THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., and MIKE HUNTER ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, v. PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., Defendants.	STATE OF OKLAHOMA } S.S. CLEVELAND COUNTY } FILED SEP 22 2017 In the office of the Court Clerk MARILYN WILLIAMS Case No. CJ-2017-816 Honorable Thad Balkman JURY TRIAL DEMANDED

DEFENDANTS PURDUE PHARMA L.P., PURDUE PHARMA INC., AND THE PURDUE FREDERICK COMPANY INC.'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM AND MEMORANDUM OF LAW IN SUPPORT

I. PRELIMINARY STATEMENT

In addition to the dispositive flaws outlined in Defendants' Memorandum in Support of their Joint Motion to Dismiss ("Joint Motion"), Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc. (together, "Purdue") file this separate motion to highlight additional Purdue-specific issues that mandate dismissal.

First, the State's claims against Purdue are preempted by federal law because they would require Purdue to make statements about the safety and efficacy of its medications that are different from what the Food and Drug Administration ("FDA") has approved. Central to each of the State's claims is its allegation that Purdue and other Defendants improperly changed longstanding medical opinion by convincing prescribers that opioids are appropriate for treating chronic non-cancer pain. Pet. ¶¶ 1-3; *see also id.* ¶ 67 (alleging Defendants fraudulently promoted opioid pain medications as "effective treatment for chronic non-cancer pain"). But FDA has determined and maintains that opioids are appropriate for that very purpose. Purdue's extended release, long acting ("ER/LA") medications are FDA-approved for long-term treatment of chronic pain, including non-cancer pain. As explained in Defendants' Memorandum in Support of their Motion to Stay Pursuant to the Primary Jurisdiction Doctrine ("Primary Jurisdiction Motion"), FDA has also denied a citizen's petition to modify the medications' labeling to exclude that use or limit it by duration or daily dose. FDA has likewise directed Purdue to provide specific warnings about addiction risks. The State's claims that Purdue should have provided different or additional information about the subject conflict with and are preempted by FDA's directives.

As another court recently found when granting defendants' motion to stay in a similar lawsuit filed by California counties against Purdue and other opioid manufacturers, "FDA

explored all the underlying issues involved in this lawsuit." *People v. Purdue Pharma*, No. 201400725287, 2015 WL 5123273, at *2 (Orange Cty. (Cal.) Super. Ct. Aug. 27, 2015). Yet the Petition here asserts state law claims against Purdue based on marketing and statements that are consistent with FDA-approved labeling, even after FDA addressed the same claims the State makes about the available evidence on the safety and efficacy of the medications for long-term use. State-law claims that disrupt the objectives of Congress or would impose a duty that a drug manufacturer cannot independently satisfy while also complying with its obligations under federal law—such as Purdue's duty to market its products consistent with their FDA-approved labeling—are preempted. The fact that FDA is continuing to assess the benefits and risks of opioid pain medications does not change this analysis. Rather, it provides further support for dismissing the State's claims because they would interfere with FDA's mandate.

Second, the State's claims fail as asserted against Purdue because the State has failed to plead with particularity any misrepresentation or omission by Purdue. The majority of the alleged misrepresentations identified in the Petition are not attributed to any particular Defendant, but rather are asserted generally against all "Defendants." And the few misrepresentations that the State does specifically attribute to Purdue are not accompanied by sufficient facts to establish the "time, place and content" of the alleged fraud.

Third, despite the Petition's sweeping 133 paragraphs of allegations of generalized conduct, the State fails to show any causal nexus between Purdue's actions and the attenuated harm for which the State seeks to recover. The State does not identify a single physician who prescribed one of Purdue's opioid medications to any patient when it was allegedly medically unnecessary, much less a physician who did so because of Purdue's allegedly misleading

marketing or promotional materials. Nor does the State identify a single claim for reimbursement for a Purdue opioid prescription (or any Defendant's opioid) that was allegedly improper.

Moreover, many of the State's allegations rest on claims that Purdue and other Defendants disseminated misleading statements through third-party physicians and medical organizations. Yet, the Petition fails to plead any facts that, if true, establish that Purdue controlled the statements made by such third-party doctors or medical organizations. Without this critical element, the State cannot rely on these third-party materials to advance claims against Purdue.

For such reasons and those detailed in Defendants' Joint Motion to Dismiss, the Petition is preempted and facially deficient as to Purdue. Dismissal thus is required as a matter of law.

II. LEGAL STANDARD

A motion to dismiss is properly granted when, as here, even accepting the allegations as true, the Petition fails to set forth sufficient facts showing Plaintiff is entitled to relief. *Frazier v. Bryan Mem'l Hosp. Auth.,* 1989 OK 73, 775 P.2d 281, 287. Moreover, as all of the State's claims against Purdue are based on allegations that Purdue fraudulently misrepresented the safety and efficacy of opioids in its promotional materials, the State's allegations must be "stated with particularity." Okla. Stat. tit. 12, § 2009(B). Failure to plead fraud-based claims with the requisite degree of particularity results in a legally insufficient claim that cannot withstand a motion to dismiss for failure to state a claim. *Gianfillippo v. Northland Cas. Co.*, 1993 OK 125, 861 P.2d 308, 311.

III. ADDITIONAL BACKGROUND

The allegations and judicially noticeable facts are set forth in full in both the Joint Motion and the Primary Jurisdiction Motion. As those pleadings establish, FDA has determined that opioids 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.'"[1] At the same time, opioids pose significant risks that are disclosed on their FDA-approved labeling: "Opioids also have grave risks, the most well-known of which include addiction, overdose, and even death." Defendants' Memorandum in Support of Defendants' Motion to Stay this Case Under the Doctrine of Primary Jurisdiction ("Prim. Jur. Memo."), Ex. 1 at 2. Purdue's opioid medications are among the most tightly regulated drugs on the market. "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.'" *Id.*

In this regard, Purdue is subject to "an elaborate regulatory system, overseen by the FDA, to control the approval and distribution of [prescription] drugs. No other class of products is subject to such special restrictions or protections in our society." *Grundberg v. Upjohn Co.*, 813 P.2d 89, 96 (Utah 1991) (internal citation omitted). The FDA drug approval process is "onerous and lengthy." *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013).

Pursuant to its exclusive authority to determine whether prescription medicines are "safe and effective" for an intended use, 21 U.S.C. § 393(b)(2)(B), FDA has approved Purdue's opioids—OxyContin, MS Contin, Butrans, and Hysingla ER—for "long-term opioid treatment"

[1] *See* Defendants' Memorandum in Support of Defendants' Motion to Stay this Case Under the Doctrine of Primary Jurisdiction ("Prim. Jur. Memo."), Ex. 1 (Sept. 10, 2013 Letter from FDA to Physicians for Responsible Opioid Prescribing ("PROP")) at 2 & nn.4-6. The Court can take judicial notice of the documents attached to Defendants' Primary Jurisdiction Memorandum as they are all publicly available and thus are "[c]apable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Okla. Stat. tit. 12, § 12-2202(B)(2).

or for when an "opioid analgesic is needed for an extended period of time." *See, e.g.*, Prim. Jur. Memo., Ex. 20.[2] In approving ER/LA opioids for treating chronic pain, FDA necessarily found that there is "substantial evidence that the drug will have the effect it purports or is represented to have," that the benefits of long-term opioid therapy for chronic pain outweighed its risks, and that the labeling is not "false or misleading in any particular." 21 U.S.C. § 355(d)(5); 21 C.F.R. § 314.125(b)(6).

As explained in the Primary Jurisdiction Motion, FDA also considered and decided the precise challenges being raised in this action in 2013 when it responded to a citizen's petition filed by Physicians for Responsible Opioid Prescribing ("PROP"). PROP's petition requested that FDA change the labeling for ER/LA opioids to include daily dose limits and a maximum duration limit of 90 days for non-cancer pain and to strike the term "moderate" from the indication for non-cancer pain. Prim. Jur. Memo., Ex. 2 at 2.

In response to PROP, FDA considered the available science and determined that opioids should continue to be available for the treatment of chronic non-cancer pain. FDA rejected any distinction between using opioids for "cancer" versus "non-cancer" pain, Prim. Jur. Memo., Ex. 1 at 6, 9, and it concluded that limiting the dose and duration of use of opioids was not supportable, *id.* at 14. FDA further found that "[t]he cited literature does not identify a duration threshold beyond which the risk of addiction outweighs the benefits of opioid treatment. PROP has selected a 90-day limit, but provides no evidence that addiction (however it is defined) increases significantly after 90 days of use such that it would support a labeling change." *Id.* at 16. FDA agreed that there was an absence of "adequate and well-controlled studies of opioid use

[2] The FDA-approved labeling for all Defendants' opioids, including Purdue's, are "[c]apable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned," and thus are appropriate for judicial notice. *See supra* n.1.

longer than 12 weeks," *id.* at 10, but it did not require any label change to add this or a similar statement. FDA also rejected the maximum daily dose argument: "[T]he scientific literature does not support establishing a maximum recommended daily dose of 100 mg [morphine equivalent dose, or] MED. Further, creating a maximum dose of 100 mg MED, or another dose ceiling, could imply a superior opioid safety profile under that set threshold, when there are no data to support such a conclusion." *Id.* at 12.

Nevertheless, the Petition, at its core, alleges that Purdue—and the other Defendants—falsely represented opioids to be safe and effective for the long-term treatment of non-cancer pain. *See* Pet. ¶¶ 3-4, 51-54. All of the State's allegations are preempted or otherwise fail to state a claim.

IV. ARGUMENT

A. The State's Claims Against Purdue Are Preempted Because They Conflict With FDA's Labeling Decisions.

The State seeks to impose liability under state law for Purdue's marketing of opioid medications consistent with the labeling that FDA has approved based on its expert review of the risk-benefit information related to opioid use, abuse, misuse, addiction, overdose, duration of use, and daily dose. *See, e.g.*, Prim. Jur. Memo., Ex. 1 at 6-17. In its 2013 response to the PROP petition, FDA addressed and rejected a request to exclude the chronic pain indication for Purdue's medications or limit it by duration or daily dose. FDA did so based on its comprehensive review of the available scientific information on the benefits and risks of ER/LA opioids and with its express acknowledgment of the limitations in the available data on long-term use. As explained in the Joint Motion, the Court should dismiss the State's claims, including those against Purdue, because they are preempted under the Supremacy Clause of the U.S. Constitution.

Generally, there are two major categories of federal preemption: express preemption and implied preemption. Implied preemption is at issue here. Under the doctrine of implied preemption, "state law is naturally preempted to the extent of any conflict with a federal statute." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Courts will find implied preemption "where it is 'impossible for a private party to comply with both state and federal requirements,' or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 78-79 (1990), and *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)); *Craft v. Graebel-Oklahoma Movers, Inc.*, 2007 OK 79, ¶ 19, 178 P.3d 170, 175.

Whether claims are preempted is a question of law that this Court may resolve at the pleading stage. The Supreme Court of Oklahoma and other courts have long recognized the appropriateness of dismissal of claims on preemption grounds. *See, e.g.*, *Wilson v. Harlow*, 1993 OK 98, 860 P.2d 793, 798-800; *Howard Family Charitable Found., Inc. v. Trimble*, 2011 OK CIV APP 85, ¶ 20, 259 P.3d 850, 857-59; *Felix v. Lucent Techs., Inc.*, 2007 OK CIV APP 33, ¶ 7, 157 P.3d 769, 772-74; *Braxton v. Dillon Cos., Inc.*, 9 F. App'x 919, 921-22 (10th Cir. 2001).

In the prescription drug context, the U.S. Supreme Court has made clear that state-law claims that seek to impose a duty to alter drug labeling in a way that conflicts with federal law are preempted. *See Bartlett*, 133 S. Ct. at 2471; *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574-76 (2011). Under those decisions, a plaintiff can maintain a claim that a prescription medicine's labeling—or marketing consistent with the labeling—is inadequate or misleading only if the manufacturer could have unilaterally changed the label to address the alleged inadequacy or misleading statement under what is known as the Changes Being Effected ("CBE") regulation,

21 C.F.R. § 314.70(c)(6)(iii). *See Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 385 (6th Cir. 2017); *In re Celexa Lexapro Mkt'g & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015); *Utts v. Bristol-Myers Squibb Co.*, --- F. Supp.3d ---, 2017 WL 1906875, at *9 (S.D.N.Y. May 8, 2017). This requires that the plaintiff first "show that there existed 'newly acquired information' such that the [manufacturer] could unilaterally change the label pursuant to the CBE regulation without FDA approval." *Utts*, 2017 WL 1906875, at *9. However, "[b]ecause the FDA 'retains the authority to reject labeling changes,' a manufacturer may still—even after the plaintiff has identified 'newly acquired information'—establish a[] [conflict preemption] defense through 'clear evidence that the FDA would not have approved a change' to the label." *Id.* (quoting *Wyeth v. Levine*, 555 U.S. 555, 571 (2009)); *Rheinfrank,* 680 F. App'x at 385.

Courts have thus repeatedly held that state law claims are subject to implied or conflict preemption where, as here, they would require a prescription drug manufacturer to make statements about safety or efficacy that are inconsistent with what FDA has required after it evaluated the efficacy or safety issue or information at hand. *See, e.g.*, *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir. 2017); *Rheinfrank,* 680 F. App'x at 386; *In re Celexa*, 779 F.3d at 42-43; *Utts*, 2017 WL 1906875, at *20; *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1173-74 (S.D. Cal. 2016); *In re Incretin-Based Therapies Prods. Liab. Litig.*, 142 F. Supp. 3d 1108, 1123-24 (S.D. Cal. 2015), *appeal filed*, No. 15-56997 (9th Cir. Dec. 31, 2015); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1276-77 (W.D. Okla. 2011). "[T]he rejection of a citizen petition," for example, "may constitute clear evidence that the FDA would have rejected a

manufacturer-initiated change to a drug label." *Cerveny*, 855 F.3d at 1105; *accord In re Incretin-Based Therapies*, 142 F. Supp. 3d at 1125-26.[3]

The same reasoning warrants dismissal of the State's claims on preemption grounds here, where FDA has addressed the question of whether opioids are appropriate for treating chronic non-cancer pain and what physicians should be told about the risks and benefits of chronic opioid treatment. In response to the 2013 PROP petition, FDA reviewed the scientific evidence on using opioids for treating chronic pain, and it found that the evidence supported that use. FDA declined to remove the chronic pain indication or require any warning to physicians that there is inadequate evidence to show that the benefits outweigh the risks of long-term use in treating chronic non-cancer pain. As to certain risks that were already included in the labeling for the medications, FDA required manufacturers of ER/LA opioids to conduct additional studies and further assess those risks along with the benefits of use, and those studies are underway. *See* Prim. Jur. Memo., Ex. 1 at 10-11. 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 physicians.

Until such evidence is available or FDA requires labeling changes, state law claims that would force Purdue to make statements that are inconsistent with the labeling FDA has required would conflict directly with its federal law obligations. *Cerveny*, 855 F.3d at 1105; *Rheinfrank,* 680 F. App'x at 386. The State has not called out any "newly acquired information" that could trigger such a labeling change and has not alleged that Purdue could have used FDA's CBE

[3] The Tenth Circuit's preemption ruling in *Cerveny* was limited to the plaintiffs' failure-to-warn claims. The court did not reach whether the plaintiffs' fraud and negligent misrepresentation claims were similarly preempted. *Cerveny*, 855 F.3d at 1109. However, the Court made clear that it was "not foreclos[ing] the possibility that these claims might be preempted," and was simply remanding for further explanation of the effect of preemption on those claims. *Id.*

regulation to unilaterally change product labeling to remove the chronic pain indication and modify the risk information that FDA had approved based on the available evidence. *See Utts*, 2017 WL 1906875, at *9. Purdue thus "could not independently change its label[s] to read as plaintiffs say it should." *In re Celexa*, 779 F.3d at 43; *Rheinfrank,* 680 F. App'x at 385-86. Accordingly, the State's allegations that Purdue should not have promoted its products for long-term use to treat chronic pain, or should have provided additional risk information that FDA has not required, conflict directly with FDA's labeling decisions and are preempted.

That the State is challenging Defendants' marketing and promotional statements, rather than expressly alleging that the medications' labeling is or has been inadequate, does not change the outcome. "In essence, virtually all communication with medical professionals concerning a drug constitutes labeling" under federal law. *Del Valle v. PLIVA, Inc.*, No. B:11-113, 2011 WL 7168620, at *4 (S.D. Tex. Dec. 21, 2011), *report and recommendation adopted by Del Valle v. Qualitest Pharms., Inc.*, No. B-11-113, 2012 WL 2899406 (S.D. Tex. June 22, 2012), *aff'd sub nom. Lashley v. Pfizer, Inc.*, 750 F.3d 470 (5th Cir. 2014). Thus, "[b]ecause ... advertising and promotional materials are considered labeling, and because labeling is limited by federal law to the information contained in the [FDA-approved] labeling," claims based on advertising are similarly preempted. *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013); *accord Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 479 (4th Cir. 2014); *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007). Thus, the State's claims based on marketing that was consistent with Purdue's FDA-approved labeling, which they could not unilaterally change for the reasons set forth above, are preempted.

In particular, the State's core allegations regarding Purdue's alleged misrepresentations are preempted because they conflict with statements and actions FDA has specifically approved:

Risk of Addiction and Long-Term Opioid Use. The State alleges that Purdue "falsely downplay[ed] the risk of opioid addiction." Pet. ¶ 3; *see also id.* ¶¶ 4, 51, 53-54, 56, 59, 61-64, 67-72, 75, 77, 85, 96, 106-112, 122-24, 131. Yet the State itself concedes that Purdue's own FDA-approved labels "acknowledge[] the risk of abuse and addiction." *Id.* ¶ 70. For example, the OxyContin label states that "[a]s an opioid, OxyContin exposes users to the risks of addiction, abuse, and misuse" and that, "[b]ecause of the risks of addiction, abuse, and misuse with opioids, even at recommended doses," prescribers should reserve OxyContin "for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain." Prim. Jur. Memo., Ex. 20 at §§ 1, 5.1. The label further instructs providers to "[a]ssess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing OXYCONTIN, and monitor all patients receiving OXYCONTIN for the development of these behaviors and conditions." *Id.* at § 5.1.

Pseudoaddiction. The State claims that Purdue promoted the concept of "pseudoaddiction"—drug-seeking behavior that mimics addiction occurring in patients receiving inadequate pain relief—to diminish concerns about addiction by falsely implying this concept is substantiated by scientific evidence. Pet. ¶¶ 4, 53, 62, 67-68, 122. But FDA has approved labeling for Purdue's medicines that embodies this concept, including after undertaking its extensive review of the safety information relating to risks of addiction in connection with its response to the PROP Petition. For example, the FDA-approved OxyContin label describes drug-seeking behavior and tactics but also states that "[p]reoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control." Prim. Jur. Memo., Ex. 20 at § 9.2.

B. The State's Claims Fail As Asserted Against Purdue Because the State Has Failed to Plead with Particularity Any Misrepresentation or Omission By Purdue.

Besides being preempted, the State's claims against Purdue fail because they are not pled with sufficient particularity. The State's claims against Purdue all are premised on the allegation that Purdue intentionally misrepresented the risks and benefits of its opioid medications to treat chronic non-cancer pain. Because all of the State's claims sound in fraud, the State must plead its claims "with particularity." Okla. Stat. tit. 12, § 2009(B); Defendants' Joint Brief at 6. To meet this heightened pleading standard, the State must allege specific facts with respect to the "*time, place and content*" of Purdue's purported misrepresentations, and connect those alleged misrepresentations to the State's alleged injury. *Gianfillippo v. Northland Cas. Co.*, 1993 OK 125, 861 P.2d 308, 310-11; *see also Dani v. Miller*, 2016 OK 35, ¶ 25, 374 P.3d 779, 791, *cert. denied*, 137 S. Ct. 481 (2016) ("[A]llegations of fraud must be stated with sufficient particularity . . . . This standard requires specification of the time, place, and content of an alleged false representation." (internal citation omitted)). The Oklahoma Supreme Court thus has affirmed the dismissal of Petitions, where, as here, the plaintiff provided only generalized and conclusory allegations of causation, because "mere allegation[s] of fraud without detailing the facts upon which the charge of fraud is predicated is a mere conclusion" and facially deficient. *See, e.g., Weston v. Acme Tool, Inc.*, 1968 OK 7, 441 P.2d 959, 962. So, too, have other courts applying Oklahoma law. *See, e.g., TKO Energy Servs., LLC v. M-I L.L.C.*, 539 F. App'x 866, 873 (10th Cir. 2013) (applying Oklahoma law and affirming dismissal of fraud-based claims where the Petition failed to allege that plaintiff actually relied on any allegedly false representation and did "not identify specific false statements meant to lure [plaintiff] into detrimental reliance").

The States' allegations against Purdue fall well short of § 2009(B)'s heightened pleading requirement. Rarely in the Petition does the State identify any misrepresentation that it attributes

to Purdue. Rather, the vast majority of the State's allegations refer generally to all "Defendants," impermissibly lumping Purdue together with twelve separate and distinct competitor opioid manufacturers. As addressed in Defendants' Joint Brief, such "group pleading" is improper under Oklahoma law. Defendants' Joint Brief at 5.

The Petition's scant references to Purdue-specific statements do not remedy its pleading deficiencies. None of the alleged statements specifically attributed to Purdue is pled with sufficient particularity to satisfy the heightened pleading requirement under § 2009(B). For example, the State alleges that Purdue made oral misrepresentations through OxyContin sales representatives, and through speakers that the Company hosted at prescriber training conferences. Pet. ¶ 55. But the Petition does not identify any sales representatives or speakers who made these alleged misrepresentations, any prescribers who received the alleged misrepresentations, the actual content of any specific alleged misrepresentations, when or where the alleged misrepresentations were made, or how the alleged misrepresentations affected any physician's opioid prescribing practices or the State's decision regarding any opioid prescription for which it paid. Without this required information, these allegations fall far short of providing sufficient facts regarding the "time, place, and content" of the alleged fraud, and therefore must be dismissed.

The State's pleading deficiencies continue regarding its allegations that Purdue made misrepresentations and fraudulent omissions regarding its opioid pain medications in various branded written materials and promotional items. For example, the Petition references:

(i) A series of advertisements known as "pain vignettes," which allegedly included cases of studies of patients with chronic pain conditions and recommended OxyContin for each;

(ii) A promotional video that allegedly stated that "the rate of addiction amongst pain patients who are treated by doctors is much less than 1%," that opioids "do not have serious medical side effects," and that Purdue's opioids were its "best,

strongest pain medications [and] should be used much more than they are for patients in pain"; and

(iii) Unspecified "medical journal advertisements" that represented OxyContin as "having been studied for all kinds of arthritis, promoting for use with the elderly without provid[ing] accompanying risk information, and omitting information about abuse and addiction potential."

Pet. ¶ 53. In addition, the State alleges that in 2007, Purdue, along with Defendant Cephalon, sponsored an American Pain Foundation ("APF") treatment guide "that omitted and understated the risks of addiction from long-term opioid treatment." Pet. ¶ 64. But again, the State fails to satisfy the requirements of § 2009(B) with respect to these allegations because the Petition does not identify *who* received these allegedly deceptive materials, *when* the allegedly deceptive materials were distributed or received, *why* these materials allegedly were deceptive, or *how* the allegedly deceptive materials affected any prescriptions for which the State paid. In fact, the State does not even allege that these written materials were distributed in Oklahoma or were otherwise viewed by Oklahoma prescribers or Oklahoma state representatives. Accordingly, any claims arising out of these allegedly deceptive written materials similarly must fail as a matter of law.

C. The Petition Does Not Adequately Plead Causation.

1. The State Fails to Plead Facts Showing Proximate Cause Concerning Reimbursement or Prescribing Practices.

Among the handful of purportedly Purdue-specific allegations, the Petition lacks facts demonstrating a causal relationship between the alleged misrepresentation and the damage the State allegedly suffered. The State broadly claims that as a result of Defendants' alleged misrepresentations, unspecified doctors prescribed "unnecessary or excessive" opioids to unspecified patients, and those prescriptions subsequently were reimbursed by the Oklahoma Health Care Authority. Pet. ¶ 34-39. Yet the State fails to allege any facts, let alone with the

particularity required under § 2009(B), to establish causation and injury with respect to any misrepresentation alleged to have been made by Purdue.[4] The State does not even attempt to allege facts to tie any of the purported misrepresentations identified with respect to Purdue—or to any Defendant, for that matter—to an opioid medication prescribed in Oklahoma for which the Oklahoma Health Care Authority paid. The Petition fails to identify a single instance in which an Oklahoma physician received, let alone was misled by, any misrepresentation by Purdue. Nor does it allege facts to establish that any such misrepresentations were the proximate cause of a "wrongly" written prescription for which the State seeks to recover.

Additionally, though the Petition relies in part on alleged misrepresentations in third-party publications and educational programs, *id.* ¶¶ 59-66, it does not identify any Oklahoma physician who received these third-party materials or attended an allegedly deceptive program. So, too, the Petition fails to identify a single Oklahoma physician who, as a result of any such alleged misrepresentations made by Purdue, prescribed OxyContin to even a single patient.

Without this basic factual support, the Petition does not establish the requisite causal nexus between statements made by Purdue and the State's alleged injuries. *See, e.g.*, *Eckert v. Flair Agency, Inc.*, 1995 OK CIV APP 151, 909 P.2d 1201, 1204 (to establish actionable fraud, a plaintiff must prove a false, material misrepresentation that "proximately causes injury or damage to another"); *TKO Energy Servs.*, 539 F. App'x at 873 (affirming dismissal of fraud-based claim where Petition failed to allege sufficient facts to state that plaintiff actually relied on defendants' representations and that representations thereby caused plaintiff's injury); *see also City of Chi. v. Purdue Pharma L.P.*, No. 14 C 4361, 2015 WL 2208423, at *13-14 (N.D. Ill. May 8, 2015) (dismissing all claims that the court found required proof of reliance and causation).

[4] As set forth in Defendants' Joint Brief, each of the State's claims requires a causal nexus between the alleged misconduct and the alleged injury. *See* Defs.' Joint Brief at 16.

2. The State's Alleged Injuries Are Too Remote to Satisfy Proximate Cause.

Under Oklahoma law, a Petition must also be dismissed for failure to state a claim if the connection between plaintiff's alleged injury and the defendant's alleged misconduct is too remote or tenuous. *Pepsi-Cola Bottling Co. of Tulsa, Okla. v. Von Brady,* 1963 OK 236, 386 P.2d 993, 996; *Henry v. Merck & Co.*, 877 F.2d 1489, 1494 (10th Cir. 1989). Here, the State's case rests on an attenuated causal chain by which the State attempts to hold Purdue (and other Defendants) liable not only for the reimbursement of opioid prescriptions, but also for the "social and economic costs" of addressing the "opioid abuse and addiction epidemic," including costs associated with "increased health care, criminal justice, and lost work productivity expenses, among others." Pet. ¶ 31. To this end, the Petition appears to seek to hold Defendants liable for the "social and economic costs" associated with the illegal use and trafficking of "illicit opioids such as heroin." *Id.* ¶ 29. Yet, Oklahoma law instructs that "liability cannot be predicated on a prior and remote cause which merely furnishes the condition for an injury resulting from an intervening, unrelated and efficient cause." *Woodward v. Kinchen*, 1968 OK 152, 446 P.2d 375, 377-78; *Butler v. Okla. City Pub. School Sys.,* 1994 OK CIV APP 22, 871 P.2d 444, 446. "The law in Oklahoma is clear that before a defendant will be liable for a plaintiff's injuries, the plaintiff must prove that his injuries resulted directly and proximately from the defendant's carelessness." *Henry*, 877 F.2d at 1494 (applying Oklahoma law).

Here, there are any number of intervening factors that render the alleged injuries far too remote from Purdue's conduct to establish proximate cause. First, there is the independent medical judgment of the prescribing physician. Each physician's determination that an opioid is medically appropriate for a particular patient is influenced by a range of personal, patient-specific, and regulatory factors unrelated to any Defendants' marketing activities. Second, there

is the potential intervening possession of medication through illicit means. Third, there are the intervening criminal activities of others, such as illegal drug possession or engaging in criminal acts. *See, e.g.*, Pet. ¶ 28 (alleging that "[t]he accessibility and availability of prescription opioids also is fueling illicit opioid addiction."); ¶ 29 (alleging that "Oklahomans addicted to prescription opioids are turning to illicit opioids such as heroin as a cheaper and more accessible alternative") This myriad of intervening and illegal acts cuts the causal chain. *See, e.g.*, *Lefthand v. City of Okmulgee*, 1998 OK 97, ¶ 8, 968 P.2d 1224, 1226 (supervening cause "breaks the causal connection between the defendant's [misconduct] and the injury"). *Prince v. B.F. Ascher Co.*, 2004 OK CIV APP 39, ¶ 20, 90 P.3d 1020, 1028 ("The general rule is that, absent special circumstances, no duty is imposed on a party to anticipate and prevent the intentional or criminal acts of a third party. Oklahoma follows that rule.").

3. The Petition Fails to Allege Facts Demonstrating That Purdue Controlled the Content of Third-Party Publications and Statements.

Several of the State's allegations relate to alleged misrepresentations in materials published by third parties. The vast majority of these allegations purport to be asserted against "Defendants" as a group, and are not asserted specifically against Purdue. Thus, as explained above, those allegations should be dismissed for lack of particularity. However, even if the State's allegations regarding third-party statements were not subject to dismissal for improper group pleading, they still would fail as asserted against Purdue because the State has not alleged that Purdue exercised control over the content of any third-party statements referenced in the Petition.

Allegations of purported misrepresentations in third-party unbranded marketing materials cannot be attributed to Purdue unless the State can show that the materials were prepared at the direction of Purdue or by its agents. *Cf. Thornton v. Ford Motor Co.*, 2013 OK CIV APP 7, ¶

18, 297 P.3d 413, 419 (reversing judgment against vehicle manufacturer for fraud, deceit, and negligent misrepresentations by the dealer who sold the vehicle).

The Petition fails to satisfy this requirement. The State does not allege any facts showing that Purdue wrote any promotional materials on behalf of third parties, told any third-party doctors or organizations what to say, or exercised any editorial control over the content of third-party publications. Indeed, with the exception of a single reference to a 2007 APF treatment guide allegedly "sponsored" by Purdue and Cephalon, Pet. ¶ 64, the Petition fails to allege any connection between Purdue and any third-party publications. And with respect to the State's allegation regarding the APF treatment guide, the State does not assert any facts demonstrating that Purdue—or any other Defendant—had an agency relationship with APF or exercised control over the content of its publications.

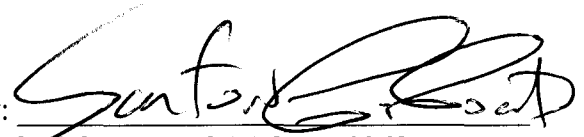
Instead, the State relies on the conclusory and unsupported allegations Purdue and Cephalon "sponsored" the 2007 treatment guide and that APF "was controlled and influenced by Defendants." Pet. ¶ 64. The State uses the same conclusory approach with all of its allegations relating to third-party publications. *See id.* ¶ 63 (alleging that "Defendants funded, directed, and controlled several [third-party] organizations"); ¶ 65 (alleging that treatment guidelines issued by the American Academy of Pain Medicine were "authored and issued under the AAPM name but were funded by Defendants"). Such speculative and conclusory allegations cannot satisfy the heightened pleading requirements of Rule 9. *See, e.g.*, *Weston*, 1968 OK 7, 441 P.2d at 963; *TKO Energy Servs., LLC v. M-I L.L.C.*, 539 F. App'x at 873. Indeed, in a recent analogous lawsuit filed by the City of Chicago against Purdue and other opioid prescription manufacturers, this same reasoning led the court to dismiss similar allegations involving purported misrepresentations contained in third-party publications and statements. *City of Chi.*, 2015 WL

2208423, at *11-12. As the court in *City of Chicago* held, Plaintiff's assertion that Purdue could be liable for purported misstatements made by third parties simply because Purdue may have provided those third parties with some financial support is legally insufficient. *Id.* Even if such allegations were true, they do not establish that Purdue exercised "editorial control" over the purported misrepresentations. *Id.* The same determination is warranted here and the claims based on these third-party statements should be dismissed.

V. CONCLUSION

For the foregoing reasons, Purdue respectfully requests the Court to dismiss all claims against Purdue.

Dated: September 22, 2017

By: 

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the above and foregoing was mailed, postage prepaid, this 22nd day of September, 2017 to:

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