SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR KING COUNTY

CITY OF SEATTLE, a municipal corporation,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; SEATTLE PAIN CENTER MEDICAL CORPORATION d/b/a SEATTLE PAIN CENTER; FRANK D. LI; AND DOES 1 THROUGH 100, INCLUSIVE,

Defendants.

No.

COMPLAINT

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I. INTRODUCTION

1. Drug companies should never place their desire for profits above the health and well-being of their customers or the communities where those customers live. Because they know prescribing doctors and other health-care providers rely on drug companies' statements in making treatment decisions, drug companies must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence.

2. The Defendants here who manufacture opioids (hereafter the "Manufacturing Defendants"[1]) broke these simple rules and helped unleash a healthcare crisis that has had far-reaching financial, social, and deadly consequences in the City of Seattle (hereinafter "Seattle" or "Plaintiff") and across the nation.

3. Manufacturing Defendants produce, market, and sell prescription opioids (hereinafter "opioids"), including brand-name drugs like Oxycontin and Percocet, and generics like oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (like back pain, migraines and arthritis),[2] opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

4. However, by the late 1990s, and continuing today, each Manufacturing Defendant began a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturing Defendant spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while

[1] Namely Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLC; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

[2] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

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overstating the benefits of using them for chronic pain. As to the risks, Manufacturing Defendants falsely and misleadingly, and sometimes contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Conversely, Manufacturing Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support these claims.

5. Manufacturing Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians Manufacturing Defendants recruited for their support of their marketing messages. Borrowing a page from Big Tobacco's playbook, Manufacturing Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Manufacturing Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Manufacturing Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

6. Each Manufacturing Defendant knew that its misrepresentations of the risks and

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benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Manufacturing Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA ("2016 CDC Guideline"). The FDA and CDC have found that continuing use of opioids for over three months creates a risk of "opioid disorder" and that opioid use creates a substantial risk of misuse, abuse, withdrawal, addiction, overdose, and death. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into settlements agreements with public entities, including (in the case of Purdue) with the State of Washington, that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even now, each Manufacturing Defendant continues to misrepresent the risks and benefits of long-term opioid use in Seattle and continues to fail to correct its past misrepresentations.

7. Manufacturing Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[3] This epidemic, fueled by a small amount of opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

8. In many regions of the country, opioid addicts also turn to licensed doctors operating so-called "pill mills," which dispense opioids without regard for the risks or patients'

[3] Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org/.

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medical needs. Seattle is one such region. In 2008, Frank D. Li[4] opened the now notorious Seattle Pain Center (together with Mr. Li, "SPC") and eventually expanded into cities across the state, including in Renton, Everett, Tacoma, Olympia, Spokane, Poulsbo, and Vancouver.

9. Tragically, at least 60 SPC patients died between 2010 and 2015. Washington officials investigated medical records for 18 of these patients and concluded that 16 died of opioid overdoses shortly after filing an opioid prescription issued by SPC, and that the other two patients were prescribed opioids despite serious health conditions.

10. On July 14, 2016, Washington's Medical Quality Assurance Commission ("MQAC") summarily suspended Mr. Li's license to practice medicine. MQAC found that while SPC had represented publicly that it was dedicated to "finding treatment alternatives to narcotic pain medications," in fact "SPC sought out vulnerable chronic pain patients enrolled in Medicaid insurance and maintained these patients on opioid therapy by providing continuing prescriptions despite knowledge of medication abuse, diversion, and overdose."[5]

11. Pill mills like SPC were a logical and foreseeable result of the Manufacturing Defendants' deceptive marketing campaign. Manufacturing Defendants not only knew that marketing their drugs for chronic pain would create addicts, but also that unscrupulous clinics like SPC were dispensing their drugs in dosages that would keep those patients addicted. As described below, Manufacturing Defendants not only looked the other way as their pills were prescribed by such doctors, but continued to market their drugs in a way that would inevitably create more.

12. The conduct of the Manufacturing Defendants and SPC (together, "Defendants") has left communities across Washington State, including Seattle, awash in opioids and engulfed in a public health crisis the likes of which have never been seen before. Analysts have reported that, in the 2010-2011 period, Washington State had the third highest opioid abuse rate, and

[4] Mr. Li's middle name is "Danger."

[5] *In the Matter of Frank D. Li, M.D., Ex Parte Order of Summary Suspension*, dated July 14, 2016, at 3; *see also In the Matter of the License to Practice as a Physician and Surgeon of Frank D. Li, MD*, Statement of Charges, dated July 13, 2016, at 1.

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second highest associated per-capita health care costs, in the nation.[6] Alarmingly, the annual number of opioid doses prescribed statewide has exceeded 112 million – enough to supply every man, woman and child living in Washington with ***16 pills each***.[7] In King County specifically, the opioid prescribing rate in 2011 was 66%, meaning that 66 opioid prescriptions were issued for every 100 King County residents and, despite aggressive efforts by local and state officials to combat the crisis, the prescribing rate remained above 47% through 2016.[8]

13. Prescription opioid abuse also has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on Seattle agencies that address heroin use and addiction. Individuals who are addicted to prescription opioids often transition to heroin because it is a less expensive, readily available alternative that provides a similar high.[9]

14. The combined effects have been catastrophic. In 2016, 435 people in Washington overdosed on prescription opioids – ***that is more than one person per day for the entire year*** – and heroin was linked to 287 overdose deaths.[10] Between 1997 and 2015, the rate of drug-involved deaths in King County spiked from 10.67 to 15.59 per 100,000 residents, a 46% increase. The bulk of this increase is attributable to prescription opioid and heroin overdoses.[11] In 2015, two out of every three drug-related deaths in King County involved prescription opioids or heroin.

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[6] Matrix Global Advisors, LLC, *Health Care Costs from Opioid Abuse: A State-by-State Analysis*, April 2015, at 1-2.

[7] University of Washington, Alcohol and Drug Abuse Institute, online report, available at adai.washington.edu/WAdata/ARCOSopiates.htm.

[8] CDC Report, U.S. County Prescribing Rates, 2011, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2011.html; CDC Report, U.S. County Prescribing Rates, 2016, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html.

[9] JAMA Psychiatry, *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, May 28, 2014.

[10] Washington Department of Public Health, *Opioid-related Deaths in Washington State, 2006-2016*, available at http://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf.

[11] University of Washington, Alcohol and Drug Abuse Institute, online report, available at https://adai.washington.edu/WAdata/KingCountyDrugDeaths.htm.

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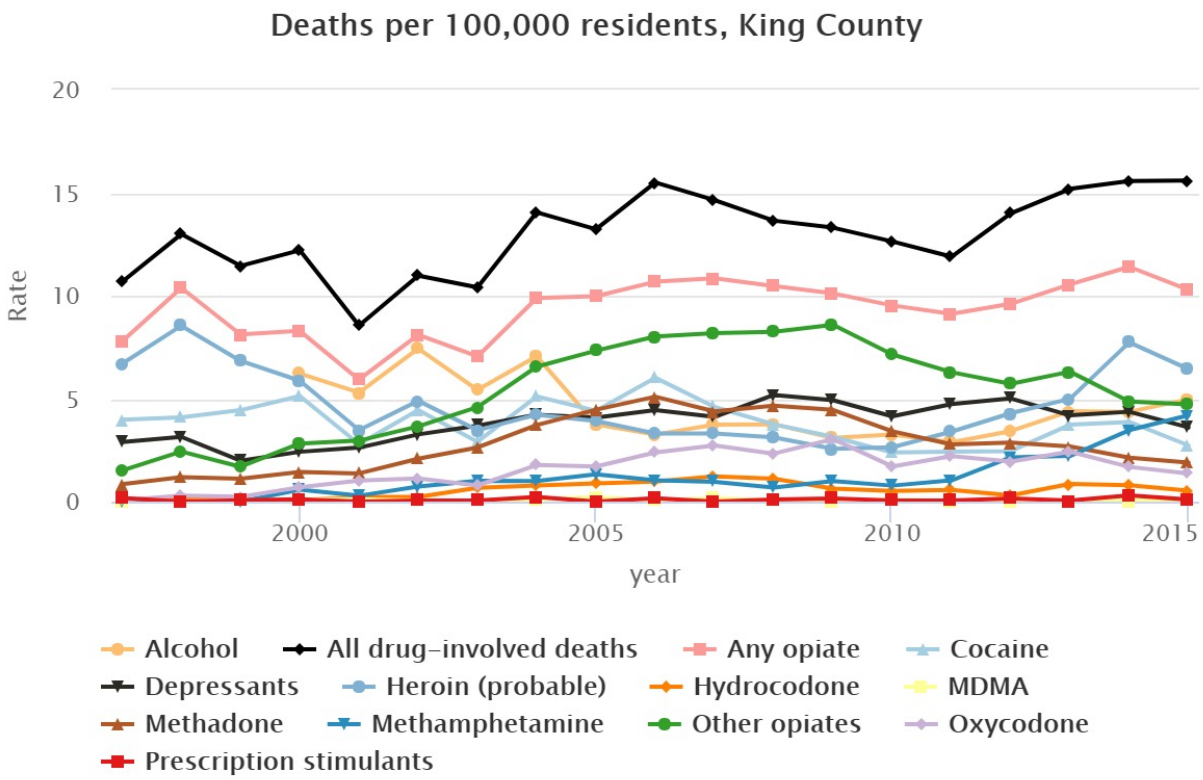

15. But even these alarming statistics do not fully illustrate the extent to which the opioid epidemic has entrenched itself within our communities. The dramatic increase in opioid prescriptions to treat chronic pain has resulted in a population of addicts who seek drugs from doctors for misuse. Manufacturing Defendants have taught doctors to treat these signs of addiction as untreated pain requiring even more aggressive opioid dosages, which of course only compounds the problem. But more than that, even Seattle physicians wishing to wean patients from opioids have found their efforts stunted by the availability of opioids through other channels, chief among them being SPC and the roster of indiscriminate opioid prescribers it employed.

16. There is no question that a significant number of Seattle residents suffer from chronic pain, which takes an enormous toll on their health, lives and families. These patients deserve both appropriate care, which SPC failed to provide, and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Manufacturing Defendants' deceptive marketing campaign deprived patients and their doctors of the ability to

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make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Patients have suffered enormously as a result.

17. Defendants' conduct also has imposed, directly and foreseeably, a financial burden on Seattle and its agencies. Seattle's Human Services Department has spent millions of dollars treating opioid addicts, often with regimens of methadone and buprenorphine, drugs that diminish opioid cravings and withdrawal. Seattle police and fire departments, likewise, have devoted an increasing amount of their limited time and resources to the opioid crisis. Members of both departments are now equipped with costly devices that inject naloxone, aka Narcan, a drug that can reverse an opioid overdose, and Seattle has incurred significant costs to ensure that this life-saving drug, which has a limited "shelf life," is properly maintained and deployed. The police department has seen a surge in opioid-related crime, often perpetrated by addicts seeking drug purchase funds. In many cases, Seattle police officers must take opioid addicts to King County detention centers, with Seattle being billed for the costs of their detention and any associated medical treatments.

18. Seattle has seen its homeless population swell, with 4,505 living without shelter in the city and other select areas of King County in 2016 – a 19% increase over 2015. Researchers estimate that over 50% of people with opioid addictions in Seattle are homeless and Seattle's Navigation Team – composed of outreach workers and police officers specially trained to interface with the homeless population – estimates that 80% of the homeless individuals they encounter in challenging encampments have substance abuse disorders.

19. Seattle spent $53 million to address the homelessness emergency in 2016, and more than $60 million is budgeted for 2017 and 2018. Included in these sums are millions of dollars for outreach and counseling services designed to help people get into other housing, including shelters, approved encampments, and traditional housing. Seattle departments have also worked extensively with unhoused persons living in 400 unsanctioned encampments which needed to be cleaned up for safety and health reasons. After providing counseling services and

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locating, wherever possible, alternative shelter for the unhoused, the encampments themselves are cleared and fenced off so people cannot simply return. This is labor intensive work requiring Seattle employees and contractors to locate personal belongings and catalog and store them for later pickup or delivery to owners, and to dispose of hypodermic needles and tons of trash. Seattle also operates a variety of programs to help homeless individuals with basic needs such as food, water and shelter, as well as providing for medical needs, addiction related services and transportation.

20. Through this action, Seattle, by and through City Attorney Peter S. Holmes, seeks to hold Defendants accountable, individually and collectively, for creating a public nuisance in violation of RCW 7.48.010 and the common law, engaging in unfair and deceptive practices contravening RCW 19.86.020, conducting a pattern of criminal profiteering activity in violation of RCW 9A.82.100, and participating in a civil conspiracy.

II. JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction by grant of authority under the Constitution of the State of Washington.

22. This Court has personal jurisdiction over Defendants under the long-arm statute of the State of Washington (RCW 4.28.185), and the Constitution of the United States, because they conduct business in Washington, purposefully direct or directed their actions toward Washington, and/or have the requisite minimum contacts with Washington necessary to permit the Court to exercise jurisdiction.

23. Venue in this Court is proper pursuant to RCW 4.12.020 because the claims for relief asserted by Seattle arose in King County.

III. PARTIES

A. Plaintiff

24. Plaintiff Seattle is a municipal corporation of the first class, organized and existing under the laws of the State of Washington, that conducts business in King County, Washington.

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B. Defendants

25. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

26. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States and Seattle. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers). In 2007, Purdue entered a Consent Judgment with the State of Washington pursuant to which it agreed not to make further misleading statements about OxyContin and agreed to create an abuse and diversion detection program.

27. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

28. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Seattle. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[12] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and

[12] Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain.

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Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

29. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Seattle, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Seattle, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in Seattle and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon.")

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of

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JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen.")

31. Janssen manufactures, promotes, sells, and distributes drugs in the United States and Seattle, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.")

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States and Seattle. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States and Seattle, by

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itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

34. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.")

35. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States and Seattle. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

36. SEATTLE PAIN CENTER MEDICAL CORPORATION, d/b/a Seattle Pain Center, is an active for-profit Washington State corporation with its principal place of business in Seattle, Washington. Seattle Pain Center Medical Corporation's corporate mailing address is PO Box 58634, Renton, WA 98058-1634.

37. FRANK D. LI is the medical director, sole shareholder, and registered agent of

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Seattle Pain Center Medical Corporation, d/b/a Seattle Pain Center. Until July 14, 2016, Mr. Li was licensed to practice medicine in the State of Washington. Mr. Li is a citizen of Washington and, on information and belief, maintains a residence at 1519 E. Denny Way, Seattle WA 98122-2620.

38. Seattle lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive, and they are therefore sued herein pursuant to Superior Court Civil Rule 10(a)(2). Seattle will amend this Complaint to show their true names and capacities if and when they are ascertained. Seattle is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

IV. FACTUAL ALLEGATIONS

39. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

40. This was as true in Seattle as it was elsewhere. Dr. John Loeser, a clinical professor emeritus at University of Washington specializing in pain medicine, has explained that in the 1980s "[i]t did not enter our minds that there could be significant numbers of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them." Instead, providers at University of Washington's pain clinic followed "the

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mantra that it was not wise to treat chronic pain patients with opioids."

41. Tens of millions of Americans suffer from and seek treatment for chronic pain. To take advantage of the lucrative market for chronic pain patients, each Manufacturing Defendant developed a well-funded marketing scheme based on deception. Each Manufacturing Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that benefited not only themselves and the third-parties who gained legitimacy, but all opioid manufacturers. Yet these statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

A. Manufacturing Defendants Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids.

42. Manufacturing Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Seattle. Manufacturing Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the United States and Seattle.

1. Manufacturing Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded opioids.

43. Manufacturing Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturing Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Manufacturing Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million

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by Janssen, and $1.1 million by Endo.

44. A number of Manufacturing Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Janssen used branded advertising and published reprints of journal articles promoting the use of opioids to treat osteoarthritis, even though the FDA found, in reviewing the New Drug Application for Janssen's drug Nucynta ER, that Nucynta ER was no more effective than placebo in reducing osteoarthritis pain. Actavis distributed a product advertisement that falsely claimed that use of Kadian to treat chronic non-cancer pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives. The FDA later warned Actavis such claims were misleading.[13]

45. Second, each Manufacturing Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. Manufacturing Defendants have not corrected this misinformation. Instead, each Manufacturing Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturing Defendants spent $168 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturing Defendants spent on detailing in 2000. The amount includes $108

[13] Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Seattle.

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million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis.

46. Manufacturing Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

47. Manufacturing Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Manufacturing Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. They were also one of the key ways Manufacturing Defendants' messages were disseminated as medical knowledge: these speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Manufacturing Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Manufacturing Defendants' prior misrepresentations about the risks and benefits of opioids.

48. Manufacturing Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face

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detailing having the greatest influence. Even without such studies, Manufacturing Defendants purchase, manipulate and analyze some of the most sophisticated data available in *any* industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Manufacturing Defendants *know* their detailing to doctors is effective.

49. Manufacturing Defendants employed the same marketing plans and strategies and deployed the same messages in Seattle as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Manufacturing Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. Manufacturing Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

50. Manufacturing Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Manufacturing Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

2. Manufacturing Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids.

51. Manufacturing Defendants also deceptively marketed opioids in Seattle through unbranded advertising – *i.e.*, advertising that promotes opioid use generally but does not name a

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specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Manufacturing Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Manufacturing Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Manufacturing Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Manufacturing Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

52. Manufacturing Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Manufacturing Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Manufacturing Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

53. Manufacturing Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted the fine print in its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**

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Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (Branded)
"People who take opioids **as prescribed usually do not become addicted**."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

a. Key Opinion Leaders ("KOLs")

54. Manufacturing Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Manufacturing Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

55. Manufacturing Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Manufacturing Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Manufacturing Defendants.

56. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Manufacturing Defendants created opportunities for KOLs to participate in research studies Manufacturing Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Manufacturing Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

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57. Manufacturing Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. Manufacturing Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

58. Pro-opioid doctors are one of the most important avenues that Manufacturing Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Manufacturing Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that through March 2015 the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

59. Thus, even though some of Manufacturing Defendants' KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, those admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and in Seattle in Manufacturing Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

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60. Manufacturing Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

(1) Russell Portenoy

61. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Manufacturing Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

62. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Manufacturing Defendants.

63. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Seattle and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[14]

64. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that

[14] Good Morning America television broadcast, ABC News (Aug. 30, 2010).

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fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[15] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[16]

(2) Lynn Webster

65. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Manufacturing Defendants (including nearly $2 million from Cephalon).

66. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

67. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving

[15] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012.

[16] *Id.*

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doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

68. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors across the country, including in Seattle.

69. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[17]

b. Front Groups

70. Manufacturing Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Manufacturing Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Manufacturing Defendants by responding to negative

[17] John Fauber, *Painkiller boom fueled by networking*, MILWAUKEE WISC. J. SENTINEL (Feb. 18, 2012).

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articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Manufacturing Defendants.

71. These Front Groups depended on Manufacturing Defendants for funding and, in some cases, for survival. Manufacturing Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. For example, Purdue's consulting agreement with APF gave it direct, contractual control over APF's work. In doing so, Manufacturing Defendants made sure that the Groups would generate only the messages Manufacturing Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

72. Manufacturing Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

(1) American Pain Foundation ("APF")

73. The most prominent of Manufacturing Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at $1.7 million.

74. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of

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addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Seattle.

75. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue) Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all of whom served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

76. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

77. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Manufacturing Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned

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largely as an advocate for the interests of Manufacturing Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

78. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

79. APF assisted in other marketing projects for drug companies. One project funded by another drug company – *APF Reporter's Guide: Covering Pain and Its Management* (2009) – recycled text that was originally created as part of the company's training document.

80. The same drug company made general grants, but even then it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year – this would be a very good issue on which to use some of that. How does that work?"

81. The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Manufacturing Defendants. APF's clear lack of independence – in its finances, management, and mission – and its willingness to allow Manufacturing Defendants to control its activities and messages support an inference that each Manufacturing Defendant that worked with it was able to exercise editorial control over its publications.

82. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization

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and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Manufacturing Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

(2) American Academy of Pain Medicine ("AAPM")

83. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Manufacturing Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Manufacturing Defendants' deceptive marketing of chronic opioid therapy.

84. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Manufacturing Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

85. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have

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included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[18]

86. AAPM's staff understood they and their industry funders were engaged in a common task. Manufacturing Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

87. In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Manufacturing Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

88. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

[18] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829.

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89. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

90. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturing Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Seattle during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

91. Manufacturing Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

92. Manufacturing Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Manufacturing Defendants combined their efforts through the Pain Care Forum (PCF), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Manufacturing Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project

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on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Manufacturing Defendants determined would reduce prescribing. PCF also worked to address a perceived "lack of coordination" among its members and developed "key" messages that were disseminated in programs and industry-run websites.

(3) Federation of State Medical Boards ("FSMB")

93. In 2007, the FSMB adapted its own opioid prescribing guidelines into a book written by KOL Dr. Scott Fishman entitled *Responsible Opioid Prescribing*, which the FSMB's website once described as the "leading continuing medical education (CME) activity for prescribers of opioid medications." The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue, as well as numerous Front Groups, including AAPM, APF, the American Society for Pain Management Nursing ("ASPMN"), the Center for Practical Bioethics, the National Pain Foundation ("NPF"), and the Pain & Policy Studies Group ("PPSG").

94. *Responsible Opioid Prescribing* contains many of the Manufacturer Defendants' misrepresentations described in this Complaint. The 2007 version taught that relief of pain improved patients' function, and described functional improvement as the goal of a "long-term therapeutic treatment course." It advised that opioids could be used safely even with high-risk patients, stating that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications, . . . other causes of non-adherence should be considered before a judgment is made." It taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, were all signs of pseudoaddiction, rather than addiction.

95. FSMB has more recently moderated its stance. Although the 2012 revision of

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Responsible Opioid Prescribing continues to teach that pseudoaddiction is real and that opioid addiction risk can be managed through risk screening, it no longer recommends chronic opioid therapy as a first choice after the failure of over the counter medication and has heightened the addiction and risk warnings.

96. In a June 8, 2012 letter to the Senate Finance Committee, FSMB acknowledged that *Responsible Opioid Prescribing* was accepted and became an "important educational resource for physicians" wherever it was distributed. And it was widely disseminated in Washington. FSMB itself has reported that 15,395 copies of *Responsible Opioid Prescribing* were distributed statewide – enough to supply every Washington primary care physician with nearly three copies each. Overall, Washington providers received nearly one out of every ten copies of *Responsible Opioid Prescribing*. Only three states received more copies.

A. Manufacturing Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

97. To convince doctors and patients in Seattle and across the nation that opioids can and should be used to treat chronic pain, Manufacturing Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Manufacturing Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Manufacturing Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

1. Manufacturing Defendants falsely trivialized or failed to disclose the known risks of long-term opioid use.

98. To convince doctors and patients that opioids are safe, Manufacturing Defendants

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deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Manufacturing Defendants have not only failed to correct these misrepresentations, they continue to make them today.

99. ***First***, Manufacturing Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in all states in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

d. Endo distributed a pamphlet with the Endo logo entitled *Living with*

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Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

h. Detailers for Purdue, Endo, Janssen, and Cephalon minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

100. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

101. The FDA further exposed the falsity of Manufacturing Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA (Extended Release/Long Acting) opioids in 2013 and for IR (Immediate Release) opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the

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"known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

102. Manufacturing Defendants' claims are further proven false by the warnings on their FDA-approved drug labels that caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

103. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in Seattle, nor has Endo engaged in a campaign to reverse the impact of previous statements that were to the contrary.

104. ***Second***, Manufacturing Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be

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treated by prescribing more opioids. Manufacturing Defendants called this phenomenon "pseudoaddiction" – a term coined by the now infamous Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real.

b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

f. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." This publication is still available online.

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105. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

106. Even one of the Manufacturing Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the State of New York, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Consistent with this, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York. Endo, however, remains free to do so in Seattle.

107. ***Third,*** Manufacturing Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Manufacturing Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Manufacturing Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more

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comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Endo, Janssen and Purdue all linked websites they ran or administered to Dr. Lynn Webster's Opioid Risk Tool, a brief questionnaire that gave doctors false confidence in prescribing opioids for chronic pain.

c. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

d. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

108. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by Manufacturing Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

109. ***Fourth***, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Manufacturing Defendants falsely claimed that opioid

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dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

110. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.

111. Manufacturing Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include 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 – and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

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112. ***Fifth***, Manufacturing Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Manufacturing Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

h. Purdue sponsored a CME entitled *Overview of Management Options* that

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is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,"[19] challenging the correlation between opioid dosage and overdose.

113. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[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." More specifically, the CDC 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." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

114. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged in response to a citizen petition by a physician group "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain.

115. ***Finally***, Manufacturing Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids, described below, has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care

[19] www.cpdd.org.

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physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.[20]

116. These abuse deterrent formulations (AD opioids) are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids are not "impossible to abuse."[21] They can be defeated – often quickly and easily – by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.

117. Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has cautioned that "[a]ny communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health."[22]

118. Despite this admonition, Manufacturing Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations. For example, until

[20] Catherine S. Hwang, *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175(2) JAMA INTERN. MED. 302-4 (Dec. 8, 2014).

[21] FDA Facts: Abuse-Deterrent Opioid, available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm [as of September 24, 2017].

[22] *Id*.

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July 2017 when Endo withdrew from the market in response to pressure from the FDA to do so, Endo marketed Opana ER as tamper, or crush, resistant and less prone to misuse and abuse even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse.

119. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

120. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017, and requested that Endo withdraw Opana ER from the market.[23] Approximately one month later, Endo did so.[24]

121. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids – i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not

[23] Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

[24] Press Release, "Endo Provides Update On Opana ER," July 6, 2017, available at: http://www.endo.com/news-events/press-releases.

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market its opioids based on their abuse deterrent properties. However, beginning in 2013 and continuing today, detailers from Purdue regularly use the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, these detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

122. These statements and omissions by Purdue are false and misleading and conflict with or are inconsistent with the FDA-approved label for Purdue's AD opioids – which indicates that abusers do seek them because of their high likability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent properties and which does not indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

123. To the contrary, testimony in litigation against Purdue and other evidence indicates that Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and Reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a study it conducted that found continued abuse of OxyContin with so-called abuse deterrent properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other opioid products.

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124. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.[25] Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

125. Similarly, 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 "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."[26]

126. These false and misleading claims about the abuse deterrent properties of their opioids are especially troubling. First, Manufacturing Defendants are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. Second, these claims are falsely assuaging doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraging doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe more AD opioids – which are far more expensive than other opioid products even though they provide little or no additional benefit.

[25] Cicero, Theodore J., and Matthew S. Ellis, "Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin" (2015) 72.5 JAMA Psychiatry 424-430.

[26] Perrone, *Drugmakers push profitable, but unproven, opioid solution*, dated Dec. 15, 2016, available at https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution.

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127. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Manufacturing Defendants successfully convinced doctors and patients to discount those risks.

2. Manufacturing Defendants grossly overstated the benefits of chronic opioid therapy.

128. To convince doctors and patients that opioids should be used to treat chronic pain, Manufacturing Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guidelines now make clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Manufacturing Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Manufacturing Defendants failed to correct these false and deceptive claims, they continue to make them today.

129. For example, Manufacturing Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are described below:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

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c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stair and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

f. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012.

g. Endo's NIPC website *painknowledge.com* 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." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.

j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.

k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic

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pain patients' quality of life, and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.

l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

130. These claims find no support in the scientific literature. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
- "Although 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."
- "[E]vidence 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."

131. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

132. The 2016 CDC Guideline was not the first time a federal agency repudiated Manufacturing Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described in paragraph 40, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a

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patient's work, physical and mental functioning, daily activities, or enjoyment of life."[27] And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

133. Manufacturing Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, Manufacturing Defendants have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by Manufacturing Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

134. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This

[27] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

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triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

135. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours. And if a doctor suggests that OxyContin does not last 12 hours, these sales representatives, at Purdue's instruction, recommend increasing the dose, rather than the frequency of use. Purdue gave its sales representatives these instructions to prevent doctors from switching to a different drug and to address the unwillingness of insurers to pay for more frequent use of OxyContin.

3. Manufacturing Defendants also engaged in other unlawful, deceptive and unfair misconduct.

136. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm,

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including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

137. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

- Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

- In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

138. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

139. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed

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Purdue about its legal "obligation to design and operate a system to disclose . . . suspicious orders of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. (*See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).)

140. For over a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

141. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

142. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement

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agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

B. Manufacturing Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

143. As a part of their deceptive marketing scheme, Manufacturing Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States, including in Seattle. For example, Manufacturing Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Manufacturing Defendants' misrepresentations. Those primary care doctors then became sources of information for other doctors, including doctors in Seattle.

144. Manufacturing Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Manufacturing Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more

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likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

C. Although Manufacturing Defendants Knew That Their Marketing of Opioids Was False and Deceptive, They Fraudulently Concealed Their Misconduct.

145. At all times relevant to this Complaint, Manufacturing Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and deceptive conduct. For example, Manufacturing Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Manufacturing Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Manufacturing Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Manufacturing Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Manufacturing Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturing Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

146. Finally, Manufacturing Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Manufacturing Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Manufacturing Defendants' deceptive messages was not

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apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Seattle.

147. Thus, Manufacturing Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that Seattle now asserts. Seattle did not know of the existence or scope of Manufacturing Defendants' industry-wide deception and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

D. SPC Operated a "Pill Mill" To Serve the Addicts that Manufacturing Defendants' Marketing Scheme Engendered.

148. In 2008, Frank D. Li established SPC and opened its first clinic on Sand Point Way in Seattle. SPC expanded rapidly and, by 2016, was operating one laboratory and seven additional pain clinics, including in Renton, Everett, Tacoma, Olympia, Spokane, Poulsbo, and Vancouver. Mr. Li was SPC's sole medical doctor, and one of its only pain management specialists. To churn through patients and maximize revenues, he employed a revolving cast of inexperienced nurse practitioners and physician assistants.

149. In interviews provided to the Washington Attorney General Medicaid Fraud Control Unit ("MCFU"), former SPC providers revealed that Dr. Li recruited them with promises of new facilities and expensive machinery that never materialized.[28] The hiring process was superficial, consisting of a single-page application and a brief Skype interview with Mr. Li. Training, if any, also was perfunctory. New SPC hires awaiting insurance accreditation often treated patients without supervision (thus bypassing insurance companies' quality control mechanisms). To conceal this breach of protocol, SPC instructed unaccredited providers to access SPC's electronic systems using the credentials of an accredited provider.

150. SPC relied in part on referrals from other providers and, to this end, claimed to apply a holistic approach to pain management. SPC's website, for example, touted at least

[28] Attorney General of Washington, Medicaid Fraud Control Unit, Memorandum dated May 12, 2015, re *Unprofessional conduct complaint against Dr. Frank D. Li*, at 5.

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seventeen methods of treating chronic non-cancer pain and stated that SPC placed emphasis on "reducing opioid reliance." But the reality was something else. Medicaid records reviewed by MCFU showed that approximately 85% of SPC patients received opioid treatment and that Mr. Li and several of his subordinates were among the top providers of opioids in the state.[29] Medicare records, discussed further below, indicate even higher opioid prescribing rates.

151. An overwhelming majority of SPC patient visits were for opioid refills. Former employees told MCFU that, in a typical refill appointment, patients would provide a urine sample to a medical assistant and then see an "SPC provider for five minutes or less, just enough time to prescribe 90 days' worth of opioids."[30]

152. SPC pressured its practitioners to work fast and write prescriptions routinely. Every provider was required to see 18-20 patients per 8 hours, and bonuses were provided for additional patients. Operating within these parameters, SPC providers could not conduct meaningful medical examinations to determine an appropriate course of treatment, and indeed they were discouraged from doing so.

153. Pressured to crank out opioid prescriptions, SPC practitioners routinely disregarded signs of abuse. Most notably, SPC's practice of collecting urine samples on every visit was only a ruse to increase medical billings.[31] The test results themselves were regularly disregarded and patients who tested positive for drug abuse – or negative for opioids, suggesting that those patients were seeking opioids to then resell on the street – were nonetheless permitted to continue opioid therapy.

154. Witnesses interviewed by MCFU indicated that SPC became "well known amongst opioid addicts and other drug seekers as an easy place to get drugs."[32] And addicts flocked to SPC clinics, sometimes travelling large distances. All told, SPC served over 25,000

[29] *Id.* at 6.

[30] *Id*. at 7.

[31] *Id.* at 7.

[32] *Id*. at 8.

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patients, many of whom obtained opioids from SPC after being rejected by practitioners at other facilities.

155. Former SPC employees have openly described SPC as a "pill mill" and acknowledged the low quality of patient "care" the center provided.[33] Concern over SPC's practices resulted in massive employee turnover. Most SPC providers interviewed by MFCU acknowledged that they left the center out of fear for their professional licenses. As worried providers jumped ship, even more unseasoned, unsupervised and unaccredited practitioners took their place.

156. At least 60 SPC patients died between 2010 and 2015.[34] SPC conducted no investigation into these deaths. Washington State's Medical Quality Assurance Commission ("MQAC") did. MQAC reviewed medical records for 18 of the 60 patients and concluded that 16 died from an opioid overdose within days or weeks of filling an opioid prescription provided by SPC. MQAC determined further that with each of these patients SPC "defaulted to opiate-centric treatment plans" without adequate review of medical histories, imaging studies, and specialty consultations.[35] Each patient was routinely given "increasing and continuing opioid doses" with subsequent visits.[36]

157. The experiences of three of SPC's deceased patients – anonymized here as Patients H, O, and R – are entirely representative of the "treatment" SPC patients received:

- Patient H, a 55-year-old paraplegic woman, overdosed on opioids just two days after receiving prescriptions from SPC for Purdue's MS Contin and generic oxycodone. Patient H had a history of hospitalizations for respiratory failure and suffered from a multitude of conditions, including chronic obstructive pulmonary disorder and opioid dependence. Disregarding Patient H's medical history, SPC placed her on a regimen of increasing opioid dosages. On her last visit to SPC, Patient H tested positive for

[33] *Id.*

[34] *In the Matter of License to Practice as a Physician and Surgeon, Frank D. Li*, Statement of Charges, at ¶ 1.4.

[35] *Id*. at ¶ 1.8.1.

[36] *Id.* at ¶ 1.8.3.

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benzodiazepines not prescribed by SPC, but received aggressive dosages of opioids all the same.[37]

- Patient O, a 28-year-old woman, overdosed on opioids just five days after filling an opioid prescription issued by SPC. She had visited SPC 11 times over the prior year complaining of knee pain. She repeatedly tested positive for THC and cocaine, but nevertheless received escalating dosages of Actavis's Norco and other opioids. Not only did SPC ignore Patient O's drug use, certain of Patient O's urine tests were negative for opioids, indicating that she wanted to obtain opioids to sell them to others on the street. SPC ignored that as well. Further, SPC failed to consider Patient O's history of depression and childhood abuse, which are potential causes of psychosomatic pain requiring non-opioid treatment.[38]
- Patient R, a 35-year-old man died less than a year after beginning treatment at SPC. He had a history of illicit drug use, bipolar disorder, depression, suicidal ideation, obesity, hypertension, numerous psychiatric hospitalizations, post-traumatic stress disorder resulting from childhood sexual abuse, and dependencies on methamphetamine and alcohol. Although Patient R failed urine drug tests administered by SPC, and admitted to over-use of prescribed medication, he was nonetheless prescribed escalating doses of Endo's Percocet and Janssen's Nucynta. Patient R died of mechanical asphyxia brought on by the combined effects of various opioids.[39]

158. As tragic – and preventable – as these deaths were, focusing solely on overdoses in SPC's patient population would grossly understate the harm SPC has caused. CDC has calculated that, on average, for every 1 overdose death there are 10 abuse treatment admissions, 26 emergency department visits for misuse, 108 people dependent on opioids, and 733 non-

[37] *Id*. at ¶ 1.24.

[38] *Id*. at ¶¶ 1.31 – 1.34.

[39] *Id*. at ¶ 1.38.

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medical users.[40] Under these ratios, SPC's prescribing conduct has led to at least 260 abuse treatment admissions, 416 emergency department visits, 1,728 opioid-dependent people, and 11,728 non-medical users.

159. On July 14, 2016, MQAC summarily suspended Mr. Li's license to practice medicine in Washington State. The suspension was warranted, MQAC concluded, because:

> SPC established a business model and clinical practice that focused on maximizing billable amounts by increasing the number of patients treated, the frequency of patient office visits, and the volume of billable services. Respondent and SPC sought out vulnerable chronic pain patients enrolled in Medicaid insurance and maintained these patients on opioid therapy by providing continuing prescriptions despite knowledge of medication abuse, diversion and overdose.[41]

160. On August 5, 2016, California suspended Mr. Li's California medical license. On February 13, 2017, the Drug Enforcement Agency ("DEA") revoked Mr. Li's registrations to dispense controlled substances.

E. The Manufacturing Defendants Knew SPC Was Operating a Pill Mill and Turned a Blind Eye

161. Pharmaceutical companies, including Manufacturing Defendants here, maintain highly sophisticated and granular prescribing databases. They know where their drugs are being prescribed, in what quantities, and by whom. They also know who is not prescribing their drugs or prescribing drugs manufactured by competitors. In theory, this information can help drug manufacturers satisfy their obligations under the Controlled Substances Act ("CSA") to report to the DEA suspicious drug orders, including orders of unusual size or frequency. The data were designed, however, to track the efficacy of marketing campaigns and to identify specific regions and even particular physicians for detailing. As set forth in Paragraphs 140 (Purdue) and 142 (Endo) above, despite having this type of information that could have been reported to law enforcement, both Purdue and Endo instead used it to identify physicians to whom to direct their marketing efforts.

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[40] *See Prescription Drug Abuse and Overdose, Public Health Perspective*, CDC's Primary Care and Public Health Initiative, Oct. 24, 2012, at 12.

[41] *In the Matter of Frank D. Li*, Ex Parte Order of Suspension, dated July 14, 2016, at 1.5.

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162. Manufacturing Defendants thus knew precisely how many of their opioids, and their competitors' opioids, SPC was prescribing. They knew that SPC was endangering patients. And they knew that SPC's over-prescription of opioids had imposed, and would continue to impose, enormous costs on Seattle and the other communities in which SPC opened clinics.

163. As a single significant example, in order to calibrate how to influence prescribers and monitor the effectiveness of their marketing efforts, Defendants purchase, manipulate and analyze data available from QuintilesIMS, whose clients include "[n]early all of the top 100 global pharmaceutical and biotechnology companies."[42] In its most recent Annual Report, QuintilesIMS stated that it is "a leading global information provider for the healthcare industry" and maintains "one of the largest and most comprehensive collections of healthcare information in the world, which includes more than 530 million comprehensive, longitudinal, anonymous patient records spanning sales, prescription and promotional data, medical claims, electronic medical records and social media."[43] Its dataset contains over 10 petabytes of unique data, and includes "over 85% of the world's prescriptions by sales value."[44] QuintilesIMS data is expensive, proprietary and in the sole possession of Defendants. According to QuintilesIMS, "[t]he breadth of the intelligent, actionable information [it] provide[s] is not comprehensively available from any other source . . . and would be difficult and costly for another party to replicate."[45]

164. Although the prescribing data from QuintilesIMS or separately maintained by Manufacturing Defendants is not freely available to the public, what public data exist provide a window into what Manufacturing Defendants should have surmised about SPC's operations.

165. In particular, ProPublica has compiled a database of prescriptions issued in 2015 to patients participating in Medicare's prescription drug benefit program, known as Part D.[46]

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[42] Form 10-K, Quintiles IMS Holdings Inc., filed February 16, 2017, at 12.

[43] *Id*.

[44] Form S-1, IMS Health Holdings, Inc., filed Jan. 2, 2014, at 1.

[45] Form 10-K, Quintiles IMS Holdings Inc., filed February 16, 2017, at 5.

[46] ProPublica Prescriber Checkup, available at https://projects.propublica.org/checkup/.

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Medicare Part D serves more than 42 million people and pays for more than one in four prescriptions written in the United States.

166. The Part D data for 2015 show red flags hanging all over SPC. Of the 12 Washington practitioners who self-identified as Pain Medicine specialists, the two most prolific prescribers worked at SPC – Mr. Li. and Jason Ly – and both prescribed opioids to nearly all of their patients. Mr. Li, for example, prescribed opioids to 87% of the patients he saw.

167. Most SPC providers doled out opioids at even more feverish clips. Jeanine Godec, a medical physician assistant at SPC, issued 8,097 Part D prescriptions in 2015, more than all but four medical physician assistants working in Washington that year. Ms. Godec prescribed opioids to 94% of her patients. That figure is alarming enough in absolute terms. But it is particularly startling when you consider that the average medical physician assistant in Washington prescribed opioids to 22% of patients, a rate Ms. Godec exceeded by some 427%.

168. SPC nurse practitioner Christina McGhee prescribed opioids to 98% of her patients, and overall she issued more Part D prescriptions in 2015 than all but 8 Washington nurse practitioners.[47] The average nurse practitioner in Washington prescribed opioids to only 21% of her patients. Not only did Ms. McGhee prescribe opioids at more than four times the average rate in 2015, she was one of the top 10 prescribers of the opioid hydromorphone in the entire country.

169. While certainly egregious, the prescribing patterns of these providers were not outside the norm at SPC. As shown in the following chart, almost every SPC practitioner that can be identified in the Part D data for 2015 prescribed opioids to at least 90% of her patients, while typical practitioners in similar positions maintained opioid prescribing rates in the 20% range.

[47] Ms. McGhee is licensed in Ohio and the data available through ProPublica ranks her among other Ohio practitioners. Because Ms. McGhee practiced in Washington, the comparison made here, and in the chart below, is to other Washington practitioners.

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Name	Self-Reported Specialty	Total Medicare Prescriptions and Rank Within Specialty	Percentage of Medicare Patients Prescribed Opioids	Average Opioid Prescribing Rate Within Specialty	Opioid Prescribing Rate Relative to Average
Frank D. Li[48]	Pain Medicine	3,737 Rank: 2 out of 12	**87%**	n/a[49]	**n/a**
Donald Baumer	Nurse Practitioner	5,682 Rank: 18 out of 338	**96%**	21%	**457%**
Sandra Canaday	Nurse Practitioner	3,656 Rank: 35 out of 338	**93%**	21%	**442%**
Jeanine Godec	Physician Assistant, Medical	8,097 Rank: 5 out of 260	**94%**	22%	**427%**
Fred Itveldt	Nurse Practitioner	2,538 Rank: 69 out of 338	**92%**	21%	**438%**
Jason Ly	Pain Medicine	4,837 Rank: 1 out of 12	**Nearly all[50]**	n/a	**n/a**
Johnnie Machado	Physician Assistant	423 Rank: 356 out of 457	**79%**	27%	**292%**
Julia Maritza	Nurse Practitioner	1,560 Rank: 127 out of 338	**88%**	21%	**419%**
Christina	Nurse	6,758	**98%**	21%	**466%**

[48] Mr. Li was initially licensed in California and the comparison data available through ProPublica ranks him among other California practitioners. Because Mr. Li practiced in Washington, the above table ranks him among other Washington practitioners.

[49] Because there are fewer than 20 self-reported pain medicine specialists in Washington, ProPublica has not calculated average opioid prescribing rates among them.

[50] Available data do not provide the total percentage of Mr. Ly's Medicare patients who received an opioid, but 39% were at some point in 2015 prescribed hydrocodone-acetaminophen, 24% were prescribed morphine sulfate ER, 20% were prescribed hydromorphone HCL, 18% were prescribed oxycodone HCL, 12% were prescribed methadone HCL, 10% were prescribed fentanyl, 11% were prescribed oxycodone-acetaminophen, 6% were prescribed Oxycontin, 5% were prescribed morphine sulfate, and 3% were prescribed tramadol HCL.

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McGhee	Practitioner, adult health	Rank: 14 out of 338			
Abigail Scott	Specialist	5,857 Rank: 8 out of 146	**95%**	17%	**500%**
Phillip Shealy	Nurse Practitioner, Family	2,128 Rank: 171 out of 497	**95%**	20%	**475%**
Lenard Tol	Physician Assistant	2,519 Rank: 77 out of 457	**93%**	27%	**344%**

170. In total, the above practitioners issued 47,792 Medicare prescriptions in 2015 – that is, 130 prescriptions per day for the entire year – and nearly all of those prescriptions were for opioids. With prescribing rates in this stratosphere, Manufacturing Defendants could only have concluded that SPC was operating a pill mill, particularly because Manufacturing Defendants possess even more comprehensive data and are obliged to track it.

171. In an effort to market their drugs, Manufacturing Defendants Janssen and Purdue also purchased multiple meals for Mr. Li and for SPC's only other supposed pain specialist, Jason Ly. Research shows that picking up meal tabs, even for small amounts, influences doctors' prescribing habits – that is precisely why pharmaceutical companies engage in the practice.[51] Thus, Manufacturing Defendants Janssen and Purdue not only acquiesced in SPC's operation of a pill mill, they took affirmative steps to ensure that their drugs would provide its grist.

F. Defendants Have Created a Public Nuisance

1. Defendants' Marketing and Prescribing Conduct Foreseeably Led to Opioid Abuse that has Wrought Havoc on Seattle Communities

172. Most opioid use begins with legitimately prescribed opioids, and that is why the Manufacturing Defendants' deceptive marketing campaign was a primary cause of the opioid

[51] DeJong C, Aguilar T, Tseng C-W, Lin GA, Boscardin WJ, Dudley RA, *Pharmacuetical industry-sponsored means and physician prescribing patterns for Medicare beneficiaries*, JAMA Intern. Med., 2016.

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epidemic that has unfolded in Seattle and across the country.[52] For opioids to be widely prescribed, Manufacturing Defendants had to convince doctors that they were a safe and effective means of treating chronic conditions such as back pain, headaches, arthritis, and fibromyalgia. And they were successful in doing so. Had doctors in Seattle and elsewhere been provided accurate and complete information, they would not have prescribed as many opioids.

173. Manufacturing Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Without Manufacturing Defendants' deception, fewer patients in Seattle would be using opioids long-term to treat chronic pain, those patients using opioids would be using less of them, and there would not have been as many opioids available for misuse and abuse.

174. The efficacy of Manufacturing Defendants' marketing efforts can be seen by comparing opioid use in the United States against other countries, where restrictions on pharmaceutical advertising typically are more stringent. Although the United States contains only 4.6% of the world's population, Americans consume 80% of the global supply of prescription opioids.[53] Moreover, escalating opioid prescribing rates in the United States neatly track the elevated sums Manufacturing Defendants have expended on marketing their drugs, sums that rose from $91million in 2000 to $288 million in 2011.

175. The causal relationship between Manufacturing Defendants' marketing scheme and the opioid epidemic has now been acknowledged by members of the medical community. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive

[52] *See* U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012), available at https://www.samhsa.gov/data/sites/default/files/2011MHFDT/2k11MHFR/Web/NSDUHmhfr2011.htm.

[53] American Society of Interventional Pain Physicians, Fact Sheet, available at https://www.asipp.org/documents/ASIPPFactSheet101111.pdf.

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marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[54]

176. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[55]

177. Scientific evidence also demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

178. The deceptive marketing of opioids also created a population addicts who, foreseeably, seek ever-higher dosages from illicit distribution channels. Some of these users obtain diverted opioids from the street. But in Seattle, addicts also could turn to SPC. Churning out opioid prescriptions with few questions asked, SPC severely exacerbated the opioid crisis in Seattle.

179. Manufacturing Defendants were fully aware, and should have been fully aware, of SPC's practices. Rather than alert authorities, the Manufacturing Defendants did nothing and watched the profits flow.

180. The individual and combined effects of Defendants' conduct has caused in Seattle and its surrounding communities an explosion in opioid prescribing, abuse, and overdose. The

[54] United States Cong., Senate Caucus on Int'l Drug Control, May 14, 2014, 113th Cong. 2nd sess. (Statement of Dr. Nora Volkow).

[55] Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org/.

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data are staggering. The opioid prescribing rate in King County for 2011 was 66%, meaning that 66 opioid prescriptions were issued for every 100 King County residents.[56] Although local and state officials have since made a concerted effort to combat opioid abuse, as detailed below, the opioid prescribing rate in King County persisted above 47% in 2016.[57]

181. In 1997, for every 100,000 King County residents there were only 1.51 deaths attributed to prescription opioids – less than cocaine and depressants. By 2009, prescription opioids were by far the leading cause of drug-related death in King County, with 8.59 deaths per 100,000 residents being reported.[58] As opioid users turned to heroin, heroin deaths also spiked. By 2015, prescription opioids and heroin together accounted for approximately 2 out of every 3 drug-related deaths in King County.[59]

182. Last year, 107 people in King County overdosed on prescription opioids, an increase over prior years, and there were more prescription opioid overdoses than there were overdoses attributed to cocaine, methamphetamine, and alcohol.[60]

[56] CDC Report, U.S. County Prescribing Rates, 2011, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2011.html.

[57] CDC Report, U.S. County Prescribing Rates, 2016, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html.

[58] University of Washington, Alcohol and Drug Abuse Institute, online report, available at https://adai.washington.edu/WAdata/KingCountyDrugDeaths.htm.

[59] *Id*. Research indicates that these statistics may even underrepresent the prevalence of opioid-involved deaths. Christopher J. Ruhm, National Bureau of Economic Research, *Taking the Measure of a Fatal Drug Epidemic*, August 2016, at 25.

[60] University of Washington, Alcohol and Drug Abuse Institute, 2016 Drug Use Trends in King County, Washington, at 11-12.

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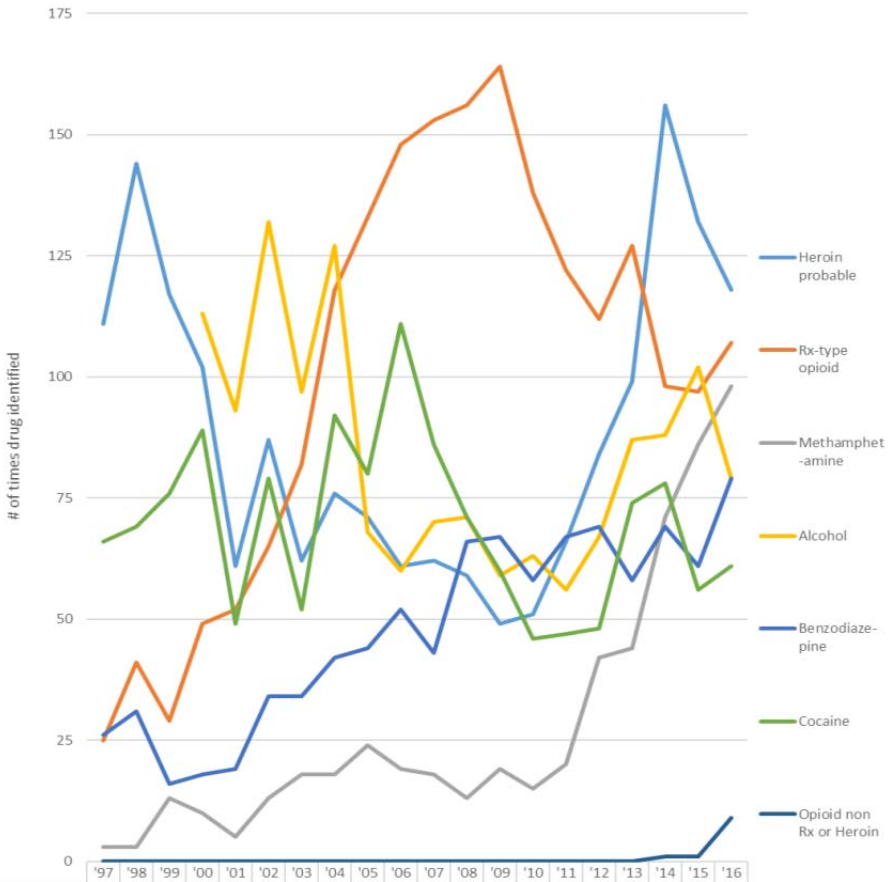

	'97	'98	'99	'00	'01	'02	'03	'04	'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	'16
Heroin probable	111	144	117	102	61	87	62	76	71	61	62	59	49	51	66	84	99	156	132	118
Rx-type opioid	25	41	29	49	52	65	82	118	133	148	153	156	164	138	122	112	127	98	97	107
Methamphet-amine	3	3	13	10	5	13	18	18	24	19	18	13	19	15	20	42	44	71	86	98
Alcohol				113	93	132	97	127	68	60	70	71	59	63	56	67	87	88	102	79
Benzodiaze-pine	26	31	16	18	19	34	34	42	44	52	43	66	67	58	67	69	58	69	61	79
Cocaine	66	69	76	89	49	79	52	92	80	111	86	71	60	46	47	48	74	78	56	61
Opioid non Rx or Heroin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	9
Total deaths	179	222	205	217	150	195	186	253	240	286	274	258	254	244	231	274	304	316	320	332

183. Statewide in 2016, prescription opioids attributed to 435 overdose deaths, meaning there was more than one prescription opioid overdose per day for the entire year.[61] No other drug accounted for as many overdoses.[62] A significant number of opioid deaths have occurred in Seattle, including in the urban center.[63]

[61] Washington Department of Public Health, Opioid-related Deaths in Washington State, 2006-2016, available at http://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf.

[62] CDC, Provisional Counts of Overdose Deaths, as of 8/6/2017, available at https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

[63] Brad Finegood & Caleb Banta-Green, *Heroin & Opiate trends and interventions*, 2016 Washington State Interagency Opioid Working Plan, at 11.

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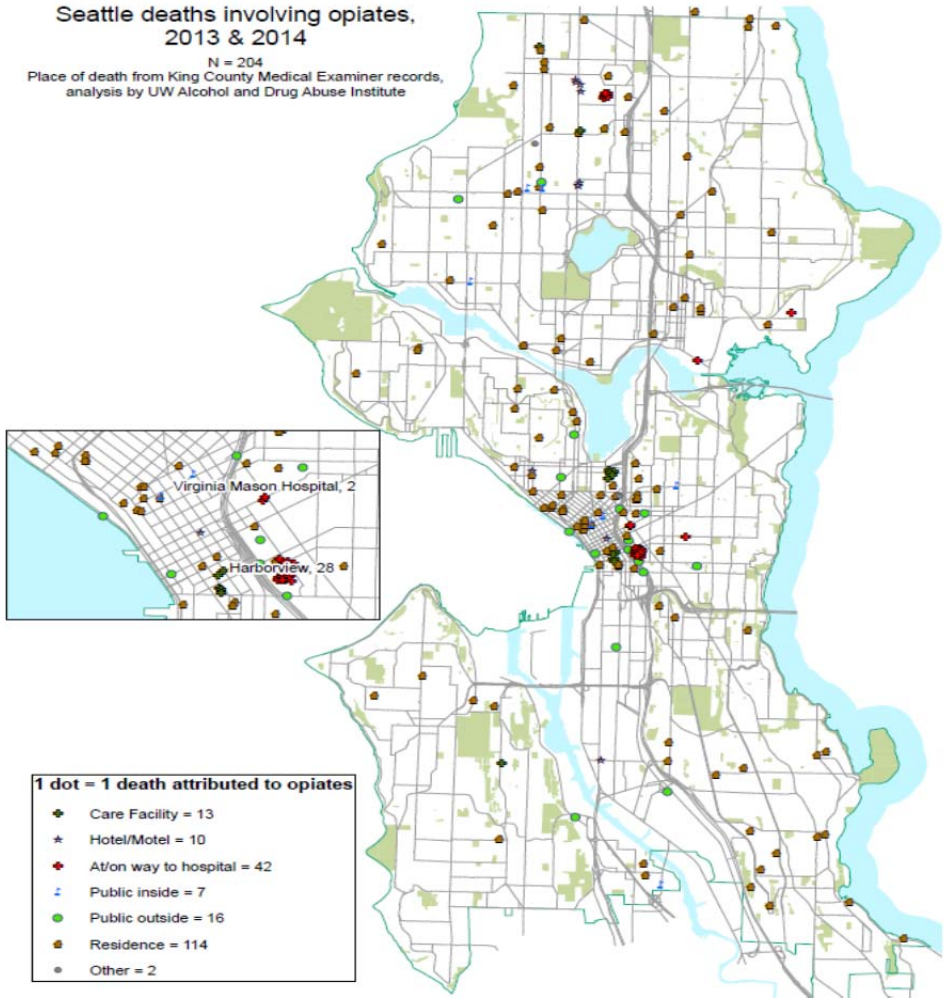

184. Similarly, treatment admissions in King County for the abuse of prescription opioids increased 492% between 1999 and 2010.[64] In 2015, the King County Mental Health, Chemical Abuse and Dependency Services Division reported that opioids were the primary substance used by 62% of persons admitted for detoxification services.[65] For each year between 2006 and 2015, King County poison centers reported more calls for pharmaceutical opioids than any other drug.[66]

[64] University of Washington, Alcohol and Drug Abuse Institute, 2015 Drug Use Trends in King County Washington, dated July 2016, at figure 3a.

[65] King County Mental Health, Chemical Abuse and Dependency Services Division, Substance Abuse Prevention and Treatment Annual Report, 2015, at 20.

[66] University of Washington, 2015 Drug Use Trends in King County Washington, at Figure 6.

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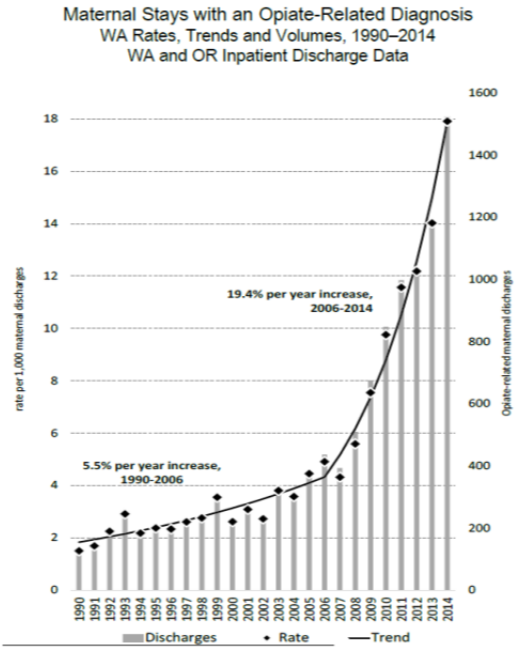
185. Sadly, opioid abuse also has affected Washington newborns. Washington's State's Office of Financial Management has studied cases in which a pregnant mother received a drug-use diagnosis during her maternal stay and concluded that opioids (including heroin) "had, by far, the highest rates and greatest number of cases—and they are markedly trending upwards."[67]



186. As opioid use among pregnant women has spiked, so too has the rate at which Washington newborns exhibit signs of drug withdrawal.[68]

[67] Washington State Office of Financial Management, *Maternal and Newborn Inpatient Stays with a Substance Use or Use-Related Diagnosis*, February 2016, at 3.

[68] *Id*.

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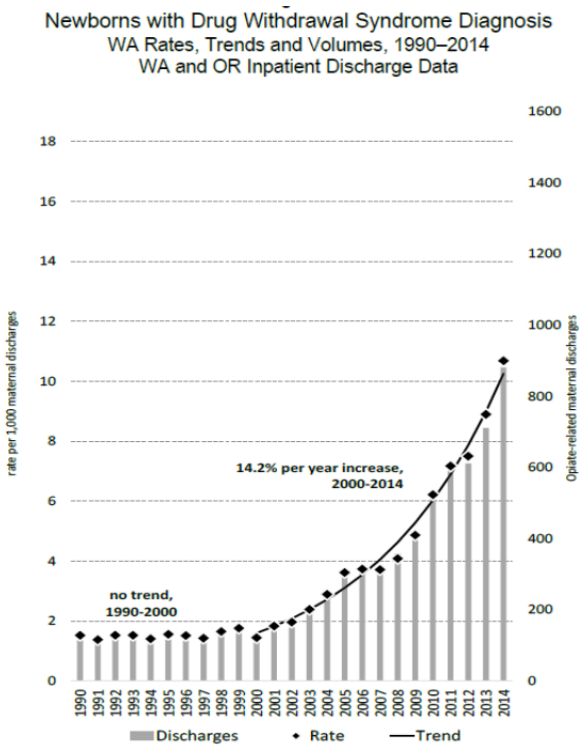

187. Seattle youth, too, have been affected by the opioid epidemic. A 2016 Healthy Youth Survey indicates that approximately 5% of King County high school seniors used prescription pain killers to get high within the prior 30 days. And while this figure has trended slightly downward in recent years, the decrease has been offset by increased incidents of heroin use in the same population.

188. In March 2016, to address these alarming trends, King County executive Dow Constantine, and the mayors of the cities of Seattle, Renton and Auburn, convened a Heroin and Prescription Opiate Addiction Task Force (hereinafter, "Task Force"). The Task Force found that "[o]pioid prescribing has increased significantly since the mid-1990s and has been paralleled by increases in pharmaceutical opioid misuse and opioid use disorder, heroin use, and fatal overdoses."[69] Seeking to counteract misimpressions Manufacturing Defendants' deceptive marketing has engendered, the Task Force recommended, among other items, efforts to "raise

[69] Heroin and Prescription Opiate Addiction Task Force, Final Report and Recommendations, September 15, 2016, at 3.

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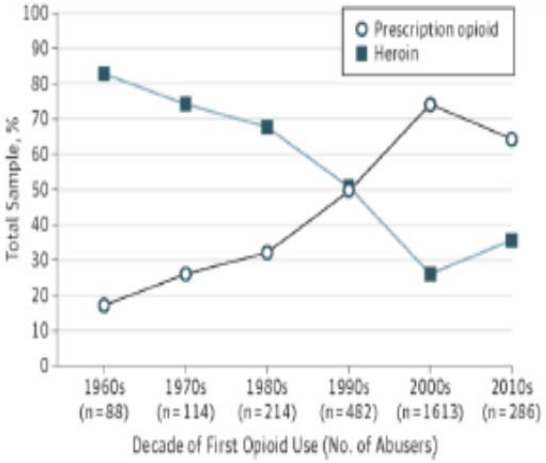
awareness and knowledge of the possible adverse effects of opioid use, including overdose and opioid use disorder."[70] The Task Force recognized specifically the need to ensure that "[p]rescribers and those they serve . . . have sufficient understanding of evidence-based risks and benefits of opioids."[71]

189. The Task Force also forcefully acknowledged the connection between prescription opioids and heroin use, observing that "[a]s pharmaceutical opioids became less available, some people with opioid use disorder switched to heroin because of its greater availability and lower cost."[72] Supporting data are compelling. Nationwide studies have indicated that at least 75% of all people who began to abuse opioids in the 2000s, started with prescription drugs.[73]



190. The same pattern holds true in Seattle. Approximately 41% of heroin users interviewed at a Seattle syringe exchange in 2015 reported using pharmaceutical opioids, an

[70] *Id*. at 12.

[71] *Id*.

[72] *Id*. at 4.

[73] JAMA Psychiatry, The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years, May 28, 2014.

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increase from 30% in 2011, and another 53% stated that they were "hooked on prescription-type opiates prior to using heroin."[74]

191. The Task Force similarly highlighted the role of opioids in the rise of homelessness, noting that the Seattle King County Coalition on Homelessness found 4,505 people living homeless on a single night in 2016, a 19% increase from the prior year. Death reports indicate that opioid abuse is increasingly responsible for fatalities within this growing population.[75] The high rate of opioid use among the homeless population is compounded by the obstacles the homeless must overcome to obtain treatment. Data maintained by the Seattle Pubic Health-King County Needle Exchange Program show that only 48% of the homeless population has success accessing methadone treatment, compared to a 75% success rate among users who are stably housed.[76]

192. State officials, too, are scrambling to address the opioid epidemic. In 2015, several Washington state agencies collaborated to develop a statewide working plan for opioid response. On September 30, 2016, Governor Jay Inslee signed Executive Order 16-09, *Addressing the Opioid Use Public Health Crisis*, directing state agencies to take actions in furtherance of the working plan. Also in September 2016, the federal government awarded Washington a grant of $1 million per year, for five years, to address the opioid epidemic.

193. Most recently, in July 2017, Washington lawmakers enacted House Bill 1427. In the Bill's preamble, the legislature found that "in 2015 an average of two Washington residents died per day in this state from opioid overdose and that opioid overdose deaths have more than

[74] University of Washington, Alcohol and Drug Abuse Institute, 2015 Drug Use Trends in King County Washington, dated July 2016, at 3.

[75] Heroin and Prescription Opiate Addiction Task Force, Final Report and Recommendations, September 15, 2016, at 6.

[76] King County Heroin and Opioid Task Force, Heroin and Opioid Trends, available at http://www.kingcounty.gov/depts/community-human-services/mental-health-substance-abuse/task-forces/heroin-opiates-task-force.aspx.

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doubled between 2010 and 2015." The legislature found, further, "that medically prescribed opioids intended to treat pain have contributed to the opioid epidemic and although Washington has done much to address the prescribing and tracking of opioid prescriptions, more needs to be done to ensure proper prescribing and use of opioids and access to treatment." House Bill 1427, at 1.

194. To these ends, House Bill 1427 directs Washington health care professional boards to adopt new rules for prescribing opioids, giving due consideration to (1) Washington's Agency Medical Directors' Group (AMDG) Interagency Guideline on Prescribing Opioids for Pain and (2) the CDC's Guideline for Prescribing Opioids for Chronic Pain. The law also expands access to Washington's Prescription Monitoring Program, which collects prescription data to, among other things, prevent prescription drug abuse.

195. These local and state efforts to combat opioid abuse reflect the tragic scope of the epidemic in Seattle and across Washington. Prescription opioid misuse, abuse and overdose have an enormous impact on the health and safety of individuals as well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. Some of the repercussions for individuals include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration. This results in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers and law enforcement. Seattle, like many municipalities across the country, is reeling from these effects and the enormous burden they impose on city resources.

2. Defendants Knew and Should Have Known That Their Conduct Would Create or Assist in the Creation of a Public Nuisance in Seattle.

196. Manufacturing Defendants knew and should have known about the harms that their deceptive marketing has caused. Manufacturing Defendants closely monitored their sales and the habits of prescribing doctors, including those at SPC. Their sales representatives, who

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visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Manufacturing Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

197. SPC likewise knew that its indiscriminate prescribing practices were harming its patients, sixty of whom died. SPC knew that an even larger number of its patients were misusing, abusing, and diverting opioids. Driven to maximize revenues, SPC never reformed its prescribing practices.

198. Defendants also knew that patients were not the only ones harmed by their conduct. They knew that opioid dependency would place enormous burdens on state and local government resources, including those of Seattle.

3. Manufacturing Defendants' Conduct and Role in Creating or Assisting in the Creation of a Public Nuisance Is Not Excused by the Actions of Any Third Parties

199. FDA approval of opioids for certain uses did not give Manufacturing Defendants license to misrepresent the risks and benefits of opioids. Indeed, Manufacturing Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

200. Nor is Manufacturing Defendants' causal role broken by the involvement of doctors, including SPC practitioners. Manufacturing Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Manufacturing Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of

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practicing medicine more compassionately.

201. While SPC providers prescribed opioids for financial gain without regard for patient safety, this in no way absolves Manufacturing Defendants of their responsibility for influencing the prescribing habits of other, well-intentioned practitioners.

G. Defendants' Conduct Has Caused Seattle Substantial Economic Injury.

202. Defendants' deceptive marketing and indiscriminate prescription of opioids has not only destroyed lives and communities, it has severely taxed the local and state resources needed to mitigate the effects of widespread opioid abuse. Seattle, in particular, has shouldered a heavy burden, having been forced to allocate and expend significant resources to address the opioid crisis unfolding across the region. Seattle has suffered economic injuries that are direct, ascertainable, quantifiable, and that would not have been incurred but for Defendants' conduct. Specifically, and by way of example:

- **Public Health Services**: In conjunction with King County, Seattle maintains a $12 million public health budget, a significant portion of which is devoted to treating opioid abuse. Seattle spends, for instance, approximately $600,000 annually on methadone and buprenorphine[77] treatments administered by Evergreen Health Services, a nonprofit which provides medication and assisted treatment for adults with opioid abuse disorders. This treatment is labor intensive, with patients being seen six days per week initially. Before either methadone or buprenorphine can be dispensed, nurses must perform in-person assessments and witness each patient ingest his or her dose (to ensure dosages are not pocketed and sold on the street). Random urine testing and regular counseling sessions are also mandatory and add to the cost. Evergreen Health Services officials estimate that ninety percent (90%) of the patients they

[77] Buprenorphine, also known by its brand name, Suboxone, is an alternative to methadone with a different delivery system. It can be taken in a pill or on a film, and is thus easier for patients travelling. Like methadone, buprenorphine can diminish opioid dependency and reduce the risk of overdose.

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treat with methadone or buprenorphine started down the road to addiction with prescription opioids.

Seattle also contributes nearly $450,000 annually to support the Robert Clewis Center Needle Exchange in the Belltown neighborhood of Seattle. At the needle exchange, opioid addicts can exchange used syringes for sterilized ones while receiving basic health services, including infectious disease testing, Hepatitis A and B vaccinations, and treatment readiness counseling. The Needle Exchange also houses the Buprenorphine First Clinic, which dispenses buprenorphine to opioid addicts. Seattle provides approximately $105,000 in additional annual funding to the Buprenorphine First Clinic.

- **Paramedic Services**: The Seattle Fire Department responds to thousands of 911 calls annually, a large and growing number of which arise from prescription opioid or heroin abuse. This can be seen, foremost, in the startling number of 911 calls involving the use of naloxone, aka Narcan, a drug that can reverse an opioid overdose. Looking only at the three months preceding September 25, 2017, Seattle Fire Department units administered naloxone 140 times – that is, more than once per day. The average Fire Department medical response call costs Seattle approximately $2,000, meaning that $280,000 was spent on response calls involving the use of naloxone in just the last three months.

And this hardly describes the totality of the Seattle Fire Department's expenditures linked to opioid abuse. For one, the injectors needed to administer naloxone are themselves expensive, as are the costs of training personnel on their proper use. But more than that, the Seattle Fire Department responds to an even greater number of opioid-related medical emergencies in which naloxone is not administered, including overdoses that are not life threatening. In the three months preceding September 25, 2017, records maintained for at least 453 Seattle Fire

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Department response calls contain opioid-related terms, such as "methadone" or "heroin", describing the medical event prompting the call. At $2,000 per response call, that is $906,000 the Seattle Fire Department devoted to opioid-related medical emergencies in the last three months alone.

- **Policing Services**: Like the Fire Department, Seattle Police Department officers, primarily the bicycle patrol, are equipped with naloxone aka Narcan. In addition to the cost of the medication, these officers receive training in its proper application. Moreover, as the opioid epidemic has progressed, the Seattle Police Department has noted an upward trend in crimes associated with opioid and heroin abuse, including car prowls, prostitution, and the theft of bicycles and scrap metal for recycling. In 2015, over 45% of drug seizures by King County law enforcement involved either prescription opioids or heroin.[78] The massive amount of time officers spend policing opioid-related offenses and preparing for their prosecution is time they cannot devote to the other services they are counted on to provide.

Moreover, to address the opioid-related crises occurring every day across the city, police officers require special training, which Seattle has spent millions providing. In 2017, by way of example, police officers in Seattle spent approximately 31,200 hours in Crisis Intervention Training ("CIT"), at costs approaching $2 million. Nearly half of Seattle's Police Department has been certified in CIT, at additional costs exceeding $1 million. The Seattle Police Department spent an additional $188,000 for additional drug-related training in 2017, including in respect to opioid use and abuse. Every year Seattle spends large additional sums providing initial training to its officers, a large portion of which deals with developing the skills needed to handle opioid and other drug-related crimes and crises.

There is a real need for this training. Increasingly, Seattle police officers are dispatched to address opioid-related emergencies. By way of example, research by the University of Washington's Alcohol and Drug Abuse Institute shows that between July and August 2016,

[78] University of Washington, Alcohol and Drug Abuse Institute, online study available at https://adai.washington.edu/WAdata/King_County_cases.htm.

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Seattle police officers responded to 49 drug-involved casualties in which opioids were certainly or likely involved. Police officers responded to an additional 234 drug-related casualties in which opioids could not be ruled out.

- **Criminal Justice Costs:** When Seattle police officers take addicts to the King County jail,[79] or to other local jails, Seattle is "billed back" for the fees and costs associated with their incarceration. And when addicts are not healthy enough to remain in general population modules, they are sent to a medical unit that bills Seattle significantly higher costs per day. The Seattle City Attorney's Office and the Office of Public Defense also have full-time employees working on drug-court and related issues. A significant segment of drug prosecutions in Seattle concern prescription opioid addicts or opioid users who have transitioned to heroin.

- **Combating Homelessness**: Opioid use is a significant cause of homelessness in Seattle and a reason why many in the homeless population remain so. Research shows, in particular, that homeless opioid users in Seattle have greater difficulty obtaining access to treatment, and the cost of maintaining a drug habit prevents users from assembling the resources needed to secure stable housing.

As Seattle's homeless population has grown with opioid abusers, city agencies have been required to devote ever-increasing resources toward combating homelessness and its effects. To begin with, Seattle spends approximately $2 million annually to provide health care for the homeless through community health clinics and mobile medical programs. In addition, a constellation of municipal departments – including the Department of Parks and Recreation, Public Utilities Department, Department of Transportation, and Finance and Administrative Services Department – have spent millions of dollars on outreach, medical and counseling services provided to unhoused persons living in homeless encampments across the city. Before

[79] If the jail determines they are not fit enough to be admitted, they may instead be moved to a hospital. Then, depending on the criminal charge, they may need to be accompanied by one or more Seattle Police Department officers to guard them.

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an encampment is cleared, Seattle makes every effort to provide counseling services to the unhoused and to assist them in locating alternative housing, including in shelters, approved encampments, and traditional housing. Extensive and repeated notice is provided.

The task of clearing the encampment, and cleaning the site, is just as labor intensive. Personal belongings are carefully cataloged and stored (with associated fees being paid by Seattle) for future pickup or even delivery to owners. The encampments generate an enormous amount of trash which must be hauled away, much of it to a facility in Eastern Oregon. Clearing encampments also nearly always involves disposing of needles used by the homeless population to inject opioids. Seattle's Department of Parks and Recreation, for example, has so far in 2017 spent over $800,000 to clear 3000 tons of waste from 140 homeless encampments, nearly all of which contained hypodermic needles. Seattle Public Utilities is also running a pilot program to collect needles from locations in Seattle and then properly dispose of them.

All of these efforts have necessitated additional staffing across multiple departments. The Seattle Police Department, for example, has 15 full-time officers, including a sergeant working exclusively on homelessness. The Mayor's Office has three full-time employees devoted to the issue. All told, Seattle spent more than $53 million combating homelessness in 2016 and that figure is expected to rise above $60 million in 2017. The role of opioid abuse in these expenditures is direct and quantifiable.

H. Defendants' Conduct Has Led To Record Profits.

203. While the use of opioids has taken an enormous toll on Seattle and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like the Manufacturing Defendants. Indeed, financial information indicates that each Manufacturing Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct

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described above.

204. SPC also profited immensely from its operation of an opioid pill mill. SPC served over 25,000 patients and the typical patient returned to SPC every 90 days to refill opioid prescriptions. For every opioid refill appointment, SPC billed third-party payors approximately $400 and patients between $400 and $500. SPC's "treatment" program was indeed designed to maximize revenues, and the center's ability to rapidly expand across the state, and employ more than 100 individuals, shows the model's success. On information and belief, Mr. Li, SPC's principal, amassed significant personal wealth through his operation of SPC, including in the form of property held in Seattle.

II. CAUSES OF ACTION

FIRST CAUSE OF ACTION

PUBLIC NUISANCE
RCW CHAPTER 7.48

(Against All Defendants)

205. Seattle realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

206. Under Washington law, a "[n]uisance consists in unlawfully doing an act, or omitting to perform a duty, which act or omission either annoys, injures or endangers the comfort, repose, health or safety of others, offends decency, or unlawfully interferes with, obstructs or tends to obstruct, or render dangerous for passage, any lake or navigable river, bay, stream, canal or basin, or any public park, square, street or highway; or in any way renders other persons insecure in life, or in the use of property." RCW 7.48.120.

207. RCW 7.48.010 further defines an "actionable nuisance" to encompass "whatever is injurious to health or indecent or offensive to the senses."

208. A "public nuisance," in turn, "is one which affects equally the rights of the entire community or neighborhood, although the extent of the damage may be unequal." RCW 7.48.130.

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209. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of Seattleites or interferes with the comfortable enjoyment of life in violation of Washington law.

210. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit.

211. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

212. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

213. The health and safety of Seattleites, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to Seattle and the entire state.

214. Defendants' conduct has injuriously affected, and continues to affect, Seattle property, patrons, employees and a considerable number of people within Seattle, and across the state.

215. Opioids are abused not only in private homes but on the streets of Seattle, in public parks and in municipal buildings. Opioid addicts who have lost stable housing have crowded into encampments on Seattle property, with the byproducts of their abuse, needles and other waste, littering Seattle streets. Opioid-caused medical emergencies and related disturbances also occur regularly on, and detract from the intended uses of, Seattle property. Much opioid-related criminal activity – including car prowls, prostitution, and petty theft crimes committed for opioid-purchasing funds – takes place on Seattle's streets and rights of way. In these ways, and many more, Seattle's real property interests have been severely impacted by Defendants' conduct.

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216. Defendants' conduct also constitutes a nuisance per se because it independently violates other applicable statutes. As set forth below, the Manufacturing Defendants have violated the Washington's Consumer Protection and Criminal Profiteering Acts. They also have violated Chapter 7.08.030 of the Seattle Municipal Code, which prohibits "deceptive or misleading" statements in the advertisement of any good. SPC has, as found by MQAC, violated a host of statutes regulating the medical profession, including RCW 18.130.180(1), (4), (7), (13), (14), and (22).

217. Pursuant to RCW 7.48.020 and 7.48.180, Seattle seeks an order that provides for abatement of the public nuisance Defendants have created, enjoins Defendants from future violations of RCW chapter 7.48, and awards Seattle damages in an amount to be determined at trial. Seattle pursues these remedies in a sovereign capacity for the benefit of the general public.

SECOND CAUSE OF ACTION

PUBLIC NUISANCE
WASHINGTON COMMON LAW

(Against All Defendants)

218. Seattle realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

219. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of Seattleites or interferes with the comfortable enjoyment of life in violation of Washington law.

220. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit.

221. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

222. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and

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addiction that now exists would have been averted.

223. The health and safety of Seattleites, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to Seattle and the entire state.

224. Defendants' conduct has injuriously affected, and continues to affect, Seattle property, patrons, employees and a considerable number of people within Seattle, and across the state.

225. Opioids are abused not only in private homes but on the streets of Seattle, in public parks and in municipal buildings. Opioid addicts who have lost stable housing have crowded into encampments on Seattle property, with the byproducts of their abuse, needles and other waste, littering Seattle streets. Opioid-caused medical emergencies and related disturbances also occur regularly on, and detract from the intended uses of, Seattle property. Much opioid-related criminal activity – including car prowls, prostitution, and petty theft crimes committed for opioid-purchasing funds – takes place on Seattle's streets and rights of way. In these ways, and many more, Seattle's real property interests have been severely impacted by Defendants' conduct.

226. Defendants' conduct also constitutes a nuisance per se because it independently violates other applicable statutes. As set forth below, the Manufacturing Defendants have violated the Washington's Consumer Protection and Criminal Profiteering Acts. They also have violated Chapter 7.08.030 of the Seattle Municipal Code, which prohibits "deceptive or misleading" statements in the advertisement of any good. SPC has, as found by MQAC, violated a host of statutes regulating the medical profession, including RCW 18.130.180(1), (4), (7), (13), (14), and (22).

227. Seattle seeks an order that provides for abatement of the public nuisance Defendants have created, enjoins Defendants from creating future common-law nuisances, and awards Seattle damages in an amount to be determined at trial. Seattle pursues these remedies in a sovereign capacity for the benefit of the general public.

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THIRD CAUSE OF ACTION

WASHINGTON CONSUMER PROTECTION ACT ("WCPA") RCW CHAPTER 19.86

(Against Manufacturing Defendants)

228. Seattle realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

229. The WCPA renders unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." RCW 19.86.020.

230. Under Washington law, a practice is unfair or deceptive if it had the capacity to deceive a substantial portion of the public.

231. As alleged herein, each Manufacturing Defendant, at all times relevant to this Complaint, violated the WCPA by making deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturing Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

232. Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to Seattle consumers that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Sponsoring, directly distributing, and assisting in the distribution of publications

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that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Exclusively disseminating misleading statements in education materials to Seattle hospital doctors and staff while purportedly educating them on new pain standards; and

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- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Seattle prescribers through in-person detailing.

233. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high-risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer

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pain and that opioids improve quality of life, while concealing contrary data;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Seattle prescribers through in-person detailing.

234. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained

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deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Seattle prescribers through in-person detailing.

235. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

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- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

- Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

- Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to Seattle prescribers through in-person detailing and speakers bureau events, when such uses are unapproved and unsafe; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Seattle prescribers through in-person detailing and speakers bureau events.

236. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Seattle prescribers through in-person detailing;

- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

- Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

237. These representations and concealments were deceptive and, as described more specifically above, they constitute a repeated course of conduct, contrary to public policy and the public's interest, which continues to this day.

238. But for these deceptive representations and concealments of material fact, Seattle would not have expended millions of dollars of its resources, and as a direct and proximate cause

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of Manufacturing Defendants' deceptive conduct, Seattle has been injured.

239. A violation of RCW 19.86.020 occurred each time a Manufacturing Defendant deceptively marketed opioids.

240. Pursuant to RCW 19.86.090, Seattle seeks a declaratory judgment that Manufacturing Defendants violated the WCPA, an injunction enjoining Manufacturing Defendants' misrepresentations described in this Complaint, costs and attorney's fees, actual and treble damages in an amount to be determined at trial, and all other relief available under the WCPA. Seattle pursues these remedies in a sovereign capacity for the benefit of the general public.

FOURTH CAUSE OF ACTION

WASHINGTON CRIMINAL PROFITEERING ACT RCW 9A.82

(Against Defendants Purdue, Janssen, Cephalon, and Endo)

241. Seattle realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

242. This claim is brought by Seattle against Defendants Purdue, Janssen, Cephalon and Endo. Throughout this Cause of Action, and the one to follow, "Defendants" refers only to these defendants.

243. Pursuant to RCW 9A.82.100, a "person who sustains injury to his or her person, business, or property by an act of criminal profiteering that is part of a pattern of criminal profiteering activity . . . may file an action in superior court for the recovery of damages and the costs of the suit, including reasonable investigative and attorney's fees."

244. A "pattern of criminal profiteering activity" is defined as "at least three acts of criminal profiteering, one of which occurred after July 1, 1985, and the last of which occurred within five years, excluding any period of imprisonment, after the commission of the earliest act of criminal profiteering." RCW 9A.82.010(12). And "[i]n order to constitute a pattern, the three acts must have the same or similar intent, results, accomplices, principals, victims, or methods of commission, or be otherwise interrelated by distinguishing characteristics including a nexus to

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the same enterprise, and must not be isolated events." *Id*.

245. RCW 9A.82.010(4) defines "criminal profiteering" as a list of specific offenses, one of which being RCW 48.80.030, which provides that "[a] person shall not make or present or cause to be made or presented to a health care payer a claim for a health care payment knowing the claim to be false" and further that "[n]o person shall knowingly present to a health care payer a claim for a health care payment that falsely represents that the goods or services were medically necessary in accordance with professionally accepted standards." A "false" claim is one that is "wholly or partially untrue or deceptive." RCW 48.80.020(3).

246. Seattle is a "person" for purposes of RCW 9A.82.100 and was injured in its business or property as a result of Defendants' deceptive marketing campaign. That campaign caused repeated violations of RCW 48.80.030, because it caused providers in Seattle to submit claims to health care payers for opioid prescriptions that were not medically necessary, injurious to the health of patients and the community, and otherwise false.

247. Defendants caused thousands, and potentially millions, of violations of RCW 48.80.030 in Seattle within a five year period after July 1, 1985. The violations were coordinated, had the same intent and results, and were part of the same enterprise.

A. The Opioids Marketing Enterprise

248. Defendants formed an association-in-fact enterprise – sometimes referred to in this Complaint as the Opioids Marketing Enterprise. The Opioids Marketing Enterprise consists of (a) Defendants, including their employees and agents; (b) the Front Groups, including their employees and agents; and (c) the KOLs.

249. The Opioids Marketing Enterprise is an ongoing and continuing business organization that created and maintained systematic links for a common purpose: to ensure the prescription of opioids for chronic pain.

250. To accomplish this purpose, the Opioids Marketing Enterprise periodically and systematically misrepresented – either affirmatively or through half-truths and omissions – to the general public and Seattle consumers, the risks and benefits of using opioids for chronic pain.

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The Opioids Marketing Enterprise concealed from the public and Seattle consumers the serious risks and lack of corresponding benefits of using opioids for chronic pain. By making those representations, the Opioids Marketing Enterprise ensured that a larger number of opioid prescriptions would be written and filled for chronic pain. This translated into higher sales (and therefore profits) for Defendants.

251. The persons engaged in the Opioids Marketing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. There is regular communication between Defendants, Front Groups and KOLs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants, Front Groups and KOLs share information regarding overcoming objections to the use of opioids for chronic pain. Defendants, the Front Groups and KOLs functioned as a continuing unit for the purposes of implementing the Opioids Marketing Scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

252. At all relevant times, Front Groups were aware of Defendants' conduct, were a knowing and willing participant in that conduct, and reaped benefits from that conduct. Each Front Groups also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of Seattle and Seattle consumers. But for the Opioids Marketing Enterprise's unlawful scheme, Front Groups would have had the incentive to disclose the deceit by Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioids Marketing Enterprise's scheme and reaped substantial benefits.

253. At all relevant times, KOLs were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that

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the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers and the State. But for the Opioids Marketing Enterprise's unlawful scheme, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Opioids Marketing Enterprise's scheme, and reaped substantial benefits.

254. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities throughout the United States, the Front Groups and KOLs did not challenge Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioids Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

255. The Front Groups and KOLs participated in the conduct of the Opioids Marketing Enterprise, sharing the common purpose of marketing opioids for chronic pain, and they knowingly made material misstatements or omissions to the general public and Seattle consumers in furtherance of the scheme, including that:

a. it was rare, or there was a low risk, that Defendants' opioids could lead to addiction;[80]

b. the signs of addiction were actually signs of undertreated pain that should be treated by more opioids;[81]

c. opioid dependence could be easily addressed by tapering and that opioid withdrawal is not difficult;[82]

d. doctors could increase opioid dosages indefinitely without added risk;[83]

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[80] American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by Cephalon and Purdue) (still available online); American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online).

[81] National Initiative on Pain Control 2009 CME program, *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia* (sponsored by Endo).

[82] American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online).

[83] American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by Cephalon and Purdue) (still available online); Endo pamphlet edited by KOL: *Understanding Your Pain: Taking Oral Opioid Analgesics*; American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online).

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e. long-term opioid use improved patients' function and quality of life;[84]

f. Purdue's OxyContin provided 12 hours of continuous pain relief;[85] and

g. the extent to which the Opioids Marketing Scheme caused Seattle consumers to pay for excessive opioid prescriptions and to incur costs associated with abating the opioid epidemic caused by the Enterprise.

256. Defendants alone could not have accomplished the purpose of the Opioids Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than Defendants themselves. Without these misrepresentations, the Opioids Marketing Enterprise could not have achieved its common purpose.

257. The impacts of the Opioids Marketing Enterprise's scheme are still in place – *i.e.*, the opioids continue to be prescribed and used for chronic pain, and the epidemic continues to consume the resources of Seattle's health care and law enforcement systems.

258. The foregoing evidences that Defendants, the Front Groups and the KOLs were each willing participants in the Opioids Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

B. Conduct of the Opioids Marketing Enterprise

259. During time period described in this Complaint, from approximately 2006 to the present, Defendants exerted control over the Opioids Marketing Enterprise and participated in the operation or management of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. Defendants created a body of deceptive and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of

[84] *Responsible Opioid Prescribing* (sponsored by Endo, Cephalon and Purdue) (remains for sale online); American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by Cephalon and Purdue) (still available online); CME entitled *Persistent Pain in the Older Patient* (sponsored by Endo).

[85] American Pain Foundation.

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independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;

b. Defendants selected, cultivated, promoted and paid the KOLs based solely on their willingness to communicate and distribute Defendants' messages about the use of opioids for chronic pain;

c. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;

e. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

f. Defendants sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

g. Defendants developed and disseminated pro-opioid treatment guidelines;

h. Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by Defendants, such as veterans and the elderly, and then funded that distribution;

i. Defendants concealed their relationship to and control of Front Groups and KOLs from the State and the public at large; and

j. Defendants intended that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

260. The scheme had a hierarchical decision-making structure that was headed by Defendants. Defendants controlled representations made about their drugs, and doled out funds to PBMs and payments to KOLs to ensure the representations made were consistent with Defendants' messaging nationwide and throughout Seattle. Front Groups were dependent on Defendants for their financial structure, and KOLs were professionally dependent on Defendants for the development and promotion of their careers.

261. The Front Groups also participated in the conduct of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding

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Defendants' opioids that were consistent with Defendants' messages themselves;

b. The Front Groups distribute through the U.S. Mail and interstate wire facilities promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

c. The Front Groups concealed their connections to Defendants.

262. The KOLs also participated in the conduct of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;

b. The KOLs distributed through the U.S. Mail and interstate wire facilities promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

c. The KOLs concealed their connections to and sponsorship by Defendants.

263. The scheme devised and implemented by Defendants, as well as other members of the Opioids Marketing Enterprise, amounted to a common course of conduct intended to encourage the prescribing and use of opioids for chronic pain and thereby secure payment for prescriptions of Defendants' opioids by Seattle patients and health care payers. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

C. Pattern of Criminal Profiteering Activity

264. Defendants conducted and participated in the conduct of the affairs of the Opioids Marketing Enterprise through a "pattern of criminal profiteering activity" as defined by RCW 9A.82.010(12). The pattern of criminal profiteering involved thousands of violations of RCW 48.80.030 – instances in which Defendants caused to be made or presented to health care payers claims for opioid prescriptions for treatment of chronic pain that were not medically necessary, injurious to the health of patients and the community, and otherwise false. The false claims that Defendants caused to be submitted can be identified from records within Defendants' possession

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showing opioid prescriptions issued for chronic pain. Each false claim constitutes criminal profiteering and, collectively, they constitute a pattern of criminal profiteering activity.

265. Each instance of criminal profiteering alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Seattle consumers and Seattle itself. Defendants, the Front Groups and the KOLs calculated and intentionally crafted the opioids marketing scheme to ensure their own profits remained high, without regard to the effect such behavior had on Seattle and other communities. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding Defendants' products.

266. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, and then subsequently failing to disclose such practices, Defendants, the Front Groups and the KOLs caused doctors to submit false claims and the unlawful course of Defendants' conduct constitutes a pattern of criminal profiteering activity.

267. The pattern of criminal profiteering activity alleged herein and the Opioids Marketing Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the Opioids Marketing Enterprise.

268. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

D. Damages Caused by Defendants' Conduct

269. Defendants' violations of law and their pattern of criminal profiteering have directly and proximately caused an opioid epidemic that, directly and foreseeably, has imposed a financial burden on Seattle and its agencies, including through the increased provision of treatment, paramedic, policing and other services specified herein.

270. Seattle's injuries were directly and proximately caused by Defendants' criminal

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profiteering activity. But for the misstatements made by Defendants, the Front Groups and the KOLs and the scheme employed by the Opioids Marketing Enterprise, Seattle would not have sustained the economic injuries it alleges.

271. By virtue of these violations of RCW 9A.82.100, Defendants are liable to Seattle for three times the damages Seattle has sustained, costs and expenses, civil penalties, and all equitable relief available by law. Seattle pursues these remedies in a sovereign capacity for the benefit of the general public.

FIFTH CAUSE OF ACTION

CIVIL CONSPIRACY
COMMON LAW

(Against Purdue, Janssen, Cephalon, and Endo)

272. Seattle realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

273. This claim is brought by Seattle against Defendants Purdue, Janssen, Cephalon and Endo. Throughout this Cause of Action only, "Defendants" refers to only these defendants.

274. Under Washington common law, a civil conspiracy occurs when (1) two or more people combine to accomplish an unlawful purpose, or combine to accomplish a lawful purpose by unlawful means, and (2) the conspirators enter into an agreement to accomplish the conspiracy.

275. As described more fully above, (a) Defendants, together with (b) Front Groups and (c) KOLs, coordinated their efforts, as part of a shared plan and pursuant to a common agreement, to deceptively market opioids for chronic pain in Seattle and across the nation.

276. The purpose of this conspiracy, deceiving health care providers, patients and the general public, was unlawful, violating, at a minimum, the Washington Consumer Protection Act (RCW 19.86.020), Health Care False Claim Act (RCW 48.80.030), and Chapter 7.08.030 of the Seattle Municipal Code.

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277. To accomplish their unlawful objectives, Defendants, Front Groups, and KOLs, acting collectively, systematically misrepresented to the general public and Seattle consumers – either affirmatively or through half-truths and omissions – the risks and benefits of using opioids for chronic pain. In particular, these conspirators concealed from the public and Seattle consumers the serious risks and lack of corresponding benefits of using opioids for chronic pain. These misrepresentations ensured that a larger number of opioid prescriptions would be written and filled for chronic pain in Seattle and elsewhere. This translated into higher sales (and therefore profits) for Defendants.

278. The conspiracy was the product of agreement and operated hierarchically with Defendants controlling the representations made about their respective drugs. The Front Groups and KOLs participated knowing, but without disclosing, that other Front Groups and KOLs were involved in the same scheme. But for their agreement to participate in the conspiracy, Front Groups and KOLs would have been incentivized to disclose Defendants' deceit to their constituents and to protect patients. They each joined the conspiracy with the expectation that the deceit would not be revealed by their co-conspirators. And when issues arose during the scheme, each agreed to take actions to hide the scheme and continue its existence.

279. Seattle seeks an order enjoining further operation of the civil conspiracy, damages in an amount to be determined at trial, and all other relief provided by law. Seattle pursues these remedies in a sovereign capacity for the benefit of the general public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays:

A. That the acts alleged herein be adjudged and decreed to be unlawful in violation of Washington State statutory and common law and that the Court enter a judgment declaring them to be so;

B. That Manufacturing Defendants be enjoined from, directly or indirectly through

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KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Washington law;

C. That Plaintiff recover all measures of damages allowable under the State statutes identified herein and the common law, and that judgment be entered against Defendants in favor of Plaintiff;

D. That Plaintiff receive an award of all civil penalties provided by law;

E. That Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorney's fees as provided by law;

F. That Defendants be ordered to abate the public nuisance that they created in violation of Washington law;

G. That Defendants be ordered to pay punitive and treble damages as provided by law; and

H. That the Court order such other and further relief as the Court deems just, necessary and appropriate.

JURY DEMAND ENDORSEMENT

Plaintiff, Seattle, by and through its City Attorney, Peter S. Holmes, demands a trial by jury on all claims to the maximum number of jurors permitted by law.

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DATED this 28th day of September, 2017.

PETER S. HOLMES
Seattle City Attorney

By: _____
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All out-of-state counsel to be admitted *pro hac vice*.

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