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MONTANA FIRST JUDICIAL DISTRICT COURT
LEWIS AND CLARK COUNTY

STATE OF MONTANA,)	
)	
Plaintiff,)	
)	
v.)	Cause No. ADV-2017-949
)	
PURDUE PHARMA L.P., PURDUE)	
PHARMA, INC., THE PURDUE)	PLAINTIFF STATE OF MONTANA'S
FREDERICK COMPANY INC., and)	MEMORANDUM IN SUPPORT OF
JANE DOES 1-10,)	MOTION FOR PRELIMINARY
)	INJUNCTION
Defendants.)	
)	
)	

I. INTRODUCTION

Opioid addiction is a public health crisis in Montana. Decl. of Dr. Marc Mentel ¶ 3 (“Dr. Mentel Decl.”) (Ex. A). According to the Montana Medical Association, “Prescription drug abuse and diversion is a growing epidemic—it affects everyone, and the statistics are staggering.” *Id.* The epidemic began not with an outbreak, but with a business plan. It is the result of Purdue’s corporate decision to promote opioids deceptively and illegally in order to dramatically increase sales and generate billions of dollars for Purdue’s private owners, the Sackler family. Purdue’s misrepresentations regarding the risks and benefits of opioids enabled, and continue to enable, the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.¹ As a direct consequence, the rampant use, overuse, and abuse of opioids is devastating Montana and its residents.²

While this case is being litigated, the opioid crisis will continue. New prescriptions will be written and more Montana citizens will become addicted. The State asks this Court to adopt a defined set of measures that, during this litigation, will mitigate the crisis, prevent further loss of life, and begin to restore the status quo that existed before Purdue’s false and misleading marketing campaign. When this litigation ends, these preliminary measures can be amended, replaced or adopted into a permanent order. But Purdue should not be allowed to continue promoting its opioids without regard to the facts and the health and safety of the people of Montana.

II. FACTUAL BACKGROUND

Purdue sells opioids and opioid-related drugs, and has virtually no other product line. Moreover, according to the State’s Medicaid spending data, Purdue manufactures the largest

¹ Consistent with the commonly accepted medical usage, the term “chronic pain” as used herein refers to non-cancer pain lasting three months or longer.

² A recent study from the University of Virginia found that “higher opioid analgesic prescriptions could explain around 85% of the rise in associated deaths” nationally from 2000-2015. Christopher J. Ruhm, “Deaths of Despair or Drug Problems?” NBER Working Paper Series, Working Paper 24188 at 37 (Jan. 2018) (available at <http://www.nber.org/papers/w24188>) (Ex. B).

share—by far—of the branded opioids prescribed in Montana. Opioids are not typical pharmaceuticals. They are highly addictive, narcotic 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[.]” DEA Drug Schedules (available at <https://www.dea.gov/druginfo/ds.shtml>). 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). CDC Guideline for Prescribing Opioids for Chronic Pain (“CDC Guideline”) at 2 (Ex. C). 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.” 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) (Ex. D).

Before Purdue’s marketing campaign, doctors wrote few opioid prescriptions, reserving their use mostly for acute cancer pain, post-surgery recovery pain, and end-of-life care. Doctors feared that opioids were too addictive for long-term use and too dangerous for relatively minor chronic pain conditions. In an aggressive marketing campaign that harnessed respected doctors, seemingly neutral patient advocacy groups, and professional associations, Purdue falsely claimed that doctors could prescribe opioids as a first-line, long-term treatment for patients with chronic pain without a material risk of addiction. Purdue spread other deceptive messages, including the concept of “pseudoaddiction,” which a Purdue key opinion leader invented to dupe doctors into believing that patients who exhibit addictive behaviors are being undertreated and should be prescribed more opioids—the medical equivalent of fighting fire with gasoline. *See* Declaration of Jeffrey C. Nelson (“Nelson Decl.”) ¶¶ 5, 10, 11 (Ex. E) (filed under seal). 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 evidence available to

Purdue. See Nelson Decl. ¶¶ 3, 6, 11, 12, 14 (Ex. E) (filed under seal). Purdue’s promotional claims were dangerously, and too often fatally, false.

The CDC reports that more than 140 Americans die each day from opioid overdoses. In Montana, more than 700 people have died from prescription opioid overdoses since 2000; thousands have been admitted to emergency rooms and hospitals; and countless families have been torn apart. Declaration of Sheila Hogan, Director of the Montana Department of Public Health and Human Services ¶¶ 4-5 (“Hogan Decl.”) (Ex. F).

Yet Purdue continues to profit by deceptively minimizing the risks of addiction, exaggerating the benefits of long-term use, and turning a blind-eye to inappropriate prescribing. As a result, and as even Purdue admits, “[t]here are too many prescription opioid pills in people’s medicine cabinets.” Purdue Pharma, Full-Page Advertisements in the Wall Street Journal at A7 (e.g., Dec. 15, 2017 and Feb. 6, 2018).³ These pills include Purdue’s opioids—OxyContin, Hysingla, and Butrans, which not only endanger the patients who obtained the prescriptions, but also expose friends and family members to dangerous supplies of these controlled substances.

The State previously attempted to stop Purdue’s illegal conduct through a negotiated resolution. In 2007, Montana joined a 27-state enforcement initiative that resulted in a Consent Judgment entered in this Court (Ex. G). The Consent Judgment contains 21 different compliance provisions, all intended to stop Purdue from marketing OxyContin in ways that are false, misleading or deceptive.

On September 21, 2017, the State issued a civil investigative demand to Purdue covering documents generated since the Consent Judgment. Purdue responded with more than 4 million

³ It is telling that Purdue is responding to the opioid epidemic created by its marketing campaign not with constructive measures to address the crisis, but with yet another marketing campaign—this one attempting to convince the public that Purdue has been spurred “to redouble [its] efforts in the fight against the prescription and illicit opioid abuse crisis.” In the course of this campaign, Purdue has only repeated its misconduct. Purdue’s full-page advertisements, which ran in the *New York Times* and the *Wall Street Journal*, promoted its abuse-deterrent formulations (“ADFs”) as evidence of its efforts to take meaningful action to reduce opioid abuse, but Purdue’s false marketing of its ADFs as safer than other opioids has only contributed to the opioid epidemic in Montana and elsewhere.

pages covering conduct as recent as September 14, 2017. The State filed its first Complaint on November 30, 2017, and sent Purdue a Notice of Violation of the Consent Judgment on December 5, 2017 (Ex. H) outlining, in detail, numerous ways in which Purdue has breached its Consent Judgment commitments. To date, the State has received no response from Purdue. Based on the State's review of Purdue's documents and other evidence, and absent any contrary explanation from Purdue, the State amended its complaint on January 30, 2018 to add allegations and a claim for relief for Purdue's multiple violations of the Consent Judgment.

On February 9, 2018, Purdue issued a short public statement indicating that its "sales representatives will no longer promote opioids to prescribers." Purdue Pharma L.P. Issues Statement on Opioid Promotion (Feb. 9, 2018) (Ex. L). The State informed Purdue that Purdue's decision to cease detailing its opioids to doctors could obviate the need for the State to seek a preliminary injunction, as planned, if Purdue were to agree to put its decision, and several other similar measures, into a binding order. Letter to William Mercer, Counsel for Purdue, from Dale Schowengerdt, Montana Solicitor General (Feb. 13, 2018) (Ex. M). The State and Purdue held a meet-and-confer on February 20, 2018, but Purdue did not agree to the proposed order.

Given Purdue's unwillingness to take meaningful steps to address its conduct in Montana, and pursuant to Mont. Code Ann. § 27-19-201, the Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. § 30-14-111, the 2007 Consent Judgment, and common law authority, the State seeks preliminary injunctive relief to stop Purdue from violating the Consumer Protection Act, to stop Purdue from violating the 2007 Consent Judgment, and to abate the public nuisance that Purdue created by prohibiting Purdue's deceptive and unlawful marketing.

III. PRELIMINARY INJUNCTION STANDARDS

A court may issue an injunction:

(1) when it appears that the applicant is entitled to the relief demanded and the relief or any part of the relief consists in restraining the commission or continuance of the act complained of, either for a limited period or perpetually;

[or]

(2) when it appears that the commission or continuance of some act during the litigation would produce a great or irreparable injury to the applicant

Mont. Code Ann. § 27-19-201.

The subsections in section 27-19-201 are disjunctive, meaning only one section must be satisfied for an injunction to issue. *Stark v. Borner*, 226 Mont. 356, 359-60, 735 P.2d 314, 316 (1987); *Sweet Grass Farms, Ltd. v. Bd. of Cty. Comm'n'rs of Sweet Grass Cty.*, 2000 MT 147, ¶ 27, 300 Mont. 66, 2 P.3d 825. “If either showing is made, then courts are inclined to issue the preliminary injunction to preserve the status quo pending trial.” *Porter v. K&S Partnership*, 192 Mont. 175, 181, 627 P.2d 836, 839 (1981). The status quo is “the last actual, peaceable, noncontested condition which preceded the pending controversy.” *Sandrock v. DeTienne*, 2010 MT 237, ¶ 16, 358 Mont. 175, 243 P.3d 1123. It is the court’s duty to minimize the injury or damage to all parties to the controversy. *Id.*

Moreover, the Montana Unfair Trade Practices and Consumer Protection Act expressly recognizes the State’s ability to immediately curtail unfair and deceptive acts that harm public health and safety or are contrary to the public interest, which may be based on past conduct:

Whenever the [D]epartment [of Justice] has reason to believe that a person is using, has used, or is about to knowingly use any method, act, or practice declared by 30-14-103 to be unlawful and that proceeding would be in the public interest, the department may bring an action in the name of the state against the person to restrain by temporary or permanent injunction or temporary restraining order the use of the unlawful method, act, or practice upon giving appropriate notice to that person.

Mont. Code Ann. § 30-14-111(1).

IV. ARGUMENT

As demonstrated below, the State is entitled to a preliminary injunction on at least two separate grounds under Mont. Code Ann. § 27-19-201. Thus, this Court should grant the relief requested.

A. This Court Should Issue a Preliminary Injunction Because the State is Entitled to the Relief Demanded.

The State is entitled to an injunction under Mont. Code Ann. § 27–19–201(1) because it has a legitimate cause of action and is likely to succeed on the merits, and an injunction is an appropriate remedy. *Sandrock*, ¶ 16. Specifically, the State has asserted valid claims that Purdue violated the Consumer Protection Act, that it violated the 2007 Consent Judgment with the State, and that it created a public nuisance.⁴ Moreover, the State is likely to succeed on each of these claims, and thus, an injunction is appropriate.

1. The State Will Likely Prevail on Its Consumer Protection Act Claim.

The Consumer Protection Act makes it unlawful to engage in “unfair or deceptive acts or practices in the conduct of any trade or commerce” in Montana. Mont. Code Ann. § 30-14-103. Marketing statements are deceptive within the meaning of the Consumer Protection Act when they are untrue at the time they are made, *WLW Realty Partners, LLC v. Continental Partners VIII, LLC*, 2015 MT 312, ¶ 32-34, 381 Mont. 333, 360 P.3d 1112, or when they contain misleading statements or omissions that have a tendency or capacity to deceive. *See FTC v. Cyberspace.com LLC*, 453 F.3d 1196, 1199-1200 (9th Cir. 2006) (“A solicitation may be likely to mislead by virtue of the net impression it creates even though the solicitation also contains truthful disclosures.”).⁵ Unfairness reaches conduct that offends established public policy and is either immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers. *Jacobson v. Bayview Loan Serv., LLC*, 2016 MT 101, ¶¶ 43-46, 383 Mont. 257, 371 P.3d 397.⁶

⁴ At this time, the State is seeking a preliminary injunction under only three counts. The State reserves the ability and right to seek an injunction on other counts.

⁵ The Montana Consumer Protection Act is modeled on the Federal Trade Commission Act, and Montana courts look for guidance from the federal courts interpreting the Federal Trade Commission Act. Mont. Code Ann. § 30-14-104; *WLW Realty Partners*, ¶ 31.

⁶ To establish violations of the CPA, the State need not allege that prescribers relied on Purdue’s misrepresentations, nor that the misrepresentations caused doctors to prescribe Purdue’s opioids. *See, e.g., F.T.C. v. Commerce Planet, Inc.*, 878 F. Supp. 2d 1048, 1088 (C.D. Cal. 2012) (“Under section 13(b) of the FTC Act, proof of injury by every individual consumer is not required to justify a restitutionary award”), *aff’d in part, vacated in part, remanded*, 815 F.3d 593 (9th Cir.

In the State’s First Amended Complaint (“FAC”), the State alleges that Purdue has committed, and continues to commit, numerous violations of the CPA. FAC ¶¶ 156-161. The State presents with this Motion several examples of evidence that it intends to introduce at trial to prove that Purdue engaged in unfair and deceptive acts.

The primary allegations in the FAC relate to Purdue’s persistent misrepresentations of the benefits of opioids along with its downplay of the risks of dependence, addiction, and overdose. “Doctors everywhere, including in this state, relied on information purporting to demonstrate that addiction did not occur with the use of opioid medications for chronic pain, based on medication trials conducted by pharmaceutical companies and provided to doctors primarily by drug representatives during detail visits.” Dr. Mentel Decl. ¶ 3 (Ex. A).

The State intends to introduce numerous examples of these misrepresentations,⁷ including the testimony of former key opinion leaders such as Dr. Russell Portenoy, who was funded by Purdue. In 2012, the Wall Street Journal interviewed Dr. Portenoy, one of the doctors Purdue paid to write and publish articles. See Nelson Decl. ¶ 2 (Ex. E) (filed under seal). According to the article, Dr. Portenoy admits that he overstated the drugs’ benefits and glossed over the risks. *Id.* “Data about the effectiveness of opioids does not exist,” Dr. Portenoy admitted. *Id.* He also stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did[.]” *Id.* In a 2010 interview also reported by the Wall Street Journal, Dr. Portenoy said it was “quite scary” to think how the growth in opioid prescribing driven by people like him had contributed to soaring rates

2016), and *aff’d in part*, 642 F. App’x 680 (9th Cir. 2016); see also *Gugliuzza v. F.T.C.*, 137 S. Ct. 624, 196 L. Ed. 2d 515 (2017), *cert. denied sub nom. F.T.C. v. Commerce Planet, Inc.*, 815 F.3d 593, 603–05 (9th Cir. 2016) (“The district court . . . followed, and properly applied, the two-step burden-shifting framework that other circuits have adopted for calculating restitution awards under § 13(b). . . .”)⁶; *F.T.C. v. Publishers Bus. Servs., Inc.*, 540 F. App’x 555, 556–58 (9th Cir. 2013) (same).

⁷ Some examples of Purdue’s deceptive promotional materials and marketing plans are also included as exhibits. Nelson Decl. (Ex. E) (filed under seal). Due to confidentiality concerns, the State will refrain from quoting or discussing them in this Motion until the parties have addressed such issues with the Court.

of addiction and overdose deaths. “Clearly, if I had an inkling of what I know now then, I wouldn’t have spoken in the way that I spoke. It was clearly the wrong thing to do[.]” *Id.*

The State also intends to introduce the testimony of former Purdue sales representatives such as Sean Thatcher. Mr. Thatcher served as a Purdue sales representative in Montana from 2009-2015. Declaration of Sean Thatcher (“Thatcher Decl.”) ¶ 1 (Ex. I). He promoted OxyContin, Hysingla and Butrans to approximately 100 doctors and other prescribers in the state. *Id.* For example, Mr. Thatcher testified by declaration that he was trained and directed to market OxyContin for chronic pain, including lower back pain and pain from arthritis, promising that the drugs improve patients’ quality of life. *Id.* at ¶ 6-7. As the State’s complaint alleges, consistent with the findings in the CDC Guideline, there is no evidence now, and was no evidence then, supporting the long-term use of opioids for chronic pain, nor was there evidence that opioids improve patients’ function or quality of life. CDC Guideline at 15, 18-19. Some doctors he visited complained that their patients who were on OxyContin for a year or more were developing a tolerance to the product. *Id.* ¶ 6. Mr. Thatcher was trained to tell doctors in such situations that they should titrate up the dose, *id.* ¶ 6, despite the greater risks of addiction, overdose, or death at higher doses. CDC Guideline at 13. Mr. Thatcher also discussed pseudoaddiction with doctors, *id.* ¶ 7, a concept that a Purdue key opinion leader invented, as described above, which endangered patients by prompting doctors to respond to signs of opioid addiction with more opioids.

The FAC also alleges that Purdue promoted OxyContin as providing a full 12 hours of pain relief, when Purdue knew that for many patients, it does not. As proof of this allegation, the State will introduce numerous “call notes” memorializing sales visits by Purdue sales representatives to prescribers in Montana that document such representations. Nelson Decl. ¶ 8 (Ex. E) (filed under seal). In addition, Mr. Thatcher testified that Purdue trained him to represent that OxyContin is more convenient than competitor drugs because it is given once every 12 hours. Thatcher Decl. ¶ 5 (Ex. I). These representations were untrue or misleading. Evidence will show that Purdue knew that for many patients, OxyContin does not provide a full 12 hours

of pain relief.⁸ Sean Thatcher’s own testimony establishes that approximately 30-40% of the doctors he called on complained that pain relief from OxyContin did not last 12 hours, as represented. *Id.* ¶ 5.

In addition, the FAC alleges that Purdue engaged in an unfair practice by encouraging doctors and medical staff to allow unlicensed Purdue representatives to review patient medical files for the purpose of identifying individuals who—in the Purdue representative’s opinion—should be prescribed Purdue’s opioids. This practice offends the State’s public policy, reflected in statutory privacy protections,⁹ is unethical and substantially injurious to consumers’ privacy rights. Mr. Thatcher testified that Purdue managers encouraged sales representatives to engage in such a practice, which they called “chart flagging,” and that the practice was “prevalent.” Thatcher Decl. ¶ 9 (Ex. I).

Based on this evidence, and the additional examples of deceptive publications attached to this Motion, Nelson Decl. (Ex. E) (filed under seal), the State can establish that it will likely succeed in proving that Purdue engaged in a pattern of unfair and deceptive practices. Because the Consumer Protection Act authorizes the issuance of injunctions in these circumstances, Mont. Code Ann. § 30-14-111(1), the State is also entitled to the specific injunctive relief demanded.

2. The State Will Likely Prevail on Its Consent Judgment Claim.

Under the Consent Judgment’s enforcement provisions, the “State may assert any claim that Purdue has violated this Judgment in a separate civil action to enforce this Judgment, or to seek any other relief afforded by law.” Consent Judgment ¶ 46 (Ex. G). The State must first give Purdue notice of the violations and an opportunity to respond. Consent Judgment ¶¶ 39-44

⁸ For example, 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. FAC ¶ 108. Purdue’s own studies showed the same results. FAC ¶ 109.

⁹ “Except [for several exceptions not applicable here], a health care provider . . . may not disclose health care information about a patient to any other person without the patient’s written authorization.” Mont. Code Ann. § 50-16-525(1).

(Ex. G). Accordingly, the Attorney General sent Purdue notice of its violations on December 5, 2017, (Ex. H), setting forth five compliance provisions of the Consent Judgment that Purdue has violated, namely:

- 1) Purdue shall not engage in false, misleading or deceptive marketing (Consent Judgment ¶ 2);
- 2) Purdue shall provide “fair balance” statements regarding contraindications and adverse events (Consent Judgment ¶ 4);
- 3) Purdue shall not misrepresent OxyContin’s potential for abuse, addiction, or physical dependence (Consent Judgment ¶ 5);
- 4) In promoting OxyContin, Purdue shall use only information that is truthful, balanced, and accurately communicated, and Purdue shall not minimize the risk of abuse, addiction or physical dependence (Consent Judgment ¶ 20); and
- 5) Purdue shall establish an OxyContin Abuse and Diversion Detection Program consisting at least of certain specified internal procedures (Consent Judgment ¶ 13).

The Attorney General notified Purdue of its specific conduct that violated the Consent Judgment. The full list appears in the Attorney General’s Notice Letter, (Ex. H), and includes:

- 1) Purdue has continued to misrepresent 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;
- 2) In numerous sales interactions, Purdue failed to disclose to Montana prescribers the risks of addiction to, and withdrawal from, its opioids. This failure to disclose the risk of addiction was deceptive in its own right, but especially in light of Purdue’s past misrepresentations regarding the risk of addiction;
- 3) Purdue touted the purported benefits of long-term opioid use to Montana prescribers, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence. Purdue claimed—without evidence—through its sales representatives and other materials that it sponsored and 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;

- 4) To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch; and
- 5) Purdue promised doctors in Montana that its abuse-deterrent opioids were safer for patients. But 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.

Purdue failed to respond to the Attorney General's notice letter. The State's specific allegations, the testimony discussed above in Section 1, the documentary evidence obtained from Purdue and included as exhibits to the Nelson Declaration (Ex. E) (filed under seal), and Purdue's complete failure to address the Attorney General's notice letter establish that the State is likely to succeed on its Consent Judgment claim. Because the Consent Judgment authorizes any relief afforded by law, the issuance of a preliminary injunction pending the outcome of the litigation is permitted and appropriate relief.

3. The State Will Likely Prevail on Its Public Nuisance Claim.

By statute, “[a] public nuisance is one which affects, at the same time, an entire community or neighborhood or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal.” Mont. Code Ann. § 27-30-102. By common law, a public nuisance is:

an unreasonable interference with a right common to the general public. Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following: a) whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.

Restatement (Second) of Torts § 821B.

To establish a public nuisance claim, the State must provide evidence from neighbors or community leaders in the area and demonstrate that specific individuals

were affected by the nuisance. *Montana v. BNSF Railway Co.*, 2010 MT 267, ¶ 37, 358 Mont. 368, 246 P.3d 1037 (affirming dismissal of the Department of Environmental Quality’s claim for public nuisance for failure to provide such evidence). The State has substantial evidence, including the testimony of community leaders, that the opioid epidemic has significantly interfered with public health and safety, and has affected thousands of Montana residents. Dr. Mentel Decl. ¶ 3 (Ex. A) (“Opioid addiction is a public health crisis in Montana.”); Hogan Decl. ¶¶ 4, 5 (Ex. F) (“[S]ince 2000, the rate of prescription drug overdose deaths has doubled, with more than 700 deaths from prescription opioid overdose alone.” “[F]rom 2011-2014 alone, prescription drug overdoses were responsible for more than 7,200 hospital emergency room visits and inpatient admissions.”); Declaration of Laura Dickerson ¶¶ 2, 6 (Ex. K) (“At any one time, about half of our [approximately 60] clients are addicted to opioids.” “The need for addiction treatment in Montana is large. According to data reported by the Montana Department of Justice in 2017, an estimated one in ten Montana adults is dependent upon or abusing substances, but 90% of such individuals with a substance use disorder are not receiving treatment.”). Furthermore, as laid out in Section IV(A)(1) – (2), Purdue’s conduct is proscribed by Montana statutes and the prior Consent Judgment enjoining Purdue’s conduct, (Ex. G), and Purdue’s specific practice of reviewing and flagging confidential patient medical files unreasonably interferes with the right of privacy enjoyed by all Montanans, *see* Mont. Code Ann. § 50-16-525(1); 45 C.F.R. Part 160 & 164, and therefore constitutes a public nuisance under common law.

This conduct is a substantial factor in creating the opioid epidemic that has continuing and long-lasting impacts on the State and its citizens.¹⁰ Purdue’s unfair and deceptive marketing

¹⁰ “[W]here there are allegations that the acts of more than one person combined to produce a result,” Montana follows a “substantial factor” test to determine causation. *Busta v. Columbus Hosp. Corp.*, 276 Mont. 342, 371-72, 916 P.2d 122 (1996). Pursuant to that test, a party’s

caused healthcare providers to prescribe opioids when they are not necessary and at doses that are too high, and influences patients to take—and keep taking—those opioids despite the risks of dependence and addiction. Dr. Aaron Kesselheim, an Associate Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women’s Hospital, where he leads the Program On Regulation, Therapeutics, And Law, testified through his declaration that numerous quantitative and qualitative studies of physicians’ behavior show that pharmaceutical marketing, like that described above and in the FAC, influence physicians and increase their prescribing of promoted brand-name drugs. Declaration of Dr. Aaron Kesselheim (“Kesselheim Decl.”) (Ex. J), at ¶ 9. Moreover, Dr. Kesselheim points out that physicians generally fail to recognize the inaccurate statements made by pharmaceutical representatives about their drugs. *Id.* ¶ 11. Dr. Kesselheim’s conclusions will be confirmed by Purdue’s own data, which show a strong correlation between Purdue’s marketing activities and the number of prescriptions that doctors write. FAC ¶ 32. Thus, the State has demonstrated that it will be able to prove that Purdue’s deceptive and unfair marketing was a substantial factor in increasing the prescribing of opioids in Montana.

As confirmed in the Hogan and Dickerson Declarations (Ex. F and Ex. K), the widespread use of opioids in Montana has had devastating effects on thousands of Montana residents who have, or will, become addicted to, die from, or otherwise be profoundly injured by opioids. In addition to the many lives lost and thousands of families destroyed, the State faces many other injuries from the opioid crisis, including inflated Medicaid and health insurance costs, treatment center expenses, law enforcement costs, and corrections center costs. Because the opioid epidemic affects, at the same

conduct that is a “substantial factor” in bringing about the harm is considered proximate cause of that harm. *Id.*; see also *Rudeck v. Wright*, 218 Mont. 41, 53-54, 709 P.2d 621 (1985).

time, a considerable number of Montanans, it constitutes a public nuisance under Mont. Code Ann. § 27-30-102.

Because an order to abate the public nuisance is the proper remedy for such claims, the Court should issue a preliminary injunction preventing Purdue from engaging in deceptive marketing that is continuing to cause the overuse of opioids.

B. This Court Should Issue a Preliminary Injunction Because Purdue's Conduct Has Caused Montanans and Their Families Great or Irreparable Injury.

A court should issue a preliminary injunction “when it appears that the commission or continuance of some act during the litigation would produce a great or irreparable injury to the applicant[.]” Mont. Code Ann. § 27-19-201(2).

In *City of Whitefish v. Bd. of Cty. Comm'rs of Flathead Cty.*, 2008 MT 436, ¶ 22, 347 Mont. 490, 199 P.3d 201, the Montana Supreme Court held that the plaintiff city established the prospect of irreparable harm from the defendant county's threatened violation of an intergovernmental agreement by re-zoning certain land at issue. *Id.* The Court concluded: “Such a situation precisely meets the criterion of § 27-19-201(2), MCA.” *Id.* Presumably, the Court was concerned that the public would rely on any re-zoning and would make substantial investments and build permanent structures in accordance with the new zoning designation—changes that would not be undone and creating harm to the city that could not be quantified, should the city prevail.

To an even greater extent here, Montanans are being greatly and irreparably harmed by the opioid crisis, which has been fueled by Purdue's marketing: families are being torn apart by addiction; lives and livelihoods are being damaged, often permanently; babies are being born with severe impairments; and Montana citizens are dying. The State is irreparably injured by the injuries and death of its citizens, who contribute much more to the State than any fiscal value. There are few, if any, injuries so great or irreparable as the mounting number of deaths caused by opioid overdoses. From 2000 to present, more than 700 people have died from opioid overdoses in Montana. Hogan Decl. ¶ 4 (Ex. F). From 2011-2014, prescription drug overdoses were

responsible for more than 7,200 hospital emergency room visits and inpatient admissions. Hogan Decl. ¶ 5 (Ex. F). Hundreds of babies in Montana are born already addicted to opioids. These newborns suffer from, and must be treated for, neonatal abstinence syndrome. Between 2000 and 2013, there were 432 newborn infants born in Montana with neonatal abstinence syndrome. Hogan Decl. ¶ 6 (Ex. F). The opioid crisis also affects families with older children. Over the last seven years, an average of more than 11% of the State's foster care placements have involved prescription drug abuse by the child's parents or guardians. Hogan Decl. ¶ 7 (Ex. F).

Nationally, opioid deaths are expected to increase from about 35,000 per year now to about 45,000 – 100,000 in 2025. The Economist, *Forecasting the Opioid Epidemic* (Oct. 28, 2017) (Ex. N). One analysis of 10 forecasts predicted the annual death toll will increase by at least 35 percent between 2015 and 2027. STAT, *Opioids Could Kill Nearly 500,000 Americans in the Next Decade* (June 27, 2017) (Ex. O). The same rate of increase would be expected in Montana.

Purdue's deceptive marketing has contributed to this crisis by significantly increasing the number of opioid prescriptions that would have been written otherwise. See Kesselheim Decl. ¶ 17 (Ex. J). The preliminary injunctive relief that the State is requesting cannot prevent all opioid addiction or overdose in Montana, but it can reduce those numbers by better informing doctors and patients about the risks of chronic opioid use and doing more to identify suspicious prescribing. Thus, preventing significant and irreparable harm to the State and its residents provides a second, discrete reason to issue a preliminary injunction.

V. RELIEF REQUESTED

The State requests a preliminary injunction that will prohibit Purdue from deceptively marketing its opioids in Montana, in violation of the Consumer Protection Act and its Consent Judgment with the State, and that will require Purdue to fulfill its obligation to detect, report, and reject suspicious orders, as laid out below.

The Court does not write on a blank slate in guiding Purdue on what it can and cannot represent in its marketing in Montana. In 2016, the CDC issued its Guideline for Prescribing Opioids for Chronic Pain (“CDC Guideline”) (Ex. C), which provides clear statements of fact, based on an exhaustive analysis of scientific evidence, regarding the use of opioids for chronic pain. The CDC Guideline relied on a thorough review of the existing evidence regarding opioids, assessed by an expert panel free from industry influence, and was subject to public comment. The CDC’s findings both establish that Purdue’s promotional activities have been deceptive and provide clear guidance on the appropriate promotion and use of opioids. For example, the CDC found that there is insufficient evidence to support a claim that opioids provide any benefit for long-term use, CDC Guideline at 15, 18-19, and that opioids should not be considered first-line or routine therapy for chronic pain, *id.* at 19.

Purdue’s recent public announcement that its sales representatives will no longer promote opioids to prescribers takes a first, voluntary step towards appropriate injunctive relief. It does not, however, address the myriad other ways that Purdue promotes its opioids to prescribers and consumers, *see* First Amended Complaint ¶¶ 28-29, 34-48, 56-75, 77-132; Kesselheim Decl. (Ex. J), and given Purdue’s track record, it must be made enforceable.

The State asks that this Court direct Purdue, pending final resolution of this litigation, as follows:

- 1) Immediately cease all sales representative promotions of opioid drugs to prescribers in Montana, committing to the announcement Purdue already made that it would halt such efforts.
- 2) In all other promotional or educational activity that could reach Montana prescribers or consumers:
 - a. Immediately cease promoting its opioid drugs, or opioids in general, as a first-line or routine therapy for chronic pain (i.e., pain continuing or expected to continue >3 months or past the time of normal tissue healing outside of active cancer, palliative, and end-of-life care), and in any promotional or educational activity, disclose that opioids are to be tried only after other treatments have failed. CDC Guideline at 19.

- b. Immediately cease making any representations or suggestions that there is evidence that opioids provide a long-term benefit for pain, function or quality of life, and in any promotional or educational activity, disclose that there is no evidence that opioids improve pain, function, or quality of life long-term. CDC Guideline at 15, 18-19.
- c. Immediately cease representing or suggesting that there are adequate screening or risk-stratification tools to classify patients as low risk for abuse or misuse, or to eliminate risks from long-term opioid therapy, and in any promotional or educational activity, disclose that there is no evidence that screening or risk-stratification tools are effective in preventing addiction or limiting other risks of long-term opioid use. CDC Guideline at 28.
- d. Immediately cease making any representations or suggestions that Purdue's abuse-deterrent formulation are effective in deterring or preventing overall abuse or addiction, and in any promotional or educational activity, disclose that abuse-deterrent formulations do not deter oral abuse and have not been shown to reduce overall abuse or addiction. CDC Guideline at 22.
- e. Immediately cease making any representations or suggestions that the use of opioids to treat chronic pain does not carry a serious risk of addiction, and in any promotional or educational activity, disclose that long-term opioid use for chronic pain is associated with serious risks including increased risk for opioid use disorder, overdose, myocardial infarction, and motor vehicle injury; and that even when opioids are indicated, prescribers should use the lowest effective dosage and should avoid increasing dosage to ≥ 90 morphine milligram equivalents ("MME") /day or carefully justify a decision to titrate dosage to ≥ 90 MME/day. CDC Guideline at 18, 22.

The injunction also should include the following measures to further abate the public nuisance Purdue has created, which are consistent with existing federal law that requires Purdue to maintain effective controls against diversion, 21 U.S.C. § 823(a)(1), and design and operate a system to disclose to the U.S. Drug Enforcement Administration suspicious orders of controlled substances, 21 C.F.R. § 1301.74(b):

- 3) Immediately implement a program to monitor suspicious orders from pharmacies, based on data available from Purdue's distributors, and suspicious prescribing patterns, based on data available from commercial sources, and timely report such suspicious orders or

prescribing patterns to the Montana Board of Pharmacy or the Montana Board of Medical Examiners, respectively.¹¹

- 4) Submit a quarterly compliance monitoring disclosure statement to the Montana Attorney General, including measures taken to implement the monitoring program required above.

These common-sense measures will help to restore a status quo that existed before Purdue changed the medical landscape, prevent many of the violations of law alleged in the State's First Amended Complaint, and reduce the incidence of new opioid addiction, overdose, and death. Implementing the requested relief is within the power of this Court and consistent with the labels for Purdue's opioids approved by the federal Food and Drug Administration ("FDA").

For example, the most recently approved label for OxyContin contains, among others, the following pertinent statements:¹²

- OXYCONTIN is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate in:
- Adults; and
- Opioid-tolerant pediatric patients 11 years of age and older who are already receiving and tolerate a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent.
- Limitations of Use
- Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations [*see Warnings and Precautions (5.1)*], reserve OXYCONTIN for use in patients for whom alternative treatment options (e.g. non-opioid analgesics or

¹¹ Although Purdue will no longer have direct access to doctor's offices to observe suspicious behavior or other circumstances when it ceases detail visits, it still has access to sales and prescribing data that will allow it to detect and report suspicious prescribing.

¹² The FDA-approved labels for Purdue's other two major opioid products, Hysingla and Butrans, include substantively identical language to the OxyContin label excerpts quoted above. The full FDA-approved labels of OxyContin, Hysingla and Butrans, which consist of Highlights, Full Prescribing Information, and Medication Guides, are attached as Exhibits 14, 15, and 16 to the Nelson Declaration (Ex. E) (filed under seal).

immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

- OXYCONTIN is not indicated as an as-needed (prn) analgesic.

OxyContin Label at 5 (see also OxyContin Label Highlights at 1 for nearly identical language).

The label also includes several black box warnings, including this warning with the title Addiction, Abuse, and Misuse:

- OXYCONTIN® exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing OXYCONTIN and monitor all patients regularly for the development of these behaviors and conditions [*see Warnings and Precautions (5.1)*].

OxyContin Label at 4 (see also OxyContin Label Highlights at 1 for nearly identical language).

The State is not seeking relief that would require Purdue to change, or act inconsistently with, any of Purdue's labeling statements. To the contrary, the State's proposed preliminary injunction would simply prohibit certain misrepresentations, consistent with the findings and recommendations in the CDC Guideline, none of which contradict Purdue's labeling statements. *See City of Chicago v. Purdue Pharma L.P.*, No. 14 C 4361, 2015 WL 2208423, at *10 (N.D. Ill. May 8, 2015) ("drug labels do not preclude fraud claims based on misrepresentations of the label information"). For example, the first measure requested in the State's proposed injunctive relief would enjoin Purdue from representing that its opioid products should be used as a front-line or routine therapy for chronic pain. Not only is this measure derived from the CDC Guideline, but it also is consistent with Purdue's current label for OxyContin. OxyContin Label at 5 ("indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment *and for which alternative treatment options are inadequate*") (emphasis added). Another requested measure would enjoin Purdue from representing that there is evidence that opioids provide a long-term benefit for pain, function or quality of life. Although OxyContin's label indicates that the drug is approved for long-term use, nothing in the labeling states that there is evidence of long-term benefits from taking opioids; and indeed, the CDC has determined that there is insufficient evidence of long-term benefits. Therefore, the State's requested relief

would not prevent Purdue from marketing its opioids for long-term use, but would simply prevent Purdue from making misrepresentations about the underlying science. In sum, the State's request that Purdue ensure that any promotion of its opioids be truthful and not misleading in no way conflicts with FDA oversight, but is required, consistent with Purdue's FDA-approved labels, to conform its conduct to Montana law and Purdue's voluntary Consent Judgment.

Furthermore, and significantly, the relief sought here relates only to Purdue's marketing of opioids. Nothing in the requested relief would prevent any particular opioid prescriptions or interfere with any doctor's exercise of his or her professional judgment in deciding whether to prescribe opioids to a particular patient. On the contrary, by correcting Defendants' prior misrepresentations and ensuring accurate scientific information about the use of opioids, this preliminary injunction would better equip doctors and patients to make informed decisions as to whether, when and how to use opioids.

VI. CONCLUSION

For the reasons stated above, the State asks this Court to grant the State's motion for a preliminary injunction.

DATED this 20th day of February, 2018.

THE STATE OF MONTANA



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CERTIFICATE OF SERVICE

I hereby certify I caused the foregoing PLAINTIFF STATE OF MONTANA'S MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION to be sent via United Parcel Service to be sent via overnight mail on February 21, 2018.:

Purdue Pharma, L.P. One Stamford Forum 201 Tresser Blvd Stamford, CT 06901	Purdue Pharma, Inc. One Stamford Forum 201 Tresser Blvd Stamford, CT 06901
Purdue Frederick Company Inc. One Stamford Forum 201 Tresser Blvd Stamford, CT 06901	William Mercer Holland & Hart LLP 401 North 31 st Street Suite 1500 P.O. Box 639 Billings, MT 59103 <i>Sent 2/20/18 to wwmerc@hollandhart.com</i> <i>Attorney for Purdue Pharma, L.P.; Purdue Pharma, Inc.; and Purdue Frederick Company, Inc.</i>

BY: _____