "opioids are safe and effective, and only in rare cases lead to addiction."[65]

115. The APF further backed up Purdue in an amicus curiae brief filed in an Ohio appeals court in December 2002, in which it claimed that "medical leaders have come to understand that the small risk of abuse does not justify the withholding of these highly effective analgesics from chronic pain patients."[66]

116. In a 2007 publication titled "Treatment Options: A Guide for People Living with Pain," APF downplayed the risk of addiction and argued that concern about this risk should not prevent people from taking opioids: "Restricting access to the most effective medications for

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[64] *See supra* note 60.

[65] *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.

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

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treating pain is not the solution to drug abuse or addiction." APF also tried to normalize the dangers of opioids by listing opioids as one of several "[c]ommon drugs that can cause physical dependence," including steroids, certain heart medications, and caffeine.

117. 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.

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

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

119. One way that Defendants worked to obstruct appropriate responses to opioid addiction was to push a concept called "pseudoaddiction." Dr. David Haddox—who later became a Senior Medical Director for Purdue—published a study in 1989 coining the term, which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[67] In other words, he claimed that people on prescription opioids who exhibited classic signs of addiction were not, in fact, addicted to opioids, but rather simply suffering from improperly managed pain—specifically, under-treatment. His solution for "pseudoaddiction"? More opioids. Although this concept was formed based on a single case study, it proved to be a favorite trope in Defendants' marketing schemes.

120. For example, using this study, Purdue informed doctors and patients that signs of addiction are actually the signs of under-treated pain which should be treated with even more

[67] 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.

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opioids. Purdue reassured doctors and patients, telling them, without any apparent evidence, that "chronic pain has been historically undertreated."[68]

121. Defendants continued to spread the concept of pseudoaddiction through the APF, which even went so far as to compare opioid addicts to coffee drinkers. In a 2002 court filing, APF wrote that "[m]any pain patients (like daily coffee drinkers) claim they are 'addicted' when they experience withdrawal symptoms associated with physical dependence as they decrease their dose. But unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain . . ."[69]

122. In a 2007 publication titled "Treatment Options: A Guide for People Living with Pain," the APF claimed: "*Physical dependence is normal*; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does **NOT** mean you are addicted."[70] In this same publication, when describing behaviors of addiction, the APF again used the idea of pseudoaddiction, claiming that people who are not substance abusers may also engage in behaviors that mirror those of actual addicts.

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[68] *See supra* note 52.
[69] *See supra* note 66.
[70] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited Sept. 7, 2017).

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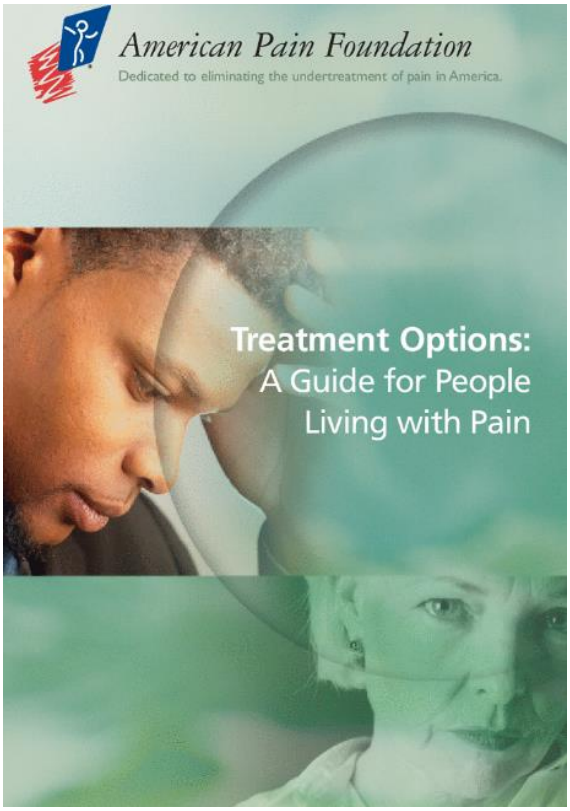

Side effects

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

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

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

Common drugs that can cause physical dependence

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

Tolerance, physical dependence and addiction

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

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

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

123. Purdue published a Risk Evaluation and Mitigation Strategy ("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."[71]

124. 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.

[71] *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf (last modified Nov. 2010).

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125. Endo sponsored a National Initiative on Pain Control (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.

126. A 2001 study which was authored by a doctor affiliated with Janssen stated that "[m]any patients presenting to a doctor's office asking for pain medications are accused of drug seeking. In reality, most of these patients may be undertreated for their pain syndrome."[72]

127. In 2009, on a website it sponsored, Janssen stated that pseudoaddiction is different from true addiction "because such behaviors can be resolved with effective pain management."[73]

128. Indeed, on its currently active website PrescribeResponsibly.com, Janssen defines pseudoaddiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately, the inappropriate behavior ceases."[74]

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

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

[74] 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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129. 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.

3. Defendants falsely claimed that risk-mitigation strategies, including tapering, could safely address any concerns about addiction.

130. Even when Defendants acknowledge there are addiction risks in the use of opioids, they dismiss these concerns by claiming that addiction can be easily avoided and addressed through simple steps. In other words, Defendants falsely communicated to doctors and patients that certain screening tools would allow them to reliably identify risks and safely

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prescribe opioids to patients, and that tapering the dose would be sufficient to manage cessation of opioid treatment. Both assertions are false.

131. 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 that all patients should be screened for their risk of abuse or addiction, and that such screening could curb the incidence of addiction.[75]

132. The APF also proclaimed in a 2007 booklet, sponsored in part by Purdue, that "[p]eople with the disease of addiction may abuse their medications, engaging in unacceptable behaviors like increasing the dose without permission or obtaining the opioid from multiple sources, among other things. Opioids get into the hands of drug dealers and persons with an addictive disease as a result of pharmacy theft, forged prescriptions, Internet sales, and even from other people with pain. It is a problem in our society that needs to be addressed through many different approaches."[76]

133. On its current website for OxyContin,[77] Purdue acknowledges that certain patients have higher risk of opioid addiction based on history of substance abuse or mental illness—a statement which, even if accurate, obscures the significant risk of addiction for all patients, including those without such a history, and comports with statements it has recently made that it is "bad apple" patients, and not the opioids, that are arguably the source of the opioid crisis:

[75] *See supra* note 71.
[76] *See supra* note 70.
[77] OxyContin, https://www.oxycontin.com/index.html (last visited Sept. 7, 2017).

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

134. Additionally, on its current website, Purdue refers to publicly available tools that can assist with prescribing compliance, such as patient-prescriber agreements and risk assessments—however, the link to these documents appears to be no longer active.[78]

135. Purdue continues to downplay the severity of addiction and claims that dependence can easily be overcome by strategies such as adhering to a tapering schedule to successfully stop opioid treatment. On the current website for OxyContin, it instructs that "[w]hen discontinuing OxyContin, gradually taper the dosage. Do not abruptly discontinue OxyContin."[79] And on the current OxyContin Medication Guide, Purdue also states that one should "taper the dosage gradually."[80]

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[78] *ER/LA Opioid Analgesics REMS*, Purdue, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/rems/ (last visited Sept. 7, 2017).

[79] *See supra* note 77.

[80] *OxyContin Full Prescribing Information*, Purdue Pharma LP, http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o (last visited Sept. 7, 2017).

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136. In its "Dear Healthcare Professional" letter in 2010, Purdue instructed doctors to gradually taper someone off of OxyContin to prevent signs and symptoms of withdrawal in patients who were physically dependent.[81] Nowhere does Purdue warn doctors or patients that tapering may be inadequate to safely end opioid treatment and avoid addiction.

137. Endo also suggests that risk-mitigation strategies enable the safe prescription of opioids. In its currently active website, Opana.com, Endo states that assessment tools should be used to assess addiction risk, but that "[t]he potential for these risks should not, however, prevent proper management of pain in any given patient."[82]

138. On the same website, Endo addresses tapering by stating "[w]hen discontinuing OPANA ER, gradually taper the dosage."[83]

139. Janssen states on its currently active website, PrescribeResponsibly.com, that opioid addiction "can usually be managed" and that tools such as Opioid Agreements between patients and doctors can aid with this.[84]

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

141. 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.

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[81] *See supra* note 71.
[82] Opana ER, http://www.opana.com (last visited Sept. 7, 2017).
[83] *Id.*
[84] *See supra* note 74.

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4. Defendants falsely claimed doctors and patients could increase opioid usage indefinitely without added risk and failed to disclose risks associated with higher dosages.

142. Defendants also made false and misleading statements regarding the volume of opioid use by patients, statements that were especially beneficial for Defendants' profits.

143. For example, in 2012, APF claimed on its website that there was no "ceiling dose" for opioids for chronic pain.[85] APF also made this claim in a guide sponsored by Purdue, which is still available online.

144. In a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should "convinc[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses. The manager directed representatives to discuss with physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations in using a dose of 240mg-320mg of OxyContin."[86]

145. In fact, the 2003 Conversion Guide for OxyContin contained the following diagram for increasing dosage up to 320 mg:

[85] Noah Nesin, M.D., FAAFP, *Responsible Opioid Prescribing*, PCHC https://www.mainequalitycounts.org/image_upload/Keynote-%20Managing%20Chronic%20Pain%20and%20Opioids_Nesin.pdf (last visited Sept. 7, 2017).

[86] *Sales manager on 12-hour dosing*, Los Angeles Times (May 5, 2016), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/.

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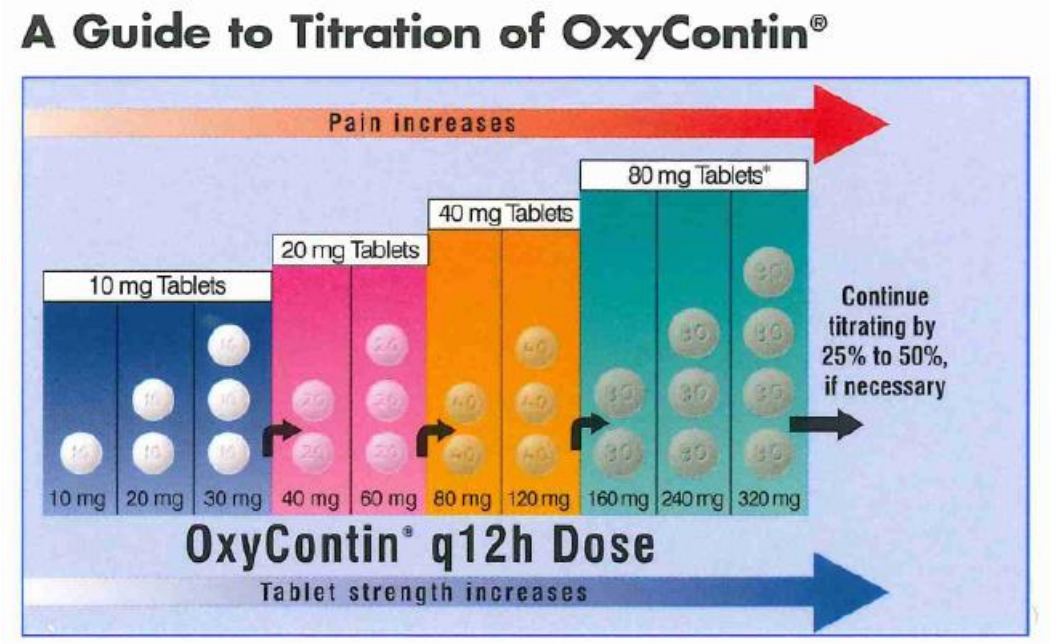

146. Purdue's 2010 REMS for OxyContin also does not address concerns with increasing dosage, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."[87]

147. In a 2004 response letter to the FDA, Purdue tried to address concerns that patients who took OxyContin more frequently than 12 hours would be at more risk of side effects or adverse reactions. Purdue contended that the peak plasma concentrations of oxycodone would not increase with more frequent dosing, and therefore no adjustments to the package labeling or 12-hour dosing regimen were needed.[88] But these claims were false, and Purdue's suggestion that there was no upper limit or risk associated with increased dosage was incredibly misleading.

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[87] *See supra* note 71.

[88] *Purdue Response to FDA, 2004*, Los Angeles Times (May 5, 20216), http://documents.latimes.com/purdue-response-fda-2004/.

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148. Contrary to these claims of no upward limit of dosing, Purdue discontinued its 160mg tablet in 2007 and stated that this step was taken "to reduce the risk of overdose accompanying the abuse of this dosage strength."[89]

149. In addition, on March 2007, Dr. Gary Franklin—the Medical Director for the Washington State Department of Labor & Industries—published *Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain*, a guideline developed in collaboration with actively practicing providers in Washington State with extensive experience in the evaluation and treatment of patients with chronic pain.

150. In response to this guideline, Purdue sent correspondence to Dr. Franklin specifically indicating, among other things, that "limiting access to opioids for persons with chronic pain is not the answer" and that the "safety and efficacy of OxyContin doses greater than 40 mg every 12 hours in patients with chronic nonmalignant pain" was well established. Purdue even went so far as to represent to Dr. Franklin that even if opioid treatment produces significant adverse effects in a patient, "this does not preclude a trial of another opioid."

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

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

153. In a publication titled "Understanding Your Pain: Taking Oral Opioid Analgesics," Endo assures opioid users that concern about developing tolerance to the drugs'

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

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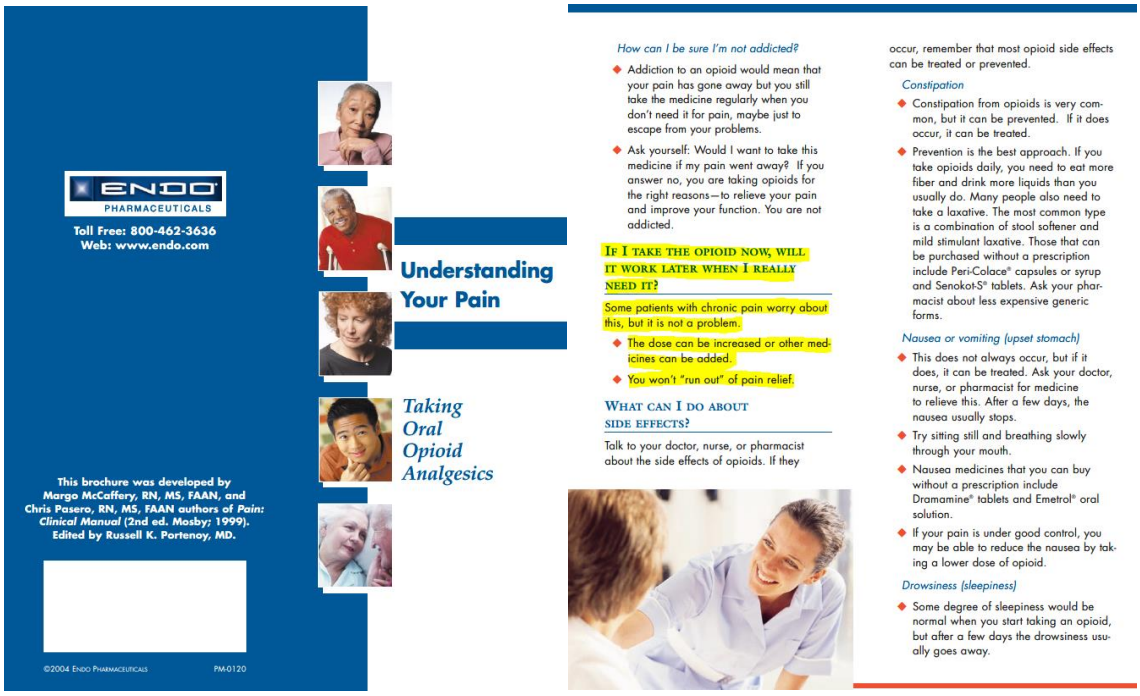
pain-relieving effect is "not a problem," and that "[t]he dose can be increased" and "[y]ou won't 'run out' of pain relief."[90]



154. Janssen also discussed the disadvantages of dosage limits for other pain medicines in a 2009 patient education guide, but failed to address the risks of dosage increases with opioids.

155. 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.

5. Defendants' deceptive marketing of the purported abuse-deterrent properties of their opioids has created false impressions that reformulated opioids can curb addiction and abuse.

156. Defendants have also made and continue to make false and misleading statements about the purported abuse-deterrent properties of their opioid pills to suggest these reformulated

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

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

157. For instance, since at least 2001, Purdue has contended that "abuse resistant products can reduce the incidence of abuse."[91] Its current website touts abuse-deterrent properties by saying they "can make a difference."[92]

158. On August 17, 2015, Purdue announced the launch of a new website, "Team Against Opioid Abuse," which it said was "designed to help healthcare professionals and laypeople alike learn about different abuse-deterrent technologies and how they can help in the reduction of misuse and abuse of opioids."[93] This website appears to no longer be active.

159. A 2013 study which was authored by at least two doctors who at one time worked for Purdue stated that "[a]buse-deterrent formulations of opioid analgesics can reduce abuse."[94] In another study from 2016 with at least one Purdue doctor as an author, the authors claimed that abuse decreased by as much as 99% in some situations after abuse-deterrent formulations were introduced.[95]

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[91] *See supra* note 52.

[92] *Opioids with Abuse-Deterrent Properties*, Purdue, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last visited Sept. 7, 2017).

[93] *Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com*, Purdue (Aug. 17, 2015), http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/.

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

[95] 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.

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160. Interestingly, one report found that the original safety label for OxyContin, which instructed patients not to crush the tablets because it would have a rapid release effect, may have inadvertently given opioid users ideas for techniques to get high from these drugs.[96]

161. In 2012, Defendant Endo replaced the formula for Opana ER with a new formula with abuse-deterrent properties that it claimed would make Opana ER resistant to manipulation from users to snort or inject it. Despite the FDA determining that the data did not back up claims that the new formula could reduce abuse, Endo advertised its reformulated pills as "crush resistant" and directed its sales representatives to represent the same to doctors. In 2016, Endo reached an agreement with the Attorney General of the State of New York that required Endo to discontinue making such statements.[97]

162. Defendants' assertions that their reformulated pills could curb abuse were false and misleading, as the CDC's 2016 Guidelines, discussed below, confirm.

6. Defendants falsely claimed that long-term opioid use improved patients' function and quality of life.

163. Not only did Defendants falsely claim there were minimal or no harms associated with opioid use, Defendants represented that there was a significant upside to long-term opioid use, including that opioids could restore function.[98]

164. For example, Purdue sponsored the development and distribution of an APF guide in 2011 which claimed that "multiple clinical studies have shown that opioids are effective in

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[96] *See supra* note 58.

[97] 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), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

[98] 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.

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

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

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

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

168. Endo's NIPC website also claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."

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

170. Through PainKnowledge.org, Endo also supported and sponsored guidelines that stated, among other things, that "Opioid Medications are a powerful and often highly effective tool in treating pain," and that "they can help restore comfort, function, and quality of life."[99]

[99] *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.

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

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

173. Furthermore, sales representatives for Purdue, Endo, and Janssen communicated and continue to communicate the message that opioids will improve patients' function, without appropriate disclaimers.

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

C. The 2016 CDC Guidelines and other recent studies confirm that Defendants' statements about the risks and benefits of opioids are patently false.

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

176. The CDC issued its *Guideline for Prescribing Opioids for Chronic Pain* on March 15, 2016 (the "2016 CDC Guideline" or "Guideline").[100] The 2016 CDC Guideline, approved by the FDA, "provides recommendations for primary care clinicians who are prescribing opioids for

[100] *See supra* note 3.

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chronic pain outside of active cancer treatment, palliative care, and end-of-life care." The Guideline also assesses the risks and harms associated with opioid use.

177. The 2016 CDC Guideline was issued after the CDC "obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee." The recommendations in the 2016 CDC Guideline were further made "on the basis of a systematic review of the best available evidence . . ."

178. With respect to the expert opinions obtained by the CDC for the Guideline, the CDC went through an extensive and detailed process to solicit these opinions. For instance, the Guideline indicates as follows:

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

179. The 2016 Guideline was also peer-reviewed pursuant to "the final information quality bulletin for peer review." In particular, the Guideline indicates:

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

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were determined to be of minimal risk; thus, no significant conflict of interest concerns were identified.

180. Accordingly, there is no doubt that the 2016 CDC Guideline is the result of a thorough and extensive process by the CDC.

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

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

183. The Guideline also alarmingly states that there is "[n]o evidence" to show "a long-term benefit of opioids in pain and function versus no opioids for chronic pain . . ." Furthermore, the Guideline indicates that "continuing opioid therapy for 3 months substantially increases the risk of opioid use disorder." Indeed, the Guideline also indicates that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use

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by discontinuing opioids" because the patient is "not receiving a clear benefit." These findings flatly contradict claims made by Defendants that there are minimal or no adverse impacts of long-term opioid use, or that long-term opioid use could actually improve or restore a patient's function.

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

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

186. The 2016 CDC Guideline also contradicts statements made by the Defendants that there are reliable risk-mitigation tactics to reduce the risk of addiction. For instance, the Guideline indicates that available risk screening tools "show insufficient accuracy for

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classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

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

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

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

188. Notably, in addition to the findings made by the CDC last year, the Washington State Agency Medical Directors' Group ("AMDG")—a collaboration among several Washington State Agencies—published its *Interagency Guideline on Prescribing Opioids for Pain* in 2015. The AMDG came to many of the same conclusions as the CDC did. For example, the AMDG found that "there is little evidence to support long term efficacy of [chronic opioid analgesic therapy, or "COAT"] in improving function and pain, [but] there is ample evidence of its risk for harm . . ."[101]

[101] *Interagency Guideline on Prescribing Opioids for Pain*, Agency Medical Directors' Group (June 2015), http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf.

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189. In addition, as discussed above, in contrast to Defendants' statements that the 1980 NEJM letter provided evidence of the low risk of opioid addiction in patients treated for pain, the NEJM recently published a letter largely debunking the use of the 1980 letter as evidence for such a claim.[102] The researchers demonstrated how the 1980 letter was irresponsibly cited and, in some cases, "grossly misrepresented," when in fact it did not provide evidence supporting the broad claim of low addiction risk for all patients prescribed opioids for pain. As noted above, the 1980 letter's authors reviewed only files of patients administered opioids in a hospital setting, rather than patients sent home with a prescription for opioids to treat chronic pain.

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

> We performed a bibliometric analysis of this [1980] correspondence from its publication until March 30, 2017. For each citation, two reviewers independently evaluated the portrayal of the article's conclusions, using an adaptation of an established taxonomy of citation behavior along with other aspects of generalizability . . . For context, we also ascertained the number of citations of other stand-alone letters that were published in nine contemporaneous issues of the *Journal* (in the index issue and in the four issues that preceded and followed it).
>
> We identified 608 citations of the index publication and noted a sizable increase after the introduction of OxyContin (a long-acting formulation of oxycodone) in 1995 . . . **Of the articles that included a reference to the 1980 letter, the authors of 439 (72.2%) cited it as evidence that addiction was rare in patients treated with opioids. Of the 608 articles, the authors of 491 articles (80.8%) did not note that the patients who were described in the letter were hospitalized at the time they received the prescription, whereas some authors grossly misrepresented the conclusions of the letter** . . . Of note, affirmational citations have become much less common in recent years. In contrast to the 1980 correspondence, 11 stand-alone letters that were published contemporaneously by the Journal were cited a median of 11 times.[103]

[102] *See supra* note 7.
[103] *Id.* (emphasis added).

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191. The researchers provided examples of quotes from articles citing the 1980 letter, and noted several shortcomings and inaccuracies with the quotations. For instance, the researchers concluded that these quotations (i) "overstate[] conclusions of the index publication," (ii) do[] not accurately specify its study population," and (iii) did not adequately address "[l]imitizations to generalizability."[104]

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. Nurs Econ 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. The Independent Review 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. Int J Clin Pract 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. Onco Targets Ther 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. Postgrad Med 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. Semin Oncol 1994;21(6):718–39.	Incorrectly identifies the index study population as cancer patients; does not otherwise address limitations to generalizability.

[104] 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.

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192. 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.[105]

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

D. Defendants have made these false and misleading statements to people, including physicians, in Tacoma.

194. There is no dispute that Defendants have made specific misrepresentations to people in Tacoma, including to family doctors and physicians responsible for treating pain. Further, as a result of Defendants' aggressive and deceptive marketing scheme, doctors in Tacoma have undoubtedly prescribed a high number of opioids to Tacoma citizens.

195. For example, a family medicine doctor who owned and operated four clinics in the Tacoma area was sentenced to several years in prison for prescribing tens of thousands of opioid prescriptions to patients without even examining them.

196. According to testimony and evidence introduced at the trial of this family medicine doctor, Dr. Antoine Johnson, the clinics he operated churned out prescriptions for Schedule II controlled substances such as oxycodone to thousands of patients. These

[105] *See supra* note 7.

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prescriptions were refilled for months and years at a time. Often, the patients would come to the clinics, get their weight and blood pressure taken by a nursing assistant, then pick up a Schedule II prescription that had been pre-signed by Dr. Johnson.

197. The Special Agent in charge of the investigation indicated that the pills Dr. Johnson prescribed caused "great harm" to the communities he purported to serve, and that he and the prescribed opioids "turned patients into addicts and facilitated others in drug dealing."[106]

198. While the City does not allege the Defendants are directly responsible for Dr. Johnson's actions, the doctor's "pill mill" establishes that Defendants knew or should have known that their opioids were being used for improper uses in Tacoma, given the precision with which they track doctors' prescription volumes. Defendants nonetheless turned a blind eye, as "pill mills" such as Dr. Johnson's generated significant profits for them. Although Dr. Johnson's actions were his own, Defendants have the ability to shut down such "pill mills" or take action to mitigate the wide proliferation of these "pill mills" because they control the product supply, and as discussed above, keep close watch on doctors' prescribing patterns through their analysis of IMS data.

199. Furthermore, many family doctors in Tacoma have been specific targets of Defendants' marketing tactics. Defendants sent sales representatives to various Tacoma-area doctors over a significant period of time to tout the benefits and lack of risks associated with opioids, including making repeated assertions to these doctors that their claims were evidence-

[106] U.S. Attorney's Office, *South Sound Doctor Sentenced to More Than 12 Years in Prison for Health Care Fraud, Tax Crimes, and Drug Distribution*, Federal Bureau of Investigation (Mar. 29, 2012), https://archives.fbi.gov/archives/seattle/press-releases/2012/south-sound-doctor-sentenced-to-more-than-12-years-in-prison-for-health-care-fraud-tax-crimes-and-drug-distribution.

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based and well researched. Defendants knew these family doctors relied on their claims and had minimal time or resources to investigate them independently.

200. In addition, it is not surprising that Tacoma doctors are prescribing significant amounts of opioids to their patients, because Defendants have made considerable payments to doctors in Tacoma promoting these drugs. For example, according to public records, between 2010 and 2013, Defendant Janssen Pharmaceuticals, Inc. paid Tacoma-based doctors over $44,000 to promote their drugs, including the opioids Nucynta and Nucynta ER.

E. Defendants have reaped unprecedented profits from the sale of opioids.

201. Defendants have reaped enormous profits from the addiction crisis they spawned. In 2014 alone, opioids generated $11 billion in revenue for pharmaceutical drug companies like Defendants.

202. In fact, Purdue has generated estimated sales of more than $35 billion from opioids since 1996, while raking in more than $3 billion in 2015. Purdue is 100% privately owned by a single family, the Sacklers, whose net worth was $14 billion as of 2015. All nine members of the Purdue board are family members, and all of the company's profits go to Sackler family trusts and entities.[107] The Sacklers are one of the wealthiest families in America, surpassing the wealth of storied families like the Rockefellers, the Mellons, and the Busches.[108]

203. Purdue's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

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[107] 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/.

[108] Alex Morrell, *The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, Forbes (July 1, 2015), 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.

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204. Endo has also profited massively from the sale of opioids. Opioids accounted for more than $400 million of Endo's overall revenues of $3 billion in 2012, and Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013.

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

F. Tacoma has been significantly harmed as a result of Defendants' conduct.

206. As a result of Defendants' misrepresentations and deceptive statements about prescription opioids, Tacoma has suffered significant and ongoing harms.

1. Defendants' conduct has dramatically increased Tacoma's health care costs.

207. Defendants' misrepresentations regarding the purported safety and efficacy of opioids have substantially increased the City's health care costs. The City of Tacoma provides health insurance to its employees and their beneficiaries. The City is self-insured and has administrative services-only agreements with two different insurers. This means that when anyone covered by the City's health insurance program visits a doctor or fills a prescription or otherwise incurs covered health-related costs, the City of Tacoma pays a substantial portion of those costs directly.

208. The City of Tacoma provides health insurance to over 9,000 people, and in connection with this coverage, the City has spent significant amounts of money on prescription opioids. For example, between 2015 and 2016 alone, the City spent well over $1,000,000 on prescriptions for opioids, including those manufactured by Defendants. The bulk of these opioids were prescribed for use in treating chronic pain, for which opioids should not be used. Thus, Tacoma should never have had to pay for these drugs.

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209. Of course, the direct costs of filling the opioid prescriptions is just a small part of the total cost to the City for prescriptions of opioids. Tacoma has paid significant amounts of money for doctors' visits, lab work, and other costs related to the prescription of opioid painkillers. Had Defendants told the truth about the risks and benefits of opioids, the City of Tacoma would not have had to pay for these drugs or the costs related to their prescription.

210. Even those costs, however, represent just the tip of the iceberg of opioid-related costs that Tacoma directly pays. Some people covered by the City's health insurance program have become addicted to opioids. As a result, the City of Tacoma has also incurred significant health care costs related to treating those opioid addictions. Had Defendants told the truth about the dangers of opioids, the City of Tacoma would not have to cover the costs of addiction treatment.

211. Even for those people covered by the City who do not get addicted, improperly prescribed opioids carry other costs for the City. For example, when patients receive opioid prescriptions, they often fail to take other steps to address the root causes of their chronic pain. Thus, even if patients are able to wean themselves off of opioids, the underlying conditions often remain, and may have become worse or more difficult and expensive to treat.

212. Across the United States, people who are prescribed opioid painkillers cost health insurers approximately $16,000 more than those who do not have such prescriptions. Those costs, including those borne by the City of Tacoma, clearly would have been avoided had Defendants not hidden the truth about the risks and benefits of opioids.

213. The City has also shouldered significant health-related costs outside of its health insurance program as a result of Defendants' actions. For instance, when City employees are prescribed opioid painkillers for chronic pain they often are forced to miss work, because the

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drugs' effects interfere with the ability to work. Since opioid prescriptions fail to treat the cause of the pain, the employees often continue to miss work due to the ongoing problems. In fact, recent studies suggest that opioids actually slow recovery times, keeping employees out of work longer than they would have been had they not taken these unnecessary pharmaceuticals. If those employees become addicted to the opioids, they are likely to miss even more work. Because of Defendants' misstatements, the City's employees have had losses in work time, which results in substantial losses to the City.

2. Defendants' conduct has significantly increased the City's workers' compensation costs.

214. The City of Tacoma administers its own workers' compensation program. When someone working for the City is injured on the job, the City pays, among other things, that person's health care costs.

215. Under Tacoma's workers' compensation program, the City has spent significant money filling opioid prescriptions.

216. The vast majority, if not all, of these prescriptions were unnecessary, as the injuries are typically back strains, and other injuries that should be treated with physical therapy, lidocaine patches, and other non-opioid therapies. Thus, Tacoma should never have had to pay for these drugs.

217. Consistent with Tacoma's costs in providing health coverage to its employees as set forth above, the direct costs of filling the opioid prescriptions is just a small part of the total cost to the City for prescriptions of opioids. Under its workers' compensation plan, Tacoma pays for doctors' visits, lab work, and other costs related to the prescription of opioid painkillers. Had

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Defendants told the truth about the risks and benefits of opioids, the City of Tacoma would not have had to pay for these drugs or the costs related to their prescription.

218. Not only are opioids inappropriate for treating the vast bulk of the people making workers' compensation claims, the use of opioids often actually slows the recovery process. This means that the injured worker is off the job longer, and the City shoulders larger workers' compensation costs.

3. Tacoma has spent significant sums of money providing human services to the community as a result of the epidemic Defendants have created.

219. The impact of the opioid epidemic on Tacoma goes well beyond its direct healthcare and employment costs. The effects of the epidemic reach across the City, imposing human and financial costs at all levels.

220. For example, the City of Tacoma spends significant resources helping its homeless population by directly providing key services or funding programs run by charitable organizations. Such human services include providing housing, shelters, and mental health counseling, among many others.

221. Over the past decade, the homeless population in Tacoma has grown at an astonishing rate. The homeless crisis has become such a tragic problem that in May 2017, Mayor Marilyn Strickland declared a state of emergency for homelessness in Tacoma.

222. While there may be several reasons for the rise in the homeless population in Tacoma, the increase is undoubtedly caused in part by the opioid epidemic, as people addicted to opioids often find it difficult to hold down jobs, which ultimately pushes them on to the street and places a huge burden onto the City. Providing the homeless population in Tacoma with

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shelter, treatment, and other services is an expensive undertaking, made dramatically more so now that the homeless population has grown and is comprised of a large number of addicts.

223. Because many people who become addicted to opioids are originally exposed to these addictive drugs through legitimate prescriptions, the opioid crisis has ensnared a broader cross-section of the population than previous drug epidemics. People who would not otherwise have encountered street drugs like heroin and opium get hooked on their dangerous cousins, prescription opioids. This has expanded the population of people who are drug addicts in Tacoma. For these people, a valid prescription for opioids was the first step to addiction and drug abuse, which ultimately led them to lose their homes, and often, their families and friends. Some young people living on the streets of Tacoma today ran away from homes that had fallen apart because a parent had become addicted to opioids.

224. Prescription opioids have not only helped to fuel the homeless crisis, but have made it immeasurably more difficult for the City to address. Mental health services, for example, are critical for many in the homeless population. Unfortunately, opioid use and addiction can make it more difficult to provide effective mental health treatment. Those who need help most often turn to opioids—legal or not—to self-medicate and avoid getting treatment and care that might lead to long-term success and more positive outcomes.

225. As a result of a recent survey, the City estimated that at least fifty percent of its homeless population is addicted to opioids. Whether opioid addiction caused these people to lose their homes or not, opioid addictions now prevent countless numbers of people from finding a way out of homelessness.

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226. Because opioid addition is highly prevalent in Tacoma, the City has had to invest significant resources in addiction programs and other human services, which are widely used by all residents of Tacoma, whether homeless or not.

227. For instance, individuals in Tacoma's Chemical Dependency Program reported that they became addicted to opioids and began buying them on the street after they ran out of doctor-prescribed opioids. Some of these individuals acknowledged that they needed to use the pills on a daily basis, would drive high on pills, and ultimately had their lives ruined as a result of taking opioids. In fact, 30 adolescents and 60 adults reported opioid abuse in their assessments to Tacoma's Chemical Dependency Program in 2016 alone.

228. The City is also investing heavily in prevention work, running programs at local high schools and sponsoring events aimed at teaching people how to avoid becoming addicted to opioids and how to help friends and family do the same.

229. In order to fund much of this opioid-related work, the City has implemented a new tax, aimed at raising approximately $10 million per biennium. The City has budgeted these dollars to be allocated to various agencies and programs addressing homelessness, including significant sums on shelters for families, behavioral health support services, mental health centers, and educational outreach, all of which directly or indirectly address many of the consequences of the opioid epidemic in Tacoma.

4. Tacoma has incurred serious costs responding to opioid-related health emergencies.

230. The City of Tacoma has also borne enormous costs responding to opioid-related health emergencies.

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231. The Tacoma Fire Department provides emergency medical services in the City of Tacoma. The Fire Department responds to emergency calls, dispatching emergency medical service personnel, including emergency medical technicians, or EMTs, in ambulances or fire trucks.

232. Although providing emergency medical services is exceedingly expensive, it is one of the most critical services the City provides its citizens. The Fire Department is the front-line responder for a wide range of medical emergencies, from heart attacks and strokes to mental health emergencies and drug overdoses.

233. Over the past decade, the number of opioid-related emergency calls to which the Fire Department has responded has risen sharply. For example, in 2013, Tacoma Fire Department administered 102 doses of naloxone—a powerful medicine, also known as Narcan, that can reverse an opioid overdose—on emergency calls. By 2016, the number of naloxone doses the Fire Department administered to people who had overdosed on an opioid had jumped 50% to 153 doses.

234. Responding to opioid overdoses is expensive; it involves sending ambulances, engines, and specially-trained staff to the emergency. People who have overdosed on opioids typically require at least one, if not several, doses of naloxone, each of which carries a significant price tag. Then the patient must be transported to the emergency room, where City employees typically must wait while the patient is treated. The costs of materials, maintenance, medication, and staff time, alone, are enormous.

235. And, of course, time, materials, and money spent addressing opioid overdoses means fewer resources and less time to respond to other medical emergencies.

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236. Overdoses are not the only opioid-related health emergencies to which the Fire Department responds. As a result, opioids have had more subtle effects on the Tacoma Fire Department and its budget. For example, opioids have helped to drive a wave of new health problems to which the Fire Department must respond. Many of these new health problems, including infections and infectious diseases as discussed below, fall outside the typical emergencies for which the Department was designed to respond or address.

237. The rise of these new emergency calls has strained the Fire Department's resources, and forced it to shift resources from its core missions. The City places medical emergencies into two categories: Advanced Life Support and Basic Life Support. Advanced Life Support ("ALS") calls include emergencies that are immediately life-threatening, such as heart attacks, strokes, overdoses, and car accidents. Responding to these types of acute medical issues is what fire departments traditionally were organized to do, and ALS calls once made up the bulk of calls to the Tacoma Fire Department. In contrast, Basic Life Support ("BLS") calls are for non-acute and non-life threatening medical issues. These might include skin infections, sore backs, non-life threatening falls or accidents. While the Tacoma Fire Department has always responded to BLS calls, they typically did not make up the focus of the Department's work.

238. Over the past decade, however, this has changed. By 2012, for example, the number of BLS incidents to which the Fire Department had responded had already surpassed ALS incident responses, with 11,985 BLS incidents compared to 8,988 ALS incident responses. But that imbalance has since skewed even more heavily toward BLS calls. In 2016, the Tacoma Fire Department responded to 16,718 BLS incidents—a rise of nearly 40% over just 4 years—while the number of ALS incident responses dropped to 6,622. The Department's inability to

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respond to more ALS incidents is directly tied to the number of BLS incidents to which it must respond. As more resources go to BLS calls, fewer are available for ALS responses.

239. The rise in BLS calls has also had a direct impact on the Fire Department's budget. Generally, on ALS calls, the patient has health insurance or other means to pay for the emergency response, and the Fire Department can bill the insurance company and patient for the costs of responding to the emergency. By contrast, the vast majority of BLS calls come from those who lack any means to pay for the emergency response—indeed, lack of access to health insurance is often a significant factor driving the person to use emergency services for chronic or sub-critical health care. Because the Tacoma Fire Department responds to all those in the City who need its services regardless of ability to pay, the rise in BLS incidents has substantially diminished the Fire Department's ability to recover emergency response costs.

240. This dramatic shift towards BLS calls has been driven, in large part, by opioids. BLS calls often come from people who are addicted to opioids who call the Fire Department in an attempt to gain access to opioids. Others, particularly those who are homeless or lack access to basic health care, call the Department for chronic health problems, such as infections or tooth pain. For many of these BLS callers, their health issues are either directly caused or exacerbated by opioids.

241. Another subtle, but pernicious, way in which the opioid crisis is affecting the Tacoma Fire Department is its impact on the emergency responders themselves. Of course, being an EMT or firefighter is a stressful job, exposing the workers to high stress and difficult situations. But, as opioid-related incidents have increased over the past decade, the stress on these first responders has intensified dramatically. As noted above, in 2016, the Fire Department administered Narcan 153 times that year. That means nearly every other day Tacoma EMTs

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saved the life of someone who had overdosed on opioids. And the overall increase in the volume of calls means each first responder is responding to ever-increasing numbers of emergency incidents. In a 24-hour shift, it is now normal for a crew to make twenty-four or more runs, many of which are done after midnight. This dramatic rise in the number and intensity of emergency incidents has significant effects on the emergency responders. As a result, the Fire Department has seen higher turnover as its employees experience burnout, and this in turn means the Fire Department must devote more time and resources to hiring and training new first responders. And those employees who remain working with Tacoma Fire Department are at higher risk of developing secondary traumatic stress, being injured on the job, and losing interest in their work.

242. The flood of opioid users in the emergency health care system has also overwhelmed Tacoma's emergency rooms. Wait times at hospitals such as Tacoma General Hospital have ballooned, as beds, doctors, and nurses are occupied by patients with opioid-related health problems.

5. Defendants' acts have caused the City to incur significant additional public safety related costs.

243. The epidemic Defendants have created through their misrepresentations about the safety and efficacy of their opioids has also dramatically increased public safety costs for the City of Tacoma.

244. The Tacoma Police Department's experience addressing the opioid crisis illustrates both Defendants' role in creating the opioid epidemic and its devastating and multifaceted impact on the City.

245. In the late 1990s, it was uncommon for police officers to find heroin during routine arrests or drug enforcement work. And, when officers did come across heroin, it was

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generally in small amounts. In fact, in 1998, when the Tacoma Police Department seized four kilograms of heroin, it was one of the biggest heroin busts on the West Coast. A seizure of this amount was so unusual and atypical at the time that the Police Department flew the heroin to be tested at the federal drug lab in Los Angeles on a Learjet.

246. Sadly, this changed in early 2000s, just as Defendants began to ramp up their massive efforts to push opioids for everyday and chronic use. In 2001 and 2002, prescription opioids, including OxyContin, began showing up in drug arrests in Tacoma, and became ubiquitous over the next few years. During that same time the presence of heroin on the streets of Tacoma rose steeply. In fact, by 2004, the Tacoma Police Department was not just seizing kilograms of heroin at a time, but not infrequently finding substantially more amounts, including recently seizing more than 50 pounds of heroin in a single operation.

247. This astounding and devastating rise of opioids—both "legal" and illegal—has profoundly affected public safety issues in Tacoma, and the Tacoma Police Department's work and resources.

248. The opioid epidemic has forced the Tacoma Police Department to expend significant resources fighting drug trafficking in the City. Of course, before Defendants created the opioid epidemic, illegal drugs were bought and sold in Tacoma. But the cocaine and methamphetamines that dominated the illegal drug market in the 1990s were more contained, involved fewer people, and, as a result, were relatively easier to address from a law-enforcement perspective.

249. In the 2000s, however, as prescription opioids and heroin became the kings of the drug trade, illegal drug trafficking in Tacoma rose significantly. Not only has drug use increased in Tacoma, drug trafficking is now more complex. Pills and heroin arrive in Tacoma through

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large, difficult-to-untangle networks that stretch across state lines. Combatting this rise in drug trafficking has forced the City to put more officers on the street and assign more detectives to work these drug cases. In fact, from 2011 through 2016, the amount of arrests made by the Tacoma Police Department directly related to opioid and/or heroin—including unlawful possession, sale, and distribution—has increased by more than 50%.

250. In addition, because many of the sources of illegal opioids in Tacoma come from large criminal networks, the City has spent considerable time and effort coordinating law enforcement efforts with other jurisdictions. For example, from October 1, 2009 until May 22, 2017, Tacoma had fulltime officer on the Pill Task Force, a joint effort involving Tacoma, regional, state, and federal law enforcement entities aimed at combatting illegal sales and distribution of prescription opioids. During that time, the Tacoma Police officer spent at least 18,000 hours with the Task Force.

251. Increased illegal drug trafficking has also caused a rise in other criminal activities in Tacoma. The price of prescription opioids on the black market is significant, forcing many addicts to turn to burglary or other property crimes in order to pay for their addiction. Not only does this impair the quality of life for everyone in Tacoma, the City is forced to address these crimes, expending police and investigatory resources, which have direct costs to the City. For example, from 2011 through 2016, both property crimes and retail theft has increased. In 2016 alone, the Tacoma Police Department made 23,153 arrests for property crimes, and 1,497 arrests for shoplifting.

252. Because the City expends significant resources to address increased drug trafficking and property crimes, the City has had to divert resources from other public safety issues in the City.

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253. The opioid epidemic has also increased public safety costs in other aspects, as well. For example, the City bears significant costs related to an increased number of arrests for opioid-related crimes. This alone has placed a serious strain on Tacoma's police resources. And individuals who are addicted to opioids present special challenges to law enforcement.

254. Typically, people who are arrested while on opioids cannot be taken directly to jail, but must first be taken to a hospital where they can be monitored and treated for withdrawal and other symptoms related to opioid abuse. Although this is the right thing to do for the safety of the person who is arrested, this practice requires the Police Department to remove an officer from her or his beat to take the arrested person to the hospital and wait there during a recovery period, thus effectively removing that officer from the remainder of her or his shift. Additionally, the costs for longer-term incarceration for an opioid addict are significant. Imprisoned addicts require extra care and attention, all of which means increased costs.

255. In sum, the opioid epidemic created by Defendants has unequivocally caused the City of Tacoma serious and ongoing harm. The City's costs for health care, public safety, human and public services, and law enforcement have all risen dramatically, and the City as a community has suffered serious and tragic consequences as a result.

V. CLAIMS FOR RELIEF

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

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

257. The Washington Consumer Protection Act is codified at RCW 19.86 *et seq.* ("CPA"). The CPA establishes a comprehensive procedure for redressing the violations of

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applicable law, and municipalities of Washington State like the City of Tacoma can enforce the CPA and recover damages. RCW 19.86.090. The conduct at issue in this case falls within the scope of the CPA.

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

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

260. These unfair methods of competition and unfair and/or deceptive acts or practices in the conduct of trade or commerce were reasonably calculated to deceive the City and its consumers, and did in fact deceive the City and its consumers. Each Defendant's misrepresentations, concealments, and omissions continue to this day.

261. The City has paid money for prescription opioids for chronic pain. The City has also paid significant sums of money treating those covered by its health insurance for other opioid-related health costs. Defendants' misrepresentations have further caused the City to spend

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substantial sums of money on increased law enforcement, emergency services, social services, public safety, and other human services in the City.

262. But for these unfair methods of competition and unfair and/or deceptive acts or practices in the conduct of trade or commerce, the City of Tacoma would not have incurred millions of dollars in payments to Defendants for harmful drugs with limited, if any, benefit, or the substantial costs to the City related to the epidemic caused by Defendants, as fully described above.

263. Logic, common sense, justice, policy, and precedent indicate Defendants' unfair and deceptive conduct has caused the damage and harm complained of herein. Defendants knew 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 from their continued production and marketing of opioids. Thus, the harm caused by Defendants' unfair and deceptive conduct to Tacoma was reasonably foreseeable, including the financial and economic losses incurred by the City.

264. Furthermore, the City brings this cause of action in its sovereign capacity for the benefit of the State of Washington. The CPA expressly authorizes municipalities to enforce its provisions and to recover damages for violations of the CPA, and this action is brought to promote the public welfare of the state and for the common good of the State.

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

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266. The Court should also grant injunctive relief enjoining Defendants from future violations of the CPA. Defendants' actions, as complained of herein, constitute unfair competition or unfair, deceptive or fraudulent acts or practices in violation of the CPA.

COUNT TWO — PUBLIC NUISANCE

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

268. Pursuant to RCW 7.48.010, an actionable nuisance is defined as, *inter alia*, "whatever is injurious to health or indecent or offensive to the senses . . ."

269. Pursuant to RCW 7.48.130, "A public nuisance is one which affects equally the rights of an entire community or neighborhood, although the extent of the damage may be unequal."

270. In addition, pursuant to Tacoma Municipal Code 8.30.030, "A public nuisance consists of doing an unlawful act, or omitting to perform a duty, or permitting an action or condition to occur or exist which: . . . [u]nreasonably annoys, injures, or endangers the comfort, repose, health, or safety of others; or . . . [i]s unreasonably offensive to the senses . . ."

271. Tacoma and its residents have a right to be free from conduct that endangers their health and safety. Yet Defendants have engaged in conduct which endangers or injures the health and safety of the residents of Tacoma by their production, promotion, and marketing of opioids for use by residents of Tacoma.

272. Each Defendant has created or assisted in the creation of a condition that is injurious to the health and safety of Tacoma and its residents, and interferes with the comfortable enjoyment of life and property of entire communities and/or neighborhoods in Tacoma.

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273. Defendants' conduct has caused deaths, serious injuries, and a severe disruption of the public peace, order and safety, including fueling the homeless and heroin crises facing the City described herein. Defendants' conduct is ongoing and continues to produce permanent and long-lasting damage.

274. The health and safety of the residents of the City of Tacoma, including those who use, have used, or will use opioids, as well as those affected by users of opioids, are matters of substantial public interest and of legitimate concern to the City's citizens and its residents.

275. Defendants' conduct has impacted and continues to impact a substantial number of people within the City of Tacoma and is likely to continue causing significant harm to patients with chronic pain who are being prescribed and take opioids, their families, and their communities.

276. But for Defendants' actions, there is no doubt that opioid use and ultimately its misuse and abuse would not be as widespread as it is today, and the massive epidemic of opioid abuse that currently exists would have been averted.

277. Logic, common sense, justice, policy, and precedent indicate Defendants' unfair and deceptive conduct has caused the damage and harm complained of herein. Defendants knew 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 from their continued production and marketing of opioids. Thus, the public nuisance caused by Defendants to the City of Tacoma was reasonably foreseeable, including the financial and economic losses incurred by the City.

278. Furthermore, the City brings this cause of action in its sovereign capacity for the benefit of the State of Washington. The applicable RCWs with respect to a public nuisance and

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the Tacoma Municipal Code expressly prohibit the conduct complained of herein, and this action is brought to promote the public welfare of the state and for the common good of the state.

279. In addition, engaging in any business in defiance of a law regulating or prohibiting the same is a nuisance per se under Washington law. Each Defendant's conduct described herein of deceptively marketing opioids violates Tacoma Municipal Code 8.30.030 and therefore constitutes a nuisance per se.

280. As a direct and proximate cause of Defendants' conduct creating or assisting in the creation of a public nuisance, the City and its residents have sustained and will continue to sustain substantial injuries.

281. Pursuant to RCW 7.48.020, Tacoma requests an order providing for abatement of the public nuisance that each Defendant has created or assisted in the creation of, and enjoining Defendants from future violations of RCW 7.48.010 and Tacoma Municipal Code 8.30.030.

COUNT THREE — NEGLIGENCE

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

283. Under Washington law, a cause of action arises for negligence when defendant owes a duty to a plaintiff and breaches that duty, and proximately causes the resulting injury. *Iwai v. State*, 129 Wn. 2d 84, 96, 915 P.2d 1089 (1996).

284. Each Defendant owed a duty of care to Tacoma, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

285. In violation of this duty, Defendants failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids in Tacoma by misrepresenting the risks and benefits associated with opioids.

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286. As set forth above, Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid usage indefinitely without added risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these misrepresentations made by Defendants violated the duty of care to Tacoma.

287. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, Tacoma has suffered and will continue to suffer harm, and is entitled to damages in an amount determined at trial.

COUNT FOUR — VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, *ET SEQ.*

288. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this complaint.

289. This claim is brought by the City of Tacoma against each Defendant for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1961, *et seq.*

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

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291. The City of Tacoma is a "person," as that term is defined in 18 U.S.C. § 1961(3), and has standing to sue as it was and is injured in its business and/or property as a result of the Defendants' wrongful conduct described herein.

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

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

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

A. Description of the Defendants' Enterprise.

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

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

297. Defendants formed such an association-in-fact enterprise—referred to herein as "the Enterprise."

298. The Enterprise consists of (a) Defendant Purdue, including its employees and agents; (b) Defendant Endo, including its employees and agents; and (c) Defendant Janssen,

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including its employees and agents (collectively, the "Manufacturer Defendants"); certain Front Groups described above, including but not limited to (a) the American Pain Foundation, including its employees and agents; (b) the American Academy of Pain Medicine, including its employees and agents; and (c) the American Pain Society, including its employees and agents (collectively, the "Front Groups"); and certain key opinion leaders, including but not limited to: (a) Dr. Russell Portenoy, and (b) Kathleen Foley (collectively, the "KOLs").

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

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

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

302. To accomplish this purpose, the Enterprise engaged in a sophisticated, well-developed, and fraudulent marketing scheme designed to increase the prescription rate for the Manufacturer Defendants' opioid medications and popularize the misunderstanding that the risk of addiction to prescription opioids is low when used to treat chronic pain (the "Scheme").

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B. The Enterprise sought to fraudulently increase Defendants' profits and revenues.

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

304. The Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, including but not limited to: (1) the marketing, promotion, and advertisement of Defendants' opioid medicines; (2) the advocacy at the state and federal level for change in the law governing the use and prescription of Defendants' opioid medicines; (3) the issuance of prescriptions and prescription guidelines for Defendants' opioid medication; and (4) the issuance of fees, bills, and statements demanding payment for prescriptions of Defendants' opioid medications.

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

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

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

308. Each Defendant participated in the operation and management of the Enterprise by directing its affairs as described herein.

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

310. Each of the Manufacturer Defendants orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME programs, medical journals, advertisements, and websites; (2) employing sales representatives or detailers to promote the use of opioid medications; (3) purchasing and utilizing sophisticated marketing data (e.g., IMS data) to coordinate and refine the Scheme; (4) employing doctors to serve as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (5) funding, controlling, and operating the Front Groups to target doctors, patients,

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and lawmakers and provide a veneer of legitimacy to the Manufacturer Defendants' Scheme; (6) retaining KOLs to promote the use of their opioid medicines; and (7) concealing the true nature of their relationship with the other members of the Enterprise, including the Front Groups and the KOLs.

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

312. In addition to the above-described actions taken in furtherance of the Enterprise, Defendant Endo specifically orchestrated the affairs of the Enterprise by: (1) making a number of misleading statements described herein; (2) sponsoring a 2009 National Initiative on Pain Control CME program which promoted the concept of pseudoaddiction; (3) funding, controlling, and operating the Front Groups, including the American Pain Foundation and the Pain & Policy Studies Group; (3) sponsoring a series of CME programs which claimed that opioid therapy has been shown to reduce pain and depressive symptoms; (4) supporting and sponsoring guidelines indicating that opioid medications are effective and can restore patients' quality of life; (5) participating in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit organizations that, collectively, spent hundreds of millions of dollars lobbying against opioid-

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

313. In addition to the above described actions taken in furtherance of the Enterprise, Defendant Janssen specifically orchestrated the affairs of the Enterprise by: (1) making a number of misleading statements as detailed herein; (2) funding, controlling, and operating Front Groups, including the Pain & Policy Studies Group; (3) supporting and sponsoring guidelines indicating that opioid medications are effective and can restore patients' quality of life; (4) sponsoring, funding, and editing a website which features an interview indicating that opioid medications can improve patients' function; (5) participating in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit organizations that, collectively, spent hundreds of millions of dollars lobbying against opioid-related measures; (6) retaining KOLs, including Dr. Russell Portenoy and Kathleen Foley to tout the benefits of opioid medicines; and (7) concealing the true nature of its relationship with the other members of the Enterprise, including the Front Groups and the KOLs.

314. The Front Groups orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids; (2) holding themselves out as independent advocacy groups, when in fact their operating budgets are entirely comprised of contributions from opioid drug manufacturers; (3) lobbying against federal and state proposals to limit opioid use; (4) publishing treatment guidelines that advised the prescription of opioids; (5) engaging in 'unbranded' advertisement for opioid medicines; (6) hosting medical education programs that

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touted the benefits of opioids to treat chronic pain while minimizing and trivializing their risks; and (7) concealing the true nature of their relationship with the other members of the Enterprise.

315. In addition to the above described actions taken in furtherance of the Enterprise, the American Pain Foundation specifically orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making a number of public statements, detailed herein, advocating for the prescription of opioids; (2) holding itself out to be an independent and scientific body despite maintaining an operating budget comprised almost entirely of donations from Defendants, including Purdue and Endo; (3) consistently lobbying against federal and state proposals to limit opioid use; (4) publishing treatment guidelines which encouraged the prescription of opioid medicines including the 2009 "Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain-Evidence Review"; and (5) sponsoring medical education programs advocating for the prescription of opioid medicines.

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

317. In addition to the above described actions taken in furtherance of the Enterprise, the American Pain Society specifically orchestrated the affairs of the Enterprise and exerted

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substantial control over the Enterprise by, at least: (1) making a number of public statements, detailed herein, advocating for the prescription of opioid medications; (2) holding itself out to be an independent and scientific body despite maintaining an operating budget comprised almost entirely of donations from Defendants; and (3) publishing treatment guidelines which encouraged the prescription of opioid medicines including the 2009 "Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain-Evidence Review."

318. The KOLs orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids; (2) holding themselves out as independent, when in fact there are systematically linked to and funded by opioid drug manufacturers; and (3) concealing the true nature of their relationship with the other members of the Enterprise.

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

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

C. Predicate acts: mail and wire fraud.

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

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

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

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

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

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

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

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

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

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

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

330. Defendant Purdue's false or misleading use of the mails and wires include, but are 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 treat chronic pain; (4) statements made on its 2000 "Partners Against Pain" website which claimed that the addiction risk of OxyContin was very low; (5) literature distributed to physicians which erroneously cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (6) August 2001 statements to Congress by Purdue Executive Vice President and Chief Operating Officer Michael Friedman regarding the value of OxyContin in treating chronic pain; (7) a patient brochure entitled "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain" indicating that OxyContin is non-addicting; (8) a 2001 statement by Senior Medical Director for Purdue, Dr. David Haddox, indicating that the 'legitimate' use of OxyContin would not result in addiction; (9) multiple communications by Purdue's sales representatives regarding the low risk of addiction associated with opioids; (10) statements included in promotional materials for opioids distributed to doctors via the mail and wires; (11) statements in a 2003 Patient Information Guide distributed by Purdue indicating that addiction to

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opioid analgesics in properly managed patients with pain has been reported to be rare; (12) telephonic and electronic communications to doctors and patients indicating that signs of addiction in the case of opioid use are likely only the signs of under-treated pain; (13) statements in Purdue's Risk Evaluation and Mitigation Strategy for OxyContin indicating that drug-seeking behavior on the part of opioid patients may, in fact, be pain-relief seeking behavior; (14) statements made on Purdue's website and in a 2010 "Dear Healthcare Professional" letter indicating that opioid dependence can be addressed by dosing methods such as tapering; (15) statements included in a 1996 sales strategy memo indicating that there is no ceiling dose for opioids for chronic pain; (16) statements on its website that abuse-resistant products can prevent opioid addiction; (17) statements made in a 2012 series of advertisements for OxyContin indicating that long-term opioid use improves patients' function and quality of life; (18) statements made in advertising and a 2007 book indicating that pain relief from opioids improve patients' function and quality of life; (19) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function; and (20) electronic and telephonic communications concealing its relationship with the other members of the Enterprise.

331. Defendant Endo Pharmaceuticals, Inc. also made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made, beginning in at least 2009, on an Endo-sponsored website, PainKnowledge.com, indicating that patients who take opioids as prescribed usually do not become addicted; (2) statements made on another Endo-sponsored website, PainAction.com, indicating that most chronic pain patients do not become addicted to opioid medications; (3) statements in pamphlets and publications described by Endo indicating that most people who take opioids for pain relief do not develop an addiction; (4) statements made on the Endo-run website, Opana.com, indicating that opioid use

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does not result in addiction; (5) statements made on the Endo-run website, Opana.com, indicating that opioid dependence can be addressed by dosing methods such as tapering; (6) statements made on its website, PainKnowledge.com, that opioid dosages could be increased indefinitely; (7) statements made in a publication entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" suggesting that opioid doses can be increased indefinitely; (8) electronic and telephonic communications to its sales representatives indicating that the formula for its medicines is 'crush resistant;' (9) statements made in advertisements and a 2007 book indicating that pain relief from opioids improves patients' function and quality of life; (10) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function; and (11) telephonic and electronic communications concealing its relationship with the other members of the Enterprise.

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

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

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

335. The American Pain Foundation ("APF") made a number of false and misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made by an APF Executive Director to Congress indicating that opioids only rarely lead to addiction; (2) statements made in a 2002 amicus curiae brief filed with an Ohio appeals court claiming that the risk of abuse does not justify restricting opioid prescriptions for the treatment of chronic pain; (3) statements made in a 2007 publication entitled "Treatment Options: A Guide for People Living with Pain" indicating that the risks of addiction associated with opioid prescriptions have been overstated; (4) statements made in a 2002 court filing indicating that opioid users are not 'actual addicts;' (5) statements made in a 2007 publication entitled "Treatment Options: A Guide for People Living with Pain" indicating that even physical dependence on opioids does not constitute addiction; (6) claims on its website that there is no ceiling dose for opioids for chronic pain; (7) statements included in a 2011 guide indicating that

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opioids can improve daily function; and (8) telephonic and electronic communications concealing its relationship with the other members of the Enterprise.

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

337. The mail and wire transmissions described herein were made in furtherance of Defendants' Scheme and common course of conduct designed to sell drugs that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them; increase the prescription rate for opioid medications; and popularize the misunderstanding that the risk of addiction to prescription opioids is low when used to treat chronic pain.

338. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of predicate acts of mail and/or wire fraud, including certain specific fraudulent statements and specific dates upon which, through the mail and wires, Defendants engaged in fraudulent activity in furtherance of the Scheme.

339. The members of the Enterprise have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the members of the Enterprise conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms, and corporations, including third-party entities and

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individuals not named as defendants in this Complaint, have participated as co-conspirators with Defendants and the members of the Enterprise in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenue, increase market share, and/or minimize losses for the Defendants and their named and unnamed co-conspirators throughout the illegal scheme and common course of conduct.

340. The members of the Enterprise aided and abetted others in the violations of the above laws.

341. To achieve their common goals, the members of the Enterprise hid from Plaintiff and the public: (1) the fraudulent nature of Defendants' marketing scheme; (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of and risk of addiction associated with Defendants' opioid medications; and (3) the true nature of the relationship between the members of the Enterprise.

342. Defendants and each member of the Enterprise, with knowledge and intent, agreed to the overall objectives of the Scheme and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprise and their co-conspirators had to agree to conceal their fraudulent scheme.

343. The members of the Enterprise knew, and intended that, Plaintiff and the public would rely on the material misrepresentations and omissions made by them and suffer damages and a result.

344. As described herein, the members of the Enterprise engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiff and the public based on their misrepresentations and omissions.

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345. The predicate acts also had the same or similar results, participants, victims, and methods of commission.

346. The predicate acts were related and not isolated events.

347. The true purposes of Defendants' Scheme were necessarily revealed to each member of the Enterprise. Nevertheless, the members of the Enterprise continued to disseminate misrepresentations regarding the nature of Defendants' opioid medications and the functioning of the Scheme.

348. Defendants' fraudulent concealment was material to Plaintiff and the public. Had the members of the Enterprise disclosed the true nature of the Defendants' opioid medications, the City of Tacoma would not have acted as it did, including relying on Defendants' misrepresentations to its detriment.

349. The pattern of racketeering activity described above is currently ongoing and open-ended, and threatens to continue indefinitely unless this Court enjoins the racketeering activity.

D. The City of Tacoma has been damaged by Defendants' RICO violations.

350. By reason of, and as a result of the conduct of the Enterprise and, in particular, its pattern of racketeering activity, the City and the public have been injured in their business and/or property in multiple ways, including but not limited to increased health care costs, increased human services costs, costs related to dealing with opioid-related crimes and emergencies, and other public safety costs, as fully described above.

351. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and proximately caused injuries and damages to the City of Tacoma and the public who are entitled

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to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. § 1964(c).

PRAYER FOR RELIEF

WHEREFORE, the City of Tacoma respectfully requests the Court order the following relief:

A. An Order that the conduct alleged herein constitutes violations of the Washington Consumer Protection Act ("CPA"), RCW 19.86 *et seq.*;

B. An Order that Plaintiff is entitled to treble damages pursuant to the Washington CPA;

C. An Order that the conduct alleged herein constitutes a public nuisance, including under RCW 7.48 *et seq.*, Tacoma Municipal Code 8.30.030, and under Washington law;

D. An Order that Defendants abate the public nuisance that they caused under Washington law;

E. An Order that Defendants are negligent under Washington law;

F. An Order that Defendants have been unjustly enriched at Plaintiff's expense under Washington law;

G. An Order that Defendants' conduct constitutes violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, *et seq.*;

H. An Order that Plaintiff is entitled to treble damages pursuant to RICO;

I. An Order that Plaintiff is entitled to recover all measure of damages permissible under the statutes identified herein and under common law;

J. An Order that judgment be entered against Defendants in favor of Plaintiff;

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K. An Order that Plaintiff is entitled to attorney's fees and costs pursuant to any applicable provision of law, including but not limited to under the Washington CPA and RICO; and

L. An Order awarding any other and further relief deemed just and proper, including pre-judgment and post-judgment interest on the above amounts.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all claims and of all issues so triable.

DATED this 13th day of September, 2017.

KELLER ROHRBACK L.L.P.

By */s/ Derek W. Loeser*

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