DISTRICT COURT, CITY AND COUNTY OF DENVER, COLORADO 1437 Bannock Street Denver, Colorado 80202	DATE FILED: November 5, 2018 6:45 PM FILING ID: 5D0A70E688A29 CASE NUMBER: 2018CV33300
THE STATE OF COLORADO *ex rel.* CYNTHIA H. COFFMAN, ATTORNEY GENERAL, Plaintiff, v. PURDUE PHARMA L.P. and PURDUE PHARMA, INC., Defendants.	▲**COURT USE ONLY**▲ Case No. 2018CV33300
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DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT

Defendants Purdue Pharma L.P. and Purdue Pharma, Inc. ("Purdue"), respectfully request the Court to dismiss the State of Colorado's Complaint.

INTRODUCTION

The heart of the State's claim against Purdue is the allegation that Purdue violated Colorado law by promoting its opioid pain medications for the treatment of chronic pain. The State alleges in the Introduction of its Complaint that Purdue "deceiv[ed] the medical community and public into believing that opioids were safe and effective to treat chronic, long-term pain,"

and that Purdue "knew that no reliable scientific and medical evidence existed to support this position." Compl. ¶ 4; *see also* Compl. ¶ 10. The conclusions of the United States Food and Drug Administration ("FDA"), the expert federal agency responsible for regulating and approving all medications, guts the State's central premise. The FDA has approved, and continues to approve, opioids, including Purdue's opioid pain medications, for the treatment of chronic pain. And the FDA has found, and continues to find, reliable scientific evidence to support this position. Therefore, as a matter of law, Purdue cannot have fraudulently or deceptively promoted its opioids for their FDA-approved use.

The State has sued Purdue, a manufacturer of opioid medications approved by the FDA as safe and effective for the long-term treatment of chronic pain. Purdue's opioids, including OxyContin® tablets, represent only approximately two percent of all prescriptions written for opioid pain medications. But the State seeks to hold Purdue alone liable for a multifaceted, complex public health crisis and the costs they claim Purdue has caused the State to bear.

The State sues in its individual capacity, and not *parens patriae* to recover for alleged damages to individual Colorado citizens. The State asserts a number of statutory and common-law claims, all of which are variations on the same theme that Purdue should be liable for the promotion and sale of opioid medications to treat chronic non-cancer pain. But these claims fail because the medications at issue are FDA-approved and any statements that are consistent with that FDA approval cannot be deceptive or fraudulent as a matter of law. The State's claims also depend on the theory that it can hold Purdue alone liable for the State's financial costs to "manage the impacts" of the opioid crisis, because Purdue allegedly misstated the risks of opioids and otherwise misled healthcare professionals, who then wrote medically unnecessary

prescriptions, which then ultimately led to opioid addiction, illegal drug use, and related criminal activity. In short, the State asks the Court to accept that there is a direct causal link between Purdue's alleged conduct and all of the harm caused in Colorado by lawful opioids and illegal drugs. The Court should decline the State's invitation because it disregards the many intervening actors and events that break the causal chain and make any alleged harm too remote to be attributed to Purdue as a matter of law. In the end, the State would have the Court ignore or distort traditional legal principles well beyond their breaking point and to assume a role in addressing this complex public health issue that is better left to expert regulators and elected officials. The Court should dismiss all claims for the following reasons:

First, as a matter of law Purdue's statements are not false or misleading: they are consistent with FDA-approved and FDA-required statements. Because every count has at its core the claim that Purdue's marketing conduct was deceptive, the Court should dismiss the Complaint in its entirety. But at a minimum, the Court should dismiss Claims One-Six[1] because the Colorado Consumer Protection Act ("CCPA") has a "safe harbor" that excludes liability for

[1] The State's six CCPA based claims are: (Claim 1) Violation of Section 6-1-105(1)(e) of the Colorado Consumer Protection Act: False representation as to the characteristics, ingredients, uses, benefits, alterations, or quantities of goods or services; (Claim 2) Section 6-1-105(1)(u), C.R.S. of the Colorado Consumer Protection Act: Fails to disclose material information concerning goods or services; (Claim 3) Section 6-1-105(1)(g), C.R.S. of the Colorado Consumer Protection Act: Represents that goods or services are of a particular standard, quality, or grade if he knows or should know that they are of another; (Claim 4) Section 6-1-105(1)(b), C.R.S. of the Colorado Consumer Protection Act: False representation as to the source, sponsorship, approval, or certification of goods or services; (Claim 5) Section 6-1-105(1)(c), C.R.S. of the Colorado Consumer Protection Act: False representation as to affiliation, connection, or association with or certification by another; and (Claim 6) Section 6-1-105(1)(h), C.R.S. of the Colorado Consumer Protection Act: Disparages the goods, services, or business of another by false or misleading representation of fact.

"[c]onduct in compliance with the order or rules of…a federal…governmental agency." C.R.S.A. § 6-1-106(1)(a).

Second, the State has not pleaded the necessary facts to allege a causal link between Purdue's alleged conduct, the claimed harm, and the damages sought by the State. This pleading failure warrants dismissal of all claims, apart from the CCPA claims to the extent they seek injunctive relief (§ 6-1-110(1)) and civil penalties (§ 6-1-112(1)). At a minimum, the Court should dismiss Claim Seven (public nuisance) and Claim Eight (negligence) to the extent they seek recovery for the State's alleged reimbursement of opioid prescriptions covered by health plans and the workers' compensation program because the State has not identified a single allegedly unnecessary prescription.

Third, the Court should dismiss the State's CCPA Claims One–Six to the extent they seek restitution (§ 6-1-110(1)), because the State has not shown that remedy is available or appropriate here.

Fourth, the Court should dismiss the sweeping public nuisance Claim Seven, which would lead to a radical expansion of Colorado law and unhinge public nuisance from its traditional limited focus on protection of indivisible "public" rights to air, water, and land.

Fifth, the State's common-law, derivative negligence Claim Eight fails because Purdue does not owe a general duty of care directly to the State, and does not owe a duty to prevent the tortious or illegal acts of non-parties who are the more direct source of the claimed harm.

BACKGROUND

The State devotes the majority of its Complaint to the contention that Purdue improperly and deceptively marketed its opioid medications for long-term treatment of chronic pain. *See, e.g.*, Compl. ¶¶ 3, 10, 57 ("Purdue began publishing misleading studies to promote the false perception that prescription opioids were effective long-term treatments for chronic pain conditions."). But the FDA specifically approved Purdue's opioid medications—including OxyContin®, Butrans®, and Hysingla®—to treat chronic pain.[2]

The FDA has exclusive authority to determine whether a prescription medicine is "safe and effective" for an intended use. 21 U.S.C. § 393(b)(2)(B). The FDA has approved Purdue's opioid medications as safe and effective for "long-term opioid treatment . . . ." *See, e.g.*, Ex. 1 § 1 ("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") (emphasis added); *see also* Compl. ¶ 21 (quoting labeling). The FDA approved extended-release and long-acting ("ER/LA") opioids such as OxyContin® to treat chronic pain only after the FDA concluded there is "substantial evidence that the drug will have the effect it

[2] *See* OxyContin Labeling at 1, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022272s027lbl.pdf (Ex. 1); Butrans Labeling at 1, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021306s027lbl.pdf (Ex. 2); Hysingla ER Labeling at 1, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206627s004lbl.pdf (Ex. 3). The State incorporates by reference Purdue's FDA-approved drug labels in its Complaint, so the Court may consider them in deciding this Motion. *See, e.g.*, Compl. ¶ 21; *Walker v. Van Laningham*, 148 P.3d 391, 397-98 (Colo. App. 2006) ("[i]n deciding whether to dismiss, the court may consider only the facts alleged in the pleadings, documents attached as exhibits or incorporated by reference in the pleadings, and matters of which the court may take judicial notice.").

purports or is represented to have," the benefits of the medications outweigh its risks, and the labeling is not "false or misleading in any particular." 21 U.S.C. § 355(d)(5), (7) (2018); *see also* 21 C.F.R. § 314.125(b)(5), (6) (2018).

Attempting to substitute its judgment for that of the expert agency charged by Congress to regulate medications in the interests of all Americans, the State neglects FDA's approval of these medications for the treatment of chronic pain as well as the benefits of Purdue's approved products. To this day, the FDA holds that Purdue's ER/LA opioid medications serve an important public health role: "When prescribed and used properly, opioids can effectively manage pain and alleviate suffering—clearly a public health priority. Chronic pain is a serious and growing public health problem: it 'affects millions of Americans: contributes greatly to national rates of morbidity, mortality, and disability, and is rising in prevalence."[3] At the same time, the FDA recognizes that "[o]pioids also have grave risks, the most well-known of which include addiction, overdose, and even death." *Id.*

As a result, the FDA requires prominent warnings about those risks, and Purdue's opioids are among the most strictly regulated controlled substances. 21 U.S.C. § 801, *et seq*. The FDA-approved labeling for the medications contains a boxed warning (also known as a "black box" warning), which is designed to emphasize serious or life-threatening risks:

[3] September 2013 letter from FDA to Andrew Kolodny, MD, President of Physicians for Responsible Opioid Prescriptions (Sept. 10, 2013) ("FDA Response") at 2 & nn.4–6 (Ex. 4). The State cites to the Physicians for Responsible Opioid Prescriptions ("PROP") petition and the FDA's Response. *See* Compl. ¶ 37, n.53, 54; *Walker*, 148 P.3d at 397-98.

WARNING: ADDICTION, ABUSE AND MISUSE . . .

Addiction, Abuse, and Misuse
OXYCONTIN exposes users to the risks of opioid addiction, abuse and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing and monitor regularly for these behaviors and conditions.

OxyContin Labeling (Ex. 1) at 1; *see also id.* § 5.1 ("As an opioid, OXYCONTIN exposes users to the risks of addiction, abuse, and misuse."); FDA Response (Ex. 4), at 2 ("The labeling for these products contains prominent warnings about these risks" including a "boxed warning [that] states that all patients should be 'routinely monitor[ed] . . . for signs of misuse, abuse, and addiction.'").

In addition, since 2012, Purdue's opioid medications have been subject to an FDA Risk Evaluation and Mitigation Strategy ("REMS"). This is a drug safety program that the FDA "can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risk. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication."[4] The FDA adopted a REMS for ER/LA opioids "to ensure that the benefits of [these medications] outweigh the risks" by requiring Purdue and other manufacturers to provide additional information and education to prescribers about the safe and effective use of opioids to treat chronic pain long-term.[5] The REMS requires

[4] FDA, Risk Evaluation and Mitigation Strategies (REMS), *available at* https://www.fda.gov/Drugs/DrugSafety/REMS/default.htm.

[5] FDA, Extended-Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) ("FDA REMS"), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_Analgesic_2018_09_18_REMS_Full.pdf. The Court should take judicial notice of the REMS, which was not cited by the State in the Complaint. The REMS is available on the FDA's website and therefore is "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Colo. R. Evid. 201(b);

Purdue to provide detailed information about the benefits and risks in specific formats beyond labeling, including a Medication Guide (a paper handout for the patient that accompanies many prescription medications), healthcare provider training materials, and FDA-approved correspondence to physicians. *Id.* at 2–4, 7-8. The Medication Guide warns patients that OxyContin "can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death." *See* OxyContin Labeling (Ex. 1), Medication Guide, at 39.

In sum, the FDA has considered the same concerns that the State raises in its Complaint. In its capacity as the expert regulator, the FDA has concluded that the benefits of Purdue's opioid medications outweigh the risks, when prescribed consistent with the FDA's REMS and the approved indication for long-term treatment of chronic pain and permit Purdue to promote its opioid pain medications for that use—the very practice the State asserts violates Colorado law.

LEGAL STANDARD

The Court must dismiss a complaint when it fails "to state a claim upon which relief can be granted." C.R.C.P. 12(b)(5); *Denver Post Corp. v. Ritter*, 255 P.3d 1083, 1088-89 (Colo. 2011) (en banc). The State's claims must be "plausible on [their] face," and as the Colorado Supreme Court has held, the Colorado and federal pleading standards are identical. *Warne v.*

Walker, 148 P.3d at 397-98; *see also Llewellyn v. Allstate Home Loans, Inc.*, Civ. No. 08-cv-179, 2011 WL 2533572, at *1 (D. Colo. June 27, 2011) (taking judicial notice of business records on Colorado Secretary of State's website) (citing *Allen v. United Props. & Constr., Inc.*, Civ. No. 07-cv-214, 2008 WL 4748511 (D. Colo. Oct. 28, 2008) ("Public records and government documents are generally considered not to be subject to reasonable dispute. This includes public records and government documents available from reliable sources on the Internet.") (citation omitted)).

Hall, 373 P.3d 588, 589 (Colo. 2016) (en banc). Allegations are not entitled to a presumption of truthfulness when they are merely "conclusory." *Id.* at 596. Because the State's claims depend on the allegation that Purdue misrepresented the safety and efficacy of their opioid medications, *see, e.g.*, Compl. ¶¶ 54-67, the State must state with particularity its deception-based claims, *i.e.*, Claims One-Six (Consumer Protection) and Claims Nine-Ten (Fraud/Fraudulent Concealment). C.R.C.P. 9(b); *Two Moms and a Toy, LLC v. Int'l Playthings, LLC*, 898 F. Supp. 2d 1213, 1219 (D. Colo. 2012).

ARGUMENT

I. All Counts Fail As A Matter Of Law Because Purdue's Statements Are Consistent With FDA-Approved Labeling And The FDA's Approval Of Opioids As A Safe And Effective Treatment For Chronic Pain.

The State bases all claims on the premise that it was a violation of Colorado law for Purdue to promote opioids for a use specifically approved by the FDA—long term treatment of chronic non-cancer pain.[6] But statements that generally comport with FDA-approved labeling are not misleading as a matter of law. *See Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 68 (2d Cir. 2016). In *Apotex*, for example, the plaintiff could not state a false advertising claim even though some statements were "not drawn from the FDA label." *Id.* The claim failed as a matter of law because a "pharmaceutical company is entitled to make advertising statements outside the four corners of an FDA label so long as none of its representations is inconsistent with it." *Id.* Similarly, in *Prohias v. Pfizer, Inc.*, the court concluded, "[t]he information

[6] *See, e.g.*, Compl. ¶¶ 4-5; 10, 276-78 (First Claim), 284 (Second Claim), 289 (Third Claim), 297-99 (Fourth Claim), 303-04 (Fifth Claim), 310-11 (Sixth Claim), 315, 321 (Seventh Claim), 328-29 (Eighth Claim), 332-33 (Ninth Claim), 337-38 (Tenth Claim).

included in the labeling of a new drug reflects a determination by the FDA that the information is not 'false or misleading' . . . . [T]he alleged advertisements generally comport with the approved label, and are therefore not misleading as a matter of law." 490 F. Supp. 2d 1228, 1235 (S.D. Fla. 2007); *see also Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (dismissing false advertising claims "as a matter of law" because challenged statements were "similar enough to the [FDA-]approved statements . . . that they [were] neither false nor misleading"). When, as here, the representations and conduct conform with determinations made by the FDA in the exercise of its regulatory authority, those representations cannot give rise to liability under Colorado law.

At a minimum, the Court should dismiss Claims One-Six, because the safe harbor provision of the CCPA states that it does not apply to "[c]onduct in compliance with the orders or rules of, or a statute administered by, a federal, state, or local governmental agency." C.R.S.A. § 6-1-106(1)(a) (2018); *see also Suarez v. United Van Lines, Inc.*, 791 F. Supp. 815, 817 (D. Colo. 1992) (applying safe harbor to dismiss CCPA claim where conduct at issue was governed by federal law).

Here, the practices the State claims were improper all were consistent with the FDA-approved product labeling. This approval means the FDA found "substantial evidence that the drug will have the effect it purports or is represented to have" and that the medication is safe and effective to treat chronic pain. 21 U.S.C. § 355(d); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239 (3d Cir. 2012) ("To obtain FDA approval, drug companies generally must submit evidence from clinical trials and other testing that evaluate the drug's risks and benefits and demonstrate that it is safe and effective for all of the indications

'prescribed, recommended, or suggested' on the drug's label.") (quoting § 355(d)). In fact, in 2013 the FDA addressed the same issues raised by the State, and concluded that no modification to the product labeling was necessary.[7] In response to a 2012 citizen's petition from Physicians for Responsible Opioid Prescribing ("PROP"), the FDA studied the available scientific evidence and concluded that it supports the use of ER/LA opioids to treat chronic non-cancer pain.[8] Thus, the FDA has communicated its disagreement with the State's specific contention that Purdue "deceiv[ed] the medical community and the public into believing that opioids were safe and effective to treat chronic, long-term pain." Compl. ¶ 4, *see generally id.* ¶¶ 56-67. PROP and other commenters raised these same concerns as a reason to limit the indication for opioid medications, but the FDA rejected the request.[9] The FDA did not direct Purdue to stop marketing the medications for long-term use.[10] The FDA also expressly declined to recommend a "maximum . . . duration of use."[11] As to certain risks that were already included in the labeling for Purdue's opioid medications, the FDA required Purdue to conduct additional studies and further assess those risks along with the benefits of use, and those studies are underway. The FDA is awaiting that new evidence to determine whether the medications' labeling should be revised to provide any different or additional information about those risks and benefits to healthcare professionals.[12] In other words, when presented with the same concerns about the

[7] *See* FDA Response at 10–11 (Ex. 4).

[8] *Id.*

[9] FDA Response at 8 (Ex. 4).

[10] *Id.* at 14 (FDA determining that limiting opioid therapy to 90 days "is not supportable.")

[11] *Id.* at 11.

[12] *Id.*

enhanced risks of using opioids in high doses and long durations, the FDA chose neither to impose those limits on opioid use nor to add warnings about those risks. Stated differently, the FDA has evaluated the State's allegations and determined that Purdue's statements complied with federal law. Yet the State asserts Purdue "engaged in unlawful deceptive trade practices" by not including the same warnings that the FDA considered and rejected. *E.g.*, Compl. ¶ 279. And throughout the Complaint, the State seeks to impose liability for Purdue's promotion of opioids as safe and effective to treat chronic, long-term pain. *E.g.*, Compl. ¶ 4. As a matter of law, these assertions cannot state a claim under any of the State's theories.

In sum, the State's Complaint is an improper attempt to impose liability on Purdue for promoting FDA-approved uses consistent with FDA-approved labeling. The Court should dismiss the Complaint in its entirety, but at a minimum the CCPA claims must fail because Purdue's FDA-approved conduct is entitled to the safe harbor of C.R.S.A. § 6-1-106(1)(a).

II. The State Has Not Adequately Alleged Causation.

The Court should dismiss all common-law claims, and the CCPA claims to the extent they seek restitution, because the State has not adequately pleaded the required element of causation. *Phillips v. Lucky Gunner, LLC*, 84 F. Supp. 3d 1216, 1228 (D. Colo. 2015) (public nuisance); *Smith v. State Compensation Ins. Fund*, 749 P.2d 462, 464 (Colo. App. 1987) (negligence); *Ballow, et al. v. Phico Ins. Co.*, 875 P.2d 1354, 1361 (Colo. 1993) (en banc) (fraud); *Burman v. Richmond Homes Ltd.*, 821 P.2d 913, 918 (Colo. App. 1991) (fraudulent concealment); *People v. Shifrin,* 342 P.3d 506, 522-23 (Colo. App. 2014) (restitution pursuant to the CCPA).

Purdue acknowledges that the Complaint is very long, and includes numerous details of Purdue's alleged conduct. But when it comes time to plead a causal connection between these allegations and any harm, the State fails to meet its burden. Instead, the State only offers the conclusory allegation that "Purdue's dissemination of fraudulent and deceptive information related to the safety and efficacy of prescription opioids for treating chronic non-cancer pain directly and proximately caused the harm suffered by the State of Colorado." Compl. ¶¶ 27; *see also id.* at ¶ 2 ("Purdue . . . originated and spearheaded a marketing campaign that led to the opioid epidemic."). The opioid crisis is enormously complex. It involves critically important public health issues, including balancing between patients' access to necessary pain relief and avoiding harm to patients and other users. Despite myriad contributors and factors, and the fact that Purdue's opioids represent less than 2% of all opioid prescriptions, the State nonetheless seeks to blame Purdue alone for the entire problem. Given that the State seeks the Court's intervention to assess that blame, it is incumbent that the State be held to satisfy its obligations to at least adequately allege the critical element of causation against Purdue. But the State does not provide any factual allegations to establish that Purdue's conduct caused any direct harm to the State, or that Purdue, as opposed to other independent actors, was the legal cause of the State's "financial costs to manage the impacts" of the opioid crisis. *See* Compl. ¶¶ 322 (public nuisance), 330 (negligence), 335 (fraud), 341 (fraudulent concealment). Accordingly, the Court should dismiss each of these claims.

A. The State Has Not Identified Any Misrepresentation That Caused A Medically Unnecessary Prescription.

To prove causation under Colorado law, a plaintiff must show by a preponderance of the evidence that the injury would not have occurred but-for the defendant's conduct. *Kaiser*

Foundation Health Plan v. Sharp, 741 P.2d 714, 719 (Colo. 1987) (en banc). "The test for causation is the 'but for' test—whether, but for the alleged negligence, the harm would not have occurred." *Smith*, 749 P.2d at 464. The State has failed to identify any Colorado doctor who received a specific purported misrepresentation made by Purdue, or who wrote a medically unnecessary prescription because of those alleged statements. The State also does not plead that any specific false statement caused the State to expend funds or devote resources to "manage the impacts" of the opioid crisis.

Rather than plead these requisite facts, the Complaint instead offers only vague and conclusory allegations that "Purdue successfully duped the medical community and the public into believing that opioids were safe and effective for treating chronic pain," and that Purdue "effectively relaxed Colorado prescribers' skepticism about prescribing opioids and expanded their use throughout the state." *See, e.g.*, Compl. ¶¶ 10, 222. Likewise, the State broadly contends Purdue disseminated misrepresentations through advertisements and Purdue-sponsored speakers and publications. *See, e.g.*, *id.* ¶¶ 76–119. But these allegations are untethered to any particular Colorado doctor or prescription. *City of Chicago v. Purdue Pharma L.P.*, No. 14 C 4361, 2015 WL 2208423, at *14 (N.D. Ill. May 8, 2015) (requiring plaintiff to allege details of causation such as identities of prescribing physicians). Indeed, even where the State's Complaint identifies three physicians who wrote inappropriate OxyContin prescriptions, there is no link between any alleged Purdue conduct and the illegal conduct of those physicians. *See* Compl. ¶¶ 226-259. And the State has failed to plead how the alleged misstatements, most of which were alleged to have occurred more than a decade ago, could have caused specific prescribing

decisions to this day. Absent this evidence, the State cannot meet its "but-for" causation burden. *Sharp*, 741 P.2d at 719; *Smith*, 749 P.2d at 464.

Alleging a general "fraud-on-the-market" does not suffice. In cases that assert claims for fraudulent or deceptive pharmaceutical marketing, "a fraud-on-the-market theory cannot plead the necessary element of causation because the relationship between defendants' alleged misrepresentations and the purported loss suffered by the patients is so attenuated . . . [as to] effectively be nonexistent." *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1054 (N.D. Cal. 2009), *aff'd* 464 F. App'x 651 (9th Cir. 2011); *see also Farmers Insurance Exchange v. Benzing*, 206 P.3d 812, 821 (Colo. 2009) (en banc) (rejecting fraud on the market theory); *Garcia v. Medved Chevrolet, Inc.*, 240 P.3d 371, 381 (Colo. App. 2009) (rejecting "the invitation to apply a fraud on the market theory to presume reliance and causation in common law fraud or statutory deceit lawsuits").

At a minimum, the Court should dismiss the request for damages for the State's reimbursement of "opioid prescriptions covered by the State's employee and retiree health plans, and the State's Workers' Compensation Program." Compl. ¶¶ 321 (public nuisance), 329 (negligence). Initially, Purdue notes that this pleading is wildly overbroad; it seeks damages for ***all*** reimbursed prescriptions, including those that were medically appropriate and caused no harm. This likely is the case because the State makes no effort to link Purdue's alleged conduct to any specific doctor and any specific improper prescription that the State reimbursed. The State alleges a "[p]reliminary analysis of state worker's compensation claims in Colorado suggest that claims in which an opioid was prescribed greatly increased both the duration and cost of such claims." Compl. ¶ 219. But the State does not allege that ***Purdue's medications***

were implicated by this "preliminary analysis," let alone identify: (a) which prescriptions of Purdue opioids were unnecessary; and (b) whether Purdue's alleged misrepresentations caused specific doctors to write those prescriptions. The State's reimbursement pleading is therefore deficient and the Court should dismiss this claim. *See City of Chicago*, 2015 WL 2208423, at *14 (dismissing misrepresentation claims for failure to allege "the identities of doctors who, as a result of one or more of defendants' alleged misrepresentations, prescribed opioids for chronic pain to a City-insured patient or worker's compensation recipient whose claim for that prescription the City paid, or any other details about such claims").

B. Purdue's Conduct Was Not The Proximate Cause Of Harm, Due To The Many Intervening Events And Actors In The Causal Chain.

The bedrock tort principle of proximate causation required the State plausibly to plead that Purdue's conduct in a "'natural and continued sequence, unbroken by any efficient, intervening cause, produce[d] the result complained of, and without which that result would not have occurred.'" *Smith*, 749 P.2d at 464 (quoting *Stout v. Denver Park & Amusement Co.*, 287 P. 650 (Colo. 1930)). The State failed to meet this pleading burden.

The State acknowledges that patients may not lawfully obtain Purdue's opioid medications without a valid prescription. Compl. ¶¶ 30-32. The State also recognizes that doctors have many sources of information about Purdue's products, including FDA-approved labeling that discloses the same risks that Purdue allegedly concealed. *See, e.g.*, *id.* ¶¶ 21, 142-205.

In the face of the information available to physicians, the State has not pleaded facts showing that Purdue's alleged misrepresentations led to the harm claimed by the State, as opposed to the undisputed multiple layers of decisions by doctors and patients when making individualized prescribing decisions. The court should dismiss claims that would require it "to

delve into the specifics of each physician patient relationship to determine what damages were caused by [the] alleged fraudulent conduct, as opposed to what damages were caused by the physician's independent medical judgment." *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 2100, 2010 WL 3119499, at *7–9 (S.D. Ill. Aug. 5, 2010). The Court should dismiss all claims because they "would require an inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit." *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP, et al.*, 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008); *see also City of Chicago*, 2015 WL 2208423, at *14; *Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 87 (3d Cir. 2015); *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs*, 873 F.3d 574, 577 (7th Cir. 2017).

Further, Purdue's conduct is too remote to be the proximate cause of the harm alleged by the State—the costs to "manage the impacts" of the opioid crisis. *See North Colo. Med. Ctr., Inc. v. Committee on Anticompetitive Conduct*, 914 P.2d 902, 908 (Colo. 1996) (en banc) ("Some other event which is a contributing factor in producing the harm may have such a predominant effect in bringing it about as to make the effect of the actor's negligence insignificant and, therefore, to prevent it from being a substantial factor." (quoting *Smith*, 749 P.2d at 464)); *Phillips v. Lucky Gunner, LLC*, 84 F. Supp. 3d 1216, 1228 (D. Colo. 2015); *see also Price v. Purdue Pharma Co.*, 920 So. 2d 479, 485-86 (Miss. 2006) (noting lack of proximate cause for opioid addiction because injuries were the result of illegally obtained and improper use of opioids).

Ashley County, Ark. v. Pfizer, Inc., 552 F.3d 659 (8th Cir. 2009), which was decided under analogous facts, is instructive. In *Ashley County*, Arkansas counties brought claims

against pharmaceutical companies for, *inter alia*, public nuisance and deceptive trade practices, seeking "compensation to recoup the costs expended by the counties in dealing with the societal effects of the methamphetamine epidemic," with liability premised on the use of the Defendants' products in the methamphetamine manufacturing process. *Id.* at 663. The Eighth Circuit affirmed the dismissal of the complaint for failure to state a claim, and determined that "[p]roximate cause seems an appropriate avenue for limiting liability in this context . . . particularly 'where an effect may be a proliferation of lawsuits not merely against these defendants but against other types of commercial enterprises—manufacturers, say, of liquor, anti-depressants, SUVs, or violent video games—in order to address a myriad of societal problems regardless of the distance between the "causes" of the "problems" and their alleged consequences.'" *Id.* at 671–72 (quoting *Dist. Of Columbia v. Beretta, U.S.A., Corp.*, 872 A.2d 633, 651 (D.C. 2005)).

Here, any connection from the alleged misconduct to State expenditures depends on multiple independent intervening events and actors. In addition to the prescribing doctor's independent medical judgment, these include at a minimum the patient's decision whether, how and how often to use the medication and the patient's response to it. The State adds more remote links to this causal chain with vague allegations about Purdue's purported influence over third-party front groups and "key opinion leaders" that allegedly influenced prescribers' decisions, and allegations about illegal opioid use, street drug use, and related criminal acts, which are the primary source of the harm identified by the State. *See, e.g.,* Compl. ¶¶ 67-119 226-259, 272. This pleading problem is exacerbated by the impossibility of tracing the costs to "manage the impact" of the opioid crisis back to Purdue's medications, as opposed to other lawful or unlawful

opioids. This is particularly challenging given Purdue's very small share of the overall market for lawful opioids.

The State's claims rely on an inaccurate and over-simplified view of the complex opioid public health problem which the State itself disavows. For example, the Complaint identifies a number of behaviors that contribute to or further addiction, such as "criminal behavior, including drug-seeking behavior resulting in assaults, burglaries, and thefts related to opioid use." Compl. ¶ 271. These are not Purdue's acts. Similarly, the State cites overdose statistics, but does not acknowledge that many of these individuals have a long history of drug use, potentially abused illegal street drugs supplied by cartels, or used opioid products manufactured by other companies—not Purdue. The State's effort to hold one company to account for this entire, complex public health problem is a dramatic oversimplification that upends every settled concept of causation.

III. The Court Should Dismiss The State's CCPA Claims To The Extent They Seek Restitution, Because The State Has Not Pleaded Facts To Show That Remedy Is Appropriate In This Case.

The State's Complaint broadly seeks "restitution, and/or disgorgement . . . to completely compensate or restore to the original position of any person injured by means of Purdue's deceptive practices, pursuant to § 6-1-110(1) of the CCPA." Compl. at Relief Requested D. But the State never pleads any specific harm for which restitution is appropriate. This is not the typical CCPA case where the State seeks restitution of money paid by individuals, insurance companies, or other entities. Rather, the State appears to seek restitution on its own behalf. But unlike the CCPA's civil penalty provision, *see, e.g. May Dep't Stores Co. v. State ex rel. Woodward*, 863 P.2d 967, 973 (Colo. 1993) (en banc), restitution damages under the CCPA

require the State to plead how Purdue's conduct caused it to obtain money that more justly belongs to the State. *See Shifrin,* 342 P.3d at 512 ("The remedy of restitution is based on the general principle that one should not be permitted to keep that which in equity and good conscience should be restored to another." (quoting *Berger v. Dixon & Snow, P.C.*, 868 P.2d 1149, 1152 (Colo. App. 1993)). The State must also show what is necessary to restore it to the position that it would have been in but-for Purdue's conduct. *Salzman v. Bachrach*, 996 P.2d 1263, 1265 (Colo. 2000) (en banc). The State has not even attempted to plead the facts needed to make this showing, let alone plead them with the particularity required by C.R.C.P. 9(b). *Two Moms and a Toy, LLC*, 898 F. Supp. 2d at 1216, 1219 (noting that "Rule 9(b) requires a plaintiff to plead in detail 'the specific who, what, when, where, and how' of the alleged fraud" and applying that standard to CCPA claims (internal citations omitted)). As a result, the Court should dismiss the CCPA claims to the extent the State seeks restitution damages.

IV. Purdue's Lawful Sale Of FDA-Approved Medications Is Not A Public Nuisance.

Through its sweeping public nuisance claim, the State seeks to hold Purdue solely liable for the entire opioid epidemic throughout Colorado, and for allegedly related State expenditures including "[h]ealth care services for the poor and nearly poor," "workers compensation benefits," "law enforcement, criminal prosecutions, probation, community corrections, imprisonment, and parole," "[c]hild welfare services," and others. Compl. ¶ 272. The State goes so far as to seek compensation from Purdue for "Lost Productivity/Lost Tax Revenue." *Id.* But the lawful marketing and sale of medications—even though it may be dangerous when misused or over-used—does not constitute a public nuisance.

Purdue is aware of no Colorado decisions that allowed a public nuisance case to proceed against a manufacturer of a lawful product for injuries sustained following its distribution. For example, in *Phillips v. Lucky Gunner, LLC*, 84 F. Supp. 3d 1216, 1228 (D. Colo. 2015), the Court dismissed Plaintiff's public nuisance claim against the manufacturer of ammunition that was used in a mass shooting. The Court found that, as the original sale of ammunition was lawful, defendant had not violated state law and its actions were not the proximate cause of the injury in question. *Id.* at 1224-25, 1228. The court's reasoning in *Phillips* is aligned with other decisions that have refused to "allow[] a public nuisance claim to proceed against manufacturers for lawful products that are lawfully placed in the stream of commerce." *Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp.*, 273 F.3d 536, 540 (3d Cir. 2001) (per curiam); *State v. Red Owl Stores, Inc.*, 115 N.W.2d 643 (Minn. 1962) (finding that lawful sale of medications, even if harmful when taken in excessive dosages, did not rise to the level of a public nuisance).

The State fails to allege how Purdue's manufacture and promotion of lawful, FDA-approved medications interferes with a public right. At most, the State contends that, despite having benefits, the use of opioid medications might sometimes result in harms and costs to the State. *See, e.g.*, Compl. ¶¶ 272. That is legally insufficient to establish interference with a public right. To begin with, the FDA recognizes that the proper use of opioid medications furthers the public good and addresses the serious public health priority of pain management. *See supra* at 5. Furthermore, "there is no authority for the unprecedented expansion of the concept of public rights" to include "a public right to be free from the threat that some individuals may use an otherwise legal product . . . in a manner that may create a risk of harm." *City of Chicago v.*

Beretta U.S.A. Corp., 821 N.E.2d 1099, 1116 (Ill. 2004). "[A] public right is more than an aggregate of private rights by a large number of injured people." *State v. Lead Indus., Ass'n, Inc.*, 951 A.2d 428, 448 (R.I. 2008). "Rather, a public right is the right to a public good, such as 'an indivisible resource shared by the public at large, like air, water, or public rights of way." *Id.* (internal citation omitted). The State alleges nothing of the sort. The alleged injuries or costs identified by the State affect interests peculiar to those individuals who use (or misuse) Purdue's opioid medications.

To allow public nuisance claims to proceed under these circumstances would "likely open the courthouse doors to a flood of limitless, similar theories of public nuisance, not only against these defendants, but also against a wide and varied array of other commercial and manufacturing enterprises and activities." *People ex. rel. Spitzer v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 96 (N.Y. App. Div. 2003). And expanding public nuisance law to include products liability "would become a monster that would devour in one gulp the entire law of tort." *Tioga Pub. Sch. Dist. No. 15 of Williams Cty., State of N.D. v. U.S. Gypsum Co.*, 984 F.2d 915, 921 (8th Cir. 1993); *accord Sturm*, 761 N.Y.S.2d at 197; *see also City of Phila. v. Beretta U.S.A. Corp.*, 126 F. Supp. 2d 882, 910 (E.D. Pa. 2000), aff'd, 277 F.3d 415 (3d Cir. 2002); *Town of Hooksett Sch. Dist. v. W.R. Grace & Co.*, 617 F. Supp. 126, 133 (D.N.H. 1984). This result would represent a radical expansion of Colorado law, and would distort beyond recognition the focus of public nuisance law as a remedy for harms to indivisible public property rights.

V. The Court Should Dismiss The Negligence Claim Because Purdue Does Not Owe A General Tort Duty of Care To The State.

The State alleges that "Purdue owed a duty of care to the State of Colorado and its citizens, including but not limited to exercising reasonable care in the marketing and sale of

opioids," Compl. ¶ 24, but does not identify the source of that duty. Nor does the State acknowledge that the harms for which the State is seeking to recover are more directly caused by the (often criminal) acts of third parties. Purdue does not owe the State a generalized duty of care, but even if it did, that duty would not extend to preventing the illegal acts of third parties. In Colorado, "[g]enerally, there is no duty to control the conduct of a third person so as to prevent him or her from causing physical harm to another. . ." *Molosz v. Hohertz*, 957 P.2d 1049, 1050 (Colo. App. 1998); *Phillips*, 84 F. Supp. at 1227. The State cannot maintain such a derivative claim unless there is a special relationship between the State and Purdue. *Molosz*, 957 P.2d at 1050; *Davenport v. Community Corrections of the Pikes Peak Region, Inc.*, 942 P.2d 1301 (Colo. App. 1997). The State has not plead the existence of such a relationship nor could it.

Moreover, Purdue is unaware of any Colorado court that has extended a special duty based exclusively on the marketing of a product. Other courts confronted with such requests have concluded that doing so would "dramatically extend the scope of liability" by "subject[ing] every manufacturer that advertises its products to liability for a 'special duty' created by such marketing." *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 935-36 (3d Cir. 1999) *see also State of Texas v. Am. Tobacco Co.*, 14 F. Supp. 2d 956, 973 (E.D. Tex. 1997), *subsequent mandamus proceeding sub nom, In re Fraser*, 75 F. Supp. 2d 572 (E.D. Tex. 1999). Accordingly, dismissal of the State's negligence action is appropriate for this additional reason.

CONCLUSION

WHEREFORE, Purdue respectfully requests that the Court dismiss the State's Complaint in its entirety. A proposed Order is attached for the Court's consideration.

Dated: November 5, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of **DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT** was filed and served via the manner indicated below this 5th day of November, 2018 to the following:

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