STATE OF WASHINGTON
KING COUNTY SUPERIOR COURT

STATE OF WASHINGTON, Plaintiff, v. 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.; and XYZ Corporations 1 through 20, Defendants.	NO. COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF UNDER THE CONSUMER PROTECTION ACT, PUBLIC NUISANCE, AND NEGLIGENCE

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I. INTRODUCTION

1.1 On average, two Washingtonians die each day from opioid overdoses. Between 2006 and 2017, opioid overdoses killed more than 8,000 Washingtonians, more than either car accidents or firearms. These deaths are attributable to a flood of prescription opioids into the state over the last two decades. Hundreds of millions of prescription opioid pills have been pumped into Washington, including 112 million daily doses of prescription opioids in 2011 alone – enough for a 16-day supply for every woman, man, and child in the state. As of 2017, four Washington counties had more opioid prescriptions than people – in 2015, the number was twice that.[1]

1.2 This enforcement action seeks to protect the public from deceptive and unfair marketing practices in the sale of opioids – dangerous and deadly drugs that are ravaging Washington's communities and overwhelming public resources.[2]

1.3 Defendants (collectively Janssen) manufacture, sell, and market extended release opioids, and should be held responsible for the foreseeable, foreseen, and ongoing consequences of marketing opioids, particularly after it became evident that opioids had caused and were continuing a national epidemic.

1.4 Opioids are unique in the scope of deaths and cost. The U.S. Department of Health and Human Services reported that 47,600 people died of an opioid overdose in 2018. That year more than 10.3 million people misused prescription opioids, and the crisis cost an estimated $78.5 billion to the economy.[3]

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[1] U.S. County Prescribing Rates, 2017, *available at* https://www.cdc.gov/drugoverdose/maps/rxcounty2017.html; U.S. County Prescribing Rates, 2015, *available at* https://cdc.gov/drugoverdose/maps/rxcounty2015.html.

[2] Executive Order 16-09, Addressing the Opioid Use Public Health Crisis (Oct. 7, 2016), *available at* http://www.governor.wa.gov/sites/default/files/exe_order/eo_16-09.pdf.

[3] The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States, 2013, U.S. Department of Health & Human Services, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5975355/.

1.5 The origin of the opioid epidemic is unique. As Washington public health officials have noted, opioid use is the "worst manmade epidemic in history."[4] Twenty years ago, this problem did not exist; it was created.

1.6 Janssen aggressively supplied and marketed what was essentially an uncontrolled experiment on the American public. There was, and is, no reliable evidence that opioids are effective at relieving chronic pain in the long term.

1.7 Nonetheless, Janssen cloaked the sale of its ingredients and products in the legitimacy of medicine. Unlike tobacco or alcohol about which no medical claims were made, patients were told by health care providers that opioids are a powerful medicine, safe to use as prescribed, and effective to relieve chronic pain. Against this message, the public had no defense.

1.8 Janssen also played a unique role in expanding the opioids market by supplying other opioid manufacturers with active pharmaceutical ingredients to be used in opioid drugs.

1.9 As part of its "pain management franchise," from the 1990s through at least 2016, Janssen wholly owned two subsidiaries that, together, supplied other opioid manufacturers with opioid active pharmaceutical ingredients to be used in opioid drugs. Tasmanian Alkaloids Limited (Tasmanian Alkaloids) cultivated opium poppy plants to be made into opioid active pharmaceutical ingredients (APIs) necessary to manufacture opioid drugs. Noramco, Inc. (Noramco) then imported the narcotic raw materials produced by Tasmanian Alkaloids, processed these materials into APIs, and sold them to other opioid manufacturers in the U.S.

1.10 Janssen, Noramco, and Tasmanian Alkaloids shared employees and resources that were required to operate the business. Noramco employees physically worked at Janssen's facilities in New Jersey at various times. Further, employees simultaneously held positions at multiple companies within the Johnson & Johnson family of companies at times.

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[4] Gary Franklin, et al., *A Comprehensive Approach to Address the Prescription Opioid Epidemic in Washington State: Milestones and Lessons Learned*, 105 Am. J. Pub. Health 463 (2015), *hereafter as:* Franklin, *A Comprehensive Approach.*

1.11 In the 1990s, Janssen's scientists at Tasmanian Alkaloids began a project to develop the thebaine poppy variety to meet anticipated demand. The result of Janssen's research project was the creation of the "Norman Poppy," which Janssen internally described as "a transformational technology that enabled the growth of oxycodone." By 2015, Janssen's "Noramco World Wide Narcotics Franchise," comprised of Noramco and Tasmanian Alkaloids, had become the top supplier of narcotic APIs in the U.S., the world's largest market.

1.12 Janssen's ownership of these subsidiaries uniquely positioned its pain management franchise to provide U.S. drug manufacturers, including Purdue Pharma L.P. (Purdue), Teva Pharmaceutical Industries Ltd. (Teva), and Johnson & Johnson itself, with a secure, potent, and dependable supply of active pharmaceutical ingredients, including oxycodone, hydrocone, morphine, codeine, buprenorphine, hydromorphone, and naloxone.

1.13 Lawsuits against opioid manufacturers like Janssen are unique because of the addictiveness of opioids. Patients quickly became dependent on opioids and, once hooked, are susceptible to a host of foreseeable adverse events including addiction and death.

1.14 Janssen systematically overstated the effectiveness of its drugs for treating pain, understated the risk of addiction, and overstated the effectiveness of risk mitigation strategies that Janssen claimed, without evidence, could render opioid use safe. Janssen fostered and propagated the idea that dependence on opioids was an acceptable physiological reaction and that overdoses were the result of addicts misusing the drugs.

1.15 Janssen knew of, and profited from, the addictive properties of its drugs.

1.16 Indeed, Janssen was ordered to pay the State of Oklahoma $465 million dollars for its role in igniting Oklahoma State's opioid crisis by deceptively marketing painkillers. By and through its deceptive marketing, the court found that Janssen "caused exponentially increasing rates of addiction, overdose deaths, and Neonatal Abstinence Syndrome."[5] The ruling

[5] *State of Oklahoma vs. Purdue Pharma L.P., et al.*, District Court of Cleveland County, State of Oklahoma, Case number CJ-2017-816, Docket No. 1044673351, Judgment After Non-Jury Trial, (filed August 26, 2019). This judgment will subsequently be referred to as "Oklahoma Judgment."

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in favor of the State of Oklahoma's public nuisance claims confirms Janssen's role in fueling the opioid crisis.

1.17 The Attorney General, on behalf of the State of Washington, asks this Court to enjoin Janssen's unfair and deceptive marketing practices related to opioids. The Attorney General further asks this Court to order Janssen to abate the public nuisance created by its marketing and business practices, to disgorge profits gained by its deceptive marketing and business practices, to impose penalties for its illegal conduct, and to award damages.

1.18 Having played a significant part in creating and profiting from this crisis, Janssen is responsible for the costs of its conduct that are now being borne by the public.

II. PARTIES

2.1 The Plaintiff is the State of Washington. The Attorney General is authorized to commence this action pursuant to RCW 19.86.080 and RCW 19.86.140. The State, by and through the Attorney General and the Consumer Protection Division, brings this action to address practices that violate the Consumer Protection Act relating to the marketing and sale of opioid medications. The Attorney General is also authorized to bring this action pursuant to its common law and *parens patriae* authority to bring an action to abate a public nuisance and vindicate the rights of the public.

2.2 Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

2.3 Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals, Inc. is currently registered to do business in Washington under UBI 602794453. It is a wholly owned subsidiary of Johnson & Johnson.

2.4 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. It is registered to do business in Washington under the UBI 602549543.

2.5 Janssen Pharmaceutical, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

2.6 Johnson & Johnson 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, Johnson & Johnson controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to Johnson & Johnson's benefit.

2.7 Collectively, the above-identified Defendants are referred to herein as "Janssen."

2.8 Janssen is in the business of manufacturing, promoting, marketing, and distributing opioids in the United States and in Washington. Janssen's opioid brands include, but are not necessarily limited to, the following:

a. Nucynta, which was originally approved as an immediate release opioid for relief of moderate to severe acute pain in patients eighteen years of age or older. The FDA subsequently modified approval to management of acute pain severe enough to require an opioid analgesic and for which alternative treatment options are inadequate.

b. Nucynta ER is an extended release version of Nucynta. In 2011, the FDA approved it for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. In 2012, the FDA approved a new indication for Nucynta ER for the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. It is currently approved for the management of: (a) pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate; and (b) neuropathic pain associated with DPN in adults severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate. The active molecule in Nucynta and Nucynta ER is tapentadol, which the FDA classifies as an opioid analgesic that provides pain-relieving effects by

interacting with opioid receptors in the body. The United States Drug Enforcement Agency placed tapentadol in Schedule II of the Controlled Substances Act because it has a high potential for abuse and may lead to severe psychological or physical dependence. Janssen completed the sale of the U.S. rights to the Nucynta franchise of products to Depomed, Inc., now Assertio Therapeutics, Inc., in April 2015.

c. Duragesic, which is a transdermal patch made out of the active pharmaceutical ingredient fentanyl. Dr. Paul Janssen invented fentanyl in the 1950s.

d. Ultram and Ultram ER, tablets made out of the active pharmaceutical ingredient tramadol.

e. Ultracet, tablets made out of the active pharmaceutical ingredients tramadol and acetaminophen.

f. Tylenol with Codeine, tablets made out of the active pharmaceutical ingredients acetaminophen and codeine.

2.9 In addition to its own brands, Janssen supplied narcotic raw materials for opioids made by other manufacturers.

2.10 Noramco and Tasmanian Alkaloids supplied active pharmaceutical ingredients to other manufacturers, including Purdue and Teva, that were used in oxycodone, hydrocodone, morphine, fentanyl, sufentanil, buprenorphine, hydromorphine, and naloxone.

2.11 Normaco sold active pharmaceutical ingredients through long-term agreements with all seven of the top United States generic companies.

2.12 Noramco became the number one narcotic active pharmaceutical ingredient supplier of oxycodone, hydrocodone, codeine, and morphine in the United States.

2.13 Upon information and belief, Defendants Does 1 through 99 are individuals whose names and addresses of residence are unknown.

2.14 Upon information and belief, Defendants Doe Corporations 1 through 99 are corporations, the names and address of which are unknown.

2.15 At all relevant times, each Defendant acted individually or jointly with every other named Defendant in committing all acts alleged in this Complaint.

2.16 At all relevant times, each Defendant acted (a) as principal; (b) under express or implied agency; and/or (c) with actual or ostensible authority to perform the acts alleged in this Complaint on behalf of every other named Defendant.

2.17 At all relevant times, one or all of the Defendants acted as the agent of the others, and all Defendants acted within the scope of their agency as if acting as the agent of the others.

2.18 At all relevant times, each Defendant and its employees had awareness of the others' conduct relating to the matters alleged within the Complaint.

III. JURISDICTION AND VENUE

3.1 The State files this complaint and institutes these proceedings under the provisions of the Consumer Protection Act, RCW 19.86; the State also brings this action in its *parens patriae* capacity for the benefit of the state's residents, to protect their health and safety.

3.2 Janssen has engaged in the conduct set forth in this Complaint in King County and elsewhere in the state of Washington. Personal jurisdiction is therefore appropriate under RCW 19.86.160.

3.3 Venue is proper in King County pursuant to RCW 4.12.020 and 4.12.025, and Superior Court Civil Rule 82 because Defendants transact business in King County by marketing and distributing the opioid products to health care providers and consumers in King County, as described more fully below.

IV. FACTS

4.1 Janssen made and marketed immediate and extended release branded opioids for the treatment of chronic,[6] long-term pain.

4.2 As set forth below, the Attorney General alleges that opioids are not effective at relieving long-term pain and that Janssen does not have sufficient evidence to make such

[6] Chronic pain means pain that lasts longer than three months.

assertions. Moreover, the risks associated with such opioid use outweigh the transient and unproven benefits of opioids.

4.3 Although the Food and Drug Administration has approved the sale of opioids, Janssen's marketing of these drugs has exceeded the labeled use and does not shield Janssen from liability for its deceptive marketing or the public nuisance created by its business model.

4.4 Washington State has a strong public policy in favor of protecting its citizens, which extends to preventing Janssen's deceptive marketing campaign and abating the public nuisance created by Janssen's opioids.

4.5 In contravention of Washington's public policy, Janssen used sophisticated and highly targeted marketing to deceive and mislead Washington health care providers into expanded and ongoing opioid prescribing in spite of massive and sustained public harms.

4.6 Using carefully selected third party materials as well as branded and unbranded marketing, Janssen disseminated deceptive and misleading statements about the effectiveness of opioids, minimized the risk of addiction, and made misleading statements about the ease with which the risk of addiction could be managed.

4.7 Washington prescribers have been directly affected by Janssen's marketing and their prescribing behaviors have changed so as to increase the prescribing of opioid pain medications.

4.8 Despite the associated risk, opioids are widely prescribed; in 2010, almost 20% of visits to the doctor for pain relief resulted in an opioid prescription.[7] This represented a 73% increase in visits resulting in an opioid prescription from 2000. Over that same period, non-opioid pain treatments remained relatively constant.[8] This means that the primary change in treating pain

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[7] Matthew Daubresse, et al., *Ambulatory Diagnosis and Treatment of Non-Malignant Pain in the United States*, 2000-2010, 51 Med. Care 870 (2013), *hereafter as*: Daubresse, *Ambulatory Diagnosis and Treatment.*

[8] *Id.*

in the United States over the last two decades has been the increased prescription of opioids, without an impact on pain. In the last 20 years, opioid prescribing has increased by 600%.[9]

4.9 At its peak in 2012, U.S. health care providers wrote 259 million prescriptions for opioid pain medication, enough for every adult in the United States to have a bottle of pills.[10] Although that number has declined somewhat in recent years, in 2017, health care providers still wrote over 191 million prescriptions, amounting to more than one prescription for every two people in the United States.[11] The United States constitutes 4.6% of the world's population, but consumed 80% of the world's opioid supply in 2011.[12]

4.10 Washington has 0.1% of the world's population, but in 2016 consumed 1.8% of the world's opioids.[13] This means Washington consumes nearly 20 times the opioids its population would suggest.

4.11 Janssen's stated motive for promoting opioids was providing pain relief, but its underlying motive was profit. Janssen's aggressive marketing of opioids for the most dangerous kind of opioid use has been exceedingly financially lucrative.

4.12 In 2012, the extended release opioid market recorded $5.2 billion in sales. In 2014, the total opioid market reached $11 billion and is projected to continue generating these levels of revenues.

4.13 Janssen generates substantial sales revenue from the opioid market. By way of minor example, Duragesic accounted for more than $1 billion in sales in 2009, and Nucynta and

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[9] Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications* (2014), citing Leonard Paulozzi et al., *CDC Grand Rounds Prescription Drug Overdoses – a U.S. Epidemic*, 61 Morbidity and Mortality Weekly Report 10 (2012), *hereafter as*: Teater, *The Psychological and Physical Side Effects*.

[10] Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016) (2016 CDC Guideline), *hereafter as:* Dowell, *CDC Guideline for Prescribing*.

[11] U.S. Opioid Prescribing Rate Maps (Oct. 3, 2018) *available at* https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

[12] Teater, *The Psychological and Physical Side Effects*, citing Daneshvari R. Solanki, et al., *Monitoring Opioid Adherence in Chronic Pain Patients: Assessment of Risk of Substance Abuse*, 14 Pain Physician E119 (2011).

[13] U.S. and World Population Clock, U.S. Census Bureau, https://www.census.gov/popclock/.

Nucynta ER accounted for $172 million in sales in 2014. By 2016, when Johnson and Johnson sold Noramco and Tasmanian Alkaloids to a private investment firm for $650 million, Noramco was a top supplier of opioid active pharmaceutical ingredients, including oxycodone (found in OxyContin and Percocet), hydrocodone (found in Vicodin), codeine, and morphine.

4.14 The result of Janssen's deceptive, unfair, and negligent conduct dramatically impacted Washington State and has caused extensive public harm.

A. "The Science of Opioids Is Clear:" The Known, Serious, and Too-Often-Fatal Risks Far Outweigh the Unproven and Transient Benefits of Opioids for Treating Chronic Non-Cancer Pain

4.15 Opioids are a class of central nervous system depressant drugs that attach to receptors in the brain, spinal cord, and gastrointestinal tract and suppress function. There are several different opioid molecules—morphine, hydrocodone, oxycodone, oxymorphone, hydromorphone, tapentadol, buprenorphine, and methadone being the most common.

4.16 Opioids come in two basic formulations: immediate release and extended release. Immediate release opioids deliver the full dose quickly as the pill dissolves. Extended release opioids are concentrated versions of the same active ingredients as immediate release drugs, but contained in a time-release matrix that is supposed to release the drug over time. OxyContin, for example, is oxycodone in a time-release matrix that claims to deliver the drug over 12 hours.

4.17 The immediate release opioid market is heavily generic. The extended release market has far more branded products. Noramco and Tasmanian Alkaloids were top suppliers for both types of products.

4.18 By design and marketing, Janssen's drugs are intended for long-term use, and Janssen has chosen to market them heavily for use with chronic non-cancer pain patients. As described below, long-term use, is the most deadly and least effective use of opioids medications.

4.19 While prescribed for pain relief, opioids also depress respiration. Respiratory depression is the primary mechanism by which opioids have killed thousands of Washington

citizens, and hundreds of thousands of Americans. It is undisputed that opioids are both addictive and deadly.

4.20 Prescription opioids constitute the largest component of the opioid epidemic, both in quantity and damage caused.[14] Overdose deaths parallel the prescribing of opioids.[15] In fact, filling an opioid prescription is a significant risk factor for overdose.[16]

4.21 Both opioid use disorder and overdose risk are present even when opioids are taken as prescribed;[17] the opioid epidemic is not a crisis of abuse – it is a crisis of use.

1. Janssen designed and conducted an uncontrolled public health experiment on the American public about the risks of prescribing opioids for chronic non-cancer pain

4.22 In the mid-1990s, the medical community was aware of both the risks of opioids and the relative ineffectiveness of long-term opioid use. Dr. Russell Portenoy, whose theories were later adopted by Janssen and other manufacturers, acknowledged the prevailing medical understanding regarding use of opioids long-term for non-cancer pain:

> The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effect over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutatory mood changes, but adverse effects will inevitably occur thereafter.[18]

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[14] In 2015, almost half of all opioid deaths involved prescription opioids, and from 1999 to 2015, 183,000 deaths involved prescription opioids. Rose A. Rudd, et al., *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*, 65 Morbidity and Mortality Weekly Report 1145 (2016), *hereafter as:* Rudd, *Overdose Deaths 2010-2015*.

[15] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, 16 American Journal of Transplantation 1323 (2016).

[16] Dowell, *CDC Guideline for Prescribing* at 22-24.

[17] Letter from Janet Woodcock, MD., Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept 10, 2013) available at https://paindr.com/wp-content/uploads/2013/09/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

[18] Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247 (1994).

Thus, in 1994, conventional wisdom predicted that opioids would appear effective in the short term, but prove ineffective over time with increasing negative effects.

4.23 The medical community knew that published reports associated opioid use "with heightened pain and functional impairment, neuropsychological toxicity, prevarication about drug use, and poor treatment response."[19] And Dr. Portenoy noted that "the problematic nature of opioid therapy in *some patients is unquestionable*, and the potential adverse impact of all possible outcomes related to treatment, including physical dependence, deserves to be addressed."[20]

4.24 Standing against the conventional wisdom, Dr. Portenoy argued in favor of expanding the use of opioids, pointing to evidence from opioid use among cancer patients. He posited that there was a population of patients *without* cancer who could benefit from long-term opioid use. Even then, he admitted, "controlled trials suggest favorable outcomes, but are very limited. The generalizability of these data are questionable due to the brief periods of treatment and follow-up."[21]

4.25 Dr. Portenoy claimed that the lack of evidence should not stop doctors from prescribing opioids, arguing there was a lack of data:

> that nonmalignant pain generally, or any patient subgroup with nonmalignant pain (such as those with neuropathic pain, low back pain, headache, or idiopathic pain), are inherently unresponsive to opioids drugs. Consequently, therapy cannot be withheld based on the a priori assumption that any particular pain or patient group will inevitably fail to benefit.[22]

4.26 Dr. Portenoy then proposed what was, in effect, an uncontrolled experiment. Expand the use of opioids and then monitor to see what would happen:

> Controlled clinical trials of long-term opioid therapy are needed, but the lack of these trials should not exclude empirical treatment when medical judgment

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[19] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A Review of the Critical Issues*, 11 J. Pain & Symptom Mgmt., 203, 206 (1996).

[20] *Id.*

[21] *Id.* at 204.

[22] *Id.* at 206.

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> supports it and therapy is undertaken with appropriate monitoring. If treatment is offered, documentation in the medical record of pain, side effects, functional status, and drug-related behaviors must be ongoing and explicit.[23]

4.27 Janssen seized on the work of Dr. Portenoy. Where Portenoy proposed a clinical experiment with "appropriate monitoring," Janssen, through its marketing, expanded the "empirical treatment" to thousands of busy primary care physicians, nurse practitioners, physician assistants, and other prescribers, none of whom had Dr. Portenoy's expertise.

4.28 Janssen's business and marketing model nationalized an experiment in the absence of good evidence. Janssen hired other health care professionals and, through an extensive marketing scheme, set about convincing the rest of the medical establishment, patients, and policy makers to participate willingly in the experiment. As described below, Janssen did so by deceptively presenting the experimental *hypotheses* – that (a) opioids would be more effective than alternatives at treating chronic non-cancer pain long-term; and (b) the risks of addiction and associated problems were both slight and manageable – as *facts*. Janssen's factual claims were unsubstantiated and, unfortunately for the many Washingtonians who have suffered as a result, untrue.

2. Opioids are ineffective for pain relief and functional improvement for chronic non-cancer pain

4.29 Central to this lawsuit is the scientific fact that there is no reliable evidence that opioids either relieve pain or improve function when taken long-term for chronic pain. The Centers for Disease Control (CDC) published a Guideline for Prescribing Opioids for Chronic Pain in 2016. This guideline, published after a "systematic review of the best available evidence" by an expert panel free of conflicts of interest,[24] determined that no study exists to show opioids are effective for outcomes related to pain, function, and quality of life.[25]

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[23] *Id.* at 212.
[24] Dowell, *CDC Guideline for Prescribing* at 2.
[25] Dowell, *CDC Guideline for Prescribing.*

4.30 Janssen's decision to market opioids for long-term use despite the absence of clinical evidence and based on the hypothesis of a few cherry-picked doctors was a calculated gamble; Janssen bet that the conventional medical wisdom was wrong and that the detrimental side effects of long-term opioid use could be acceptably managed.

4.31 The scientific reality is otherwise. As Dr. Thomas Frieden, the Director of the CDC from 2011 to 2017, and Dr. Debra Houry, the Director of the National Center for Injury Prevention and Control, explained in 2016: "the science of opioids for chronic pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh unproven and transient benefits."[26]

4.32 A University of Washington pain specialist, Dr. John Loesser, explained that based on clinical experience, his clinic had developed a rule that it was not wise to use opioids for chronic pain treatments. Of Dr. Portenoy's theory that there was a population of non-cancer patients who could safely and effectively use opioids, Dr. Loesser explained,

> It 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.[27]

4.33 On a nationwide scale, opioids did not offer a solution for what Janssen claimed was the widespread under treatment of pain. Despite the fact that opioid prescriptions quadrupled from 1999 to 2015, the overall prevalence of patient-reported pain has remained consistent.[28] Thus, the massive expansion of prescribing opioids for pain has made little progress in reducing chronic pain.

4.34 At first blush, it may seem counterintuitive that opioids, used to treat pain for centuries, are ineffective at relieving pain. But the conventional wisdom of 1994 was prophetic.

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[26] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501 (2016), *hereafter as:* Frieden, *Reducing the Risks.*

[27] John D. Loeser, *Five Crises in Pain Management*, 20 Pain Clinical Updates 1 (2012).

[28] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Non-Malignant Pain in the United States*, 2000-2010, 51 Med. Care 870 (2013), *hereafter as*: Daubresse, *Ambulatory Diagnosis and Treatment.*

Opioids, when used long-term, cause tolerance, meaning larger and larger doses are necessary to get the same effect. Long-term use also causes dependence, meaning that attempts to stop using the drug cause withdrawal symptoms.[29] In addition, long-term opioid use is associated with hyperalgesia, or heightened sensitivity to pain.[30]

4.35 While opioids may provide relief in the short term, they fail for their stated purpose of relieving pain in chronic pain conditions. In 2009, Dr. Andrea Rubenstein described a common experience for patients on long-term opioid treatment:

> Opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.[31]

4.36 The 2016 CDC guideline notes that "patients who do not experience clinically meaningful pain relief early in treatment (i.e. within 1 month) are unlikely to experience pain relief with longer-term use."[32]

4.37 A 2006 Danish study found that "it is remarkable that opioid treatment of chronic non-cancer pain does not seem to fulfill any of the key outcome goals; pain relief, improved quality of life and improved functional capacity" and noted that in one study, opioid users were more likely to report pain, having more pain locations, being more depressed and physically disabled than non-opioid users."[33]

4.38 A 2006 Canadian meta-study, which noted that a majority of studies were funded by the pharmaceutical industry, still found no evidence that opioids improved function more than

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[29] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain*, 170 Archives of Internal Med. 1422 (2010).

[30] Marion S. Greene & R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, 2 Current Addiction Reports 310 (2015).

[31] A. Rubenstein, *Are We Making Pain Patients Worse?*, Sonoma Medicine (Sept. 2009) , *hereafter as*: Rubenstein, *Are We Making Pain Patients Worse?*

[32] Dowell, *CDC Guideline for Prescribing* at 2.

[33] Jørgen Eriksen, et al., *Critical Issues on Opioids in Chronic Non-Cancer Pain: An Epidemiological Study*, 125 Pain 172, 176-77 (2006).

other non-opioid analgesics, finding instead that, "for functional outcomes the other analgesics were significantly more effective than were opioids.[34]

4.39 The deleterious effects of long-term opioid use are supported by a 2008 study, which found daily opioid use at modest doses over six months is linked with self-reported poorer physical function and poorer general health.[35] Similarly, a 2008 study in the journal *Spine* found that long-term opioid users are more likely to be disabled and unable to work, as well as more likely to be addicted.[36]

4.40 A 2012 study in the Journal of Pain, which followed 69,000 women over three years, found that patients who received opioid treatment were less likely to have improvement in pain, and had worsened function.[37]

4.41 In 2012, a group of medical providers petitioned the FDA to impose limits on opioid use. The FDA considered the state of evidence and concluded that it was "not aware of adequate and well-controlled studies of opioid use longer than 12-weeks."[38] The FDA went on to note that more data was needed "on the point at which the risk of opioid use at escalating doses and longer durations of treatment may outweigh the benefits of opioid analgesic therapy."[39]

4.42 The evidence from real world opioid use similarly reflects a lack of efficacy. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, owing to greater side effects and slower

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[34] Andrea D. Furlan, et al., *Opioids for Chronic Noncancer Pain: A Meta-analysis of Effectiveness and Side Effects*, 174 Canadian Med. Ass'n J. 1589 (2006), *hereafter as*: Furlan, *Opioids for Chronic Noncancer Pain.*

[35] Rubenstein, *Are We Making Pain Patients Worse?*, citing Kathryn Sullivan Dillie et al., *Quality of Life Associated with Daily Opioid Therapy in a Primary Care Chronic Pain Sample*, 21 Journal of the American Board of Family Medicine 108 (2008).

[36] Jeffrey Dersh, et al., *Prescription Opioid Dependence Is Associated With Poorer Outcomes in Disabling Spinal Disorders*, 33 Spine 2219 (2008), *hereafter as*: Dersh, *Prescription Opioid Dependence.*

[37] Frieden, *Reducing the Risks*, citing Jennifer Brennan Braden et al., *Predictors of Change in Pain and Physical Functioning Among Post-Menopausal Women with Recurrent Pain Conditions in the Women's Health Initiative Observational Cohort*, 13 J. Pain 64 (2012).

[38] Woodcock Letter (Sept. 10, 2013).

[39] Woodcock Letter (Sept. 10, 2013).

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returns to work.[40] In addition, receiving an opioid for more than seven days increased patients' risk of being on work disability one year later; and that an opioid prescription as the first treatment for a workplace injury doubled the average length of the claim.

4.43 Thus, just as was the case with Dr. Portenoy's work in 1990s, the pattern of the opioid experiment remained the same: in the face of mounting evidence of a developing opioid epidemic, Janssen was marketing drugs for which there was no evidence of effectiveness.

3. Evidence from the last two decades has confirmed that opioids are deadly drugs with dangerous side effects, particularly in vulnerable populations

4.44 The last 20 years have proven that the conventional understanding of the danger and relative ineffectiveness of opioids was more accurate than Dr. Portenoy's hypothesis and Janssen's marketing in support of their widespread use. Opioids are massively dangerous.

4.45 Between 1999 and 2014, more than 165,000 Americans died of opioid overdose.[41] Deaths related to opioids are accelerating. In 2015, opioids killed 33,091 people and the opioid death rate increased by 15.6%.[42]

4.46 Dr. Freidan from the CDC explained, "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[43]

4.47 Aside from overdose, long-term opioid use is associated with a significant increase in mortality from other causes.[44]

4.48 Opioids are also associated with numerous other side effects including gastrointestinal impacts, delayed recovery from injury, cognitive impacts, endocrine impacts, hyperalgesia (increased sensitivity to pain), increased risks of fractures, gastrointestinal bleeding,

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[40] Gary M. Franklin, et al., *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries*, 33 Spine 199 (2008).

[41] Dowell, *CDC Guideline for Prescribing.*

[42] Washington experienced a 12.5% increase in opioid death rates in 2015. Rudd, *Overdose Deaths 2010-2015.*

[43] Frieden, *Reducing the Risks.*

[44] Wayne A. Ray, et al., *Prescription of Long-Acting Opioids and Mortality in Patients With Chronic Noncancer Pain*, 315 J. Am. Med. Ass'n 2415 (2016).

hospitalization among the elderly, tolerance (need for increasing dose to maintain effect), dependence (causing withdrawal if stopped), and addiction.[45]

4.49 Opioids carry special risks for certain vulnerable populations. For example, opioid use during pregnancy has seen a three to four-fold increase between 2000 and 2009, with increased fetal, obstetrical, and neonatal abstinence syndrome risk. Neonatal abstinence syndrome may occur in up to 60-80% of infants exposed to opioids and has increased every year through 2013.[46] Of pregnant women enrolled in Medicaid from 2000 to 2007, 21.6% filled an opioid prescription during pregnancy.[47]

4.50 Opioids also pose risks for children and adolescents. Most of the use in this population is off-label, as opioids are not approved for children. Use of prescription opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse. The misuse of opioids in adolescents strongly predicts the later onset of heroin use.[48] Nonetheless, the 2016 CDC guidelines found that there have been significant increases in opioid prescribing for children and adolescents, for conditions such as headaches and sports injuries.

4.51 Opioids also pose special risks for older patients as well, in part due to the decline in the ability to metabolize and excrete opioids. Older patients on opioids are particularly prone to constipation, have increased risk for falls and fractures, and have a higher risk of opioid-related adverse drug events.[49]

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[45] Teater, *The Psychological and Physical Side Effects.*

[46] Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on Prescribing Opioids for Pain*, 49, 3rd ed. (2015), *hereafter as*: WSAMDG, *Interagency Guideline.*

[47] WSAMDG, *Interagency Guideline* at 42.

[48] Dowell, *CDC Guideline for Prescribing.*

[49] WSAMDG, *Interagency Guideline* at 47-48.

4. Evidence from the last two decades has confirmed that opioids are highly addictive

4.52 Opioids are also extremely addictive. Studies have found diagnosed addiction rates in primary care settings as high as 26%.[50] Among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-use disorder.[51]

4.53 Once a patient starts opioid treatment, it is extraordinarily difficult to stop. A 2017 CDC study determined that the probability of long-term use escalates most sharply after five days, and surges again when one month of opioids are prescribed.[52] A patient initially prescribed one month of opioids has a 29.9% chance of still using at one year.[53] In one study, almost 60% of patients who used opioids for 90 days were still using opioids five years later.[54]

4.54 The difficulty in stopping use is particularly true for patients first prescribed an extended release opioid. Patients who initiated treatment on an extended release opioid – such as Nucynta ER – have a 27.3% likelihood to be using opioids one year later, and a 20.5% likelihood of using opioids three years later.[55]

4.55 In 2013, the FDA observed that extended release opioids, like those Janssen markets, present "disproportionate safety concerns" and that the data show that the risk of misuse and abuse is greater for extended release opioids.[56] In requiring a new black-box warning on the

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[50] Dowell, *CDC Guideline for Prescribing.*

[51] Joseph A. Boscarino, Stuart N. Hoffman & John J. Han, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates*, 6 Substance Abuse and Rehabilitation 83 (2015); *see also* Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30 Journal of Addictive Diseases 185 (2011) (showing a 34.9% lifetime opioid use disorder).

[52] Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66 Morbidity and Mortality Weekly Report 265–269 (2017).

[53] *Id.*

[54] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26 J. Gen. Internal. Med. 1450 (2011).

[55] Shah, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015.*

[56] Woodcock Letter (Sept. 10, 2013).

labels of all immediate release opioids in March 2013, the FDA noted the "known serious risk[] of . . . addiction" which was present "even at recommended doses of all opioids."[57]

4.56 The CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" – a technical term for addiction.[58] The CDC emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[59]

4.57 Whether in the end a patient meets the clinical definition of addiction or is simply dependent and unable to stop using opioids, once opioids are prescribed for even a short period of time, patients are hooked.

4.58 Janssen's marketing strategy, and business model, relied on this fact and its profits depended on maintaining patients on opioids long term.

4.59 Because opioids cause tolerance and dependence, patients who take these drugs for even a short time become a physiologically captured market. If Janssen convinced a doctor and patient to start opioid treatment, Janssen knew that the patient would continue to take opioids.

5. Opioids are most dangerous when taken long-term and when taken in high doses

4.60 The risk of addiction and negative consequences increase when opioids are administered long-term.[60] In 2013, the FDA noted that the data shows that risk of misuse and abuse is greatest for extended release opioids and observed that these drugs are often used chronically.[61]

4.61 One study has shown that the duration of opioid therapy is a strong risk factor for opioid use disorder, even more important than daily dose (which in itself is a strong predictor of

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[57] Woodcock Letter (Sept. 10, 2013).

[58] Dowell, *CDC Guideline for Prescribing* at 2.

[59] Dowell, *CDC Guideline for Prescribing* at 21.

[60] *See e.g.* Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81 Drug and Alcohol Dependence 103, 104 (2006) (noting increased risk of addiction for long-term administration of opioids).

[61] Woodcock Letter (Sept. 10, 2013).

continued opioid use).[62] In fact, a study published in 2015 found that 1 in 5 patients on long-term opioid treatment will develop opioid use disorder.[63]

4.62 Higher doses of opioids are dangerous in a number of ways. A CDC clinical evidence review found that higher opioid dosages were associated with increased risks of motor vehicle injury, opioid use disorder, and overdose, and that the increased risk rises in a dose-dependent manner.[64] Another study found that higher daily doses and possible opioid misuse were also (a) strong predictors of continued use, and (b) associated with increased risk of overdoses, fractures, dependence, and death.[65]

4.63 Accordingly, the CDC recommended that physicians carefully reassess increasing opioid doses beyond 50 morphine milligram equivalents (MMEs), and avoid exceeding 90 MMEs/day.[66]

4.64 Measured against the general risk, the likelihood of developing an opioid use disorder increases threefold for acute patients prescribed even low dose opioids. For patients taking a daily dose of more than 120 MMEs over the long term, the chance of developing an opioid use disorder increases 122-fold.[67]

4.65 At high doses, patients are also at higher risk of poor functional status, increased pain sensitivity, and continuation of opioid treatment for a prolonged period.[68]

4.66 Overdose risk from opioids begins at very low doses and the risk doubles when the daily dose is between 20 MMEs and 49 MMEs; by 100 MMEs, the risk of death increases 9-

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[62] Mark J. Edlund, et al., *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-cancer Pain*, 30 Clin. J. Pain 557–564 (2014).

[63] WSAMDG, *Interagency Guideline*, citing Louisa Degenhardt et al., *Agreement between definitions of pharmaceutical opioid use disorders and dependence in people taking opioids for chronic non-cancer pain (POINT): a cohort study*, 2 The Lancet Psychiatry 314–322 (2015).

[64] Dowell, *CDC Guideline for Prescribing* at 22-24.

[65] Edlund, *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-cancer Pain.*

[66] Dowell, *CDC Guideline for Prescribing* at 22-24.

[67] WSAMDG, *Interagency Guideline* at 7-8.

[68] WSAMDG, *Interagency Guideline* at 13.

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fold.[69] Recent studies of Washington workers' compensation and Medicaid populations found that nearly half of all overdose hospitalizations occur in patients who are on intermittent or lower dose opioids. [70]

4.67 Overall, 1 in every 550 patients on opioid treatment dies of opioid-related causes a median of 2.6 years after their first opioid prescription. That number increases to 1 in 32 for patients receiving 200 MMEs/day.[71]

4.68 In short, there are no safe opioid doses, but the higher the dose and the longer the treatment duration, the more likely it is serious adverse events will occur.

6. Opioids are only moderately effective at short-term relief

4.69 Although there is evidence that opioids are effective in treating acute and short-term painful conditions, the perception of their effectiveness exceeds their actual utility.

4.70 Even for short-term use, opioids are only modestly effective. In a 2004 meta-analysis, opioids reduced pain by only 30%, or 2 points on a scale of 1-10 over placebo for neuropathic pain conditions. For osteoarthritis, musculoskeletal pain, and mixed pain conditions, opioids provided either insignificant relief or less than the 30% reduction.[72] Even then, several studies suggest that ibuprofen and acetaminophen are better than opioids at relieving pain such as dental pain, low back pain, and moderate acute traumatic pain.[73]

B. FDA Requirements for Promotion of Prescription Drugs

4.71 The Food and Drug Administration (FDA) regulates drugs manufactured for sale in the United States. But the FDA's regulatory scheme is limited in important ways and Janssen took advantage of those limitations. While the FDA approves drugs and drug labels, the drug companies remain liable for misleading marketing under both federal and state law.

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[69] WSAMDG, *Interagency Guideline* at 12.
[70] WSAMDG, *Interagency Guideline* at 13.
[71] Frieden, *Reducing the Risks.*
[72] Rubenstein, *Are We Making Pain Patients Worse?*
[73] Teater, *The Psychological and Physical Side Effects.*

4.72 As a pharmaceutical manufacturer that markets opioids, Janssen is subject to federal rules requiring truthful marketing of prescription drugs. The Food, Drug & Cosmetic Act (FDCA) regulates the promotion of prescription drugs. 21 U.S.C. §§ 301, *et seq.* The FDA must approve a drug's label and promotional activity at the time of application.[74]

4.73 Drug companies' promotional activity can be branded or unbranded. Unbranded marketing does not refer to a specific drug, but promotes a type of treatment generally, and unbranded materials are not typically reviewed by the FDA. Moreover, by using unbranded communications, drug companies can evade the regulatory framework governing branded communications.

4.74 Conversely, branded marketing, which identifies and promotes a specific drug, such as Nucynta ER, is subject to FDA review and must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[75]

4.75 The FDCA expressly prohibits the sale of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[76] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional

[74] The FDCA, 21 U.S.C. § 321(m), defined labeling to include "all labels and other written, printed, or graphic matter . . . accompanying [a drug]." Title 21, Code of Federal Regulations, Section 202.l(1)(2) provided that labeling included brochures, booklets, mailing pieces, detailing pieces, bulletins, letters, motion picture films, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug which were disseminated by or on behalf of a drug's manufacturer, packer, or distributor. Such items "accompanied" a drug if they were designed for use and used in the distribution and sale of the drug.

[75] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 21 C.F.R. § 202.1(e)(6).

[76] 21 U.S.C. § 352(a).

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material.[77] Thus, Janssen's promotional materials are part of its drugs' labels and required to be accurate, balanced, and not misleading.[78]

4.76 Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to any presentation of efficacy." The FDA notes that "[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included."[79] Promotional materials or marketing that fail to present the drug's most significant risks as prominently as its benefits lack fair balance and are therefore deceptive.[80]

4.77 Janssen is also prohibited from distributing materials that exclude contrary evidence or information about the drug's safety or efficacy or that present conclusions that "clearly cannot be supported by the results of the study."[81] Pharmaceutical companies must not make comparisons between their drugs and other drugs in which they represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[82]

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[77] 21 U.S.C. § 321(m) "The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.

[78] The FDCA, 21 U.S.C. § 321(n), states that "[i]n determining whether the labeling . . . [was] misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representation or material with respect to the consequences which may result from the use . . . to which the labeling . . . relates under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual."

[79] FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, at 14 (2009).

[80] The State is not alleging a cause of action against Johnson & Johnson for mislabeling under the Food, Drug & Cosmetic Act. The State's deception claims are alleged herein pursuant to Washington's Consumer Protection Act, RCW 19.86.

[81] 21 C.F.R. § 99.101(a)(4).

[82] 21 C.F.R. § 202.1(e)(6)(ii).

4.78 The public policy underpinning this regulatory framework is designed to ensure that drug companies, which are in the best position to understand the effects and risks of their drugs, are responsible for providing prescribers with the information the prescribers need to accurately assess the risks and benefits of drugs for their patients. Janssen's misbranded marketing and deceptive unbranded marketing of opioids are contrary to that purpose.

4.79 While the FDA must approve a drug's label, it is Janssen's responsibility to ensure that the material in its label is accurate and complete and to update the label[83] to reflect any new information. Promotional materials also must be submitted to the FDA when they are first used or disseminated, however the FDA does not have to approve these materials in advance.

4.80 The FDA does not monitor the in-person sales representatives detailing visits to prescribers. The FDA does not ask companies to submit preplanned messages or training materials such as sales scripts, talking points, sales bulletins, or sales training videos that are provided to sales representatives for their study and use making a sales pitch to prescribers. The FDA does not require submission of any prepared text in response to unsolicited drug queries made to pharmaceutical companies by prescribers; and the FDA does not directly regulate funding for or content of continuing medical education.[84]

4.81 The FDA-approved labeling does not address the most crucial component of this lawsuit—the long-term (beyond 12 weeks) use of opioid medications. Through this gap in FDA regulation, Janssen drove a multibillion-dollar experiment with disastrous results.

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[83] *See* 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); see also *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6)(iii)(A-C) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction" or "strengthen a statement about drug abuse, dependence, psychological effect, or overdosage").

[84] Jesse R. Catlin & Cornelia (Connie) Pechmann, *An Investigation of Consumer and Doctor Regulatory Beliefs and Regulatory Knowledge About Pharmaceutical Drug Promotions*, 1 J. Ass'n of Consumer Research 392 (2016); U.S. Dep't of Health and Human Servs. et al., *Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices* (2011), *hereafter as*: Catlin, *An Investigation.*

4.82 In addition, Janssen's marketing, described below, operated outside the FDA labeling system. For example, as the FDA explained, the label is designed to encourage prescribers to exercise "thoughtful determination" that pain is "*severe enough* to require daily, around-the-clock, long-term opioid treatment."[85] Janssen's marketing through unbranded, and therefore unregulated, materials manipulated prescribers' and patients' perception of when pain was severe enough and when opioids were required.

4.83 Additionally, although the labels contain warnings about addiction, the severity of that risk is not quantified. Janssen's marketing, both branded and unbranded, asserted that screening, abuse deterrent formulations, or urinalysis can adequately manage the risk of developing an addiction without evidence to support those claims.

C. Washington State Has a Public Policy Interest in Reducing Opioid Addiction and Abuse

4.84 In contrast to the federal labeling regulatory scheme, Washington State's consumer protection statute and common law protect consumers from the kind of marketing conduct that Janssen employed to encourage the most dangerous kind of opioid use in spite of growing and irrefutable evidence of widespread negative impacts.

4.85 Washington State has a strong public policy to preserve and protect the health and welfare of its citizens by ensuring high-quality health care and preventing abuse of prescription and non-prescription drugs.

4.86 Washington regulates the practice of medicine because "the health and well-being of the people of this state are of paramount importance." RCW 18.71.003.

4.87 Washington has a strong public policy to prevent opioid addiction and abuse. Washington has categorized opioids as Schedule II drugs, RCW 69.50.206(b)(1), meaning that

[85] Woodcock Letter (Sept. 10, 2013).

they have "a high potential for abuse," which "may lead to severe psychological or physical dependence."[86]

4.88 To further its public policy, Washington has taken steps to regulate opioid use. This was prompted initially by the Washington workers' compensation system, which saw a dramatic increase in Schedule II opioid prescribing from 1996 to 2002, and a 50% increase in the average daily MME among injured workers taking these potent medications.[87] By 2000, the Department of Labor & Industries noted an alarming rise in overdose deaths.[88] A manual review of all opioid overdose death certificates by the Department of Health showed an increase in the number of overdose deaths involving prescription opioids from 24 in 1995 to 351 in 2004. By 2006, the CDC had identified Washington to be in the highest tertile of mortality (10.8 deaths/100,000)[89] from unintentional drug overdoses in the United States. At that same time, approximately 10,000 Washington patients in public insurance programs were taking at least 120 milligrams per day MED.[90] Accordingly, Washington acted.

4.89 In March 2007, the Washington State Agency Medical Directors' Group (AMDG), consisting of the medical directors for the Washington State Departments of Corrections, Social and Health Services (Medicaid), Labor and Industries, and the Health Care Authority, published its "Interagency Guideline on Opioid Dosing for Non-cancer Pain: An educational guide to improve care and safety with opioid therapy." Washington was the first jurisdiction in the country to issue guidelines recommending caution in using high dose opioids.[91]

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[86] RCW 69.50.205(a)(1) & RCW 69.50.205(a)(3).

[87] Franklin, *A Comprehensive Approach* at 464, citing to n.16.

[88] *Id.*

[89] Franklin, *A Comprehensive Approach* at 464, citing to n.14.

[90] Franklin, *A Comprehensive Approach* at 464; Strong epidemiological studies now support a dosing threshold or range around 80 to 100 milligrams per day. Franklin, *A Comprehensive Approach* at 465, citing to n.27-29.

[91] Franklin, *A Comprehensive Approach,* at 464, citing to n.18. In 2006 a consortium of all WA agencies that purchase or regulate health care (the Agency Medical Directors' Group (AMDG) collaborated with 15 WA pain management experts (the Clinical Advisory Group) to develop an opioid prescribing guideline.

4.90 The 2007 AMDG guidelines were relatively simple, with modest recommendations. Noting that increasing opioid doses may not improve pain control and function, the guideline recommended the lowest possible effective dose, and monitoring of function rather than pain scores. If function did not improve, if adverse effects occurred, or if there were drug-seeking behaviors, the guidelines recommended discontinuing opioids. The guidelines proposed a 120 MME dose as threshold for seeking specialized care.

4.91 In 2009, the Washington Attorney General's office funded a study on how the AMDG guideline was functioning. Among the findings from the study was that Schedule II opioids represented the largest increase in opioid prescriptions from 1996 to 2008, and the average daily dose of long-acting opioids, like those sold by Janssen, had steadily increased from the late 1990s.

4.92 In 2010, the AMDG issued updated guidelines that provided tools for calculating dosages, screening for substance abuse, mental health, and addiction, clinical tools, and patient education materials and resources.

4.93 Also in 2010, the Washington Legislature began enacting legislation to address the threat opioids posed to public health. Public testimony, as summarized by non-partisan legislative staff, revealed the concerns motivating lawmakers:

> Over the last decade we've seen a huge increase in the dosing levels of narcotics and that has driven a dramatic increase in dependency, addiction, overdoses, deaths, and bad interaction with other drugs. This is a public health emergency. More people die from prescription drug overdoses in this state than in car accidents. We have to change prescribing practices, through education and setting guidelines, to help practitioners who are under pressure to increase doses well beyond what is safe and useful. The rampant use of opiods [*sic*], sold as prescriptions, means that kids think these are safe and are using them straight out of their parents' medicine cabinets . . . . We have to stop drug surfing and find ways to assist practitioners and pharmacists who feel at risk because the demand for these drugs is so high.

4.94 This public testimony about the burgeoning opioid epidemic resulted in a strong bi-partisan consensus to confront the public health problems caused by opioid use. The Senate

voted 36-12 and the House of Representatives voted 96-1 to require Washington medical boards to adopt new regulations.

4.95 In accordance with the Legislature's directive, those agencies promulgated new standards for opioid prescriptions for the treatment of chronic non-cancer pain. The Department of Health explains that:

> The boards and commissions are committed to protecting and improving the health of people in Washington State. The pain management rules' goals are to keep patients safe, and to give practitioners who prescribe opioids the best practices in pain management. A key component of the rules is to encourage practitioners to become better educated in the safe and effective uses of these powerful drugs.

4.96 As it had with the first set of guidelines, Janssen opposed Washington's efforts to urge caution. As discussed below, Janssen partnered with the American Pain Foundation and provided significant material support to the Washington Pain Alliance to oppose the new regulations in Washington State.

4.97 The new guidelines had a significant effect. Prescription opioid overdose death rates in Washington declined by 27% from 2008 to 2012, and overdose hospitalization rates declined for the first time in 2012. The percentage of Washington residents who have used prescription pain medication nonmedically in the past year declined from 6.2% in 2009-2010 to 5.1% in 2011-2012.

4.98 Unfortunately, although Washington has seen a decline in prescription overdose deaths, it has been more than offset by a corresponding rise in heroin and fentanyl related overdose deaths. The rise in illicit opioid deaths is a foreseeable consequence of Janssen's manipulation of the opioid market. Nearly 80% of heroin users report using prescription opioids before beginning heroin use.[92] Having created physically dependent patients through widespread

[92] *Prescription Opioids and Heroin*, National Institute on Drug Abuse, https://www.drugabuse.gov/publications/research-reports/prescription-opioids-heroin.

opioid prescribing, efforts to restrict prescribing inevitably pushed those patients into finding alternate sources of opioids.

4.99 In June 2015, the AMDG released another update to the Interagency Guidelines. Washington Secretary of Health John Wiseman noted that "Washington and many other states are in the midst of an epidemic of opioid misuse, abuse, and overdose," and warned that "[a]lthough opioids can be a useful option for pain management, their inappropriate use can result in significant harms, including addiction and death." He therefore urged prescribers to "help us improve the health of Washington residents by following this updated AMDG evidence-based practice guideline."[93]

4.100 The 2015 AMDG guidelines recommend reserving opioids for acute pain resulting from severe injuries or medical conditions when alternatives are ineffective or contraindicated. Even then, opioids should be prescribed at the lowest necessary dose and for the shortest duration and should not be prescribed at all for low back pain, headaches, or fibromyalgia. Long-term opioid use is not recommended unless there is sustained clinically meaningful improvement in function, and, even then, it is to be carefully monitored.

4.101 In 2016, Governor Jay Inslee issued an executive order recognizing that medically prescribed opioids have contributed to an opioid epidemic that is devastating Washington communities and families, and overwhelming law enforcement, health care, and social service providers. Governor Inslee directed state agencies to prevent inappropriate opioid prescribing, reduce opioid misuse and abuse, expand treatment resources, and use data to detect and intervene to prevent mortality. At the same time, Washington created an interagency opioid working plan to implement the Governor's order.

4.102 In addition to medical guideline and legislative action, Washington's consumer protection laws also prohibit Janssen from engaging in unfair or deceptive acts or practices in the conduct of any trade. As is detailed below, Janssen played a unique role in expanding the opioids

[93] WSAMDG, *Interagency Guideline*.

market, acting as both a supplier of pharmaceutical ingredients to other manufacturers and as a manufacturer itself. Its marketing was both deceptive and misleading and, in the context of the addictive and deadly properties of opioids, unfair to the citizens of Washington.

D. Janssen Was a Top Supplier of Raw Ingredients for Other Opioid Manufacturers

4.103 From the 1990s through at least 2016, Johnson & Johnson wholly owned two subsidiaries that, together, supplied other opioid manufacturers with APIs to be used in opioid drugs.

4.104 Johnson & Johnson owned a subsidiary based in Tasmania, Tasmanian Alkaloids Limited, which cultivated and processed opium poppy plants to manufacture narcotic raw materials that were imported into the U.S. to be processed and made into APIs necessary to manufacture opioid drugs.

4.105 Johnson & Johnson also owned a subsidiary based in the U.S., Noramco, which imported the narcotic raw materials produced by Tasmanian Alkaloids, processed these materials into APIs, then sold these APIs to other opioid manufacturers in the U.S.

4.106 Up until 2016 when Johnson & Johnson sold Noramco and Tasmanian Alkaloids, Tasmanian Alkaloids and Noramco were sister companies, as both of them were members of Janssen's "family of companies."

4.107 Janssen, Noramco, and Tasmanian Alkaloids shared employees and resources that were required to operate the business. Noramco employees physically worked at Janssen's facilities in New Jersey at various times. Further, employees simultaneously held positions at multiple companies within the Johnson & Johnson family of companies at times.

4.108 During this time, Noramco and Tasmanian Alkaloids were key parts of Janssen's "pain management franchise" or "pain franchise." This "pain franchise" included all of Janssen's pain products and was an important part of Janssen's business from the mid-1990s to after 2010.

4.109 Janssen, through these subsidiaries, supplied the following opioid active pharmaceutical ingredients to other drug manufacturers in the U.S., including Purdue and Teva:

oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.

4.110 Johnson & Johnson's ownership of these subsidiaries uniquely positioned its pain management franchise to provide U.S. drug manufacturers, including Johnson & Johnson itself, with a reliable supply of and direct access to narcotic raw materials.

4.111 Janssen, in concert with its subsidiary Tasmanian Alkaloids, anticipated demand for oxycodone. Specifically, Janssen's scientists at Tasmanian Alkaloids began a project to develop a high thebaine opioid poppy variety to meet anticipated demand. The result of Janssen's research project was the creation of the "Norman Poppy," which Janssen internally described as "a transformational technology that enabled the growth of oxycodone."

4.112 In 1994, Purdue filed its new drug application (NDA) for OxyContin. Through Noramco, Janssen met the anticipated opioid demand by selling APIs, including oxycodone, to Purdue.

4.113 Purdue relied largely on Johnson and Johnson's thebaine supply for its production of its drugs, including OxyContin. A 1998 letter from an executive from Noramco, another Johnson and Johnson subsidiary, to Purdue Frederick Laboratories (later Purdue Pharma) read, "Noramco will work with PF Laboratories to secure its entire, worldwide requirements. This is not a minor point. As we have discussed, access to raw materials is going to be critical to obtaining security of supply." It goes on, "gaining access to raw materials on a worldwide basis . . . simply cannot be provided by any other company."[94]

4.114 Through Noramco, Janssen also supplied APIs to other opioid manufacturers, including Teva. Noramco sold the majority of its products pursuant to long-term agreements it had with all seven of the top U.S. generic companies.

[94] Letter from Michael B. Kindergan, Noramco of Delaware, Inc., (October 15, 1998) available at https://www.documentcloud.org/documents/6145945-Letter-From-Noramco-to-PF-Laboratories.html.

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4.115 By 2015, Janssen's "Noramco World Wide Narcotics Franchise," comprised of Noramco and Tasmanian Alkaloids, had become the top supplier of narcotic APIs in the U.S., the world's largest market.

E. Janssen Used Sophisticated Branded and Unbranded Marketing Targeted at Washington Health Care Providers and Patients to Boost Opioid Prescribing and Its Own Profits

4.116 Janssen's pain management franchise engaged in a marketing campaign to deceive health care providers and patients into believing that opioids in general and Janssen drugs in particular were effective and safe, and should therefore be widely prescribed. Upon information and belief, Janssen centrally developed its marketing strategies and materials, which were deployed at the local level in Washington and nationwide.

4.117 After seeing the success Purdue had in marketing OxyContin for chronic, non-cancer pain, Janssen set out to market its fentanyl-based Duragesic patch and Nucynta for chronic, non-cancer pain as well.[95]

4.118 Janssen's deceptive opioid marketing focused on convincing doctors that (a) opioids were effective at relieving pain and improving function; (b) the adverse effects of opioids (including addiction) were overstated and could be managed; and (c) in light of (a) and (b), opioids were a superior option to other pain treatments.

4.119 Janssen, in coordination with others, began a major campaign to use branded and unbranded marketing to disseminate the messages that pain was undertreated, and that there was a low risk of abuse and low danger of prescribing opioids to treat chronic, non-malignant pain. The campaign also overstated the efficacy of opioids as a class of drug.[96] This campaign benefitted Janssen's branded product as well as the raw product sold by Janssen's pain management franchise to generic and other branded products.

[95] Oklahoma Judgment, Finding of Fact 17.
[96] Oklahoma Judgment, Finding of Fact 18.

4.120 Janssen marketed to Washington doctors in a number of ways, including but not limited to providing "education" by sales representatives, publishing literature in medical journals and publications that Janssen funded, disseminating materials from professional societies and advocacy groups, funding continuing medical education paid for by Janssen and others, and funding unbranded marketing materials. Janssen also paid speakers, and sponsored dinners, seminars, symposiums, and conferences.[97]

4.121 Janssen advanced the concept that chronic pain was undertreated, and that increased prescriptions for opioids would solve the problem. Janssen used unbranded marketing to heighten "awareness of under treatment of pain," and used "emotional selling" to physicians to convince them that undertreated pain was harming patients.[98]

4.122 Janssen also promoted an unbranded marketing message that increasing opioid use was necessary to avoid undertreated acute pain inevitably turning into chronic pain.[99]

4.123 Janssen knew that its in-person marketing worked. The effects of sales calls on prescribing behavior are well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling of sales calls.[100] A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[101] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures.[102]

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[97] Oklahoma Judgment, Finding of Fact 19. Upon information and belief, the same marketing occurred in Washington.

[98] Oklahoma Judgment, Finding of Fact 20.

[99] Oklahoma Judgment, Finding of Fact 21.

[100] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221–227 (2009), *hereafter as*: Van Zee, *The Promotion and Marketing of OxyContin.*

[101] Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. Am. Med. Ass'n 1785 (2017).

[102] *Id.*

4.124 Janssen pushed this central, deceptive message in ways strategically designed to deceive health care providers and patients. As discussed below, Janssen authored and disseminated both its own branded materials, as well as unbranded materials from third-party groups that Janssen funded but which were designed to look independent. Janssen followed these materials with one-on-one visits to health care providers to persuade them to prescribe more Janssen opioids.

1. Janssen chased growth by promoting both opioids generally and its brand-name drugs in particular

4.125 Unsurprisingly, Janssen's marketing strategy encompassed promotion of both (a) opioid therapy in general, and (b) its own opioids – Nucynta and Nucynta ER, Durgesic, Ultram, Ultram ER, Ultracet, and Tylenol with Codeine– in particular. Promotion of opioids in general was important to Janssen's business plan and marketing strategy for several reasons.

4.126 First, by deceptively changing the medical community's and public's perception of opioids as a class of drugs, Janssen also sought to change the perception of its own opioid products, which were part of that larger class. Although Janssen would not capture *all* the benefits of its investment in general opioid re-education, it would profit handsomely by increased prescriptions of its own brand-name drugs. Additionally, Janssen's pain management franchise would benefit from increased prescriptions of generic and other branded products by selling by selling raw materials to many of those manufacturers.

4.127 Janssen carefully coordinated its sponsored Continuing Medical Education courses (CME) marketing with its one-on-one sales representative visits to maximize conversions to Nucynta ER and its other extended release opioids.

4.128 For example, Janssen paid knowledge opinion leaders (KOLs) to give speeches, talks, and speak at continuing medical education seminars (CMEs) about opioids, advocating that they could be used effectively to treat things like chronic pain and downplaying the risk of addiction and abuse. By operating through KOLs, Janssen added perceived legitimacy and/or

impartiality to their misrepresentations regarding opioids. Janssen continued to selectively support and disseminate misleading materials from third party groups.

4.129 Janssen enhanced the credibility of its marketing messages by distributing, presenting, or causing to be published studies, articles, and presentations. To disseminate this content, Janssen funded multiple front groups. This sponsorship created "[s]ignificantly greater advocacy strength" for Janssen.

4.130 Janssen had an active grant program supporting third party organizations. Janssen made substantial payments to the following groups:

a. American Academy of Pain Management/Academy of Integrative Pain Management;

b. American Academy of Pain Medicine;

c. American Pain Society;

d. American Pain Foundation;

e. American Geriatrics Society;

f. American Chronic Pain Foundation;

g. Pain and Policies Study Group;

h. Pain Care Forum;

i. American Society of Pain Management Nursing;

j. National Pain Foundation;

k. Center for Practical Bioethics; and the

l. Joint Commission on Accreditation of Healthcare Organizations.

4.131 On information and belief, many of these grants were targeted for specific purposes to assist Janssen's marketing efforts. For example, pharmaceutical companies, including Janssen, provided almost all of the funding for the American Pain Foundation (APF), which

offered publications for health care providers, patients, policymakers and journalists.[103] APF's materials, discussed below, contain misrepresentations about opioids' efficacy and safety.

4.132 Janssen provided funding for the Let's Talk Pain Coalition, founded by the American Pain Foundation and other advocacy groups.

4.133 The Coalition's Let's Talk Pain website stated that "the stigma of drug addiction and abuse" associated with opioids stemmed from a "lack of understanding about addiction." The website perpetuated the concept of "pseudoaddiction," associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception," with undertreated pain that can be addressed with "effective pain management."

4.134 Two organizations funded by Janssen, American Academy of Pain Management and American Pain Society, issued a "Consensus Statement" in 1996. A committee drafted this statement, and included the following individuals:

i. Robert Angarola, an attorney who represented opioid manufacturers,

ii. David Haddox, a medical director for Purdue, another opioid manufacturer,

iii. David Joranson, founder of Pain and Policies Study Group,

iv. Richard Payne, co-leader of Janssen's National Pain Education Council program,

v. Matthew Midcap, who had a financial relationship with Janssen,

vi. Daniel Carr, who had a financial relationship with Janssen,

vii. Dr. Portenoy, a knowledge opinion leader described above.

[103] Charles Ornstein & Tracy Weber, *The Champion of Painkillers*, Propublica, Dec. 23, 2011, https://www.propublica.org/article/the-champion-of-painkillers.

4.135 The Consensus Statement suggests pain is undertreated and doctors should prescribe more opioids, and described fears of addiction, regulatory action, and diversion as "impediments" to the use of opioids.[104]

4.136 Janssen actively promoted the Consensus Statement, and repeated its statements in its own marketing.[105]

4.137 Janssen also provided funding to the American Geriatrics Society, a nonprofit organization that serves health care professionals who work with the elderly. In 2002 and 2009, this organization disseminated guidelines regarding the use of opioids for chronic pain.[106] Janssen contracted with the organization to disseminate the guidelines and create continuing medical education based on them.

4.138 The 2009 guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any reliable scientific evidence.

4.139 Dr. Gilbert Fanciullo, a retired Dartmouth medical professor who served on the panel that developed the guidelines, has now described them as "skewed" by drug companies, and "biased in many important respects," by, among other things, promoting a including high presumptive maximum dose, omitting urine toxicology testing, and including false claims of low addiction risk.

4.140 The American Geriatrics Society impacted the national medical community. The guidelines are still available online, were reprinted in the Journal of Pain, influenced treating physicians, and have been cited in academic literature over 1,600 times according to Google Scholar.

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[104] Oklahoma Judgement, finding of fact 38.

[105] Oklahoma Judgment, finding of fact 39.

[106] The American Geriatrics Society 2002 Guidelines are called The Management of Persistent Pain in Older Persons. The 2009 Guidelines are called Pharmacological Management of Persistent Pain in Older Persons.

4.141 Janssen's marketing strategy also included medical education activities. Janssen created and funded the National Pain Education Council, which provided continuing medical education to primary care physicians, pain specialists, oncologists, residents, nurses, and pharmacists related to pain and opioids. Janssen's 2003 Business Plan Summary for Duragesic described this Council as serving "to benefit not only DURAGESIC but also all future Janssen pain products." [107]

4.142 National Pain Education Council continuing education materials included false and misleading statements regarding opioids and pain management.[108]

2. Janssen engaged in deceptive marketing to Washington health care providers

4.143 Janssen marketed its brand-name opioids, such as Nucynta, Nucynta ER, and Duragesic directly to health care providers in Washington through visits from sales representatives. These sales representatives misleadingly portrayed the risks and benefits of opioids – particularly Janssen-branded drugs – for the treatment of chronic non-cancer pain, and worked systematically to increase prescriptions of Janssen opioids.

4.144 Janssen sought to reach doctors through multiple means and at multiple times through their professional education and career. Examples of such outreach include "education" from sales representatives, literature funded by Janssen in medical journals and publications, the development and dissemination of materials from professional societies and patient advocacy groups, continuing medical education funded by Janssen, unbranded marketing materials, and Janssen paid speakers. Other examples include dinners, doctor presentations, seminars, symposiums, and conferences. These efforts were intended to influence the prescribing behavior of physicians to increase Janssen's profits from opioids.[109]

4.145 Upon information and belief, Janssen carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of Janssen's drugs in

[107] Oklahoma Judgment, findings of fact 40-41.
[108] Oklahoma Judgment, finding of fact 42.
[109] Oklahoma Judgment, finding of fact 19.

particular and opioids in general. To ensure that sales representatives delivered the desired messages to prescribers, Janssen directed and monitored its sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' call notes from each visit. Janssen likewise required its sales representatives to use sales aids reviewed, approved, and supplied by the company and forbade them from using promotional materials not approved by the company's marketing and compliance departments. Janssen further ensured marketing consistency nationwide through national and regional sales representative training.

4.146 Janssen trained its sales representatives to avoid the "addiction ditch," which meant to avoid negative terminology such as the word "addiction," and to emphasize positives such as the purported efficacy of opioids in its sales calls. Janssen also trained its representatives to use a study from Dr. Portenoy to "create dialogue about Opiophobia as a barrier."[110]

4.147 Janssen trained its sales representatives that there was a 2.6% or lower risk of addiction when using opioids prescribed by a doctor. Janssen also trained its sales representatives to "establish that moderate to severe acute pain continues to be undertreated."[111]

4.148 It did so for a reason: studies indicate that marketing can and does impact doctors' prescribing habits,[112] and also indicate that face-to-face "detailing" – which Janssen engaged in heavily, as described below – has the greatest influence.

In addition to "handling" the "objections" of health care providers who were not inclined to prescribe opioids, Janssen sought to become a "resource" and a source of information to which health care providers looked in making prescribing decisions. Upon information and belief, they

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[110] Oklahoma Judgment, finding of fact 27.

[111] Oklahoma Judgment, finding of fact 28.

[112] *See, e.g.*, Puneet Manchanda & Pradkeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 Mktg. Letters 129 (2004) (detailing impacts prescriptions written); Ian Larkin, et al., *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33 Health Aff. 1014 (2014) (academic medical centers that restricted direct promotion by sales representatives resulted in 34% decline in on-label use of promoted drugs).

did so by delivering and discussing the sort of deceptive unbranded materials described below directly to Washington prescribers to help "educate" them one-on-one.

4.149 Janssen paid bonuses to sales representatives based on the number of Nucynta prescriptions written by prescribers they visited. Some representatives received bonuses exceeding $20,000 per quarter. Some representatives had daily goals of eight prescriber visits and three pharmacy visits.

4.150 Janssen trained its sales representatives to target physicians who prescribed high amounts of opioids, including certain pain specialists and primary care physicians. Janssen refereed to certain primary care physicians as "Key Customer[s]" for its pain franchise. [113]

4.151 To promote Nucynta and Nucynta ER, Janssen created a "speakers' bureau program." Janssen created this program by hiring, training, and deploying speakers—mostly practitioners—to present a slide deck written by Janssen to encourage healthcare providers to prescribe Janssen products.

4.152 The speakers' bureau was a reward for writing Nucynta prescriptions. Janssen handsomely compensated speakers in the program. This incentivized physicians to prescribe Nucynta.

4.153 Janssen trained hundreds of speakers nationwide to promote Nucynta on a branded slide deck even before the FDA approved the drug. After the FDA approved Nucynta, Janssen sponsored thousands of in-person and on-line speaker programs each year. In 2010, Janssen sponsored over 3,000 live speaker programs.

4.154 By 2012, Janssen speakers promoted Nucynta through many platforms, including in-person speaker programs, live on-line virtual speaker programs, archived video presentations, dissemination of slide decks used by its sales force, and web-based news channels.

4.155 By 2012, Janssen used two primary virtual platforms, "Speaker Direct" and "Meeting Direct." Speaker Direct involved live video conferences with healthcare providers.

[113] Oklahoma Judgment, finding of fact 30.

Meeting Direct involved live and archived video conferences with predetermined meeting schedules. In the first 15 weeks of Meeting Direct, Janssen sponsored 128 programs with 5,423 attendees.

4.156 Slide decks used by Janssen speakers also referred prescribers to its Prescribe Responsibly website, discussed in more detail below.

4.157 Janssen did not train its sales representatives about red flags that could indicate a "pill mill," such as patients lining up out the door of a pain clinic, or passed out in the waiting room.[114]

4.158 Janssen promoted Nucynta and Nucynta ER through sales representatives who called or visited Washington prescribers. Upon information and belief, Janssen's sales representatives verbally conveyed messages to prescribers in targeted, one-on-one settings, and showed or distributed to prescribers printed or electronic marketing materials promoting Nucynta and Nucynta ER.

4.159 Finally, both third-party materials and Janssen-branded educational resources were targeted at patients, and designed to persuade patients through misleading statements, that opioids were both effective and safe. Janssen created and disseminated marketing materials directly to patients, such as the patient brochure "Finding Relief." The Finding Relief brochure promoted the concept that pain was undertreated.[115] In addition, the guide claimed, without evidence, that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'" The guide stated that people should expect functional improvements such as sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

4.160 Upon information and belief, Janssen also disseminated non-branded marketing materials directed toward patient consumers, such as the Let's Talk Pain website, patient comfort

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[114] Oklahoma Judgment, finding of fact 33.
[115] Oklahoma Judgment, finding of fact 24.

assessment guides, and other resources guiding patients to use opioids. Similarly, as discussed below, various third party groups produced patient guides and pamphlets that Janssen either distributed or sponsored.

F. Using These Marketing Channels, Janssen Disseminated Deceptive Statements and Assertions Designed to Increase Opioid Prescriptions

4.161 As described in more detail below, Janssen engaged in numerous deceptive or unfair acts and practices designed to convince health care providers to continue prescribing opioids despite the lack of evidence of effectiveness and despite the risks of opioid use, including without limitation:

a. Marketing Janssen's opioid drugs, both directly and indirectly through third party groups, as a solution to the under treatment of pain and either stating directly, or implying, that opioids are effective to treat or relieve long-term chronic pain;

b. Marketing Janssen's opioid drugs, both directly and indirectly through third party groups, for the treatment of specific pain conditions including neurological pain, headaches, low back pain, and fibromyalgia, despite evidence that opioids were not effective at treating these conditions;

c. Selectively supporting third party groups and employing unbranded marketing to promote and defend the long-term use of opioids and at higher doses as an effective pain relief tool for the treatment of chronic pain;

d. Misrepresenting and making unsubstantiated claims that, and the extent to which, opioids improve function;

e. Misrepresenting the truth and making unsubstantiated claims about how (and how frequently) opioids lead to addiction and the extent to which addiction risk can be managed and addiction prevented;

f. Misleadingly using terms like addiction, dependence, tolerance, physical dependence, and "pseudoaddiction" to persuade health care providers and patients that the addiction risk of opioids could be successfully managed;

g. Misrepresenting and making unsubstantiated claims that increased doses of opioids do not pose significant additional risks;

h. Misrepresenting and making unsubstantiated claims about the challenges entailed in managing withdrawal;

i. Misrepresenting and making unsubstantiated claims regarding the factors for comparing the risks and benefits of opioids with those of alternative forms of pain treatment; and

j. Marketing Janssen's abuse deterrent formulations of opioid medications as a means of reducing abuse and addressing the opioid epidemic without any evidence to support such a claim. Janssen intended prescribers and policy makers to believe these abuse deterrent formulations were safer than opioids without these formulations.

1. Janssen's deceptive acts or practices relating to opioids' ability to improve function

4.162 Consistent with Janssen's marketing strategy described above, Janssen made deceptive and unsubstantiated claims regarding the efficacy of opioids in general and its own drugs in particular.

4.163 Opioids may initially improve function by providing pain relief in the short term, but as explained above there is no evidence that opioids improve patients' function in the long-term.

4.164 Despite the lack of evidence of improved function long-term, Janssen deceptively promoted opioids as improving function and quality of life without disclosing the lack of evidence for this claim. For example:

a. Janssen portrayed its Nucynta and Nucynta ER products as having a "dual mechanism of action," acting as both an opioid and a norepinephrine reuptake inhibitor (NRI). NRIs communicate between brain cells. But Janssen's evidence for this second aspect of functionality was only preclinical studies, which are, according to the FDA, "not a substitute for studies of ways the drug will interact with the human body."[116] Nucynta's exact mechanism of action is unknown, however. Janssen therefore used this line of promotion both to overstate the functionality of Nucynta, and to understate its risk for addiction by portraying it as a milder option to other Schedule II opioids.

b. Needing evidence to enhance its promotion of Nucynta, Janssen and its subsidiaries funded and created their own studies. One 2011 study, funded by Ortho-McNeil Janssen Scientific Affairs, LLC, a Janssen subsidiary, and authored by that company's employees, concluded that patients suffering from "mixed pain" suffered from worse quality of life than non-mixed pain patients, and therefore needed broad-spectrum or dual action opioids such as Nucynta to improve functionality and quality of life.

c. Another study, in 2010, funded by the same subsidiary, concluded that patients with mixed pain in the neck or back had higher costs and more work absence than those with single component pain. Again, the self-serving conclusion of the study was for prescribers to use more broad-spectrum pain medications such as Nucynta and Nucynta ER.

4.165 As noted above, the available evidence indicates opioids are not effective to treat chronic non-cancer pain – indeed; they may harm patients' health.[117] Thus, "for the vast majority

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[116] FDA, "The Drug Development Process, Step 3: Clinical Research," https://www/fda/gov/For{atients/Approvals/Drugs/ucm405622.htm.

[117] *See, e.g.* Furlan, *Opioids for Chronic Noncancer Pain*. Furlan noted that even those studies that did show efficacy did not typically show data on opioid addiction, and also pre-screened the study pool to remove patients who might have been more prone to addiction; *see also* Dersh, *Prescription Opioid Dependence*.

of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[118] Janssen's claims of efficacy for its Nucynta pain franchise, and other opioids, were misleading and false.

2. Janssen downplayed the risk of addiction

4.166 Consistent with the marketing strategy described above, Janssen also sought to mislead health care providers and patients about the adverse effects of opioids, particularly the risk of addiction.

4.167 Janssen funded, influenced and distributed third party publications of doctor and patient "educational" materials that misled their target audiences about the additional danger of prescription opioids. Indeed, many of these publications sought to turn the tables and asserted that doctors who did not treat patients' pain complaints with opioids were failing their patients, while those who prescribed long-term opioid treatment were following the compassionate (and professionally less risky) approach.

4.168 For example, employees of Janssen Pharmaceutical Research and Development, LLC, a Janssen subsidiary, authored a 2012 study published in the Journal of Opioid Management that the "great majority" of healthcare providers who prescribe opioids "appear to have no opioid shoppers in their practice."[119]

4.169 Janssen, in concert with others, embarked on a major campaign using both branded and unbranded marketing to disseminate the messages that pain was undertreated and that "there was a low risk of abuse and a low danger" of prescribing opioids to treat chronic, non-malignant pain.[120]

4.170 A key element to Janssen's opioid marketing strategy to overcome barriers to liberal prescribing was to promote the concept that chronic pain was undertreated and increased

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[118] *See* Frieden, *Reducing the Risks,* at 1503.

[119] M. Soledad Cepeda et al., "Characteristics of prescribers whose patients shop for opioids," Journal of Opioid Management (2012).

[120] Oklahoma Judgment, finding of fact 18.

opioid prescribing was the solution. Janssen trained its sales representatives on the use of "emotional selling" for opioids by convincing physicians that undertreated pain harmed patients.[121]

4.171 Janssen also sought to accomplish the "[b]ehavior [c]hange" of "increase[d] opioid use" by asserting that undertreated acute pain inevitably would turn into chronic pain.[122]

4.172 Janssen's misleading marketing relating to the risk of opioid abuse included representations specific to Nucynta and Nucynta ER. Janssen represented that Nucynta and Nucynta ER were "less addictive" than other Schedule II opioids. Janssen deceptively represented that these drugs bridged the gap between non-opioid pain relievers and Schedule II opioids, leaving the impression that they were more similar to over the counter pain medications.

4.173 Training materials related to Nucynta demonstrate the reach of Janssen's false marketing campaign. One section of these materials was entitled "Reality and Misperceptions." One "perception" was that "opioid use . . . may lead to misuse or abuse." The material sought to negate this "perception" by responding that opioids "improve[] function" and that the "collected data . . . demonstrate that the majority of patients . . . did not display behaviors consistent with misuse, abuse, or addiction."

4.174 Janssen's sales representatives echoed the false messages from the training material and made additional misrepresentations in meetings with prescribers. For example, one former sales representative said that Nucynta was considered a "bridge" between non-prescription pain medications like ibuprofen and harder pain medications. In other words, it was marketed as a "milder opioid" and "less addictive" than other opioids.

4.175 These representations were false, as Nucynta was a Schedule II opioid just like the "harder" opioids it was compared to. This was confirmed by the FDA approved labels, which state that they contain "a high potential for abuse similar to . . . oxymorphone."

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[121] Oklahoma Judgment, finding of fact 20.
[122] Oklahoma Judgment, finding of fact 21.

4.176 Other former Janssen sales representatives also said that they marketed Nucynta and Nucynta ER as a safer or less addictive alternative to other opioids, particularly when faced with concerns about addiction.

4.177 Another message minimizing the addictive risk of Nucynta was that it did not have a euphoric effect, and therefore did not have a high street value.

4.178 These messages about Nucynta's low risk for abuse were false. They were also contrary to the FDA labeling which stated that Nucynta and Nucynta ER "expose users to risks of addiction, abuse, and misuse, which can lead to overdose and death," and that it had a "high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone."

4.179 Representations that Nucynta ER had a low risk of addiction were false. Studies show that at least 8% of long-term opioid users and perhaps as many as 40% experience problems with addiction. The 2016 CDC guidelines also confirm that "extensive evidence" demonstrates substantially increased risk of opioid use disorder for those who use opioids for more than three months.

4.180 Training materials for sales representatives taught them to highlight the difference between tolerance and physical dependence (supposedly benign and expected effects of opioids), and addiction (supposedly a rare side effect). This distinction was false and left prescribers the incorrect impression that the risk of opioids and Nucynta products specifically had a low risk of addiction.

4.181 In fact, as discussed above, up to 26% of opioid users and as many as 30% or even 40% of long-term opioid users experience problems with addiction. Janssen's representations that the risk of addiction was either low or acceptable were misleading.

4.182 Janssen knew it probably could not persuade doctors to disregard the risk of opioid addiction entirely, and therefore sought to reassure them that doctors could effectively

manage risks and prevent addiction in their patients by using tools that Janssen and its third-party groups provided.

4.183 Janssen deceptively claimed that screening patients could effectively manage addiction risk. For example:

a. Through its Prescribe Responsibly website, Janssen also falsely instructed Washington prescribers and patients that addiction risk screening tools, urine drug screens, and similar strategies allow healthcare providers to identify patients predisposed to addiction, thereby purportedly allowing prescribers to manage the risk of opioid addiction in their patient populations. The 2016 CDC Guideline -- which was based on a review of existing medical evidence -- confirms the lack of scientific substantiation to support Janssen's claims regarding the utility of screening tools and patient management strategies in managing addiction risk.

4.184 Janssen falsely told prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction. Janssen failed to disclose the lack of evidence that these strategies actually mitigate addiction risk.

4.185 Upon information and belief, Janssen's deceptive statements about prescribers' ability to manage the risk of addiction and prevent abuse by their patients influenced Washington prescribers. They made prescribers more comfortable with starting long-term opioid therapy by providing misinformation to general practitioners who lacked time or expertise to manage higher-risk patients on opioids. Janssen's statement also led practitioners to believe that opioid addiction was based on the failure of other prescribers to mitigate addiction risk, rather than a risk inherent in the drugs themselves.

4.186 Convincing prescribers that they could effectively manage risk and prevent addiction was essential to Janssen's marketing strategy of increasing the number of prescriptions of opioids and its own branded drugs. It was also unsubstantiated.

4.187 A 2014 Evidence Report by the Agency for Healthcare Research and Quality (AHRQ) "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" and identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[123]

4.188 Similarly, the evidence shows that methods for preventing abuse and addiction when prescribing opioids to high-risk patients – like those with a documented predisposition to substance abuse – such as patient contracts, more frequent refills, and urine drug screening often do not work in the real world.[124]

4.189 Even if these risk mitigation strategies did work, prescribers to which Janssen marketed often did not use them. In practice, opioids are all too often prescribed to patients at serious risk for addiction or who are already addicted to opioids – often at high doses.[125] In the call notes and medical board actions described in this complaint, pain sufferers frequently have a history of substance abuse or current substance abuse issues and were still prescribed opioids. Janssen knew that this was a common practice, and continued marketed to prescribers who were doing so.

4.190 Through its Prescribe Responsibly website, Janssen published articles that misrepresented or minimized known risks of opioids. One article described concern about opioid

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[123] *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, Agency for Healthcare Res. & Quality, Sept.19, 2014.

[124] Michael Von Korff et al., *Long-Term Opioid Therapy Reconsidered*, 155 Annals of Internal Med. 325 (2011); Laxmaiah Manchikanti, et al., *American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 Pain Physician S1 (2012).

[125] Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan,* 307 J. Am. Med. Ass'n 940 (2012). In addition to studies, a review of Johnson & Johnson call notes and MQAC disciplinary actions reveal that health care providers regularly prescribe opioids to patients with a history of substance abuse and/or current substance abuse issues.

addiction as "often overestimated," and stated that "only a small percentage" of patients receiving chronic opioid analgesics suffered from "true addiction."

4.191 The same article stated that "with appropriate dosing and titration," opioids "can be effective and safe medications for the treatment of painful conditions." These representations were deceptive and not supported by evidence.

4.192 The Prescribe Responsibly website also falsely represented that risk screening tools, urine drug screens, and similar strategies were adequate to identify people predisposed to addiction. One example of such a tool was the "Opioid Risk Tool," created by opioid advocate Dr. Lynn Webster. It was nothing more than a five-question, one-minute screening tool that relied on patient self-reporting, and was not effective in identifying patients predisposed to addiction.

4.193 The 2016 CDC Guidelines confirm the absence of evidence related to such tools. The guidelines, based on a review of existing medical evidence, explain that there are no studies assessing the effectiveness of risk mitigation strategies such as screening tools, patient contracts, urine drug testing, or pill counts for "improving outcomes related to overdose, addiction, abuse, or misuse."[126] The guidelines conclude that these tools "show insufficient accuracy" and counsel that prescribers "should not overestimate" their effectiveness.[127]

4.194 Another example of misleading the public and prescribers about the risk of addiction involved a YouTube video disseminated by the Let's Talk Pain Coalition, created by Janssen. The video was called "Safe Use of Opioids." It featured an interview between a healthcare professional and patient. In the video, the patient encourages individuals to seek opioids from healthcare professionals, saying the "burden is upon . . . the person in pain." She explains that after two years of opioid use, she developed a tolerance, but that her pain decreased after increasing her dosage.

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[126] 2016 CDC Guideline at 11.
[127] 2016 CDC Guideline at 28.

4.195 The patient complains that her pain involved "suffering" that was "inexcusable" and "horrendous."

4.196 The patient and healthcare professional say nothing about the risks of addiction resulting from long-term opioid use.

3. Janssen's deceptive acts or practices relating to the significant additional risks posed by increased opioid doses

4.197 Because Janssen urged doctors to respond to evidence of addiction by increasing opioid dosage, it had to convince those doctors that the escalated doses were safe. It did so through deceptive marketing materials.

4.198 Furthermore, Janssen knew or should have known that the prescribers targeted by sales representatives – which, upon information and belief, included high volume pain clinics, primary care physicians, nurse practitioners, and physician assistants – frequently had limited resources or time to scrutinize Janssen's claims or conduct the necessary research about the efficacy and risks of high doses of extended release opioids themselves.

4.199 Janssen downplayed the problem of addiction by simply re-labeling it. According to Janssen, the signs of addiction are actually the product of untreated pain, which should be treated by prescribing even more opioids.

4.200 The term "pseudoaddiction" was coined by Dr. J. David Haddox and Dr. David E. Weissman, and popularized for opioid treatment for chronic pain by Janssen. "Pseudoaddiction" was meant to differentiate between "undertreated pain" and "true addiction" – as if the two were mutually exclusive.

4.201 Janssen promoted the concept of "pseudoaddiction" while failing to disclose that it was not substantiated by competent scientific evidence. For example, Johnson & Johnson ran a website called Prescribe Responsibly. The website repeated Johnson & Johnson messaging that the solution to "pseudoaddiction" was "to prescribe more opioids.[128]

[128] Oklahoma Judgment, finding of fact 23.

4.202 The Centers for Disease Control Guideline for prescribing opioids rejects the concept of pseudoaddiction based on a systematic review of the best available evidence. The Guideline rejects the practice of increasing opioid dosage when a patient does not experience pain relief early in treatment. The Guideline recommends assessing pain and function within a month do determine whether opioid use should be discontinued due to the risks of long-term use where the patient has not received a "clear benefit."[129]

4.203 The Prescribe Responsibly website had numerous articles promoting pseudoaddiction, calling it a syndrome resulting from inadequate drugs being described. The website asserted that when pain is treated appropriately [by prescribing more opioids], "the inappropriate behavior ceases." The Let's Talk Pain website contained similar material.

4.204 Janssen also promoted pseudoaddiction through continuing medical education materials. It funded, along with three other opioid manufacturers, a medical education guide published in 2009 called "Opioid Prescribing: Clinical Tools and Risk Management Strategies." The intended audience was primary care physicians and other healthcare professionals. The guide misleadingly minimized the risk of addiction, stating for example, "fear of addiction and abuse prevents physicians from properly prescribing opioids, particularly for those with a substance abuse history who could benefit from opioids[.]". The guide stated that those with pseudoaddiction should be given more opioids and then their "aggressive drug-seeking behavior ceases."

4.205 In fact, Janssen key opinion leader Dr. Lynn Webster acknowledged: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. It led us down a path that caused harm. It is already something we are debunking as a concept."[130]

4.206 To ally prescriber concerns about addiction, Janssen promoted distinctions between words like "dependence," "addiction," "abuse," and "aberrant behavior." Although there

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[129] 2016 CDC Guideline at 13.

[130] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel, Feb. 19, 2012.

are differences between these words, Janssen engaged in deception by obscuring or trivializing the serious risks of opioid addiction.

4.207 Janssen's Prescribe Responsibly website also used the same tactic. It suggested to respond to patients concerned about addiction by determining if the concern was technically "physical dependence," in which case all that was necessary was "reassurance from the healthcare professional." The website also asserted that "aberrant behavior," or behavior "outside the boundaries of an agreed upon treatment plan," was an "unreliable sign of addiction." Another article also tried to distinguish "aberrant behavior," including things such as "aggressively requesting medication" may simply be a sign of unrelieved pain and not necessarily an indicator of opioid addiction. By encouraging prescribers to ignore signs of opioid addiction, Janssen misled prescribers and patients.

4.208 Janssen made similar claims in its medical education guide, "Opioid Prescribing: Clinical Tools and Risk Management Strategies." The guide sought to dismiss even extreme behaviors associated with addiction, such as obtaining opioids from multiple sources, forging prescriptions, and repeatedly calling a clinic to obtain opioids, as simply resulting from undertreated pain rather than addiction.

4.209 Janssen taught its sales force to repeat these messages. Janssen taught its sales representatives to differentiate "tolerance, cross-tolerance, physical dependence, and addiction" to overcome resistance to prescribing opioids. Janssen trained its sales force that resistance from prescribers may be "opiophobia" which could negatively impact a patient's pain treatment. Rather than acknowledge health professionals' valid concerns about opioid addiction, the sales representatives were to fill in "knowledge gaps" about these different concepts. In other words, Janssen trained its sales force to promote a new vocabulary that called addiction something else.

4. Janssen made misleading claims when comparing its products to competitors' products.

4.210 Janssen marketed its fentanyl-based patch Duragesic by asserting that it had a lower potential for abuse than competing products. Janssen's own hired scientific advisory board advised Janssen that many of its marketing messages related to both Duragesic and opioids generally were misleading and should not be disseminated. Janssen ignored the warning and pursued the marketing anyway.[131]

4.211 Specifically, the advisory board told Janssen that messages about Duragesic having a low abuse potential were misleading. The advisory board told Janssen that no data supported the claim, and that similar marketing of OxyContin by Purdue had gotten that company in trouble. The advisory board also informed Janssen that minimizing the risk of abuse of Duragesic was "dangerous" because it is a lethal drug, and that increasing Duragesic sales would cause an increase in abuse and addiction to the drug. The advisory board told Janssen, "Conclusion: Do not include the abuse message. Do not sell opioids on the abuse issue."[132]

4.212 Later, the Food and Drug Administration informed Janssen by letter that a professional file card Janssen used to promote Duragesic contained "false or misleading claims about the abuse potential and other risks of [Duragesic], and include[d] unsubstantiated effectiveness claims for Duragesic." The FDA also stated that the file card misbranded the drug by "suggesting that Duragesic has a lower potential for abuse compared to other opioid products," and "the file card could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation."[133]

4.213 Just as its own advisors had predicted, the FDA found that Janssen's suggestion that Duragesic was "less abused than other opioid drugs" was "false or misleading" because no

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[131] Oklahoma Judgment, finding of fact 46.
[132] Oklahoma Judgment, finding of fact 46.
[133] Oklahoma Judgment, finding of fact 47.

substantial evidence supported the claim, available data did not provide a valid comparison between opioid products, and the database that Janssen had relied on was not a clinical database but rather a surveillance system for emergency room visits and deaths.[134]

4.214 The FDA concluded that the Duragesic file card made "false or misleading safety claims and unsubstantiated effectiveness claims for Duragesic" and "thus misbrand[ed] Duragesic in violation of the Act (21 U.S.C. § 352(a))." The FDA told Janssen to "immediately cease the dissemination of promotional materials for Duragesic the same as or similar to those described" in its letter. The FDA stated that the "violations" it cited were not "exhaustive" and that Janssen was required to "ensure that [its] promotional materials for Duragesic comply with each applicable requirement of the Act and FDA implementing regulations."[135]

4.215 Janssen used many other promotional materials with the same false and misleading messaging as the file card for Duragesic.[136]

4.216 Janssen engaged in similar conduct in relation to Nucynta, asserting to doctors and other health professionals that its potential for abuse was less than that of competing products.

4.217 Janssen asserted that Nucynta and Nucynta ER were "unlike traditional opioids" and had "non-opioid" properties. These portrayals were false, as Nucynta and Nucynta ER are addictive narcotics with a high potential for abuse similar to OxyContin, fentanyl, and other Schedule II opioids.

4.218 Janssen also falsely represented that Nucynta, in contrast to other opioids, did not cause withdrawal symptoms.

4.219 Janssen sought to "disrupt [the] chronic [pain] market" and increase demand for its Nucynta products. It did so by using "patient segmentation," or the identification of patients who would be susceptible to Janssen's marketing. Among its "preferred" segments were patients who were satisfied with their current prescription, but who were very trusting of their doctors and

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[134] Oklahoma Judgment, finding of fact 48.
[135] Oklahoma Judgment, finding of fact 49.
[136] Oklahoma Judgment, finding of fact 50.

would "take Tapentadol" if recommended by their doctor. Janssen referred to these patients as "doctor trustees."

4.220 Janssen promoted the idea that chronic pain stems from a mixture of nociceptive pain, caused by harmful stimuli to receptors, and neuropathic pain, caused by damage to neurons. Janssen advocated to prescribers and patients that this "mixed pain" was best treated through "broad-spectrum" or "multi-pathway" opioids, or in other words, an opioid with a "dual mechanism of action" such as Nucynta. Janssen referred to this scheme as increasing the need for a "broad spectrum treatment approach."

4.221 After creating demand for such a product, Janssen then established an initial footprint with the immediate release version of Nucynta, approved for acute pain. Janssen then promoted the more profitable extended release version of the drug, and sought to covert immediate release patients to the extended release version. Extended release drugs were more profitable.

4.222 Even before the FDA approved the extended release version of Nucynta, Janssen's business plan intended to convert patients to the extended release version. Janssen referred to this conversion as "owning the tapentadol patient across their evolution of pain," "own[ing] the long-term patient to maximize opportunity," and "maximiz[ing] the value of the entire tapentadol molecule."

4.223 Janssen sought to "displace the oxycodone molecule," which is the active molecule in OxyContin, by "elevat[ing] Nucynta beyond the traditional opioid footprint." Janssen projected this goal could result in $2 billion in peak sales for the Nucynta franchise.

4.224 As if 2013, Janssen had caused these and other studies to be presented in over 500 conferences or other settings across North America, and over 850 settings worldwide.

4.225 Between the time Janssen launched Nucynta in 2009 to the time it sold the Nucynta franchise in 2015, Janssen spent over $100 million dollars to market the drugs.

5. Janssen's deceptive acts or practices relating to the comparison between the risks and benefits of opioids and those of alternative forms of pain treatment

4.226 As the final element of its marketing plan – after misrepresenting opioids' efficacy and adverse effects – Janssen presented a misleading comparison between the risks and benefits of opioids and other pain treatment methods by influencing and controlling marketing materials that (a) omitted known risks of chronic opioid treatment; and (b) emphasized or exaggerated risks of competing products. These practices had the capacity to deceive prescribers and patients, who would then be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs. For example:

a. Janssen misleadingly compared its products to nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen. Janssen contrasted the absence of a limit on dosage for opioids with such limits for NSAIDs. In addition, Janssen would explain the risks from NSAIDs while failing to disclose the most serious risks from opioids. For example, its *Finding Relief: Pain Management for Older Adults*, Janssen explained that NSAIDs caused kidney damage, liver damage, and increased risk of heart attack and stroke while opioids could cause upset stomach, sleepiness, and constipation. This guide did not mention the very serious risks of opioids, such as hyperalgesia (becoming more sensitive to pain over time), hormonal dysfunction, decline in immune function, mental clouding, confusion and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome (resulting from opioid exposure prior to birth and withdrawal after birth), and potentially fatal interactions between opioids and alcohol or benzodiazepines.

b. Janssen sales representatives asserted that Nucynta "was bringing patients to life." They promoted that patients might be "maxed out" from the side effects of NSAIDs such as internal bleeding, and need Nucynta to allow them to work or engage

in other daily functions. Janssen created the mistaken impression that the risks from NSAIDs exceeded the risks of Nucynta, when in fact, the opposite was true.

4.227 Janssen's campaign worked, and opioids replaced other, safer options in health care providers' pain treatment repertoires. For example, a study of 7.8 million doctor visits between 2000 and 2010 found that while prescriptions for NSAIDs and acetaminophen fell from 38% to 29%, opioid prescriptions increased from 11.3% to 19.6% of visits, driven primarily by the decline in NSAID prescribing.[137]

G. Washington Prescribers and Their Patients Have Been Directly Affected by Janssen's Marketing

4.228 Janssen's marketing has been effective in changing the prescribing patterns of health care providers both nationally and in Washington. These methods were specifically tailored to deceive health care providers and increase opioid prescriptions, including prescriptions of Janssen products.

4.229 The following examples illustrate the interaction between Janssen's misrepresentations, delivered through "educational" materials and personal sales calls, and opioid prescribing practices.

4.230 Janssen portrayed Nucynta and Nucynta ER as less addictive than other Schedule II opioids, Janssen deceptively promoted Nucynta and Nucynta ER as drugs that bridged the gap between non-opioid pain relievers and Schedule II opioids – providing the misleading impression that these drugs were not in the same class as other highly addictive and dangerous Schedule II narcotics, but were rather more akin to safer, over the counter pain medications. Janssen made deceptive statements to both patients and prescribers that the risk of opioid addiction could be

[137] Daubresse, *Ambulatory Diagnosis and Treatment*. For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady; *see also* John N. Mafi et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173 J. Am. Med. Ass'n Internal Med. 1573 (2013).

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controlled, that certain patients were at increased risk for addiction but could be identified through screening tools, and that the vast majority of patients could receive opioids, even for periods of 90 days without increased risk of addiction.

4.231 Janssen's Prescribe Responsibly website deceptively misrepresented risks of addition associated with opioid use. Through its prescribe responsibly website, Janssen published multiple articles that misrepresent, trivialize, or fail to disclose the known risks of opioid products.

4.232 The Let's Talk Pain Coalition deceptively misrepresented the risks of addition associated with opioid use. Janssen has misrepresented or intentionally omitted the risks of addiction associated with opioid use through its production and dissemination of on-line videos, which Janssen created as part of its affiliation with the Let's Talk Pain Coalition. Through that Coalition, Janssen sponsored several videos that were designed to encourage patients to seek treatment for chronic pain. One such video, which is titled "Safe Use of Opioids," and which is currently accessible via www.YouTube.com, over states the benefits of chronic opioid use and omits discussions of the risks of addiction and abuse associated with opioids.

4.233 Janssen minimized the risks and severity of withdrawal symptoms in its promotion of Nucynta and Nucynta ER. For example, Janssen's brochure "Finding Relief: Pain Management for Older Adults," contains misrepresentations about increased functionality that could result from opioid use.

H. Opioids Have Severely Impacted Washington State

4.234 Opioid use, morbidity, and mortality have increased exponentially nationwide and across Washington State in the years since Janssen first began aggressively marketing opioids for long-term use. Prescriptions and sales of opioids in Washington skyrocketed more than 500% between 1997 and 2011.[138]

4.235 In 2011, at the peak of overall sales in Washington, more than 112 million daily doses of all prescription opioids were dispensed in the state – enough for a 16-day supply for

[138] Franklin, *A Comprehensive Approach.*

every woman, man, and child in the state. Although rates of prescription drugs have declined somewhat, they remain dangerously high, with 68.2 prescriptions per 100 Washingtonians in 2015.[139]

4.236 Nearly one-fourth of all Washington residents received at least one opioid prescription in 2014.[140] Even as prescription rates decline, in 2016 there were still seven counties in which enough opioid prescriptions were dispensed for every person in that county to have one, and in 2017, four.[141]

4.237 According to the CDC, between 1999 and 2017 more than 218,000 people died in the United States from prescription-related overdoses. There have been more than 10,000 deaths attributable to any opiate in Washington alone since turn of the 21st century.[142]

a. Overall, the majority of drug overdose deaths in Washington (more than 6 out of 10) involve an opioid.[143]

b. Overdose deaths—specifically opioid overdose—have overtaken those causes that have traditionally had the highest rates of accidental death. Between 2014 and 2017, the number of overdose deaths in Washington (2,915) surpassed the number of deaths in car accidents (2,132) and nearly matched the number of deaths from firearms—suicide, homicide, and accidental (2,955).[144]

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[139] National Institute on Drug Abuse, *Washington Opioid Summary* (Feb. 2018), *available at* https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/washington-opioid-summary.

[140] *PDMP County Profiles 2014: Executive Summary*, Washington State Department of Health, http://www.doh.wa.gov/Portals/1/Documents/2600/PMPcountyProfiles/630-126-CountyProfilesExecutive Summary2014.pdf .

[141] Centers for Disease Control and Prevention, *U.S. County Prescribing Rates, 2017* (Jul. 31, 2017), *available at* https://www.cdc.gov/drugoverdose/maps/rxcounty2017.html; Centers for Disease Control and Prevention, *U.S. County Prescribing Rates, 2016* (Jul. 31, 2017), *available at* https://cdc.gov/drugoverdose/maps/rxcounty2016.html.

[142] Washington State Department of Health, Washington State Residents Drug Overdose Quarterly Report (Mar. 2019), available at https://www.doh.wa.gov/Portals/1/Documents/8300/wa_lhj_quarterly_report_18_1_2_pub.html.

[143] Rudd, *Overdose Deaths 2010-2015*.

[144] Alcohol & Drug Abuse Institute, University of Washington, *Opioid trends across Washington state* (Nov 4, 2019), *available at*, https://adai.washington.edu/WAdata/deaths.htm; Insurance Institute for Highway Safety Highway Loss Data Institute, *General statistics Crashes took 37,133 lives in the U.S. in 2017* (2017),

c. Drug-caused deaths involving opioids increased 77% statewide between 2002-2004 and 2015-2017, with increases in most counties. The total number of drug-caused deaths involving opioids in 2018 was 776, with over 8,000 deaths total from 2006–2017.[145] The annual rate of opioid deaths have remained relatively steady since 2006. A similar pattern emerges with prescription-type opioids peaking between 2008–2010, while heroin continued increasing through 2013.

d. In King County, prescription-type opioid trends are down somewhat from peaks around 2010, however prescription-type opioid-involved deaths are persisting at elevated rates and are second only to heroin in terms of most common drugs identified in fatal overdoses.[146]

4.238 Geographic areas with higher per-capita rates of opioid prescribing show a strong correlation with higher overdose rates.

4.239 The death rates in Washington are geographically disparate and are concentrated in the counties with the highest rates of opioid prescriptions. For instance:

a. In 2014, Asotin County in the southeastern corner of the state had a rate of opioid substance use of 286.9 patients prescribed opioids per 1,000 residents and a corresponding 12.4 deaths attributable to any opioid per 100,000 residents between 2015 and 2017. That overdose death rate was a more than 270% increase from 2002 to 2004. Similarly, Cowlitz County in the southwestern corner of the state had a rate of opioid substance use of 273 patients prescribed opioids per 1,000 residents in 2014, and a corresponding 12.06 deaths attributable to any opioid per 100,000 residents between 2015 and 2017. This pattern can be seen repeated in many Washington counties.

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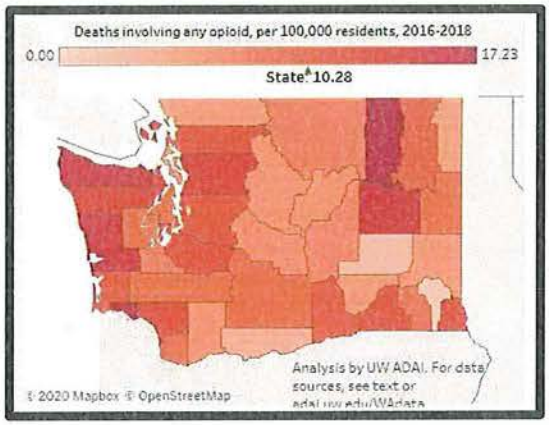
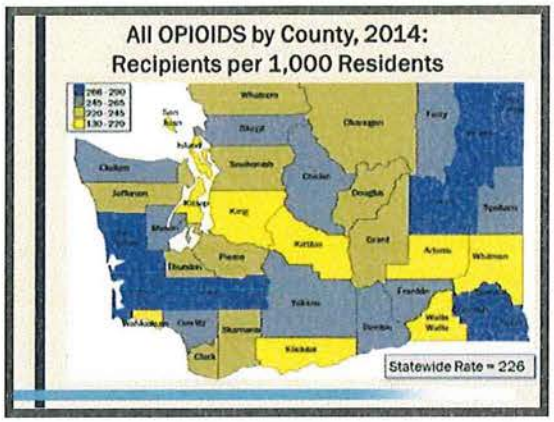
available at https://www.iihs.org/iihs/topics/t/general-statistics/fatalityfacts/state-by-state-overview/; Centers for Disease Control and Prevention, *Firearm Mortality by State* (Jan. 2019) *available at* https://www.cdc.gov/nchs/pressroom/sosmap/firearm_mortality/firearm.htm.

[145] *Washington State Residents Drug Overdose Quarterly Report*, Washington State Department of Health, https://www.doh.wa.gov/Portals/1/Documents/8300/wa_lhj_quarterly_report_18_1_2_pub.html.

[146] Alcohol & Drug Abuse Institute, University of Washington, *Opioid trends across Washington state* (Oct. 9, 2018), *available at*, https://adai.washington.edu/WAdata/deaths.htm.

4.240 Clallam, Cowlitz, King, Asotin, Ferry, Lincoln, Columbia, Walla Walla, Benton, Pacific, Gray's Harbor, Jefferson, Pierce, Mason, and Snohomish counties have opioid overdose rates higher than the state average. While not located in the one of the four corners, Snohomish County has experienced an 83.3% increase in deaths involving any opiate between 2002-2004 and 2016-2018.





4.241 The scope of human suffering and economic cost of opioids on Washington reverberates far beyond overdose mortality rate. The State spends significant public resources on medical services, law enforcement, corrections, workers' compensation, diversion programs, prosecution, probation, treatment, and child welfare.

a. The cumulative rate of opioid-related inpatient hospital and clinic stays increased by 60.1% in Washington between 2009 and 2014, the fourth greatest increase in the nation.[147] That rate of 313.2 opioid-related inpatient stays per 100,000 in population placed Washington eighth in the nation.[148]

b. The Washington State Toxicology Laboratory, housed within Washington State Patrol, has received a significant increase in the number of cases

[147] Audrey J. Weiss et al., *Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009-2014* (Dec. 15 2016, revised Jan. 26, 2017), Healthcare Cost and Utilization Project (HCUP), available at https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.jsp.

[148] *Id.*

submitted for testing in recent years by approximately 1,000 cases per year since 2013. The increased caseload results in a backlog of samples waiting to be tested.[149]

c. Crime lab data for police evidence testing for opioids indicate an 85% increase statewide between 2002-2004 and 2011-2013, with increases in most counties.[150] Police evidence testing results show that oxycodone has consistently been the most common prescription-type-opioid detected in all years.[151]

d. Publicly funded drug treatment admissions for opioids as the primary drug increased 197% statewide, with increases in 38 of 39 counties.[152]

4.242 Deceptive and unfair marketing of opioids by Janssen also has a significant detrimental impact on children in Washington. Adolescent misuse of prescription-type-opioids is very important because it is the peak period in life when people first misuse opioids.[153] The overprescribing of opioids for chronic pain has given young children access to opioids, nearly all of which were prescribed for adults in their household or to the children by dentists.[154]

a. The 2016 Healthy Youth Survey revealed that a significant portion of Washington students misuse prescription drugs – about 4,500 twelfth graders use

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[149] Washington State Department of Health, *Reducing the Supply of Illegal Opioids in Washington State* (Nov. 2017), *available at* https://www.doh.wa.gov/Portals/1/Documents/2300/2017/ReducingSupplyIllegalOpioidsInWA-AAG.pdf.

[150] Alcohol and Drug Abuse Institute, University of Washington, *Opioid Trends Across Washington State* (Apr. 2015), *available at* https://adai.uw.edu/pubs/infobriefs/ADAI-IB-2015-01.pdf.

[151] Alcohol and Drug Abuse Institute, University of Washington, *2016 Drug Use Trends in King County, Washington* (Jul. 2017), *available at* http://adai.uw.edu/pubs/pdf/2016drugusetrends.pdf.

[152] Alcohol and Drug Abuse Institute, University of Washington, *Opioid Trends Across Washington State* (Apr. 2015), *available at* https://adai.uw.edu/pubs/infobriefs/ADAI-IB-2015-01.pdf.

[153] Caleb Banta-Green et al., *Opioid Trends in Pierce County*, Alcohol and Drug Abuse Institute, University of Washington, (Feb. 2017), p. 5, citing to Meier et al., 2012 *available at* https://www.tpchd.org/home/showdocument?id=2002.

[154] Washington State Department of Health, *Reducing the Supply of Illegal Opioids in Washington State* (Nov. 2017), p. 7, 13-14, *available at* https://www.doh.wa.gov/Portals/1/Documents/2300/2017/ReducingSupplyIllegalOpioidsInWA-AAG.pdf.

prescription opioids to get high in any given month, and about 3,600 have tried heroin at least once.[155]

b. Washington dentists are the biggest prescribers of opioids to youth; prescribing more than 13,000 pills to youth age 14-19 in one six-month period in 2015. For comparison, emergency medicine providers, the second highest prescribers, issued prescriptions for approximately 2,500 pills in the same period.

c. While Healthy Youth Survey data for King County tenth graders indicate a significant decline in the proportion reporting past month use of prescription-type-opioids to get high, that decline is being offset somewhat by increased rates of heroin use. In 2006, 10% of King County tenth graders reported past month use of prescription-type-opioids to get high; that number has steadily declined in bi-annual surveys to 4% in 2014 and the same proportion in 2016.[156] However, in 2016 there was a strong association between reporting use of prescription-type-opioids to get high and having ever used heroin (26%), compared to only 2% reporting ever having used heroin if they had not used prescription-type- opioids to get high.

4.243 Even infants have not been immune to the impact of opioid abuse and over prescription. There has been a dramatic increase in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome (NAS), which can occur in an infant exposed in utero to addictive, illegal or prescription drugs.

a. Neonatal abstinence syndrome (NAS) can occur in an infant exposed in utero to addictive, illegal or prescription drugs. Babies born with NAS may experience a variety of withdrawal symptoms, medical complications and have prolonged hospital stays. According to the Centers for Disease Control and Prevention, the incidence rate of

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[155] 2016 Washington State Healthy Youth Survey, *Data Brief: Prescription Drugs and Opiates*, Washington State Department of Health (2016), *available at* http://www.doh.wa.gov/Portals/1/Documents/8350/160-NonDOH-DB-Opiates.pdf.

[156] *Id.*

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NAS in Washington State increased from a rate of 1.5 for every 1,000-hospital births in 1999 to a rate of 7.9 for every 1,000-hospital births in 2013.[157] In Washington, prenatal exposure to opioids increased from 11.5% of all drug-exposed neonates in 2000 to 24.4% in 2008, and 41.7% of infants diagnosed with NAS were exclusively exposed to opioids.[158]

4.244 Opioid use has had a significant impact on Washington's child welfare system. Parental substance abuse is a major risk factor for child fatalities, child maltreatment, and involvement with the child welfare system.

a. From calendar year 2013 to 2016, the Office of the Family & Children's Ombuds identified 33 maltreatment related fatalities of children ages zero to three years where a caregiver's opiate use was a known risk factor.[159]

b. Upon information and belief, a review of a representative sample of dependency petitions filed 2014-2016 in Snohomish County found that in more than 95% of cases where children were removed from the home due to parental drug use, the drug involved was an opioid.

c. Children removed from their home as a result of parental substance abuse are likely to remain in foster care longer and have significantly higher rates of adoption than those in foster care for other reasons.[160] A higher rate of adoption indicates that

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[157] Jean Y. Ko, et al., *Incidence of Neonatal Abstinence Syndrome – 28 States, 1999-2013*, 65(31):799-802, Morbidity and Mortality Weekly Report (Aug., 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm.

[158] Washington Office of the Family and Childrens' Ombuds, *Child Fatalities and Near Fatalities in Washington State,* (Aug. 2017), *available at* http://ofco.wa.gov/wp-content/uploads/OFCO-Report-Child-Fatalities-and-Near-Fatalities-in-Washington-State-2016.pdf, p.21-22, citing to *Neonatal Abstinence Syndrome: How States Can Help Advance the Knowledge Base for Primary Prevention and Best Practices of Care*, (2014), *available at* http://www.astho.org/prevention/nas-neonatal-abstinence-report.

[159] Washington Office of the Family and Childrens' Ombuds, *Child Fatalities and Near Fatalities in Washington State,* (Aug. 2017), available at http://ofco.wa.gov/wp-content/uploads/OFCO-Report-Child-Fatalities-and-Near-Fatalities-in-Washington-State-2016.pdf.

[160] *Id.* at p.20, citing to Karen E. Hanson et al., *Family-Based Recovery: An Innovative In-Home Substance Abuse Treatment Model for Families with Young Children.*

children removed from their homes remain in foster care longer and are less likely to exit from foster care to reunification with biological parents.

4.245 The initial rise in prescription-type opioids came while heroin deaths, crime lab cases, and treatment rates were on the decline, and the recent decline for prescription-type opioids comes as heroin returns to prominence and illicit fentanyl emerges as a threat. Following the statewide peak in 2011, the number of prescriptions of extended release opioids has declined and correspondingly so has the rate of overdose deaths attributed to prescription opiates. The overall rate of overdose in Washington State, however, increased due to increase in heroin and fentanyl use and overdose deaths attributed to heroin and fentanyl.

4.246 Many individuals who use heroin, and the majority of young adults who use heroin, report using prescription-type opioids prior to switching to heroin.[161]

4.247 In a 2014 study, 5% of Pierce County 10th graders reported lifetime heroin use and current painkiller use "to get high". While most students reported using neither, 3% had tried heroin, 4.4% reported using painkillers only, and 1% reported using both. Among those who tried heroin, 34.7% reported the use of painkillers, while only 4.5% who had not tried heroin reported the use of painkillers. Nearly one in five students who reported painkiller use during the last month in the study also admitted to having used heroin in the past.[162]

4.248 Heroin indicators remain at high levels in 2016 across all measures:

a. Heroin deaths more than doubled between 2010 and 2015.[163]

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[161] K. Michelle Peavy et al., *"Hooked on" Prescription-Type Opiates Prior to Using Heroin: Results from a Survey of Syringe Exchange Clients*, 44(3) Journal Of Psychoactive Drugs (Aug. 2012); Emily R. Cedarbaum & Caleb J. Banta-Green, *Health behaviors of young adult heroin injectors in the Seattle area*, 158 Drug And Alcohol Dependence (Nov. 2015).

[162] Caleb Banta-Green et al., *Opioid Trends in Pierce County*, Alcohol and Drug Abuse Institute, University of Washington, (Feb. 2017), p. 5, *available at* https://www.tpchd.org/home/showdocument?id=2002.

[163] Washington State Department of Health, *Opioid-related Deaths in Washington State, 2006-2016*, (May 2017), *available at* http://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf.

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b. Heroin was the most common drug reported as primary in 2016, accounting for 31% of all treatment admissions, a numerical and proportional increase compared to 2012.[164]

c. There were more than four calls per day to King County's Recovery Helpline seeking assistance regarding heroin.[165] Heroin-related calls to the Recovery Helpline have consistently been the most common drug for calls regarding young adults. There were 476 calls in 2016, similar to prior years. For adults 26 and older, heroin was consistently the second most common substance reported in calls to Recovery Helpline, and there were a total of 1,179 calls in 2016 similar to the prior year.

d. For adults ages 18-25 admitted to treatment, heroin was numerically and proportionally much more common than other drugs, with a relatively large proportion, 19%, of admissions for heroin ages 18-25.[166]

e. In Pierce County, a recent increase in police evidence testing cases and drug overdose deaths is being driven by increases in heroin use.[167] Correspondingly, treatment admissions in Pierce County for heroin and first admissions for heroin have risen precipitously since 2013.

4.249 More recently, deaths attributed to highly dangerous illicit fentanyl have skyrocketed in the past few years. While 53 Washingtonians died of fentanyl overdoses in 2015,[168] that number ballooned to 81 in the first half of 2018 alone.[169]

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[164] Caleb Banta-Green et al., *2016 Drug Trends for King County, Washington,* Alcohol & Drug Abuse Institute, University of Washington, (Jul. 2017), *available at* http://adai.uw.edu/pubs/pdf/2016drugusetrends.pdf.

[165] *Id.*

[166] *Id.*

[167] Caleb Banta-Green et al., *Opioid Trends in Pierce County*, Tacoma-Pierce County Health Department (Feb. 2017), *available at* https://www.tpchd.org/home/showdocument?id=2002.

[168] Mamadou Ndiaye, *Fentanyl Overdose Deaths in Washington State*, Washington State Department of Health (May 5, 2017), *available at* https://www.doh.wa.gov/Portals/1/Documents/1600/DOHFentanylReport2017Final.pdf.

[169] Ryan Blethen, *Huge rise in overdose deaths, in Washington state and the nation, from fentanyl, which can kill even in tiny doses*, Seattle Times (Dec. 5, 2018), *available at* https://www.seattletimes.com/seattle-news/health/overdose-deaths-from-powerful-narcotic-fentanyl-on-the-rise-in-washington/.

4.250 The staggering rise in use of heroin and fentanyl and heroin- and fentanyl-related overdose deaths is a predictable result of the saturation of prescription opioids in Washington.[170]

4.251 Janssen's business model depends on creating addicts to fuel its sales of branded extended release opioids. When dependent users are unable to obtain prescription opioids they turn to illicit sources of opiates such as heroin.

I. Janssen Is Responsible for Washington's Opioid Crisis

4.252 As detailed in this complaint, the impacts of opioids on Washington are inextricably linked with Janssen's marketing campaign designed to convince prescribers, patients, and the public that opioids were an effective medical solution for chronic pain.

4.253 When evidence of the widespread impacts opioids were having on Washington and across the nation, Janssen carefully packaged and targeted its messages to convince prescribers that the risks of addiction were overstated and could be managed.

4.254 As a result of Janssen's efforts, opioid use has grown to epidemic proportions and the death rates continue to rise while Janssen continue to market and sell drugs that it knows are deadly.

4.255 The Attorney General asks the court to stop Janssen's deceptive marketing and order legal and equitable remedies to begin addressing the opioid epidemic.

V. FIRST CAUSE OF ACTION
(VIOLATIONS OF THE CONSUMER PROTECTION ACT, RCW 19.86)

5.1 The State incorporates Paragraphs 1.1 through 4.255 herein as if set forth in their entirety.

5.2 RCW 19.86.020 prohibits "unfair" or "deceptive" acts or practices in trade or commerce.

5.3 The marketing, distribution, and sale of opioids to health care providers and consumers in Washington constitutes "trade" or "commerce" defined by RCW 19.86.010(2).

[170] Franklin, *A Comprehensive Approach*, citing to n.45-47.

5.4 Janssen engaged in numerous deceptive acts or practices, including the following:

a. Marketing opioids, including its own drugs, both directly and indirectly through third party groups, as a solution to the under treatment of pain and either stating directly or implying that opioids are effective to treat or relieve long-term chronic pain and improve function and quality-of-life.

b. Misrepresenting and making unsubstantiated claims that, and the extent to which, opioids improve function over the long term.

c. Misrepresenting the truth and making unsubstantiated claims about how (and how frequently) opioids lead to addiction and the extent to which addiction risk can be managed and addiction prevented.

d. Misleadingly using terms like addiction, dependence, tolerance, physical dependence, and "pseudoaddiction" to persuade health care providers and patients that the addiction risk of opioids could be successfully managed.

e. Misrepresenting and making unsubstantiated claims that increased doses of opioids do not pose significant additional risks.

f. Misrepresenting and making unsubstantiated claims regarding the factors for comparing the risks and benefits of opioids with those of alternative forms of pain treatment.

g. Marketing Janssen's abuse deterrent formulations of opioid medications as a means of reducing abuse and addressing the opioid epidemic without any evidence to support such a claim.

5.5 Janssen engaged in numerous unfair acts or practices, including the following:

a. Marketing and selling opioids for long-term use in treating chronic pain without sufficient evidence of efficacy, while also understating the risk of addiction and the ease with which addiction could be treated.

b. Influencing health care providers' prescription decisions for particular patients in sales calls for which the patient was not present.

c. Encouraging health care providers to ignore or reject regulatory guidance from the Washington's Agency Medical Director's Group, thereby undermining Washington's public policy to diminish the amount of addictive and dangerous opioids prescribed to its residents.

d. Targeting and encouraging health care providers with high rates of opioid prescription through in-person detailing, dissemination of educational materials and programs, and third party materials containing misleading statements about the efficacy and risks of opioids. This targeted marketing sought to cause prescribers to continue prescribing at those rates and encouraging additional prescriptions despite observing indications that the health care provider was not meeting the standard of care, and/or that opioids were being diverted or abused, thereby harming the public health.

e. Failing to report and/or concealing from relevant law enforcement and medical regulators suspicious, excessive, and illegal opioid prescribing practices, while profiting from inflated prescriptions of Janssen-branded and other opioids.

5.6 Janssen's unfair and deceptive conduct in the marketing, distribution, and sale of opioids to health care providers and consumers in Washington affects the public interest because the opioids were marketed and issued to numerous consumers in Washington, injured numerous Washington consumers, created a public health crisis and a public nuisance, were part of Janssen's very business model and regular course of business operations, and were repeated.

VI. SECOND CAUSE OF ACTION (PUBLIC NUISANCE)

6.1 The State incorporates Paragraphs 1.1 through 5.6 herein as if set forth in their entirety.

6.2 RCW 7.48.120 provides that:

> [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.

6.3 Pursuant to RCW 7.48.130, a "public nuisance" is a nuisance that "affects equally the rights of the entire community or neighborhood, although the extent of the damage may be unequal."

6.4 Finally, RCW 7.48.010 defines an "actionable nuisance" to include "whatever is injurious to health or indecent or offensive to the senses."

6.5 Through the actions described above, Janssen has contributed to and/or assisted in creating and maintaining a condition that is unreasonable and harmful to the health of Washingtonians and/or interferes with the comfortable enjoyment of life in violation of Washington law. For example:

a. Opioid use, abuse, and overdose deaths have increased throughout the state.

b. Locations such as the offices of high-prescribing health care practitioners and the pharmacies at which their patients fill opioid prescriptions have attracted drug dealers and addicts.

c. Locations such as abandoned homes and some public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to over-prescribing, and the foreseeable failure to safely dispose of opioids.

d. The greater demand for emergency services, law enforcement, addiction treatment, and social services places an unreasonable burden on State and local resources.

e. Expanding the market for prescription opioids to primary care patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury.

f. The creation of additional illicit markets in other opiates, particularly heroin and fentanyl. Many users who were initially dependent on prescription opioids and then were unable to obtain or afford prescription opioids turned to heroin and fentanyl as an alternative, fueling a new epidemic in the process.

g. Increased health care costs for individuals, families, and the State.

h. Janssen also interfered with enjoyment of the public right by failing to report suspicions of illicit prescribing to the State, law enforcement, or the Board of Medicine, allowing health care providers who were profitable to Janssen but problematic for the public health to continue prescribing increasing numbers of opioids throughout the state.

6.6 The public nuisance created by Janssen's actions is substantial and unreasonable – it has caused significant harm to communities across Washington, outweighing any offsetting benefit. Janssen knew or should have known that its sales and promotion of long-term opioid use for chronic pain would create a public nuisance.

6.7 Janssen's actions described above were a substantial factor in opioids becoming widely available, used, and all too often abused. These actions were a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic non-cancer pain, and in distorting the medical standard of care for treatment of chronic pain that resulted in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment.

6.8 But for Janssen's 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. Janssen's actions have and will continue to injure and harm many residents

throughout the state, including patients with chronic non-cancer pain who take opioids, their families, and their communities at large.

6.9 The public nuisance and associated financial and economic losses were foreseeable to Janssen, who knew or should have known that its unfair business practices and deceptive statements regarding the risks and benefits of opioids were creating a public nuisance. As alleged herein, Janssen engaged in and disseminated widespread deceptive promotion of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death.

6.10 The intent of Janssen's sale of active pharmaceutical ingredients, the sale of their own extended release opioids, and the promotion of opioids was for health care providers to prescribe opioids for treatment of long-term chronic pain, for patients to fill those prescriptions, and then to keep filling those prescriptions at higher and higher doses. A reasonable person in Janssen's position would foresee not only a vastly expanded market for chronic opioid therapy, but also the other likely and foreseeable result of Janssen's conduct – the widespread problems of opioid addiction and abuse. In fact, Janssen was on notice and aware of signs that health care providers were prescribing unreasonably higher numbers of opioids and that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

6.11 Janssen's business practices generated a new and very profitable circular market with the promotion of opioids – providing both the profitable supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

6.12 Janssen is liable for a public nuisance because they acted without express authority of a statute in knowingly promoting off label opioid prescribing; in engaging in a pattern of conduct that overstated the benefits of long-term opioid use, misrepresented the duration of efficacy of extended release opioids, failed to disclose the lack of evidence supporting long-term use of opioids, and misrepresented the serious risk of addiction from legitimate and prescribed use of opioids; and in creating and maintaining the prescription and

sale of opioids for long-term treatment of chronic pain at such volumes and degree as to create an epidemic.

6.13 The health and safety of Washington residents, 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 the State, whose duty to protect the health, safety, and well-being of its residents is paramount. Washington and its residents have a right to be free from conduct that endangers their health and safety. Janssen's deceptive marketing and unfair business practices interfered in the enjoyment of this public right by the State and its citizens.

6.14 Pursuant to RCW 7.48.020 and 7.48.180, the State seeks an order that provides for abatement of the public nuisance Janssen has created, enjoining Janssen from future violations of RCW 7.48, and awards the State damages in an amount to be determined at trial.

VII. THIRD CAUSE OF ACTION (COMMON LAW NEGLIGENCE)

7.1 The State incorporates Paragraphs 1.1 through 6.14 herein as if set forth in their entirety.

7.2 Under Washington law, a cause of action arises for negligence when defendant owes a duty to a plaintiff and breaches that duty, and proximately causes the resulting injury.

7.3 Janssen owed a duty of care to the citizens of Washington, including but not limited to exercise reasonable care in the marketing and sale of a highly addictive ingredients, and drugs like opioids. Janssen knew or should have known that its affirmative conduct in aggressive and misleading marketing and sale of opioids created an unreasonable risk of harm.

7.4 A reasonably prudent manufacturer would be aware that aggressively marketing opioids for chronic pain would result in the severe harm of addiction for large numbers of Washingtonians and that increasing the numbers of prescription opioids available in the market would lead to massive harm to the public including increased hospitalizations, overdoses, and deaths.

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7.5 In fact, Janssen was aware from internal sales data, adverse event reports, publicly available studies and reports, and other sources that the rapid expansion of prescription products, including its specific opioid products, was causing the massive public harm that was reasonably foreseeable. Janssen failed to take reasonable steps in response to that information, choosing instead to offer inadequate measures to mitigate risk while continuing to aggressively market drugs in such a way as to ensure high prescribing of opioids continued.

7.6 A reasonably prudent manufacturer of opioids could reasonably foresee that long-term use of opioids at increasing dosages was a particularly addictive and dangerous use of opioids and that aggressively marketing opioids for long-term treatment of chronic pain would make opioids more dangerous and deadly.

7.7 In fact, Janssen was aware from internal sales data, adverse event reports, publicly available studies and reports, and other sources that its aggressive marketing was expanding the use of opioids for long-term treatment of chronic pain conditions and was causing massive public harm.

7.8 A reasonably prudent manufacturer of opioids could reasonably foresee that aggressive, targeted marketing of opioids would lead to increased opioid prescriptions. A foreseeable consequence of expanded opioid prescriptions is the expansion of use of illicit and diverted opioids.

7.9 Janssen was aware from internal sales data, adverse event reports, publicly available studies and reports, and other sources that its aggressive, targeting marketing of opioids was causing increased opioids prescriptions in Washington state and was fueling a massive increase in heroin use and the diversion of opioid pain medications. Even knowing that, Janssen continued its marketing of these drugs.

7.10 By misrepresenting the addictive nature of opioids, aggressively promoting its opioids, and opioids generally, for long-term treatment of chronic pain, Janssen breached its duty of reasonable care as a manufacturer of dangerous opioids and increased the risk for public harm.

7.11 As set forth above, and incorporated by reference, Janssen's misrepresentations include the deceptive conduct described above.

7.12 Janssen's conduct was a proximate cause of increased opioid prescribing along with the inevitable and foreseeable consequences and public harms.

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

VIII. PRAYER FOR RELIEF

Wherefore, the State prays for the following relief:

8.1 A declaration that Defendants' acts described above are unfair or deceptive acts or practices in trade or commerce, affecting the public interest, and in violation of the Consumer Protection Act, RCW 19.86;

8.2 An injunction pursuant to RCW 19.86.080(1) enjoining Defendants and from engaging in any acts that violate the Washington Consumer Protection Act, including, but not limited to, the unfair and deceptive acts and practices alleged herein;

8.3 An order necessary to restore to any person an interest in any moneys or property, real or personal, which may have been acquired by means of an act prohibited by the Consumer Protection Act, pursuant to RCW 19.86.080(2);

8.4 An award of a civil penalty in the amount of $2,000.00 for each and every violation of Washington's Consumer Protection Act, pursuant to RCW 19.86.140;

8.5 An award of the State's reasonable costs and attorney's fees incurred in this action, pursuant to RCW 19.86.080(1);

8.6 An order requiring Defendants to abate the public nuisance that they created;

8.7 An award of damages in an amount determined at trial for injury sustained by the State as a result of Defendants' unreasonable and negligent conduct;

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8.8 Equitable relief requiring restitution and disgorgement of the revenues wrongfully obtained from sale of extended release opioids as a result of Defendants' wrongful conduct;

8.9 An award of pre-judgment and post-judgment interest, as provided by law; and

8.10 Any other and further relief the Court deems just and equitable.

IX. JURY DEMAND ENDORSEMENT

Plaintiff, State of Washington, demands a trial by jury on public nuisance and negligence claims to the maximum number of jurors permitted by law.

DATED this 2nd day of January 2020.

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