

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA  
THIRD JUDICIAL DISTRICT IN ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

PURDUE PHARMA L.P.,  
PURDUE PHARMA, INC., THE  
PURDUE FREDERICK  
COMPANY, and RHODES  
PHARMACEUTICALS L.P., and  
JANE DOES 1-10

Defendants.

Case No. 3AN-17-\_\_\_\_ CI

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I. PRELIMINARY STATEMENT

1. On February 14, 2017, Governor Bill Walker issued a Declaration of Disaster Emergency due to “an outbreak and a condition of public health disaster emergency” statewide. In the Declaration, the Governor announced that the “severity and magnitude” of opioid overdoses in Alaska was “beyond the timely and effective response and recovery capability of local resources” and required “emergency assistance.” The Governor’s Declaration acknowledged that the impact of prescription opioids in Alaska was akin to a natural disaster.

2. This was, of course, no act of nature. The opioid epidemic in Alaska is, in medical terms, “iatrogenic”—that is, caused by a medical treatment. The toll of opioid overuse, abuse, addiction, and death in in the state is not the result of pain conditions warranting the use of a class of narcotic drugs deemed by the U.S. Drug Enforcement Administration (“DEA”) as having “a high potential for abuse.”<sup>1</sup> It was caused, in large measure, by a campaign by Purdue Pharma L.P., and its related corporate entities and agents (collectively, “Purdue”) to persuade doctors and patients that compassionate treatment of pain requires opioids and that opioids can be used long-term to treat chronic pain<sup>2</sup> without causing abuse and addiction. None of these claims was—or is—supported by scientific evidence, and they were—and are—dangerously and too often fatally false.

3. Purdue’s early deceptive promotion of OxyContin, for and around which the use of opioids for chronic pain was built, resulted a decade ago in criminal pleas by

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<sup>1</sup> Since 1970, opioids have been regulated under the Controlled Substances Act (“CSA”). Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence; Schedule III drugs are deemed to have a lower potential for abuse, but their abuse may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. OxyContin and Hysingla ER are Schedule II drugs; Butrans is a Schedule III drug.

<sup>2</sup> Consistent with the commonly accepted medical usage, “chronic pain” is used to refer to non-cancer pain lasting three months or longer.

Purdue and three of its senior executives. However, since 2007 through the present, Purdue has continued to fraudulently market its opioids in Alaska by:

- a. misrepresenting the risk of abuse and addiction and failing to disclose the risk of addiction along with other side effects;
- b. falsely claiming that opioids improve patients' ability to function and their quality of life and failing to disclose the other harmful side effects of long-term opioid use;
- c. failing to disclose the lack of evidence that opioids are safe and effective long-term and that they will require higher and higher doses, increasing the risk of addiction, abuse, overdose and death;
- d. telling doctors that OxyContin works for 12 hours, when Purdue knew that, for many patients, it did not, contributing to a cycle of drug-craving that fueled addiction; and
- e. falsely claiming that opioids are safer than alternative, non-narcotic treatments.

4. Purdue's misrepresentations enabled the widespread use of opioids for common chronic pain conditions, such as low back pain, headaches, and arthritis, creating a far larger and more lucrative market for its drugs. Prior to Purdue's campaign, doctors used opioids for short-term acute pain or for cancer or end-of-life pain; opioids—rightly—were seen as too addictive and debilitating to be used long-term and inappropriate, therefore, for chronic pain. Through its ongoing, fraudulent marketing, Purdue transformed medical thinking about opioids, persuading doctors that the risk of addiction for legitimate pain patients is modest and manageable and outweighed by the benefits in reduced pain and improved quality of life for their patients. Purdue also increased the comfort level of doctors and patients in converting opioids prescribed for

acute pain—surgery or injuries, for example—to long-term use by patients who experienced or reported ongoing pain.

5. Patients were subject to the same types of marketing messages and trusted that drugs prescribed by their doctors must be safe and useful. As one recent report that surveyed Alaska residents noted, “[s]ince opioids are not illegal but prescribed by a doctor that lends to the misperception that prescription opioids are not dangerous.” Rather than dispel that false confidence, Purdue’s marketing deliberately stoked it.

6. Purdue’s deceptive marketing of opioids is particularly dangerous because it ties patients to a drug that might kill them, yet they cannot stop taking. As many as one in four patients who receive prescription opioids long-term for chronic pain in primary care settings will become addicted—a condition with which they will struggle their entire lives. According to the U.S. Centers for Disease Control and Prevention (“CDC”), one out of every 550 patients started on opioid therapy die of opioid-related causes a median of 2.6 years after their first opioid prescription.<sup>3</sup> The CDC director concluded: “We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.”<sup>4</sup>

7. Purdue has claimed in other contexts that its responsibility for the opioid epidemic is relieved by the independent actions of doctors who make their own decisions about whether to prescribe opioids and which drugs to use. However,

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<sup>3</sup> Frieden and Houry, Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline, NEJM, 4/21/16, at 1503.

<sup>4</sup> *Id.*

Purdue's marketing, as described below, deliberately set out to change prescribers' attitudes about opioids. Therefore, the company can hardly claim to be either surprised by or blameless for those results. [REDACTED]

[REDACTED]; indeed, it would have made little sense for Purdue to make such a significant investment in promoting its drugs to doctors if it did not believe its efforts would yield results.

8. While many people in treatment programs in Alaska seek help with heroin addictions, many of these patients started with prescription opioids but turned to heroin when pills were no longer available to them or too expensive. Providers from addiction treatment programs across the state report that more than half and up to 90% of their heroin-addicted patients were first exposed to opioids through doctors' prescriptions.

9. Opioid overdoses, whether from prescription opioids or heroin, have become common. In 2011, Alaska saw 66 fatal opioid overdoses; by 2016, that number reached 96, adding up to 475 deaths over those six years. The number continues to rise. In the first two weeks of May 2017, Anchorage averaged two heroin overdoses *per day*.

10. Beyond overdoses, Alaska hospitals have struggled to deal with other effects of the opioid epidemic. Doctors and administrators report dealing with patients who threaten violence or suicide if they are not given prescription opioids. One doctor described opioids as a daily part of practice – from patients seeking refills, to patients with complications from injecting opioids, to patients in active withdrawal from opioids. Depending on the day, 15 to 30 of the patients in one emergency department will be there on issues related to opioids, and one doctor described it as surprising to see

a patient who is not on opioids. In addition, hospitals report dramatic increases in septic infections, Hepatitis C, and endocarditis (infections of the heart) –often life-threatening conditions requiring expensive treatment— related to opioid abuse.

11. Law enforcement, likewise, has both shouldered and witnessed the costs of opioid abuse. The State’s most recent Annual Drug Report notes that the “increased availability of opioid-based medication remains a high-priority concern.” Reflecting the increase in opioid supply and demand, dosage units of Purdue’s OxyContin and generic oxycodone seized in Alaska increased from 1,183 in 2014 to 4,552 in 2016.<sup>5</sup>

Prescription drugs have been linked to homicides, assaults, home-invasion thefts, property thefts, driving under the influence, prostitution, pharmacy robberies, and the use of methamphetamines (to counteract the depressive effects of opioids), as well as narcotics offenses.

12. Teens and adolescents in Alaska have been introduced to prescription opioids and heroin through their own prescriptions and through prescription drugs found in medicine cabinets in their homes. In either case, their misuse of opioids can be traced to prescriptions for conditions and in quantities and doses that were unheard of before Purdue’s deceptive marketing campaign. As many as 80% to 90% of high school students in Anchorage report that pain pills are readily available in their homes.

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<sup>5</sup> Alaska State Troopers Annual Drug Report (2016)  
<http://dps.alaska.gov/getmedia/f259530b-5277-408e-9d45-4999958fe530/2016-Annual-Drug-Report-6-28-17final;.aspx>

Homeless adolescents in one treatment facility in Anchorage report being given opioids for injuries at age 14 or 15 and staying on them.

13. Even infants have been impacted by opioids. From 2014 to 2015, 97 newborns admitted to Providence Hospital's neonatal intensive care unit suffered from neonatal abstinence syndrome ("NAS"). Alaska Regional Hospital recently began the Neonatal Abstinence Evaluation Support and Treatment, or NEST, program; since October 2014, 33 infants have been treated in the program as they painfully withdraw from the drugs, while their mothers get help to address their opioid addictions. From 2001 to 2012, the average hospital costs for a NAS infant, typically covered by Medicaid, were \$88,869.

14. Even with its support to opioid-addicted mothers, half of the NEST infants will be discharged to foster care. Overall, the State's placement of children into foster care has increased dramatically as a result of the opioid crisis. As of October 2, 2017, 280 Alaska children in out-of-home placements supervised by the State involved a parent abusing an opioid.

15. Faced with the toll of its marketing efforts, Purdue did not pull back, but doubled down. In 2010, with the imminent expiration of its patent on OxyContin (and the prospect of generic competition for its marquee product), Purdue launched a reformulated OxyContin that was labeled "abuse-deterrent" because they are harder to crush and inject. Purdue went much further, promising doctors in Alaska that its abuse-deterrent opioids were safer for patients and "impossible" to abuse. Purdue knew that many users are still able to tamper with OxyContin, that oral abuse persists, and that

many users turn to heroin—none of which it disclosed to doctors. By deceptively promoting its abuse-deterrent opioids as a strategy to cope with the epidemic of opioid addiction and death it helped unleash, Purdue has prolonged and deepened the crisis in Alaska, persuading doctors and patients that they can continue to use opioids—so long as they are Purdue’s.

16. Purdue positioned itself as a responsible manufacturer not only with its introduction of abuse-deterrent opioids, but by claiming that it partnered with law-enforcement to address the diversion of opioids by “bad apple” doctors and patients, who are the real problems. Purdue has a duty to report suspicious orders of its drugs, but has *never once* reported a *single* prescriber to state law enforcement or the Alaska State Medical Board even though:

- a. Purdue has detailed information on the prescribing and dispensing of its opioids by doctor, pharmacy, volume, and dose, which allows it to detect orders of unusual size or frequency or at high doses favored by diverters;
- b. Purdue frequently visits doctors, allowing it to observe signs of diversion, such as waiting rooms crowded with young patients;
- c. Purdue maintains a list of doctors whose prescribing is troubling enough to no longer allow its sales agents to visit them; and
- d. the Alaska State Medical Board has received complaints about (from sources other than Purdue) and taken disciplinary action against doctors for improperly prescribing opioids, [REDACTED]

17. Purdue knew that a small set of doctors were responsible for the vast majority of its sales in Alaska. [REDACTED]

[REDACTED]

18. Purdue's deceptive, unfair, and unlawful conduct in Alaska has penetrated virtually every corner of the state. As a key element of its marketing, Purdue sends sales representatives to doctors' offices, which allows the company to address doctors' individual practices, questions, and concerns, build greater awareness of its products, and differentiate them from its competitors'. Purdue's sales representative(s) have an astonishing footprint in the state— [REDACTED]

[REDACTED]. Other opioid makers visited doctors once or twice a year, if at all, prompting one doctor to wonder why his Purdue representative visited so frequently, especially when there were no new developments with its drugs to promote or explain.

19. Purdue's diligence paid off. Purdue's sales in Alaska far exceed those of other opioid makers. Purdue drugs constitute 95% of Alaska's branded opioids paid for by Medicaid between 2013 and 2016. (The State examines spending on branded drugs since drug companies' promotions focus on these drugs.)

20. The Attorney General brings this action pursuant to her constitutional, statutory, and common law authority, alleging that Purdue has violated, and continues to

violate, the Alaska Unfair Trade Practices and Consumer Protection Act (“UTPA”), AS 45.50.471 *et seq.*; and the Alaska Medical Assistance False Claim and Reporting Act (“FCA”), AS 09.58.010 *et seq.* The Attorney General also alleges that Purdue’s unlawful conduct has created a public nuisance and that Purdue has acted fraudulently and negligently and unjustly enriched itself.

21. While Purdue has profited enormously from its deceptive marketing— with revenues of \$35 billion from OxyContin alone—the State of Alaska and its residents have borne its costs. Many of these costs—in lives ended or lost to addiction—can neither be calculated nor ever adequately compensated. Through this civil enforcement action, the State seeks: (a) injunctive relief to stop Purdue’s deceptive marketing and prevent it from failing to report suspicious prescribing; (b) damages for and abatement of the public health epidemic that Purdue has created; (c) three times the damages for the costs paid by the State for prescribing opioids and treating their adverse effects through the State’s medical assistance program; (d) restitution of money acquired as a result of Purdue’s conduct; (e) disgorgement of Purdue’s unjust profit; and (e) the maximum civil penalties allowed by law for each violation of the law, along with any other injunctive and equitable relief within this Court’s powers to redress and halt Purdue’s unlawful practices.

## II. PARTIES

22. The Plaintiff State of Alaska brings this action, by and through its Attorney General, Jahna Lindemuth, in its sovereign capacity in order to protect the interests of the State and its citizens. The Attorney General brings this action pursuant

to her constitutional, statutory, and common law authority, including the authority granted to her by AS 44.23.020, the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 *et seq.*; and the Alaska Medical Assistance False Claim and Reporting Act, AS 09.58.010 *et seq.*

23. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut. Rhodes Pharmaceuticals, L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. These parties are collectively referred to as "Purdue."

24. Through each of these entities, Purdue manufactures, markets, and sells prescription opioid pain medications, including the brand name drugs OxyContin, Butrans, and Hysingla ER, as well as generic opioids. Purdue has been a leading force in the prescription opioid market, both nationwide and in Alaska. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

25. Jane Does 1-10 are Purdue officers, directors, executives, or agents who were directly and personally involved in developing and executing its marketing efforts.

### III. JURISDICTION AND VENUE

26. Jurisdiction over the subject matter of this cause of action is proper based upon AS 22.10.020, 09.58.015, and 45.50.501. The State seeks damages in excess of \$100,000.

27. This Court has personal jurisdiction over Purdue because Purdue does business in Alaska and/or has the requisite minimum contacts with Alaska necessary to constitutionally permit the Court to exercise jurisdiction, with such jurisdiction also being proper under Alaska's long arm statute as codified in AS 09.05.015.

28. Venue is appropriate in the Third Judicial District at Anchorage pursuant to Rule 3 of the Alaska Rules of Civil Procedure, in that many of the unlawful acts committed by Purdue were committed in Anchorage, including the making of false statements and misrepresentations to Anchorage prescribers and patients.

29. Because the State of Alaska is not a citizen for purposes of diversity jurisdiction, no federal court can exercise subject matter jurisdiction over this case by virtue of diversity of citizenship. The Attorney General does not represent or seek relief on behalf of consumers, either individually or as a class, but acts pursuant to her statutory authority to ask this Court to "make additional orders or judgments that are necessary to restore to any person in interest any money or property, real or personal, which may have been acquired by means of an act or practice declared to be unlawful." AS 45.50.501.

30. The Attorney General has determined that pursuit of this action is in the public interest, as required by AS 45.50.501(a).

**IV. PURDUE CREATED THE MARKET FOR CHRONIC USE OF OPIOIDS THROUGH FRAUD.**

31. Purdue's pain franchise is built on deception. Before 2007, when Purdue entered its criminal plea and agreed to pay \$650 million to resolve state and federal fraud charges, opioids were widely recognized as highly addictive and, therefore, only suitable for severe pain and, except when a patient was dying, for short-term use. There was no evidence that opioids were appropriate or could be used safely long-term for most patients.

32. But the market for acute and end-of-life pain was relatively small. Thus, when Purdue launched OxyContin, it sought to broaden its use to chronic pain – back pain, arthritis, and headaches, for example – which not only is more widespread, but entails not just days or weeks, but months and years of drugs. Purdue, however, found that doctors were too worried about the risk of addicting their patients to prescribe its opioids for regular aches and pains.

33. To overcome this barrier to widespread prescribing, Purdue set out to—and did—convince doctors that, while opioids were generally addictive, patients with legitimate pain under a doctor's care would not become addicted. For example, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Purdue promised, in

one video, that fewer than 1% of patients would become addicted to opioids – a statement that had *no* basis in science. Purdue also falsely promised that its long-acting

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opioids were “steady-state” and therefore less likely to yield a high that fostered abuse and addiction.

34. Purdue engaged in aggressive branded promotion—giveaways of stuffed animals, CDs, and clocks and luxury getaways for top OxyContin sellers and prescribers—but also used general, unbranded materials, produced by Purdue or by seemingly independent third parties, to build the market for chronic opioids.

(Unbranded promotion does not name a specific drug and is often more persuasive because it does not seem to be product advertising.) Purdue secured exclusive rights to distribute “Pain as a Fifth Vital Sign,” an initiative of the Joint Commission for the Accreditation of Hospital Organizations (“JCAHO”), and ensured that virtually every health care facility and provider in the country learned its recommendation that pain should be assessed along with a patient’s pulse and blood pressure. Once doctors asked about pain, they were obligated to treat it, and Purdue made sure that doctors knew that opioids were an appropriate option.

35. The long-term use of opioids for chronic pain is particularly dangerous because patients develop tolerance to the drugs over time, requiring higher doses to achieve their effect. At high doses, opioids depress the respiratory system, eventually causing the user to stop breathing, which is what makes opioid overdoses fatal. Patients also quickly become dependent on opioids and will experience often severe withdrawal symptoms if they stop using the drugs, making it very hard for patients to discontinue their use after even relatively short periods of time. The risk of addiction increases with the duration of use, and causes patients to use opioids at ever-higher doses, even when

they are causing harm. It is this mix of tolerance, dependence, and addiction that has made the use of opioids for chronic pain so lethal. Contrary to Purdue's misrepresentations, as laid out below, pain patients who use opioids precisely as prescribed by a legitimate doctor can—and do—become addicted. Addiction is the result of using opioids, not just misusing or abusing them.

**V. PURDUE CONTINUED TO AGGRESSIVELY AND DECEPTIVELY MARKET ITS OPIOIDS FOR CHRONIC PAIN**

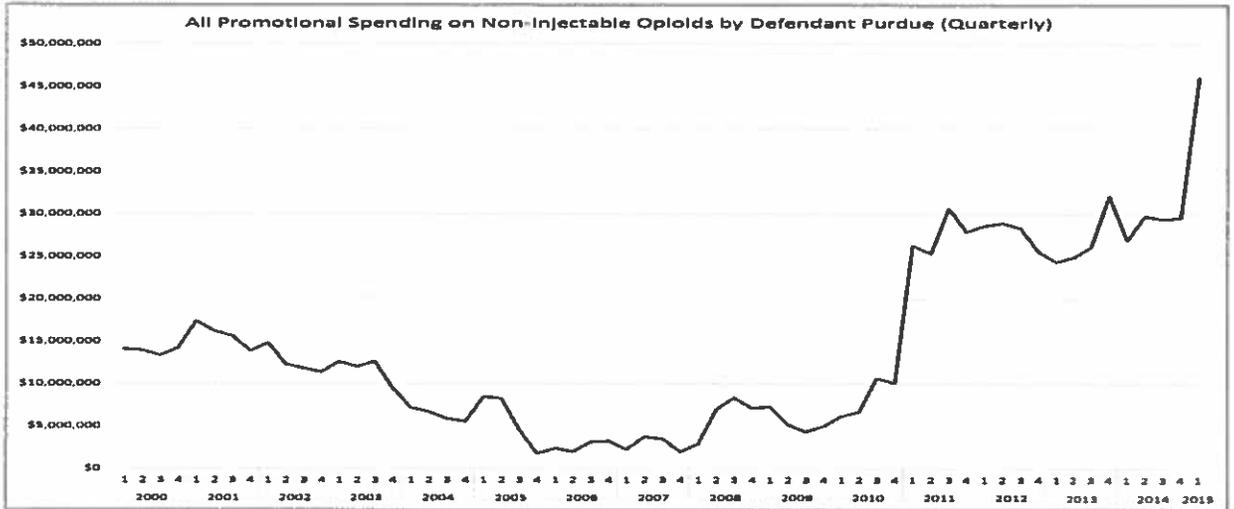
36. The 2007 settlements did not mark a change in Purdue's culture or conduct. Because what Purdue was told by doctors in the mid-1990s remains true—that doctors will not prescribe a highly addictive drug long-term for relatively modest pain—Purdue's multi-billion dollar franchise depends upon continuing to mislead doctors (and their patients). Purdue developed and deployed a comprehensive, sophisticated strategy to do so. Purdue's marketing budget has grown steadily since the launch of OxyContin, with the largest promotional spending *after* 2007. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Doctors from across Alaska describe their Purdue representative's visits as "relentless" and "like clockwork," every 6 weeks or two months, even absent any new developments in the drugs requiring explanation.

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37. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Even

doctors who say they rarely prescribe Purdue drugs received regular visits, [REDACTED]

[REDACTED]

Purdue's sales visits far exceeded those of any other opioid maker.

38. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

39. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

40. Purdue also used “key opinion leaders” (“KOLs”)—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or “CMEs”) that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from Purdue, and the CMEs were often sponsored by Purdue—giving Purdue considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected “misinformation” and were “clearly the wrong thing to do.”

41. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Purdue and other pharmaceutical companies exerted influence over these groups by providing major funding directly to them, as well. These “front groups” for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Purdue distributed these publications to prescribers or posted them on its website.

42. In addition, Purdue employees and KOLs identified, funded, published, and disseminated research that was designed to assist Purdue’s marketing efforts and skewed or misrepresented the scientific evidence. For example, to back its claims that opioids were rarely addictive, Purdue included in promotional and educational materials a cite to the prestigious *New England Journal of Medicine*, but failed to disclose its source was a letter to the editor.<sup>6</sup> The drug companies used his letter to conclude that their new opioids were not addictive, “[b]ut that’s not in any shape or form what we suggested in our letter,” according to one of its authors, Dr. Hershel Jick. A recent analysis in the *Journal* in June 2017 found that citation of the letter significantly increased after the introduction of OxyContin and “contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’

<sup>6</sup> J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J Med* 123 (1980)

concerns about the risk of addiction associated with long-term opioid therapy." It continued to be widely cited in literature and materials available until present.

43. Neither these third-party, unbranded materials, nor the marketing messages or scripts relied on by Purdue's sales representatives, were reviewed or approved by the U.S. Food & Drug Administration ("FDA"). All of the messages described below were disseminated to Alaska prescribers and patients through sales representative visits, medical education programs, marketing materials, websites, and other sources.

44. Set out below are examples of Purdue's false, deceptive, and unfair conduct that the Attorney General's investigation has identified to date. It is not an exhaustive list, and discovery may identify additional practices that were part of the same overarching scheme by Purdue to build and maintain a market for its opioids in Alaska, which will be part of the State's evidence and claims for relief in this matter.

**VI. MOST DANGEROUSLY, PURDUE MISREPRESENTS THE RISK THAT CHRONIC PAIN PATIENTS WILL BECOME ADDICTED TO ITS OPIOIDS.**

45. Purdue misrepresents, even today, to Alaska doctors and patients the risk of opioid addiction. Specifically, Purdue affirmatively misrepresents that: (a) pain patients do not become addicted to opioids; (b) its long-acting opioids are steady-state and less addictive; (c) doctors can identify and manage the risk of addiction; (d) patients who seem addicted are merely "pseudoaddicted," and should be treated with more opioids; (e) opioid addiction is the product not of narcotic opioids, but problem patients and doctors; and (f) opioid abuse and addiction manifest in snorting and injecting the

drugs, when oral abuse is far more common. In addition, Purdue failed to disclose to Alaska prescribers and patients the risks of addiction to and withdrawal from its opioids.

*A. Misrepresenting or failing to disclose the risk of addiction.*

46. Purdue's sales representatives omitted from their sales conversations with Alaska prescribers any discussion of the risk of addiction from long-term use of opioids. This failure to disclose the risk of addiction—an adverse effect that Purdue knew was material—was deceptive in its own right, but especially in light of Purdue's past misrepresentations regarding the risk of addiction.

47. Moreover, Purdue continued to affirmatively misrepresent that pain patients would not become addicted to opioids. In the words of one Alaska doctor, Purdue's message could be summarized as follows: opioids were safe and non-addictive, and doctors would be in trouble if they did not prescribe them. One former Purdue sales representative confirmed telling prescribers that opioids were safe when prescribed to legitimate patients with actual pain. Other Alaska prescribers were told that, although OxyContin is a narcotic, patients being treated for pain will not become addicted and that its drugs, used properly, were safe to use.

48. Purdue also disseminated misleading information about opioids and addiction through the front group American Pain Foundation ("APF"), over which

Purdue exercised control.<sup>7</sup> For example, *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain had been “undertreated” due to “[m]isconceptions about opioid addiction.” This guide also revived Purdue’s pre-2007 assertion, though in slightly different form, that “less than 1% of children treated with opioids become addicted,” and perpetuated the concept of pseudoaddiction. On information and belief, based on Purdue’s close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*. It is still available to Alaska prescribers online.<sup>8</sup>

49. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain*, which downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. Although it included the Purdue copyright at the bottom of each page, the website did not promote particular Purdue products and cultivated the “impression that it [was] neutral and unbiased.” While the website discusses opioids and side-effects from their

<sup>7</sup> [REDACTED]. Purdue grant letters informed APF that Purdue’s contributions reflected the company’s effort to “strategically align its investments in nonprofit organizations that share [its] business interests.” [REDACTED]

<sup>8</sup> See American Pain Foundation., *A Policymaker's Guide to Understanding Pain & Its Management* (2011), <http://s3.documentcloud.org/documents/277603/apf-policymakersguide.pdf>.

use and the *fear* of addiction (as a barrier to use), it *never* disclosed the risk of addiction to opioids. At the same time, the website contained testimonials from several dozen physicians speaking positively about opioids. Eleven of these advocates received a total of \$231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the website.

50. The fact that Alaska prescribers were misled about opioid addiction is confirmed by the experience of Alaska patients. A survey of more than 200 Alaska residents prescribed opioids found that fewer than 10% were warned of the risk of addiction at the time of the prescription.<sup>9</sup> Doctors and programs treating individuals who have overdosed from or are addicted to opioids also confirm that many were first exposed to opioids through prescriptions and were not warned at the time of the risk of addiction.

51. As before the 2007 settlements and criminal pleas, Purdue continued to tell Alaska doctors that its long-acting opioids are “steady-state,” with no peaks and troughs. This promise of steady-release implies (and is understood by prescribers to mean) that Purdue’s opioids are less addictive because they do not trigger the euphoric rush and crash that fuel drug cravings.

52. Purdue sales representatives also failed to disclose to Alaska prescribers the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause

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<sup>9</sup> Healthy Voices Healthy Choices & Alaska Injury Prevention Center, *Prescription Opioid Misuse and Heroin Use Among Youth and Young Adults in Anchorage, Alaska, Needs Assessment*. (2017)  
[https://www.voak.org/pdf\\_files/partnerships-for-success](https://www.voak.org/pdf_files/partnerships-for-success)

intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. Withdrawal symptoms can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

***B. Overstating the ability of doctors to manage the risk of addiction and failing to disclose the lack of evidence that these strategies they work.***

53. Moreover, Purdue, falsely and without competent evidence, claimed that, by using a simple questionnaire, doctors can identify high-risk patients, and safely prescribe to all other patients without the risk of addiction. Purdue failed to disclose the lack of evidence that screening and other risk management strategies (such as patient contracts) mitigate addiction risk.

54. Former Purdue sales representatives acknowledged conveying that doctors can screen out patients at high risk of addiction through urine tests and patient contracts, and that doctors can address that risk by prescribing only to trusted patients. Purdue also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences attended by or available to Alaska prescribers.

55. For instance, Purdue shared its *Partners Against Pain* “Pain Management Kit,” which contains several “drug abuse screening tools” and CDs with catalogues of Purdue materials, which included these tools, with prescribers. Alaska prescribers report receiving these materials and using screening tools and patient agreements with the understanding that they would help ensure that opioids are used appropriately.

56. Purdue also sponsored CMEs that spread the same deceptive message. For example, a 2011 CME program taught by Dr. Lynn Webster, another KOL who the

company also funded, titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.” Another Purdue-funded 2012 CME, *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids.

57. Purdue used its involvement in the College on the Problems of Drug Dependence (“CPDD”), which provides training and support to addiction treatment professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue was allowed more opportunities to present than other drug companies at each CPDD conference, and — with provided very different messages from non-Purdue talks. One of Purdue’s consistent themes is that “bad apple” patients, not opioids, are the source of the addiction crisis, and that once those patients are identified doctors can safely prescribe opioids without addicting patients. Hundreds of addiction treatment specialists from across the country attended these conferences, which likely included Alaska prescribers as well. [REDACTED]

C. *Promoting the unsubstantiated concept of pseudoaddiction to discount signs of addiction.*

58. Purdue also deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction counseled that signs of addiction, such as asking for a drug by name or seeking early refills, reflect undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel. Though pseudoaddiction was coined by a doctor, David Haddox (later hired by Purdue) based on the observation of a single patient, Purdue deceptively described pseudoaddiction as an accepted scientific concept. In *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 [REDACTED] [REDACTED] for prescribers and law enforcement, Purdue described pseudoaddiction as a term that “has emerged in the literature to describe the inaccurate interpretation of [drug-seeking] behaviors in patients who have pain that has not been effectively treated.”

59. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

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[REDACTED] 10

[REDACTED]. Purdue also promoted pseudoaddiction through at least 2013 on its website, *Partners Against Pain*.<sup>11</sup> Numerous Alaska prescribers were informed of or encouraged to visit the website or given materials on the website.

***D. Falsely portraying addiction as a problem of opioid abuse and diversion, not opioid use.***

60. In addition to deceptively ascribing signs of addiction to pseudoaddiction, Purdue falsely portrayed “true” addiction in its narrowest form. *Providing Relief, Preventing Abuse*, for instance, shows pictures of the signs of injecting or snorting opioids—track marks and perforated nasal septa—under the heading “Indications of Possible Drug Abuse.” Purdue knew that opioid addicts who resort to these extremes are uncommon; users far more typically become dependent and addicted by swallowing intact pills. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time.

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<sup>10</sup> Unless otherwise indicated, the basis for information and belief is that Purdue’s marketing was executed according centralized plans with common messages, such that misrepresentations made in another state would have been made in Alaska, too.

<sup>11</sup> *Partners Against Pain* consists of both a website, styled as an “advocacy community” for pain care, and education resources distributed to prescribers by Purdue sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

61. These skewed depictions misleadingly reassured doctors that, in the absence of these extreme signs, they need not worry that their patients are abusing or addicted to opioids. [REDACTED]

*E. Purdue's statements and omissions regarding the risk of addiction are contrary to and unsupported by scientific evidence.*

62. Purdue's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Prescription opioids are, for the most part, "no less addictive than heroin."<sup>12</sup> Studies have shown that at least 8-12%, and as many as 30-40%, of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk[] of ... addiction"—"even at recommended doses"—of all opioids."<sup>13</sup> That same month, after a "systematic review of the best available evidence," the CDC published the CDC Guideline for Prescribing Opioids for Chronic Pain ("CDC Guideline"). The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).<sup>14</sup> The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."<sup>15</sup>

<sup>12</sup> See note 3, *supra*.

<sup>13</sup> FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics, FDA (Sep. 10, 2013).

<sup>14</sup> CDC Guideline at 2.

<sup>15</sup> *Id.* at 21.

63. There is no evidence that long-acting opioids, like Purdue's, are any less addictive than other opioids. In fact, long-acting opioids, including Hysingla and OxyContin, are, and have long been, Schedule II narcotics for their "high potential for abuse" and "may lead to severe psychological or physical dependence." Purdue's representation that its long-acting opioids had fewer peaks and valleys or were less addictive was one of the deceptive statements cited in its 2007 criminal plea and settlements, and it is no more true today.

64. Further, patients that "doctor-shop," that is, visit multiple prescribers to obtain opioid prescriptions, are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid overprescribing is not, contrary to Purdue's assertions, the result of problem patients or doctors.

65. The CDC Guideline also confirms the falsity of Purdue's claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from longterm opioid therapy."<sup>16</sup>

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<sup>16</sup> CDC Guideline at 2

66. No competent scientific source has validated the concept of pseudoaddiction, and the CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a Purdue key opinion leader, admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

**VII. PURDUE OVERSTATED THE BENEFITS OF OPIOIDS FOR CHRONIC PAIN WHILE HIDING THE LACK OF EVIDENCE SUPPORTING THEIR USE.**

67. To convince Alaska prescribers and patients that opioids should be used to treat chronic pain, Purdue also had to persuade them of a significant upside to long-term opioid use. But as the CDC Guideline makes clear, there is “*insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain.*”<sup>17</sup> In fact, the CDC found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later”<sup>18</sup> and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The few longer-term studies of opioid use had “consistently poor results,” and “several studies have showed that opioids for chronic pain may actually worsen pain and functioning ...”<sup>19</sup> The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was “not aware of

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<sup>17</sup> *Id.* at 10.

<sup>18</sup> *Id.* at 9.

<sup>19</sup> *See* note 3, *supra*.

adequate and well-controlled studies of opioids use longer than 12 weeks.”<sup>20</sup> As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

*A. Failing to disclose the lack of evidence supporting the use of opioids long-term for chronic pain.*

68. Nevertheless, Purdue touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence. Moreover, based on interviews with Alaska prescribers, Purdue sales representatives promoted its drugs for chronic pain, but did not disclose in their sales conversations the lack of evidence supporting long-term use.

69. Two prominent professional medical membership organizations, the American Pain Society (“APS”) and the American Academy of Pain Medicine (“AAPM”), each received substantial funding from Purdue.<sup>21</sup> Upon information and belief, based on their funding and the involvement of Purdue KOLs in leadership roles, Purdue was able to exercise considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox (also responsible, as noted above, for coining

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<sup>20</sup> Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

<sup>21</sup> [REDACTED]

pseudoaddiction), was at the time a Purdue KOL and later became a senior executive for the company. Dr. Russell Portenoy, a pain management specialist who received Purdue research grants and was a Purdue consultant (*see also*, paragraph 40), was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

70. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines were particularly important to Purdue in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines, including Dr. Portenoy, received support from Purdue, and another eight received support from other opioid manufacturers.

71. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, made to the sponsoring organizations and committee members. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who also served on

the panel, has described them as “skewed” by Purdue and other drug companies and “biased in many important respects,” including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

72. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain* and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited 1,647 times in academic literature, and at least one Alaska doctor recalled going to talks on the Guidelines.

73. APS and AAAPM are just two of a number of professional and patient advocacy organizations over which Purdue exercised control, which, upon information and believe, also failed to disclose the lack of evidence for chronic opioid therapy.

74. [REDACTED]

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75. Purdue also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, related to a chronic condition, but only provided opioids for 30 days. The authors acknowledge that the “results... should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis].”<sup>22</sup> Yet, the authors conclude that “[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids longterm.”<sup>23</sup> This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there were no reported data regarding addiction, and the study was not long-term.

76. Upon information and belief, based on Purdue’s pattern of conduct, Purdue conducted, directed, and disseminated other misleading studies.

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<sup>22</sup> Jacques R. Caldwell, et al., , *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 *Journal of Rheumatology* 862-869 (1999).

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

*B. Overstating opioids' effect on patients' function and quality of life.*

77. Purdue also claimed—without evidence—through its sales representatives and other materials disseminated in Alaska that long-term opioid use would help to improve patients' function and quality of life and get them back to work and to their lives. However, as one Alaska prescriber noted, his patients seemed to function better when he took them off long-term opioids.

78. Purdue and Purdue-sponsored materials distributed or made available in Alaska reinforced this message. For example, the 2011 publication *A Policymaker's Guide* falsely claimed that “multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients.” A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes”—case studies featuring patients with chronic pain conditions—that implied functional improvement. One advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively.

79. Likewise, Purdue's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression,

anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

80. As one pain specialist observed, “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.”<sup>24</sup> Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers’ compensation claims have found that workers who take opioids are almost four times more likely to reach costs over \$100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients’ risk of being on work disability one year later.

Assessing existing science, the CDC Guideline found that there was “[n]o evidence show[ing] a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later”<sup>25</sup> and advised that “there is

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<sup>24</sup> Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), <http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonomamedicine-are-we-making-pain-patients-worse?>

<sup>25</sup> CDC Guideline at 15.

no good evidence that opioids improve pain or function with long-term use.”<sup>26</sup> The FDA and other federal agencies have made this clear for years.<sup>27</sup> The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.”<sup>28</sup> In that vein, a recent study Princeton economist Alan Krueger found that opioids may be responsible for roughly 20% of the decline in workforce participation among prime-age men and 25% of the drop for women.<sup>29</sup>

81. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.”<sup>30</sup> According to the CDC, “for the vast majority of patients, the known, serious, and too-often-fatal risks

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<sup>26</sup> *Id.* at 20.

<sup>27</sup> The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See*, Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), *available at* (rejecting claims that Actavisthe opioid, Kadian, had an “overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that “patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”). The FDA’s warning letters were available to Purdue on the FDA website.

<sup>28</sup> CDC Guideline at 2.

<sup>29</sup> Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, Brookings Papers on Economic Activity Conference Draft (26 Aug 2017).

<sup>30</sup> CDC Guideline at 18.

far outweigh the unproven and transient benefits [of opioids for chronic pain].”<sup>31</sup> As one doctor noted, the widespread, long-term use of opioids “was an experiment on the population of the United States. It wasn’t randomized, it wasn’t controlled, and no data was collected until they started gathering death statistics.”

82. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

*C. Omitting or mischaracterizing adverse effects of opioids*

83. In materials Purdue produced, sponsored, or controlled, Purdue omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen), which do not impose a risk of addiction. None of these claims were corroborated by scientific evidence.

84. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Purdue routinely omitted the risks of hyperalgesia, a “known serious risk associated with chronic opioid analgesic

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<sup>31</sup> See Note 3, *supra*.

therapy,”<sup>32</sup> in which the patient becomes more sensitive to certain painful stimuli over time; hormonal or endocrine dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally painfully withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety that are often also used by pain patients. [REDACTED]

[REDACTED]

[REDACTED]

85. Purdue sponsored publications, such as APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which misleadingly emphasized the risks from NSAIDs. *Treatment Options* counseled patients that opioids differ from NSAIDs in that they have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids). This publication also warned that risks of NSAIDs increase if “taken for more than a period of months,” with no corresponding warning about opioids.

86. Similarly, Purdue sponsored APF’s *Exit Wounds* (2009), a book aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with

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<sup>32</sup> See note 13, *supra*.

post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

87. Purdue used its CMEs in the same way. For example, a Purdue sponsored CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

88. These omissions regarding adverse side-effects are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the “intolerable effects” of opioids.<sup>33</sup> Moreover, the CDC, in its evidence review, did not find evidence that opioids were more effective for pain reduction than NSAIDs for back pain or antidepressants for neuropathic pain (typically, nerve pain), and found that non-opioids were better tolerated and better at improving physical function, with little or no risk of addiction and lower risks of overdose and death.<sup>34</sup>

89. Purdue’s misrepresentations were effective in increasing its own sales and driving down those of this alternative, less risky and costly treatment. A study of 7.8

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<sup>33</sup> Meredith Noble M, *et al.*, *Long-term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010.).

<sup>34</sup> See Note 3, *supra*.

million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%.

### VIII. PURDUE PROMOTED THE USE OF OPIOIDS IN EVER-HIGHER DOSES WITHOUT DISCLOSING THE GREATER RISKS.

90. Purdue falsely claimed to Alaska prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Purdue needed to generate this comfort level among doctors to ensure the doctors maintained patients on the drugs.

91. Purdue did not disclose to Alaska prescribers the risks associated with increasing the dose. In addition, Purdue and Purdue-sponsored publications and CMEs available in Alaska also misleadingly suggested that higher opioid doses carried no added risk.

92. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should find a doctor who would.

93. Purdue publications and CMEs were similarly biased. For example, A *Policymaker's Guide*, the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary,"

but did not disclose the risks from high dose opioids. This publication is still available online.<sup>35</sup>

94. Likewise, Purdue's 2012 Conversion and Titration Guide advises prescribers to "[i]ncrease the OxyContin dose by increasing the total daily dose, not by changing the 12-hour dosing interval." This advice was not accompanied by warnings regarding increased risk of addiction associated with increased doses.

95. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses.

96. As noted in Section VI(C), Purdue also advocated that patients who exhibit signs of addiction should, as a first response, be given higher doses of opioids as their pain is likely undertreated.

97. Purdue's assertions and omissions are contrary to scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses.

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<sup>35</sup> See note 8, *supra*.

98. The CDC Guideline concludes that the “[b]enefits of high-dose opioids for chronic pain are not established”<sup>36</sup> while “[o]verdose risk increases in a dose-response manner ...”<sup>37</sup> That is why the CDC advises doctors to “avoid increasing doses” above 90 mg MED.

99. In Alaska, Purdue knew, or should have known, that its sales depended upon high dose use. [REDACTED]

[REDACTED]

[REDACTED]

100. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

<sup>36</sup> CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”<sup>36</sup> CDC Guideline at 16.

<sup>37</sup> See note 3, *supra*.

than dose ceilings (which were being pressed through regulatory and legislative efforts) were the best strategies for preventing overdose.

**IX. PURDUE MISLEADINGLY PROMOTED OXYCONTIN AS SUPPLYING 12 HOURS OF PAIN RELIEF WHEN PURDUE KNEW THAT, FOR MANY PATIENTS, IT DID NOT.**

101. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch and that Alaska prescribers confirmed. While OxyContin's FDA-approved label directs 12-hour dosing, Purdue sought that dosing frequency in order to maintain a competitive advantage over other opioids that required more frequent dosing. Yet Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours by affirmatively claiming that OxyContin lasts for 12 hours and by failing to disclose that OxyContin fails to provide 12 hours of pain relief to many patients.

102. Since it was launched in 1996, OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency. It was Purdue's decision to submit OxyContin for approval with 12-hour dosing. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," Purdue has conducted no such studies.

103. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing “smooth and sustained pain control all day and all night.” But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a “substantial number” of chronic pain patients taking OxyContin experienced “end of dose failure”—*i.e.*, little or no pain relief at the end of the dosing period.

104. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—“rescue medication”—in between OxyContin doses. In another study, 95% of patients resorted to rescue medication at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%. [REDACTED]

105. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin’s 12-

hour dosing “the perfect recipe for addiction.”<sup>38</sup> Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

106. Twelve-hour dosing is key to OxyContin’s market dominance and comparatively high price. Without this advantage, the drug had little to offer over less expensive, short-acting opioids. Its internal marketing plans indicate that 12-hour dosing was the key to differentiating the drug from short-acting, typically combination opioids (combinations of an opioid and another pain reliever such as acetaminophen) on the market when OxyContin was launched. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours) because 12-hour dosing was “a significant competitive advantage.”

107. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its

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<sup>38</sup> Harriet Ryan, “‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem,” *Los Angeles Times*, May 5, 2016, <http://www.latimes.com/projects/oxycontin-part1/>.

label to reflect appropriate dosing and to disclose to prescribers what it knew about OxyContin's actual duration, regardless of any marketing advantage.<sup>39</sup>

108. [REDACTED]

[REDACTED] Doctors understood Purdue's promotion to mean that OxyContin provides 12 hours of relief. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

109. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

110. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence, including by Alaska prescribers. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—

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<sup>39</sup> Kadian, an opioid manufactured by Allergan, was designed to be taken once a day, but the label acknowledges and advises dosing of up to every 12 hours for certain patients.

including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill.

111. [REDACTED]

[REDACTED] This advice was not accompanied by appropriate disclosures regarding OxyContin's shorter-than-12-hour relief in many cases, nor warnings regarding increased risk of addiction associated with increased doses, as discussed in Section VIII.

**X. TO PROTECT ITS MARKET AND PROFITS, PURDUE MISREPRESENTED THE IMPACT OF ITS OPIOIDS IN REDUCING ABUSE AND ADDICTION.**

112. By the mid-2000s, widespread addiction to and abuse of OxyContin had emerged in the public eye. Rather than acknowledge that these problems were the inevitable result of widespread prescribing of OxyContin for chronic pain, Purdue claimed that abuse and addiction resulted from diversion by abusers snorting or injecting the drugs. Purdue also brought to market an "abuse-deterrent" formulation ("ADF") of OxyContin but deceptively marketed it to doctors as a solution to the opioid epidemic.

113. Reformulated, ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Purdue launched Hysingla ER, extended-release hydrocodone in 2014, the product included similar abuse-deterrent properties.

114. The FDA noted in permitting ADF labeling that “the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse).” Purdue’s labels also acknowledge that abusers seek out the drugs because of their high likeability when snorted, that the abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and do *not* indicate that ADF opioids prevent or reduce addiction, abuse, misuse, or diversion.

115. Despite their limitations, Purdue sales representatives in Alaska regularly used the so-called abuse-deterrent properties of Purdue’s opioids as a primary selling point to differentiate those products from their competitors. Specifically, Purdue detailers:

- a. claimed that Purdue’s ADF opioids *prevent* tampering and that its AD products could not be crushed or snorted;
- b. claimed that Purdue’s ADF opioids *reduce* opioid addiction, abuse, and diversion;
- c. asserted or suggested that Purdue’s ADF opioids are “safer” than other opioids; and
- d. failed to disclose that Purdue’s ADF opioids do not impact oral abuse or misuse.

116. Dr. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue’s ADF opioids are being abused in large numbers. [REDACTED]

[REDACTED]

[REDACTED] Purdue marketed both Hysingla

ER and OxyContin, nationally and in Alaska, as reducing abuse and addiction, despite the lack of supporting evidence.

117. In Alaska, Purdue's sales representatives made claims about abuse deterrence that go well beyond the drugs' labeling and the scientific evidence. The abuse-deterrent properties of OxyContin and Hysingla have been central to Purdue's recent marketing efforts in Alaska. [REDACTED]

[REDACTED] Doctors report that abuse-deterrence is Purdue's primary marketing message in sales visits. Purdue sales representatives have told Alaska prescribers that its abuse-deterrent formulations are "safer," "non-addictive" or less addictive, "could not be abused or tampered with" and do not have a street value. Ironically, Purdue also claimed that its abuse-deterrent opioids are a sign that it is a more responsible company than in the past, and is aggressively trying to address the problem of opioid addiction and death.

118. Purdue did not disclose to Alaska prescribers that ADF opioids are subject to oral abuse, can be tampered with, and shift abuse to other opioids.

119. Purdue's marketing of its ADF is and was false and misleading and are inconsistent with the FDA-approved labels for Purdue's ADF opioids and with the scientific evidence. Purdue knew or should have known, but did not disclose, that

“reformulated OxyContin is not better at tamper resistance than the original OxyContin”<sup>40</sup> and is still regularly tampered with and abused.

120. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. [REDACTED]

[REDACTED] A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue’s abuse-deterrent labeling based on the firm’s ability to easily prepare OxyContin to be snorted or injected.

121. [REDACTED] One-third of the patients in a non-Purdue 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue’s ADF opioids was reduced, those addicts simply shifted to other drugs such as heroin.

122. As in other areas, Purdue distorted its own research to support its promotional claims and to bury confounding evidence. For example, a 2013 article presented by Purdue employees based on review of data from poison control centers concluded that ADF OxyContin can reduce abuse, but ignored important negative findings. On close review, the study reveals that abuse merely shifted to other drugs and

<sup>40</sup> *In re OxyContin*, 1:04-md-01603-SHS, Docket No 613, Oct. 7, 2013 hr’g, Testimony of Dr. Mohan Rao, 1615:7-10.

that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin.

123. The CDC Guideline confirms that “[*n*]o studies” support the notion that “abuse deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes.”<sup>41</sup> The original FDA medical review of reformulated OxyContin explicitly stated in 2009 that “tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse) – at the time estimated to be 72% of OxyContin abuse. The 2012 medical office review of Purdue’s application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug. The FDA’s Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin “actually made a reduction in abuse,” between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue’s own funded research shows that half of OxyContin abusers continued to do so orally after the reformulation rather than shift to other drugs. Tom Frieden, the Director

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<sup>41</sup> CDC Guideline at 22 (emphasis added).

of the CDC, reported that his staff could not find “any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death.”<sup>42</sup>

124. Purdue itself knew that claiming AD formulations reduces abuse was not supported by evidence. [REDACTED]

[REDACTED]

125. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew its supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue “evaluating the misuse and/or abuse of reformulated OxyContin” and whether those studies “have demonstrated that the reformulated product has a meaningful impact on

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<sup>42</sup> Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), <http://www.detroitnews.com/story/news/nation/2017/01/02/painkillersdrugmakers-addictive/96095558>.

abuse."<sup>43</sup> Given the absence of any public hearings or advisory meetings on the topic, it seems that Purdue still has not presented the data to the FDA, presumably because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

126. Purdue's false and misleading marketing of the benefits of its ADF opioids preserved and expanded its sales by persuading doctors to write prescriptions for ADF opioids in the mistaken belief that they were safer. It also allowed prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—*i.e.*, it allowed them to believe that while patients might abuse, become addicted to, or die from other, non-ADF opioids, Purdue's opioids did not carry that risk.

127. Purdue's misleading marketing preserved not only its price, as well as its sales. Generic versions of OxyContin, which became available in February 2011, threatened to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires. [REDACTED]

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<sup>43</sup> Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

[REDACTED]

128. Purdue's knew that its ADF marketing changed prescribers' perceptions of its opioids and their willingness to continue to prescribe them. [REDACTED]

[REDACTED]

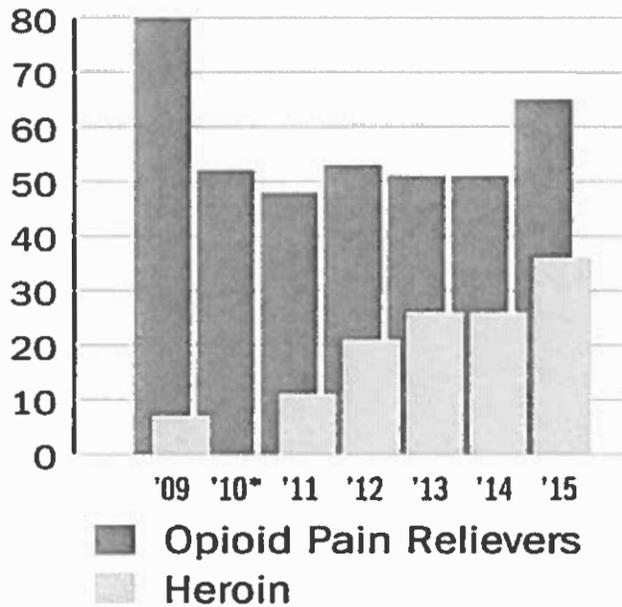
[REDACTED] According to law enforcement, doctors, and treatment providers in Alaska, OxyContin continues to be widely abused, even after its reformulation in Alaska, as elsewhere. It is still as sought after in illicit street sales, it is still snorted and injected, and it continues to result in overdoses and deaths. [REDACTED]

[REDACTED]

[REDACTED] On a larger scale, while overdoses dropped briefly after the introduction of reformulated OxyContin in 2010, the number of heroin deaths

increased immediately, and the number of prescription opioid overdose deaths dropped, and then continued to rise again.

### Alaska overdose deaths 2009 - 2015



\*2010 heroin number statistically unreliable

Source: State of Alaska Epidemiology

PAM DUNLAP-SHOHL / Alaska Dispatch News

#### XI. PURDUE FAILED TO REPORT SUSPICIOUS PRESCRIBING BY ALASKA PRESCRIBERS.

129. Purdue deceptively and unfairly failed to report to Alaska authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its “constructive role in the fight against opioid abuse,” including its commitment to ADF

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opioids and its “strong record of coordination with law enforcement.”<sup>44</sup> Purdue converted the opioid epidemic into a promotional opportunity: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

130. As described above, Purdue’s public stance long has been that “bad apple” patients and drug diversion to illicit secondary channels are to blame for widespread addiction and abuse. While opioids have been diverted through illicit prescribing and street sales, it is the regular, legitimate prescribing of opioids that created and fueled this crisis. A study of 254 accidental opioid overdose deaths in Utah found that 92% of the decedents had been receiving prescriptions from health care providers for chronic pain. Sales to patients who doctor-shop (or visit multiple doctors to hide illicit or over-use) constitute approximately only 1% to 2% of opioid volume.

131. Yet, Purdue prefers to keep attention on illicit use and diversion, and promotes its funding of various drug abuse and diversion prevention programs and introduction of ADF opioids as the solution to the opioid epidemic. This sleight of hand diverts attention from the real problem of widespread prescribing of opioids, which

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<sup>44</sup> Purdue, *Setting The Record Straight On OxyContin’s FDA-Approved Label*, May 5, 2016, <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-onoxycontins-fda-approved-label/>; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, <http://www.purduepharma.com/news-media/get-the-facts/setting-therecord-straight-on-our-anti-diversion-programs/>.

Purdue normalized, and allows Purdue to present itself as a responsible corporate citizen doing what it can to address the opioid crisis.

132. Since at least 2008, Purdue has consistently trumpeted its partnership with law enforcement and government agencies to combat opioid abuse and diversion. The message of close cooperation features in virtually all of Purdue's recent pronouncements regarding opioid abuse.

133. Touting the benefits of ADF opioids, Purdue's website asserts, for instance: "we are acutely aware of the public health risks these powerful medications create ... That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse ..."<sup>45</sup> Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with ... communities, law enforcement, and government."<sup>46</sup> Responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long

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<sup>45</sup> Purdue website, *Opioids With Abuse-Deterrent Properties*, <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrentproperties/>.

<sup>46</sup> Purdue website, *Opioids Corporate Responsibility*, <http://www.purduepharma.com/news-media/opioids-corporate-responsibility/>.

record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion.”<sup>47</sup>

134. These statements, among others, create the misimpression that Purdue is proactively working with law enforcement and government authorities, nationwide and in Alaska, to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to portray Purdue as committed to reining in opioid abuse and thereby enhances the image that the company, and its drugs, must be safe and worthy of patients’ and doctors’ trust.

135. Yet, contrary to its public representations, Purdue has consistently failed to monitor and report suspicious prescribing to authorities and has *never* reported a prescriber to the Alaska Board of Medicine or other state enforcement authorities.

136. Purdue can track distribution and prescriptions of its opioids down to the retail and prescriber level. It has detailed data on opioid prescribing and sales and, through its extensive network of sales representatives, can – and does -- observe signs of diversion.

137. Purdue did identify those doctors—*internally*. Since at least 2002, Purdue maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash

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<sup>47</sup> Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-antidiversion-programs/>.

transactions, patient overdoses, and unusual prescribing of the highest-strength pills. (80 mg OxyContin pills or “80s,” as they were known on the street, were a prime target for diversion.) Health care providers added to the database no longer were detailed, and sales representatives received no compensation tied to their prescriptions.

138. Yet, Purdue failed to cut off these providers’ opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. In an interview with the *Los Angeles Times*, which first reported this story, Purdue’s former senior compliance officer acknowledged that over five years of his investigations, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

139. The same was true of prescribers. Despite Purdue’s knowledge of illicit prescribing from one Los Angeles clinic which Purdue’s district manager called an “organized drug ring,” Purdue did not report its suspicions from 2009 until 2013—long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

140. Purdue is obligated by state and federal law applicable to manufacturers of controlled substances to monitor and report suspicious conduct.<sup>48</sup> The DEA in 2006 and 2007 sent letters to manufacturers and wholesalers of opioids, including Purdue, reminding them of their legal “obligation to design and operate a system to disclose . . .

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<sup>48</sup> See AS 17.30.020 & 17.30.080; 21 U.S.C. 823(e); 21 C.F.R. 1301.74(b).

suspicious orders of controlled substances,” to inform the DEA “of suspicious orders when discovered,” and to “maintain effective controls against diversion” of controlled substances. Registrants’ “responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels.”

141. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

142. Purdue knew that a small set of doctors were responsible for the vast majority of its sales in Alaska. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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143. Within the Medicaid system, 3% of prescribers also accounted for half of Purdue's revenue, and three prescribers each billed over \$1 million on Purdue opioids.

[REDACTED]

[REDACTED]

144. As one example, last year, the State Medical Board summarily suspended the license of Dr. Mahmood Ahmad. According to the Board's decision. Dr. Ahmad typically saw patients in 15-minute intervals from 7:00 a.m. through 8:30 p.m., including on weekends. Ten different pharmacists complained to the Board because, among other reasons, of Dr. Ahmad's high volume and high dose prescribing of opioids (and his failure to write low dose prescriptions). In one three-day period, Dr. Ahmad wrote 229 separate controlled substance prescriptions.<sup>49</sup> Patients were described in the Board's record as "extremely young" and with "little physical evidence" of needing high doses of opioids and as paying cash for their prescriptions—all indicators of diversion and all known or knowable to Purdue. In fact, Dr. Ahmad's problem prescribing was so clear that one area hospital refused to fill his prescriptions; when, one day, it mistakenly filled one of his prescriptions for a controlled substance, it was overrun with Dr. Ahmad's patients. In the words of the Board's expert, "There is no population of chronic pain patients anywhere in the world who would uniformly require

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<sup>49</sup> In the Matter of Mahmood Ahmad, Decision of Summary Suspension, June 27, 2016, at 7.

the high dose opioids Dr. Ahmad prescribes.” The expert found that Dr. Ahmad’s prescribing creates “a clear and immediate danger to the public health and safety.”<sup>50</sup>

145. [REDACTED]

[REDACTED] Purdue itself—despite its opportunities to observe Dr. Ahmad and its access to data regarding the volume and dosage at which he prescribed, never reported him.

146. In addition, evidence suggests that Purdue placed several potentially suspicious Alaska prescribers on its internal do-not-call list, but, again, failed to report these prescribers to state authorities. These doctors, who were identified by other doctors in their areas for suspicious prescribing, were not detailed at all by Purdue in recent years, according to public records. Given Purdue’s diligent travel across the state, its failure to visit these particular doctors—whose high volume of prescribing would have been evident to Purdue and would have made them particularly attractive sales targets—suggest a conscious decision not to promote to them.

147. Purdue’s failure to monitor and report this suspicious prescribing that was actually known to it, as well as suspicious prescribing of which it should and could have been aware, constitutes both unfair and deceptive practices.

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<sup>50</sup> In the Matter of Mahmood Ahmad, Decision of Summary Suspension, June 27, 2016, at 7.

**XII. BY INCREASING OPIOID USE, PURDUE'S DECEPTIVE MARKETING FUELED THE OPIOID EPIDEMIC AND SIGNIFICANTLY HARMED ALASKA AND ITS RESIDENTS.**

148. Purdue's unlawful conduct has reshaped the prescribing of opioids in Alaska. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace treatment for chronic pain. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. [REDACTED]

[REDACTED] In 2015, Purdue reaped an estimated \$2.4 billion in revenue, virtually all of it from opioids. OxyContin alone has generated \$35 billion in sales. The Alaska Medicaid program spent over \$25 million on Purdue drugs from 2009 to 2017. Nearly 95% of Purdue's revenue from Alaska's Medicaid program came from the patients who were prescribed an opioid for 90 or more days, though this was a minority of the total number of patients receiving a Purdue opioid.

149. According to law enforcement officials, doctors, and treatment providers in Alaska, the problem of opioid abuse is, in large measure, a problem of overprescribed opioids, a problem of overprescribed opioids, in particular OxyContin, which is the most commonly abused prescription opioid. Often, the use of opioids begins with acute pain—a sport or work-related injury, dental surgery or a car accident—for which the patient is prescribed opioids. The doctor and patient, made comfortable by Purdue's educational efforts and in-person assurances, continues to use opioids for lingering pain needs or demands. Others begin and stay with opioids for common chronic pain

conditions, such as low back pain or arthritis. Either way, as a consequence of long-term use, they may become addicted.

150. The dramatic rise in heroin use is the direct result of the over-use and over-supply of prescription opioids for chronic pain. Opioid users who begin with prescription pills often move on to heroin, either because their doctors refuse to continue prescribing, or because they can no longer afford the medication. Research shows that 75% of heroin users in treatment started their addiction through the use of prescription medication. An individual who abuses prescription pain medication is 40 times more likely to develop a heroin addiction. According to one emergency department doctor, every one of her patients who abuses heroin began with prescription opioids – theirs or someone else’s.

151. Rural communities have experienced the same deadly transition. An organization that provides medical and behavioral health services in federally qualified health centers in Adak, Akutan, Cold Bay, False Pass, King Cove, Nelson Lagoon, Sand Point and Whittier began seeing overprescribing and diversion of opioids several years ago. The organization barred the prescribing of opioids for chronic pain and switched chronic pain patients to non-narcotic medications. When pills were not available, those who were introduced to opioids by their doctors turned to heroin, which was previously unknown in these communities. This year, used syringes have surfaced in villages of 40 residents. The organization saw a direct correlation between the decrease in prescription opioids and the increase in heroin use. The opioid epidemic resulted in other criminal activity, too: the organization’s post office and pharmacy have been the object of

numerous break-ins. There is no ability to provide addiction treatment in these rural communities that are off the road system and the waiting list for programs in Anchorage is often weeks or months long.

152. Statewide, the Department of Health and Social Services counts 512 deaths between 2009 and 2015 in which a prescription drug was noted as the primary or contributing cause of death and 128 in which heroin was a primary or contributing cause of death. The number of Medicaid claims related to heroin overdoses increased almost ten-fold from 2004 to 2013, and inpatient hospital stays attributed to heroin overdoses increased six times from 2010 to 2012, at an average cost of \$30,000 per stay. In 2016, the Alaska AIDs Assistance Association collected 523,245 syringes and gave out 438,578, which was double the number dispensed just two years earlier.

153. Purdue's deceptive marketing has imposed two primary categories of harm on the State of Alaska: (a) spending on prescribing and using opioids for chronic pain as a result of Purdue's deceptive marketing – from the drugs themselves to doctor visits and toxicology screens – by the State through the Alaska Medicaid program and the State's employee health plans and workers compensation program and by consumers and other third party payors; and (b) spending to address the consequences of opioid prescribing, from opioid-induced constipation (a condition now prevalent enough to warrant advertising during the Super Bowl), to addiction and overdose treatment, to the treatment of Hepatitis C, sepsis, endocarditis, and neonatal withdrawal, among others. The State also has experienced additional costs from the non-medical costs of opioids, such as increased foster care placements, greater and more expensive

levels of disability (since many patients on long-term opioids will become less active and more subject to other illnesses, including obesity, depression, diabetes, and accidents), law enforcement and corrections expenses, and decreased productivity and revenue due to opioid addiction and death.

154. In order to mitigate these costs, the State has undertaken significant efforts to rein in the volume of opioid overprescribing and to remediate its adverse consequences. This includes:

- a. passing SB 174, requiring all prescribers to register with and use the State's prescription drug monitoring program, requiring education on pain management and opioid use and addiction;
- b. passing HB 159 proscribing initial prescriptions of opioids or prescriptions for more than a 7-day supply;
- c. distributing 8,181 naloxone kits and training organizations and individuals to use naloxone. If caught in time, naloxone can reverse the respiratory depression caused by an overdose of opioids and prevent death;
- d. distributing 25,000 drug disposal bags to help eliminate the excess drugs that accumulate in patients' medicine cabinets, which can be misused, diverted, and/or stolen;
- e. developed television, radio, and digital public service announcements, CMEs, and other educational outreach aimed at preventing the overprescribing and misuse of opioids; and
- f. provided federally-funded grants to increase access to medication assisted treatment and implemented access to medication assisted treatment for inmates.

155. However, the State will still need to incur significant expenses in the future to abate the nuisance caused by Purdue's deceptive advertising. This will include the costs of continuing to dispose of unused prescriptions; re-educating doctors and

patients about the appropriate use of opioids and about the signs of addiction and the availability of treatment; and treatment for opioid addiction and overdose, including naloxone and medication-assisted addiction treatments, like Suboxone.

156. This treatment is not cheap. The average hospital stay for a baby with neonatal abstinence was 16 days with an average Medicaid charge of \$88,869. According to the CDC, Hepatitis C (“HCV”) is largely contracted through the sharing of needles during injection drug use, and, applying national data, 675 of newly identified HCV cases in Alaska reported in 2014 would have resulted from intravenous drug use (largely due to heroin). Addiction treatment providers in Alaska confirm these numbers, reporting report that 60% to 80% of their patients have HCV. A treatment course for HCV can cost between \$85,000 and \$94,500. In 2015, Alaska’s Medicaid program spent \$5.9 million dollars on HCV treatments; in 2016, the number hit \$13.6 million. One calculation estimates that to treat all the Alaskans who contracted HCV from injecting drugs in 2015 alone would cost \$90 million.

157. Addiction treatment needs far outstrip available capacity. Some treatment programs report waitlists and patients have to travel considerable distances to find treatment. Hospitals also keep patients for weeks longer than needed because there is no place to send them where they can receive appropriate treatment.

158. These are just some of the costs that Alaska and its residents bear as a result of the state’s opioid epidemic. These costs were imposed, in large measure, by Purdue, and should be borne by Purdue—not the State of Alaska and its residents. Like any other public health crisis, the opioid epidemic has caused illness, death, and grief—

parents, spouses, and children who can never be brought back or made whole. But unlike any other epidemic in Alaska's history, there was no outbreak of disease requiring treatment, but a treatment that caused the disease—a treatment promoted by Purdue for profit despite risks that it knew and could have mitigated, but instead distorted and denied.

### XIII. CAUSES OF ACTION

#### FIRST CLAIM FOR RELIEF

#### (Violations of the Unfair Trade Practices and Consumer Protection Act)

159. The State incorporates the preceding paragraphs as if fully set forth herein.

160. Purdue is engaged in trade or commerce in the State of Alaska.

161. Purdue violated the UTPA, as codified in AS 45.50.471, *et seq.*, by engaging in deceptive trade practices through its marketing and advertising of opioids.

These violations include:

- a. Purdue represented that prescription opioids have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have, in violation of AS 45.50.471(b)(4);
- b. Purdue disparaged the goods, services, or business of another by false or misleading representation of fact, in violation of AS 45.50.471(7);
- c. Purdue engaged in other conduct creating a likelihood of confusion or of misunderstanding and which misled, deceived, or damaged a buyer or a competitor in connection with the sale or advertisement of goods or services, in violation of AS 45.50.471(b)(11); and
- d. Purdue used or employed deception, fraud, false pretense, false promise, misrepresentation, or knowingly concealed, suppressed, or omitted a material fact with intent that others rely upon the concealment, suppression, or omission in connection with the sale

or advertisement of goods or services, in violation of AS 45.50.471(b)(12).

162. The violations include, but are not limited to, deceptively and misleadingly:

- a. Denying that pain patients would become addicted to opioids;
- b. Omitting that opioids are highly addictive and may result in overdose or death;
- c. Claiming that signs of addiction were “pseudoaddiction” reflecting undertreated pain, and should be responded to with *more* opioids;
- d. Claiming that the risk of addiction to opioids could be managed and avoided through risk screening tools and other strategies;
- e. Claiming that opioid doses can be increased, without disclosing the greater risks of addiction, other injury, or death at higher doses;
- f. Misleadingly comparing opioids and NSAIDs, including overstating the risks of NSAIDs and citing risks of NSAIDs without disclosing risks of opioids;
- g. Claiming that opioids are an appropriate treatment for chronic pain, and failing to disclose the lack of long-term evidence for their use;
- h. Claiming chronic opioid therapy would improve patients’ function and quality of life;
- i. Promoting OxyContin as providing a full 12 hours of pain relief, and failing to disclose that it does not for many patients;
- j. Claiming abuse-deterrent opioids reduce addiction and abuse and are safer than other opioids, and failing to disclose that the do not limit oral abuse, can be defeated with relative ease, and may increase overall abuse;
- k. Promoting itself as cooperating with law enforcement and taking any available steps to prevent opioid abuse;
- l. Omitting other material facts that it had a duty to disclose by virtue of Purdue’s other representations to Alaska consumers, including other adverse effects from opioid use.

163. Purdue's acts and practices described in this Complaint had the capacity and tendency to deceive and were capable of being interpreted in a misleading way.

164. Purdue's acts and practices were also unfair under AS 45.50.471(a). These acts or practices, which relied on deceptive marketing to promote addictive drugs that patients would be unable to stop taking, were immoral, unethical, oppressive, or unscrupulous, caused substantial injury to consumers and businesses, and violated public policy, including:

- a. Alaska's efforts to curb the opioid epidemic, which has become so severe that Governor Walker issued a Declaration of Disaster due to a statewide "public health disaster emergency;"
- b. The policy of "Harm reduction, Overdose prevention, and Education" being implemented by the Department of Health and Human Services;
- c. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, which suggests a focus on "preventing the inappropriate transition from acute and subacute opioid use to chronic opioid use and to avoid [chronic opioid analgesic therapy] COAT altogether when other alternatives for treating pain may be equally effective and safer in the long-term;"
- d. The policy, reflected in the Alaska Opioid Policy Task Force Final Recommendations (2017) of increasing public awareness and understanding of appropriate opioid use and opioid abuse and addiction;
- e. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, that continuing to prescribe opioids for chronic pain in the absence of clinically meaningful improvement in function, or after development of a severe adverse outcome, such as an overdose event, is not appropriate care;
- f. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, of prescribing the lowest possible effective dose;

- g. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, of ensuring informed consent regarding the risks and benefits of treating chronic pain with opioids;
- h. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, of reducing the risk to the community from diversion of opioids, which has been shown to correlate with the amount of opioids prescribed; and
- i. The policy, reflected in 21 U.S.C. 823(e); 21 C.F.R. 1301.74(b) and AS 17.30.020 & 17.30.080 aimed at reducing diversion and requiring reporting suspicious orders of opioids.

165. Purdue's acts and practices as alleged constituted unfair competition. At all times relevant to this Complaint, Purdue promoted OxyContin as providing 12 hours of pain relief and promoted abuse-deterrent formulations of its opioids as more difficult to abuse and less addictive as means of maintaining a competitive advantage against other opioids. At all times relevant to this Complaint, Purdue promoted opioids as superior to other competing analgesics, such as NSAIDs, and exaggerated the risks of NSAIDs while ignoring risks of adverse effects of opioids.

166. As a direct result of the foregoing deceptive acts and practices, Purdue obtained income, profits, and other benefits that it would not otherwise have obtained.

167. Purdue's acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other State government functions, and caused significant actual harm.

168. Purdue's acts and practices as alleged herein were motivated by a desire to retain and increase its market share and profits.

169. Purdue's use of acts or practices in violation of the UTPA warrant the maximum amount of civil penalties under AS 45.50.551.

170. As a result of Purdue's conduct as alleged herein, Alaska consumers, including the State and its agencies, suffered and continue to suffer injury.

171. In addition to penalties and restitution, Purdue is liable for attorneys' fees and costs, including costs of investigation, under AS 45.50.537(d).

**SECOND CLAIM FOR RELIEF**  
**(Violations of the Alaska Medical Assistance False Claim and Reporting Act)**

172. The State incorporates the preceding paragraphs as if fully set forth herein.

173. AS 09.58.010(a) provides that:

A medical assistance provider or medical assistance recipient may not

(1) knowingly submit, authorize, or cause to be submitted to an officer or employee of the state a false or fraudulent claim for payment or approval under the medical assistance program;

(2) knowingly make, use, or cause to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim for payment paid or approved by the state under the medical assistance program;

(3) conspire to defraud the state by getting a false or fraudulent claim paid or approved under the medical assistance program ...

174. AS 09.58.100(2) defines a claim as:

a request for payment of health care services or equipment, whether made to a contractor, grantee, or other person, when the state provides, directly or indirectly, a portion of the money, property, or services requested or demanded, or when the state will, directly or indirectly, reimburse the

contractor, grantee, or other recipient for a portion of the money, property, or services requested or demanded;

175. Purdue's practices, as described in this Complaint, violated AS 09.58.010.

Purdue, through its deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used a false statement to get a false or fraudulent claim for payment approved by the State.

176. Purdue knew that the doctors, pharmacists, other health care providers, and/or agents of the State Medicaid program to whom they deceptively marketed prescription opioids had treated and would continue to treat Alaska medical assistance patients.

177. Purdue knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of getting the State's medical assistance program to pay for opioids for long-term treatment of chronic pain. In addition, Purdue knew, deliberately ignored, or recklessly disregarded, that its marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

178. Purdue knew their false statements were material to healthcare providers' decision to prescribe opioids to patients included in Alaska's medical assistance program. Indeed, Purdue intended such statement to be material to encourage additional opioid prescriptions.

179. Purdue's scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the State's medical assistance program for payment. The State's medical assistance program only covers the cost of a prescription if it "is medically necessary as determined by criteria established under 7 AAC 105 - 7 AAC 160 or by the standards of practice applicable to the provider."<sup>51</sup> Doctors, nurses pharmacists, other health care providers, and/or agents of the State medical assistance programs expressly or impliedly certified to the State that opioids were medically necessary to treat chronic pain because they were influenced by the false and misleading statements disseminated by Purdue about the risks, benefits, and superiority of opioids for chronic pain.

180. Purdue knew, deliberately ignored, or recklessly disregarded that, as a natural consequence of its actions, the State would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Purdue's fraud.

181. Purdue's misrepresentations and omissions were material because if the State had known of the false statements disseminated by Purdue and their third-party allies that doctors, pharmacists, and other health care providers or agents of the State medical assistance program were certifying and/or determining that opioids were

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<sup>51</sup> Alaska Admin. Code tit. 7, § 105.100(5); *see also* Alaska Admin. Code tit. 7, § 105.100 (covered services); Alaska Admin. Code tit. 7, § 105.110 (non-covered services).

medically necessary, the State would have undertaken efforts to avoid its payment of false claims.

182. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the State.

183. By virtue of the above-described acts, Purdue knowingly made, used or caused to be made or used false records and statements, and omitted material facts, to induce the State to approve and pay such false and fraudulent claims.

184. But for Purdue's false statements and deceptive marketing scheme, the false claims at issue would not have been submitted for payment and would not have been paid by the State's medical assistance program.

185. The State, unaware of the falsity of the records, statements and claims made, used, or presented or caused to be made, used or presented by Purdue, paid claims that would not be paid but for Purdue's illegal business practices.

186. By reason of Purdue's unlawful acts, the State has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. From 2013-2016, the State's medical assistance program spent over \$4 million to pay for prescriptions of Purdue branded opioids, and additional funds for Purdue's generic opioids, and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain. The State medical assistance program also spent over \$8 million over the same period for medication assisted treatment for opioid addiction—a number that will continue to grow.

187. Because Purdue's unbranded marketing caused doctors to prescribe and the State to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Purdue caused and are responsible for those costs and claims as well.

188. Pursuant to AS 09.58.010(c), Purdue is liable for to pay three times the amount of damages sustained by the State for each violation of AS 09.58.010. In addition, Purdue's statutory violations warrant the maximum amount of civil penalties allowed by law.

189. Pursuant to AS 09.58.010(c), the State is entitled to recover costs and attorneys' fees arising from this action from Purdue.

**THIRD CLAIM FOR RELIEF**  
**(Public Nuisance)**

190. The State incorporates the preceding paragraphs as if fully set forth herein.

191. A public nuisance is an unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property.

192. Purdue's conduct, as described in the Complaint, involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, and unreasonably interferes with a public right.

193. Purdue knew and should have known that its promotion of opioids was false and misleading and that its deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of a public nuisance.

194. Purdue has created or assisted in the creation of a condition that is injurious to public health, public safety, public peace, public comfort and public convenience, and offends the moral standards of communities throughout the State and significantly harmed any considerable number of the State's residents.

195. The public nuisance is substantial and unreasonable. Purdue's actions caused and continue to cause the public health epidemic and state of emergency described in the Complaint, and that harm outweighs any offsetting benefit.

196. Purdue's actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, in deceiving prescribers and patients about the risks and benefits of opioids for the treatment of chronic pain, and in the public health crisis that followed and has reached a state of emergency.

197. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Purdue can be abated and further recurrence of such harm and inconvenience can be abated.

198. The State has been, and continues to be, injured by Purdue's actions in creating a public nuisance.

**FOURTH CLAIM FOR RELIEF**  
**(Fraud and Negligence/Negligent Misrepresentation)**

199. The State incorporates the preceding paragraphs as if fully set forth herein.

200. As alleged in this Complaint, Purdue engaged in false representation and concealment of material facts about the use of opioids to treat chronic pain.

201. Purdue knew, deliberately ignored, or recklessly disregarded, that:

- a. its statements about the risks and benefits of opioids to treat chronic pain were false or misleading;
- b. it failed to correct prior misrepresentations and omissions about the risks and benefits of opioids
- c. its statements made to promote the use of opioids to treat chronic pain omitted or concealed material facts; and
- d. for many patients the pain relief of “12-hour” OxyContin dosing lasts well short of 12 hours; and
- e. there is no evidence to support statements that abuse-deterrent formulations of Purdue’s opioids make the drugs less likely to be abused or diverted or less addictive; and
- f. it lacked the commitment it professed to reducing or deterring abuse and to cooperating with law enforcement, as evidenced by its failure to report suspicious prescribers as required by law and its misrepresentations regarding the abuse-deterrent properties of is opioids.

202. The statements Purdue made, or caused to be made about the use of opioids to treat chronic pain, the duration of pain relief provided by 12-hour dosing of OxyContin, and abuse-deterrent formulations of its opioids, were not supported by or were contrary to its own knowledge and studies and to the scientific evidence more

generally, as confirmed by the CDC and FDA based on that evidence, and were false and fraudulent.

203. Purdue intended that healthcare providers and patients would rely on its misrepresentations and deceptive marketing regarding the use of opioids to treat chronic pain, the characteristics of Purdue's branded opioids, and Purdue's efforts to cooperate with law enforcement and assist in avoiding addiction, abuse, and overdose.

204. Purdue had a duty to the State and its residents to exercise due care in the advertising, marketing, promotion, and sale of opioid drugs.

205. Purdue had a duty to the State and its residents not to make false, misleading, or deceptive statements about opioids and treatment for chronic pain.

206. Purdue had a duty to the State and its residents to report suspicious prescribers and to refrain from providing opioids to providers and pharmacies it believed, or had reason to believe, were dispensing its opioids illegally, as well as a duty not to misrepresent its commitment to adhering to this obligation.

207. Purdue knew or should have known that it breached the duties described above.

208. Purdue's misrepresentations, omissions, and carelessness in this regard was done with the intention and effect of inducing the State to pay for or reimburse the costs of using opioids to treat chronic pain, and with reckless disregard for the costs the State would incur as a direct and proximate result, including the costs of treating addiction and implementing programs to mitigate or reverse the public health epidemic.

209. Purdue knew, or should have known, that prescribers, patients, and State programs would rely on its misrepresentations and deceptive statements, and would be misled by its material omissions.

210. Purdue identified many prescribers engaged in suspicious prescribing of its opioids, but failed to report its suspicions, as required by law, and failed to stop filling the prescriptions of prescribers it suspected of illegal activity with more drugs.

211. Purdue knew, or should have known, that as an inevitable consequence of the conduct described herein, Alaska citizens would suffer opioid addiction, overdose, death, and associated economic loss, and the State would suffer economic loss. Further, Purdue knew, or should have known, that its failure to report suspicious prescribing has resulted in continued illicit prescribing of opioids by prescribers who could have been investigated and stopped.

212. In addition, Purdue's false representations and concealments were reasonably calculated to deceive the State and health care providers who treated patients whose care was paid for or reimbursed by the State and the patients who received the care.

213. Prescribers, patients, and the State relied to their detriment on Purdue's misrepresentations and concealment of material fact.

214. But for Purdue's misrepresentation and concealment of material facts, the State would not have incurred damages in paying for medically unnecessary prescriptions and in addressing the public health crisis that Purdue's actions have created.

215. As a direct and proximate result of Purdue's acts and omissions as alleged herein, the State has sustained and will sustain substantial expenses and damages, described in this Complaint.

**FIFTH CLAIM FOR RELIEF**  
**(Strict Products Liability – Design Defect and Failure to Warn)**

216. The State incorporates the preceding paragraphs as if fully set forth herein.

217. Purdue's opioids failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner because: (1) Purdue's opioids carried far greater risk and actual rate of addiction than the public was lead to believe; (2) Purdue's opioids failed to provide functional improvement for chronic pain patients and caused side effects, including addiction, that diminished their function and quality of life; and (3) OxyContin failed to provide the 12-hour relief promised and its end-of-dose failure fueled addiction and abuse.

218. Under the circumstances, which include Purdue's unfair and deceptive marketing and its failure to change its opioids' labels to account for post-marketing information, Purdue failed to provide adequate warning that clearly indicated the scope of the risk or danger posed by its opioids, reasonably communicated the extent or seriousness of harm that could result from this risk or danger, and was conveyed in a manner that would alert a reasonably prudent person.

219. Purdue actually knew of the defective nature of its opioids, but continued to market and sell them without proper warning, and with misrepresentations and

omissions that contradicted and undermined its drug labels, in order to increase its sales and profits, in conscious disregard for the foreseeable harm caused by these drugs.

220. As a proximate cause and legal result of Purdue's opioids failure to perform as reasonably expected and Purdue's failure to appropriately warn of known and reasonably knowable dangers associated with the use of its opioids, the State has suffered and will continue to suffer damages as outlined in this Complaint.

**SIXTH CLAIM FOR RELIEF**  
**(Unjust Enrichment)**

221. The State incorporates the preceding paragraphs as if fully set forth herein.

222. Purdue has unjustly retained a benefit to the State's detriment, and Purdue's retention of that benefit violates the fundamental principles of justice, equity, and good conscience.

223. As alleged herein, the State has reimbursed opioid prescriptions covered by the State's employee health plan and workers compensation program and paid for with public funds. Due to Purdue's deceptive and illegal conduct in promoting opioids to treat chronic pain, the State reimbursed prescriptions for opioids for chronic pain that otherwise would not have been written or reimbursed. Further, the State has suffered, and continues to cope with, a crisis of opioid addiction, overdose, injury, and death that Purdue helped create.

224. Purdue has reaped revenues and profits from the State's payments, enriching itself at the State's expense. This enrichment was without justification, and the State lacks an adequate remedy provided by law.

225. Accordingly, under principles of equity, Purdue should be disgorged of money retained by reason of their deceptive and illegal acts that in equity and good conscience belong to the State and its citizens.

#### **XIV. PRAYER FOR RELIEF**

WHEREFORE, the State prays for judgment against Defendants as permitted by Alaska law, as follows:

226. For a declaration that Purdue has violated the UTPA and FCA;

227. For an injunction pursuant to AS 45.50.501 enjoining Purdue from engaging in any acts that violate the UTPA, including, but not limited to, the unfair and deceptive acts and practices, and unfair methods of competition alleged in this Complaint;

228. For restoration of money Purdue obtained from the State and its consumers under AS 45.50.501(b);

229. For civil penalties in the amount of \$25,000 for each and every violation of the UTPA under AS 45.50.551;

230. For an award of treble damages under AS 09.58.010(c)(2);

231. For civil penalties in the amount of \$11,000 for each and every violation of the FCA under AS 09.58.010(c)(1);

232. For an injunction permanently enjoining Purdue from engaging the acts and practices that caused the public nuisance;

233. For an order directing Purdue to abate and pay damages for the public nuisance;

234. For compensatory damages for Purdue's fraud, negligence, and negligent misrepresentation;

235. For restitution or disgorgement of Purdue's unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

236. For costs, interest, and attorney's fees; and

237. For all other relief deemed just by the Court.

DATED: October 30, 2017.

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