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MONTANA FIRST JUDICIAL DISTRICT COURT
LEWIS AND CLARK COUNTY

STATE OF MONTANA, Plaintiff, v. PURDUE PHARMA L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY INC., and JANE DOES 1-10, Defendants.	)	Cause No. ADV-2017-949 **FIRST AMENDED COMPLAINT**

I. PRELIMINARY STATEMENT

1. There is an opioid crisis in Montana. "Prescription drug abuse and diversion is a growing epidemic—it affects everyone, and the statistics are staggering."[1] The epidemic began not with an outbreak, but with a business plan. It is the result of a corporate decision by Purdue Pharma L.P., and the related corporate entities named as Defendants in this lawsuit (collectively, "Purdue"), to promote opioids deceptively and illegally in order to significantly increase sales and generate billions of dollars in revenue for Purdue's private owners, the Sackler family. As laid out below, Purdue's misrepresentations regarding the risks and benefits of opioids enabled, and is continuing to enable, the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.[2] As a direct consequence, the rampant use, overuse, and abuse of opioids is devastating Montana and its families.

2. Purdue is not a typical pharmaceutical company. It sells powerful narcotics called opioids, and it has virtually no other product line.[3] Purdue is also—by far—the largest opioid marketer in Montana.

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[1] Montana Medical Association, *Know Your Dose*, http://knowyourdosemt.org (last visited Nov. 30, 2017).

[2] Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

[3] 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.

While described as a class, opioids also have different active pharmaceutical ingredients ("API"). The API in Purdue's OxyContin is oxycodone, Hysingla is hydrocodone, and Butrans is buprenorphine. There also are extended release or long-acting opioids and immediate release or short-acting opioids. OxyContin, Butrans, and Hysingla are all extended-release opioids.

3. Likewise, opioids are not typical pharmaceutical products. They are highly addictive synthetic drugs derived from opium—pharmacologically similar to heroin. The U.S. Drug Enforcement Administration ("DEA") has categorized opioids as having a "high potential for abuse[.]" The Centers for Disease Control and Prevention ("CDC") declared that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[4] As the Director of the CDC has noted: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[5]

4. Before Purdue's marketing campaign, doctors wrote few prescriptions for opioids, reserving their use mostly for acute cancer pain, post-surgery recovery pain, and end-of-life care. That is because doctors feared that opioids were too addictive to be used long-term and too dangerous to use for relatively minor chronic pain conditions. In an aggressive marketing campaign, which harnessed respected doctors and seemingly neutral patient advocacy groups and professional associations, Purdue falsely claimed that opioids could be prescribed by doctors and used as a first-line, long-term treatment for patients with chronic pain without a material risk of addiction. Other deceptive messages spread by Purdue included the concocted concept of "pseudoaddiction," which a Purdue key opinion leader invented to make doctors wrongly believe that patients who exhibit addictive behaviors are instead exhibiting signs of undertreated pains and should be treated with more opioids—the medical equivalent of fighting fire with gasoline. Purdue also misrepresented the risks, benefits, and superiority of using opioids to treat chronic pain, and claimed that its abuse-deterrent opioids were not only safer than alternatives, but prevent abuse, diversion, and injury—claims not only unsupported by, but contrary to, the

[4] CDC Guideline for Prescribing Opioids for Chronic Pain ("CDC Guideline") at 2.

[5] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

evidence available to Purdue. Purdue's promotional claims were dangerously, and too often fatally, false.

5. In truth, roughly one in four patients who receive prescription opioids long-term for chronic pain in primary care settings will become addicted. According to the CDC, one out of every 550 patients started on opioid therapy dies of opioid-related causes a median of 2.6 years after their first opioid prescription. Moreover, several studies show that long-term opioid use may actually worsen pain and function. This is in addition to the symptoms of withdrawal that long-term users often face.

6. The results of Purdue's marketing campaign have been extremely good for Purdue and the Sackler family, but disastrous for America. With less than 5% of the world's population, the United States now consumes about 80% of the world's opioid supply. [redacted]

7. At the same time, opioids have created a national and a statewide emergency. According to the CDC, 145 Americans now die every day from opioid overdoses. In Montana, since 2000, there have been more than 700 deaths from opioid overdoses. In 2011-2013 alone, prescription drug overdoses were responsible for at least 369 deaths in the state and more than 7,200 hospital inpatient admissions and emergency department visits; and opioids are the most common substance associated with drug poisoning deaths in Montana. Prescription drug abuse in the state is 15 times more deadly than methamphetamines, heroin and cocaine combined.

8. The road, for most opioid victims, began with a prescription. They went to their doctor for a back injury, arthritis or other such painful condition and were prescribed and took opioids, trusting that they were safe. Others began with opioids found in medicine cabinets, the direct result of an oversupply of opioids; this diversion from legitimate uses is a special problem in rural states, including Montana.

9. The human toll of the opioid epidemic is too easily lost in the statistical tally, but they tell the story of the opioid epidemic in Montana.

10. Gail Robin Sharp was named the first Ms. Blackfeet. She worked as a certified nursing assistant on the Blackfeet Reservation in Browning. She started taking prescription drugs after an injury and became addicted. Ultimately, she was found on the street, brain-dead. "I had to take her off life support because she was never going to come back." "I mean, to me, if a doctor gives it to you, you know, it should be okay, right?" Instead, "addiction happened to her." "Prescription drug abuse took a lot of [my mother's] dignity." Willie Ramirez, Livingston.[6]

11. "[A]n injury that required my daughter to have surgery catapulted her into massive prescription and non-prescription drug use: OxyContin, Fentanyl patches, methamphetamines, alcohol, cocaine, marijuana, etc. She was getting them anywhere she could. Stealing them, buying them on the street, over the internet, and doctor shopping." Mother in the Flathead. [7]

12. "My mom is also a prescription drug addict. She and my husband have used together for the past two years. The only difference between the two of them is that my mom is

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[6] Resolve Montana, Montana Attorney General's Office of Consumer Protection, www.https://resolvemontana.org/ (last visited Nov. 8, 2017).

[7] *Id.*

prescribed her pills and my husband is not." "When I was growing up she was an amazing mother. She never used any type of drugs and worked three jobs to support my brother and me. It wasn't until she was diagnosed with these problems that I saw her downfall." Great Falls.[8]

13. The State of Montana and its citizens have borne the costs of Purdue's deceptive marketing. Many of these injuries—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; (b) damages for, and abatement of, the public health epidemic that Purdue has created; (c) three times the amount of damages sustained by the State in paying for opioids for first-line treatment of chronic pain and treating the adverse effects of opioid use through the Montana Medicaid Program and the Montana Healthcare Plan; (d) damages, including punitive damages, for money spent by the State as a result of Purdue's conduct; (e) disgorgement of Purdue's unjust profit; and (e) the maximum civil penalties allowed 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

14. The Plaintiff State of Montana brings this action, by and through its Attorney General, Tim Fox, in its sovereign capacity in order to protect the interests of the State and its citizens as *parens patriae*. The Attorney General brings this action pursuant to his constitutional, statutory, and common law authority, including the authority granted to him by Mont. Code Ann. §§ 2-15-501 and 502; the Montana Unfair Trade Practices and Consumer Protection Act, Mont.

[8] *Id.*

Code Ann. §§ 30-14-101 through 30-14-144; and the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 through 17-8-416.

15. 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 Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. These parties are collectively referred to as "Purdue."

16. 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 Montana. [redacted]

17. Jane Does 1-10 are Purdue officers, directors, executives, or agents who were directly and personally involved in developing and executing its marketing efforts, whose names the State does not now know and cannot now ascertain. The State, therefore, sues said Defendants by such fictitious names and will ask leave to amend this Complaint to show their true name(s) when ascertained.

III. JURISDICTION AND VENUE

18. Jurisdiction over the subject matter of this cause of action is proper based upon Mont. Code Ann. § 3-5-302.

19. This Court has personal jurisdiction over Purdue because Purdue does business in Montana and/or has the requisite minimum contacts with Montana necessary to constitutionally permit the Court to exercise jurisdiction, with such jurisdiction also being proper under Montana's long arm rule. Mont. R. Civ. P. 4. Among other business activities in Montana, Purdue employs a substantial number of people in Montana to visit Montana doctors in their Montana offices for the purpose of delivering marketing messages and encouraging such doctors to write prescriptions for Purdue's products.

20. Venue is appropriate in this Court pursuant to Mont. Code Ann. § 30-14-111(3).

21. Because the State of Montana 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 his constitutional, common law, and statutory authority to protect the interests of the State.

22. The Attorney General has constitutional, common law and statutory authority to pursue legal actions in the public interest and has determined that this action on behalf of the State of Montana is in the public interest, including for purposes of Montana Code section 30-14-111.

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

23. Purdue's pain franchise is built on deception. Before Purdue launched OxyContin in 1996, opioids were widely recognized as highly addictive, and therefore only suitable for severe pain and short-term use, except for when a patient was dying. There was no evidence that opioids were appropriate or could be used safely long-term for most patients.

24. 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 months or even years of treatment–and, thus, sustained revenue. Purdue, however, found that doctors were too worried about the risk of addicting their patients to prescribe its opioids for regular aches and pains.

25. [redacted]

26. [redacted]

27. [redacted]

[redacted]

28. Not only did Purdue fail to correct this obvious misperception of OxyContin's strength, but it also misrepresented its risks. 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]

29. In addition to its branded promotion, Purdue 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.) [redacted] "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, including those in Montana, 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.

30. 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 often experience physically and psychologically agonizing withdrawal symptoms, which may last for weeks, 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.

31. Purdue attributed the problem of opioid abuse and overdose to patients who were seeking the opioids, not the drugs themselves. A public statement by Purdue executive Michael Friedman was typical of Purdue's tilt: "Virtually all of these reports [of opioid abuse] involve people who are abusing the medication, not patients with legitimate medical needs."[9] Yet, contrary to Purdue's misrepresentations, 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.

[9] Patrick Radden Keefe, "The Family That Built an Empire of Pain," *The New Yorker* (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

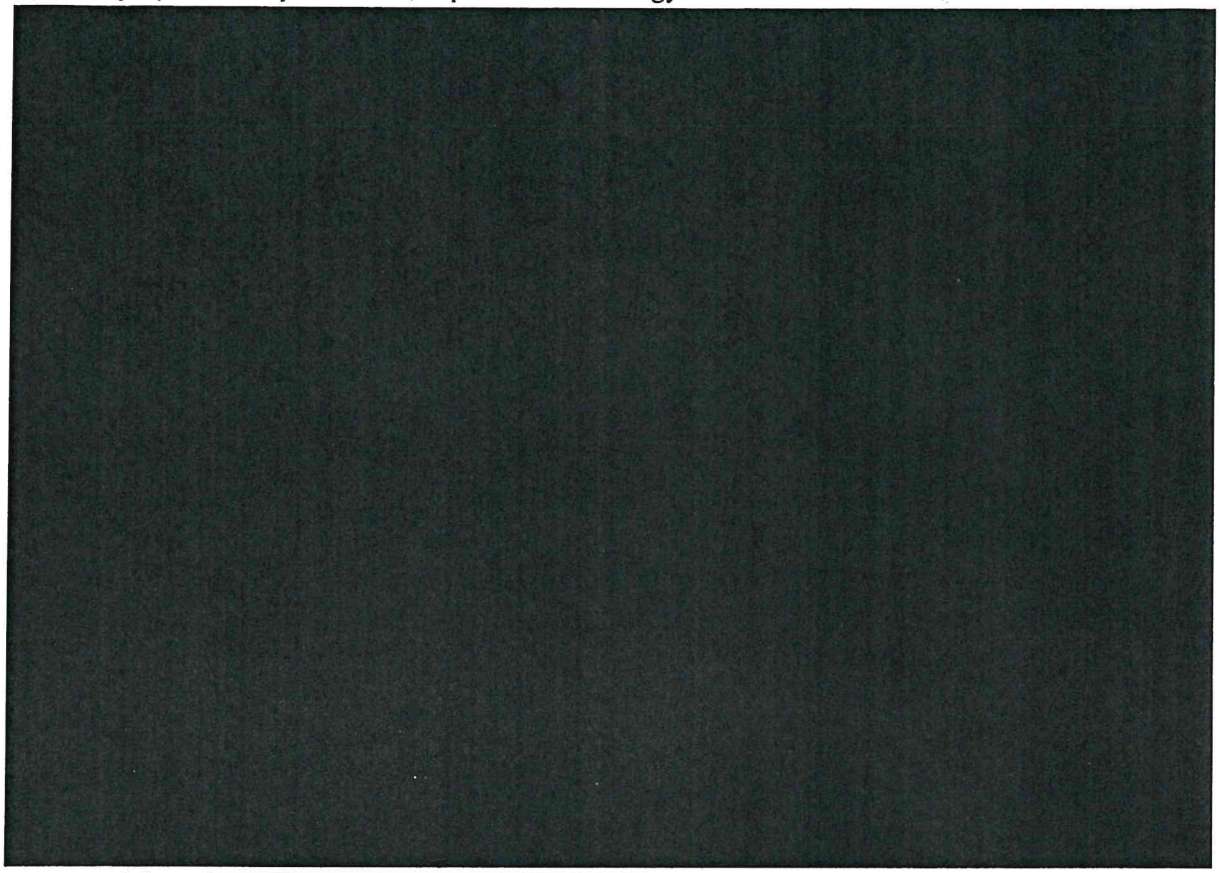
32. Furthermore, Purdue has claimed in other contexts that its responsibility for the opioid epidemic is relieved by the independent actions of doctors who make their own decisions about whether to prescribe opioids and which drugs to use. However, Purdue's marketing deliberately set out to change prescribers' attitudes about opioids. Therefore, the company can hardly claim to be either surprised by or blameless for those results. Purdue knows from its own tracking that its promotion influences prescribers' decisions, [redacted]. That explains why Purdue invests heavily in ensuring that its sales representatives visit doctors frequently—it works.

33. In 2007, Purdue entered into a plea agreement and settlements with federal and state governments, including Montana, to resolve potential civil and criminal enforcement actions. Purdue pleaded guilty to the federal felony of misbranding of a drug with intent to defraud or mislead, admitting that it had lied to doctors about OxyContin's abuse potential, and paid $600 million in fines. Purdue also entered into a Consent Judgment with the State of Montana, agreeing, as in other states, to cease its fraudulent marketing, to no longer misrepresent the risk of addiction to OxyContin, to provide "fair balance" in conveying the risks and benefits of OxyContin, and to implement an abuse and diversion detection system to identify and address suspicious prescribing.

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

34. 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 consumers. Purdue developed and deployed a comprehensive, sophisticated strategy to do so.



35. [redacted]

36. To ensure that sales representatives deliver the desired messages to prescribers, Purdue directs and monitors its sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of call notes from each visit. (Call notes are brief descriptions by sales representatives of their conversations with prescribers made shortly after the visit and submitted to the company). Purdue likewise requires its sales

representatives to use only sales aids that are reviewed, approved, and supplied by the company. Thus, Purdue's sales force in Montana carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

37. To deliver these messages, Purdue inundated Montana prescribers with promotional sales visits. From May 8, 2007 to September 14, 2017, Purdue made *39,961* visits to 1,932 prescribers or pharmacies in *67* communities across Montana, for an average of more than 15 interactions every workday.

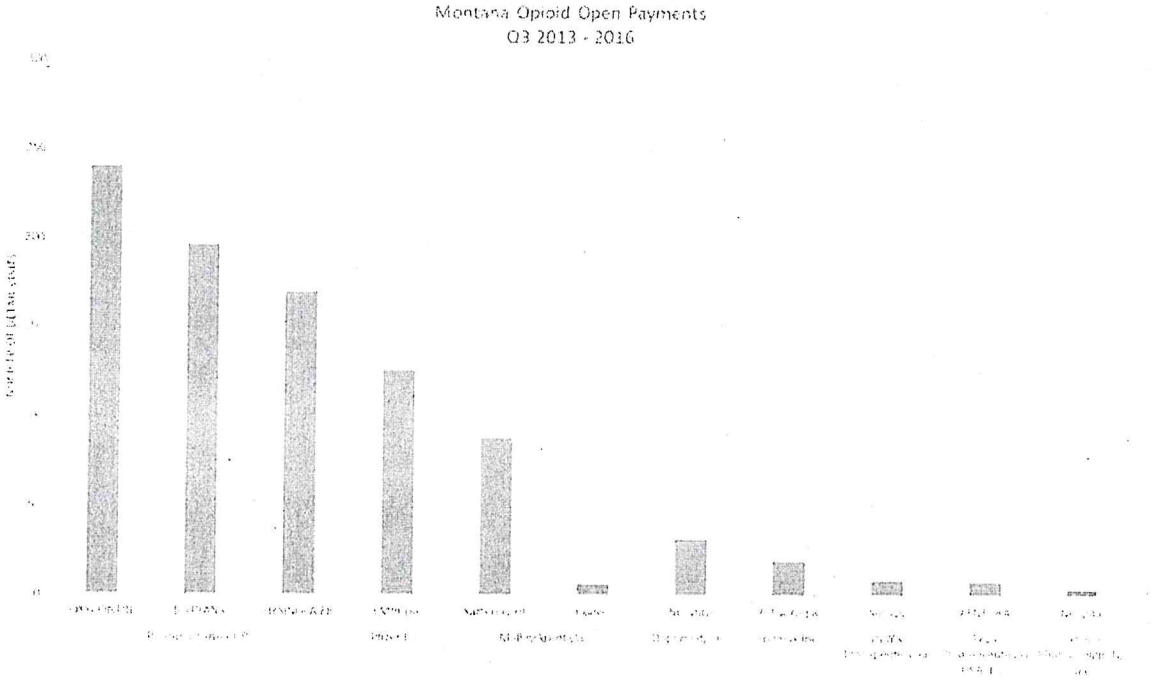
38. The ten prescribers most frequently visited by Purdue were seen an average of once every two-and-a-half weeks. The most visited doctor, a physician in Billings, received 293 visits from Purdue. But advertising messages were not the only thing that Purdue sales representatives provided to doctors. Another doctor in Billings, for example, received payments or items of value worth more than $16,500 over approximately three years from Purdue sales representatives. Even doctors who rarely prescribed Purdue drugs received regular sales visits.

39. One practice used by Purdue is to encourage and assist nurses and medical assistants in a physician's office to go through patient files and "flag" those patients who would—in the opinion of the nurse or medical assistant, and with guidance from the Purdue sales representative—be appropriate for a prescription of opioid medication. The flagged charts, or medical files, are then provided to the physician, who is told by the Purdue representative or the physician's staff that the identified patients may be appropriate for opioid prescriptions.

40. On information and belief, a similar practice used by Purdue involves Electronic Medical Record ("EMR") or Electronic Health Record ("EHR") databases. These commercially available databases of tens of millions of patients and their records are used by Purdue to identify

healthcare providers with large numbers of patients who—in Purdue's opinion—are appropriate for opioid prescriptions and therefore good targets for marketing visits.

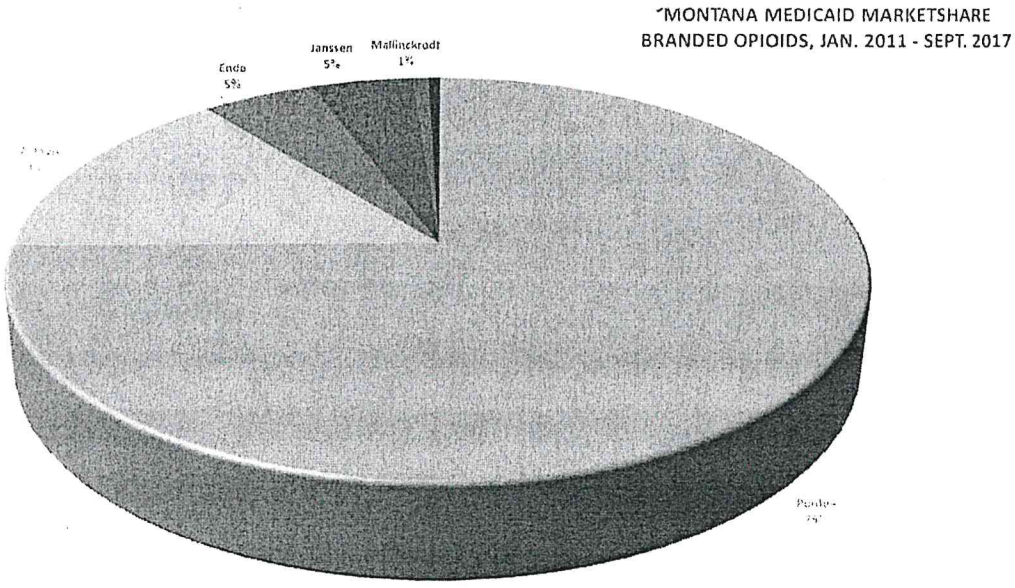
41. Purdue's sales visits in Montana far exceeded those of any other opioid maker.



42. Purdue knew that a small set of doctors were responsible for the vast majority of its sales in Montana, and their prescribing patterns should have sounded alarms. During the past six years, about 800 doctors wrote Purdue opioid prescriptions that were submitted to the Montana Medicaid Program, yet just 31 of these prescribers accounted for about half of such spending. [redacted] Instead of reporting potentially suspicious prescribing by these doctors, Purdue continued to profit from it.

43. Purdue's sales persistence has paid off. In the Montana Medicaid Program, Purdue drugs constituted 75% of spending on branded Schedule II and III opioid analgesics between January 2011 and September 2017.

44. [redacted]



45. Sales visits are not Purdue's only marketing tactic. 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") to prescribers that provided information about treating pain and the risks, benefits, and use of opioids. This was a strategy originally pioneered by Arthur Sackler, one of three Sackler brothers who founded Purdue, who is credited for first promoting pharmaceutical drugs directly to doctors, with clinical-looking ads in medical journals, visits to doctors' offices, and prominent medical thought-leaders. 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 who were supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities. 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."[10]

46. 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.

47. In addition, Purdue employees and KOLs identified, funded, published, and disseminated research that was designed to assist Purdue's marketing efforts and skewed or misreported the scientific evidence. For example, to substantiate 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. Drug companies used this 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

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

authors, Dr. Hershel Jick.[11] 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' concerns about the risk of addiction associated with long-term opioid therapy."[12] It continued to be widely cited in literature and materials available until the present.

48. 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 in this Complaint were disseminated to Montana prescribers and patients through sales representative visits, medical education programs, websites, and other sources.

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

49. Purdue misrepresents, even today, to Montana 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 manifests in snorting and injecting the drugs, rather than in oral abuse. In addition, Purdue failed

[11] Taylor Haney and Andrea Hsu, "Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis," *National Public Radio* (Jun. 16, 2017) http://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisi.
[12] *Id.*

to disclose to Montana prescribers and patients the risks of addiction to, and withdrawal from, its opioids.

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

50. Purdue's sales representatives often omitted from their sales conversations with Montana 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, which Purdue failed to correct.

51. Moreover, Purdue continued to affirmatively misrepresent that pain patients would not become addicted to opioids. Montana prescribers were told that, although OxyContin is a narcotic, patients being treated for chronic pain will not become addicted and that its drugs, used properly, were safe.

52. Purdue also disseminated misleading information about opioids and addiction through the front group American Pain Foundation ("APF"), over which Purdue exercised control. *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 repurposed Purdue's pre-2007 assertion, now claiming that "less than 1% of children treated with opioids become addicted," which would help support OxyContin's market for children 11-years and older—an indication Purdue sought and received in 2015. A *Policymaker's Guide* also 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 Montana prescribers online.

53. 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. While the website discussed opioids and side-effects from their use and the *fear* of addiction (as a barrier to use), it *never*, anywhere on the website, 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.

54. As before the 2007 settlements and criminal pleas, Purdue continues to tell Montana doctors in sales visits 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.

55. Purdue sales representatives also failed to disclose to Montana prescribers the difficulty of opioid withdrawal. Discontinuing or delaying opioids can cause agonizing physical and psychological effects that can last for weeks, including anxiety, nausea, headaches, painful muscle cramps, and delirium, among others. Withdrawal symptoms can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction. In the words of one physician, "I see all these people who are convinced they are one of the 'legitimate' pain patients. They're on a massive dose of opioids and they're telling me they need this medication,

which is clearly doing them *harm.* For many of them, the primary benefit of therapy, at this point, is not going into withdrawal." (Emphasis in original).[13]

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

56. Upon information and belief, Purdue sales representatives conveyed to doctors that they can screen out patients at high risk of addiction through screening tools, urine tests and patient contracts, and safely prescribe to their other "appropriate" patients. Upon information and belief, Purdue also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences attended by or available to Montana prescribers. Purdue failed to disclose the lack of evidence that these risk management strategies mitigate addiction risk.

57. Upon information and belief, 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 Montana prescribers.

58. Purdue also sponsored an online 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." The CME currently is available online to Montana prescribers.[14] Upon information and belief, it has

[13] Patrick Radden Keefe, "The Family That Built an Empire of Pain," *The New Yorker* (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.
[14] Emerging Solutions in Pain, "Managing Patient's Opioid Use: Balancing the Need and the Risk," http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Nov. 30, 2017).

been available online for approximately six years and it has been viewed by additional Montana prescribers since it was first broadcast in September 2011.

59. Another Purdue-funded CME, *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, deceptively instructs doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior can be treated safely with opioids. Upon information and belief, this CME was presented live on October 11, 2012, by webinar available in Montana, and the CME currently is available online to Montana prescribers. Upon information and belief, it has been available online for approximately five years and it has been viewed by additional Montana prescribers since its live broadcast.

60. Similarly, "Drug Diversion—The Scope of the Problem," a 2015 Purdue presentation that appears to have been shown to doctors, blames problem patients and prescribers for diversion and promotes patient agreements to help prevent opioid misuse.

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

61. Purdue also deceptively advised doctors to ignore signs of addiction as the product of "pseudoaddiction." The theory of 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 with gasoline. Purdue deceptively described pseudoaddiction as an accepted scientific concept, although the term was coined by a single doctor named David Haddox, who was later hired by Purdue, and based on the observation of a single patient. In *Providing Relief, Preventing Abuse,* a pamphlet published by Purdue for prescribers and law enforcement beginning in 2011, 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."

62. Sales representatives in Montana promoted pseudoaddiction to doctors. [redacted]

63. The "Pain Management Kit" used by Purdue's sales force endorses pseudoaddiction by claiming that "pain-relief seeking behavior can be mistaken for drug-seeking behavior." Upon information and belief, the kit was in use in Montana from roughly 2011 through at least June 2016.

64. Purdue promoted pseudoaddiction through at least 2013 on its website, *Partners Against Pain*.[15]

65. Purdue also sponsored the publication *Responsible Opioid Prescribing* (2007), which taught that patient behaviors such as "requesting drugs by name, "demanding or

[15] *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."

manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction. [redacted]

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

66. In addition to deceptively ascribing signs of addiction to pseudoaddiction, Purdue falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse* 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 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.

67. 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]

68. 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 and Purdue has been a frequent presenter at CPDD conferences. One of Purdue's consistent themes was 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. Hundreds

of addiction treatment specialists from across the country attended these conferences. Upon information and belief, the attendees included Montana prescribers.

69. More generally, Purdue had no basis to assert that addiction is the result of patients who manipulate either the drugs or their doctors. Patients who "doctor-shop," that is, visit multiple prescribers to obtain opioid prescriptions, are responsible for roughly 2% of opioid prescriptions.[16] The epidemic of opioid overprescribing is not, as Purdue often asserts, the result of problem patients or doctors.

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

70. 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."[17] Studies have shown that at least 8-12%, and as many as 30-40%, of long-term users of opioids experience problems with addiction.

71. Purdue's own evidence bears that out. [redacted]

72. More recently, in March 2016, after a "systematic review of the best available evidence," the CDC published the CDC Guideline for Prescribing Opioids for Chronic Pain

[16] National Institute on Drug Abuse, "Although Relatively Few, 'Doctor Shoppers' Skew Opioid Prescribing," (May 27, 2014) https://www.drugabuse.gov/news-events/nida-notes/2014/05/although-relatively-few-doctor-shoppers-skew-opioid-prescribing (last visited Nov. 30, 2017).

[17] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1502 (Apr. 21, 2016).

("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).[18] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[19]

73. 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 because of 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 acknowledged in its 2007 criminal plea and settlements, and it is no more true today.

74. 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 long-term opioid therapy."[20]

75. No competent scientific source has validated the concept of pseudoaddiction. Not surprisingly, the CDC Guideline nowhere recommends attempting to provide more opioids to

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[18] CDC Guideline at 2.

[19] *Id.* at 21.

[20] CDC Guideline at 28

patients exhibiting symptoms of addiction. Dr. Lynn Webster, a Purdue KOL, 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."[21]

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

76. To convince Montana 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."[22] 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" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[23] 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 . . . ."[24] As a result, the CDC recommends that opioids be used not in the first instance, but only after prescribers have exhausted alternative treatments.

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[21] John Fauber, "Painkiller Boom Fueled by Networking," Milwaukee Wisc. J. Sentinel, Feb. 18, 2012.

[22] *Id.* at 10.

[23] *Id.* at 9.

[24] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1501-02 (Apr. 21, 2016).

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

77. 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 Montana 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.

78. Two professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Purdue.[25] 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 the term "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, was the sole consultant. The consensus statement remained on AAPM's website until 2011.

79. 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. Such

[25] From 2009 to 2012, APS received nearly $500,000 from Purdue and from 2006 to 2016, AAPM received $1.2 million from Purdue.

guidelines 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.

80. 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, 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.

81. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain* and have influenced not only treating physicians and chemical dependency treatment providers, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited 1,647 times in academic literature.

82. Purdue also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. For example, 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]."[26] 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 long-term."[27] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects; there was no reported data regarding addiction; and the study was not long-term. Another Purdue study of a chronic pain condition only evaluated patients over seven days, but found oxycodone effective in its treatment.[28]

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

83. Purdue also claimed—without evidence—through its sales representatives and other materials disseminated in Montana, 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.

84. Purdue and Purdue-sponsored materials distributed or made available in Montana reinforced this message. 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

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[26] 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).

[27] *Id.*

[28] Martin E. Hale, Roy Fleischmann, Robert Salzman, James Wild, Tad Iwan, Ruth E. Smanton, Robert F. Kaiko, and Peter G. Lacouture, *Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain*, The Clinical Journal of Pain, Sep. 1, 1999, https://www.ncbi.nlm.nih.gov/pubmed/10524470.

OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with chronic pain conditions—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

85. Purdue sponsored the Federation of State Medical Board's ("FSMB's") *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." This publication claimed that because pain had a negative impact on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction. [redacted]

86. 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 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.

87. 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."[29] 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.

88. 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"[30] and advised that "there is no good evidence that opioids improve pain or function with long-term use."[31] Similarly, the FDA has warned other opioid product manufacturers that claims of improved function and quality of life were misleading.[32] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[33] In that vein, a recent study by Princeton

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[29] 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?

[30] CDC Guideline at 15.

[31] *Id.* at 20.

[32] *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' 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."). These warning letters were available to Purdue on the FDA website.

[33] CDC Guideline at 2.