1038141950

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, vs. (1) PURDUE PHARMA L.P.; (2) PURDUE PHARMA, INC.; (3) THE PURDUE FREDERICK COMPANY; (4) TEVA PHARMACEUTICALS USA, INC.; (5) CEPHALON, INC.; (6) JOHNSON & JOHNSON; (7) JANSSEN PHARMACEUTICALS, INC.; (8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; (11) WATSON LABORATORIES, INC.; (12) ACTAVIS LLC; and (13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., Defendants.	§ §	STATE OF OKLAHOMA } S.S. CLEVELAND COUNTY FILED In The Office of the Court Clerk OCT 30 2017 In the office of the Court Clerk MARILYN WILLIAMS Case No. CJ-2017-816 JURY TRIAL DEMANDED

THE STATE'S OMNIBUS RESPONSE TO (1) DEFENDANTS' JOINT MOTION TO DISMISS BASED ON PREEMPTION, (2) PURDUE'S MOTION TO DISMISS BASED ON PREEMPTION, AND (3) DEFENDANTS' JOINT MOTION TO STAY THIS CASE UNDER THE PRIMARY JURISDICTION DOCTRINE AND THE COURT'S INHERENT AUTHORITY TO STAY PROCEEDINGS

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

I. INTRODUCTION 1

II. BACKGROUND 4

A. Defendants Deceptively Marketed their Opioids 4

B. PROP Petition and Post-Approval Studies 6

C. Recent FDA Actions and CDC Guidelines 8

III. ARGUMENT AND AUTHORITIES 10

A. Defendants' Joint Motion to Dismiss and Purdue's Individual Motion to Dismiss Based on Preemption Should Be Denied 10

1. Legal Standards 11

a. Congress Did Not Intend for the FDA To Completely Preempt State Law Claims Related to Prescription Drugs 11

b. There is a Strong Presumption that State Law Claims are Not Preempted 12

2. Impossibility Preemption Does Not Apply – There is No Direct Conflict Between the State's Claims and the FDA's Regulations of Opioids 13

a. The State Does Not Allege A Claim for Failure to Warn. 13

b. The State's Allegations Do Not Conflict with the FDA's Labeling Decisions 14

B. Defendants' Joint Motion to Stay Based on the Primary Jurisdiction Doctrine or the Court's Inherent Power Should Be Denied 15

1. Legal Standards 16

2. The Issues of Fact in This Case Are Within the Conventional Experience of the Court. 17

3. The Issues of Fact in This Case Do Not Require the Exercise of Administrative Discretion. 19

4. The Issues of Fact in This Case Do Not Risk Inconsistency in the Regulation of Business Entrusted to the FDA. 22

5. The Court Should Not Stay This Action Under Its Inherent Authority 24

IV. CONCLUSION 25

TABLE OF AUTHORITIES

Cases

City of Chi. v. Purdue Pharma L.P.,
211 F. Supp. 3d 1058 (N.D. Ill. 2016) 3, 17, 20, 23

City of Chi. v. Purdue Pharma L.P.,
No. 14-cv-4361, 2015 U.S. Dist. LEXIS 60587 (N.D. Ill. May 8, 2015) 19

Crystal Clear Communs., Inc. v. Sw. Bell Tel. Co.,
415 F.3d 1171 (10th Cir. 2005). 16

Davis v. GHS HMO, Inc.,
2001 OK 3, 22 P.3d 1204 16

Edwards v. Basel Pharm.,
1997 OK 22, 933 P.2d 298 23

Frydman v. Portfolio Recovery Assocs., LLC,
2011 U.S. Dist. LEXIS 69502 (N.D. Ill. June 28, 2011) 23

Gisvold v. Merck & Co.,
62 F. Supp. 3d 1198 (S.D. Cal. 2014) 19

Imagenetix, Inc. v. Frutarom USA, Inc.,
No. 12-CV-2823, 2013 U.S. Dist. LEXIS 173193 (S.D. Cal. Dec. 9, 2013) 18

In re 5-Hour Energy Mktg. & Sales Practices Litig.,
No. MDL 13-2438, 2014 U.S. Dist. LEXIS 149732 (C.D. Cal. Sep. 4, 2014) 21

In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.,
701 F. Supp. 2d 356 (E.D.N.Y. 2010) 14

In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.,
No. M: 05-1699 CRB, 2006 U.S. Dist. LEXIS 95500 (N.D. Cal. 2006) 12, 18

In re Frito-Lay N. Am., Inc.,
No. 12-MD-241, 2013 U.S. Dist. LEXIS 123824 (E.D.N.Y. Aug. 29, 2013) 18

In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practice Litig.,
955 F. Supp. 2d 1311 (S.D. Fla. 2013) 18

Ivie v. Kraft Foods Global,
961 F. Supp. 2d 1033 (N.D. Cal. Jun. 28, 2013) 18

Jasper v. Musclepharm Corp.,
No. 14-cv-02881, 2015 U.S. Dist. LEXIS 64588 (D. Colo. Apr. 9, 2015).....18

Landis v. N. Am. Co.,
299 U.S. 248 (1936).....17, 24

Marshall v. El Paso Nat. Gas Co.,
874 F.2d 1373 (10th Cir. 1989).....16

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996).....12

Nader v. Allegheny Airlines, Inc.,
426 U.S. 290 (1976),.....17

Pace Membership Warehouse, Inc. v. U.S. Sprint Commc'ns Co. Ltd. P'ship,
No. 90-F-2121, 1991 U.S. Dist. LEXIS 19788 (D. Colo. Feb. 8, 1991).....16

Reid v. Johnson & Johnson,
780 F.3d 952 (9th Cir. 2015).....20

Riegel v. Medtronic, Inc.,
552 U.S. 312 (2008).....12

RJB Gas Pipeline Co. v. Colo. Interstate Gas Co.,
1989 OK CIV APP 100, 813 P.2d 1.....20, 22

Seufert v. Merck Sharp & Dohme Corp.,
187 F. Supp. 3d 1163 (S.D. Cal. 2016).....13

Tr. Co. v. Jage (In re Wallace),
2009 OK 34, 219 P.3d 536.....17, 24

United States v. Purdue Frederick Co.,
495 F. Supp. 2d 569 (W.D. Va. 2007).....2

United States v. Zweifel,
508 F.2d 1150 (10th Cir.), *cert. denied*, 423 U.S. 829 (1975).....16

Weinberger v. Bentex Pharmaceuticals, Inc.,
412 U.S. 645 (1973).....18

Wyeth v. Levine,
555 U.S. 555 (2009).....11, 12, 14, 23

Zapka v. Coca-Cola Co.,
Case No. 99 C 8238, 2001 U.S. Dist. LEXIS 20155 (N.D. Ill. Dec. 3, 2001).....18

Rules

21 U.S.C. § 355.....21

21 U.S.C. § 360k.....12

I. INTRODUCTION

Defendants' preemption arguments and related stay motion under the primary jurisdiction doctrine imagine a case pending in federal court alleging Defendants had inadequate labeling in the past[1] and seeking to regulate Defendants' labeling in the future.[2] That, of course, is not this case.

This case is brought by the State of Oklahoma to hold Defendants responsible for a sprawling and coordinated, decades-long false and deceptive marketing campaign whereby they downplayed the risks of addiction and touted unsubstantiated benefits of long-term opioid treatment ***contrary to their own labels***. *See, e.g.*, Pet. ¶¶ 67, 70. This state court case asserts public nuisance, fraud (actual and constructive) and deceit, unjust enrichment, Oklahoma Medicaid False Claims Act, Oklahoma Medicaid Program Integrity Act, and Oklahoma Consumer Protection Act claims arising under state common law and statutory tort principles. *See id.* ¶¶73–133.

Rather than challenge the real allegations in this case, Defendants focus on their imagined case and ask the Court to either: (1) dismiss this case under the doctrine of preemption based on federal Food and Drug Administration ("FDA") labeling regulations; or (2) indefinitely stay this case pending potential action by the FDA related to future labeling changes. Defendants' arguments fail.

First, the State's claims are not preempted. The linchpin of Defendants' preemption argument is that it would have been impossible for them to comply with a state law duty to modify

---

[1] *See, e.g.*, Purdue MTD at 6 ("the State seeks to impose liability under state law for Purdue's marketing of opioid medications **consistent with the labeling that FDA has approved.**") (emphasis added); Jt. MTD at 15 ("any claim seeking to hold Defendants liable for the promotion of opioids as safe and effective for their FDA-approved indications . . . is preempted.").

[2] *See, e.g.*, Mot. to Stay at 11 ("The State seeks to have this Court resolve complex and nationally important scientific issues before the FDA completes its own ongoing review.")

their opioid labeling without violating federal law. *See* Purdue MTD at 6; Jt. MTD at 12. But, the State does not allege the labels were inadequate or seek to modify the labels. For example, the State alleges:

> Through misrepresentations and omissions . . . Defendants convinced doctors and consumers that, **despite the instructions on their drug labels** and the longstanding practice of prescribing opioids only in limited circumstances, there is a low risk of addiction with long-term opioid use.
>
> Defendants knew their misrepresentations were false and unsupported. Among other things, **Defendants' marketing efforts often contradicted their own labels**, which acknowledged the risk of abuse and addiction.

Pet. ¶¶67, 70 (emphasis added). The foregoing allegations make clear this action seeks to hold Defendants responsible for their false and deceptive marketing campaign to misrepresent the risks and benefits of opioids—often contradicting their labels—in order to expand their sales. This is precisely the type of conduct the Purdue Defendants (*see* Pet. ¶13) pled guilty to in 2007. *See United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007) ("certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications[.]"). Defendants' preemption argument rests entirely on an intentional distortion of the State's allegations and, on that basis alone, should be rejected.

Second, and for similar reasons, the Court should not stay this case based on the primary jurisdiction doctrine or its inherent authority. Again, Defendants' argument is based on their imagined case in which the State seeks to regulate Defendants' labeling in the future. That is not this case. Defendants falsely marketed their opioids giving rise to claims under state common law and statutory tort principles. To be clear—this case does not challenge the language of any opioid label, past or future.

Moreover, the discretionary primary jurisdiction doctrine is unavailable here because determining whether marketing is false or misleading is not within the special competence of the FDA. Courts regularly decide these issues, as the Northern District of Illinois held under substantially similar facts, "the Court is not being asked to adjudicate whether opioids are appropriate for the treatment of chronic, non-cancer pain or whether defendants' drugs' labels are accurate, but whether defendants deliberately misrepresented the risks, benefits, and superiority of opioids when marketing them to treat chronic pain, 'contrary to . . . scientific evidence and their own labels.' 'Courts are equipped to adjudicate such claims.'" *City of Chi. v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058, 1065 (N.D. Ill. 2016) (internal citation omitted).

Finally, because this case does not challenge the language of any opioid label, there is no issue pending before the FDA that impacts the Court's ability to resolve this case. Defendants disingenuously characterize the FDA's investigations as necessary to establish the benefits and risks of narcotic opioids. But, the FDA plainly states "the data will further the understanding of ***the known serious risks*** of opioid misuse, abuse, overdose and death."[3] FDA investigations and regulations regarding opioid labeling—particularly potential changes to those regulations in the future—are irrelevant to Defendants' *prior* misrepresentations of the known risks and benefits of opioids.

In sum, the issue in this case is whether Defendants' past marketing misrepresented the risks, benefits and superiority of opioids to treat pain—a determination this Court and a jury are well-equipped, and entitled, to make. No FDA labeling regulation, past or future, is dispositive of this issue. Accordingly, Defendants' joint motion to dismiss based on preemption, Purdue's motion

[3] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm (emphasis added) (last visited October 18, 2017).

to dismiss based on preemption, and Defendants' joint motion to stay under the primary jurisdiction doctrine or the court's inherent power to manage its docket should all be denied.

II. BACKGROUND

The State's Omnibus Response to Defendants' Joint Motion to Dismiss for Failure to State a Claim[4] contains detailed recitations of the factual background of this case, and is incorporated by reference as though set forth fully herein. Accordingly, only a summary of Defendants' deceptive marketing of their opioids is provided here.

A. Defendants Deceptively Marketed their Opioids

Defendants manufacture and sell opioids. Petition, ¶2. Historically, medical professionals only prescribed these highly addictive drugs in limited circumstances, for cancer patients, the terminally ill, and acute short-term pain. *Id.* ¶3. To expand the market for their drugs, Defendants created and implemented an unlawful marketing campaign to convince medical professionals to prescribe more opioids to a broader range of patients with chronic non-cancer pain. *Id.* This campaign targeted the medical community with precision to change its perception of opioids, and thus prescribing patterns, in two key ways: falsely downplaying the risk of opioid addiction and touting unsubstantiated benefits of opioids to treat chronic non-cancer pain. *Id.* ¶¶3–4.

Defendants spent millions of dollars spent on branded and unbranded marketing to spread Defendants' false messaging nationwide to physicians, pharmacists and consumers, including

---

[4] This document, the full title of which is "The State's Omnibus Response To: (i) Defendants' Joint Motion to Dismiss for Failure to State a Claim; (ii) Motion of Defendants Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma Inc. To Dismiss Plaintiff's Petition for Failure to State a Claim, or, Alternatively, For a More Definite Statement Requiring the State To Plead the Detail of Any Alleged Fraud; (iii) Defendants Janssen Pharmaceuticals, Inc. and Johnson and Johnson's Motion to Dismiss for Failure to State a Claim; and (iv) Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc.'s Motion to Dismiss for Failure to State a Claim," is filed concurrently herewith.

those in Oklahoma. Defendants distributed advertisements in medical journals and promotional videos that falsely minimized the risk of addiction and touted, without real support, the efficacy of "opioid therapy" for chronic non-cancer pain. *Id.* ¶53. Defendants trained large sales forces to repeat their false messaging directly to health care professionals through office visits, including to Oklahoma medical professionals. *Id.* ¶¶53–54.

Defendants also spent millions to manufacture "scientific" support for their misrepresentations and funded "Key Opinion Leaders" ("KOLs") to spread their false messaging throughout the medical community. *Id.* ¶¶59–62. Defendants also funded and collaborated with many seemingly neutral third-party organizations ("Front Groups") to promote opioid use and further spread Defendants' false messaging. Notably, Defendants' marketing efforts often contradicted their own labels, which acknowledged the risk of abuse and addiction. *Id.* ¶¶63–66.

Defendants' deceptive marketing campaign proved highly effective. Beginning with Purdue's massive marketing efforts in the late 1990s, and with the other Defendants continuing this deceptive marketing campaign for years, the sales of opioids skyrocketed, as did prescription opioid overdose deaths.

The rapid increase in opioid sales is the direct and intended result of Defendants' deceptive marketing campaign, with particularly disastrous consequences for Oklahoma. *Id.* ¶5. According to 2016 statistics, Oklahoma ranks *number one* in the nation in by at least one measure of opioid prescribing, with approximately 877 milligrams of opioids distributed per adult resident. *Id.* This rate of distribution and the resulting dependency on these drugs has caused the State of Oklahoma millions of dollars in health care costs, including excessive opioid prescriptions, treatment services, ambulatory services, inpatient hospital services and emergency department services. *Id.*

¶6. Defendants' conduct also caused the State to incur substantial social and economic costs including criminal justice costs and lost work productivity. *Id.*

To remedy these wrongs, the State of Oklahoma, by and through its Attorney General, Mike Hunter (the "State), filed its Original Petition in this Court against thirteen opioid manufacturers ("Defendants"), asserting causes of action for: (i) violations of the Oklahoma Medicaid False Claims Act, 63 O.S. §§ 5053.1–7; (ii) violations of the Oklahoma Medicaid Program Integrity Act, 56 O.S. §§ 1001–1008; (iii) violations of the Oklahoma Consumer Protection Action, 15 O.S. §§ 751–65; (iv) public nuisance; (v) fraud (actual and constructive) and deceit; and (vi) unjust enrichment.

B. PROP Petition and Post-Approval Studies

Although neither the PROP Petition (defined below) nor post-approval studies are implicated by the allegations in this case, because Defendants raise these issues in their motions, some background is required. On July 25, 2012, a group of fourteen physicians, researchers, and health officials from a wide range of disciplines filed a citizen petition with the FDA on behalf of The Physicians for Responsible Opioid Prescribing ("PROP"). Mot. to Stay, Exhibit 2, p. 1 (PROP Petition). The PROP Petition requested three specific changes to opioid analgesic ***labels***:

1. Strike the term "moderate" from the indication for non-cancer pain;
2. Add a maximum daily dose, equivalent to 100 milligrams of morphine for non-cancer pain; and
3. Add a maximum duration of 90 days for continuous (daily) use for non-cancer pain.

Id., p. 2. The FDA resolved the PROP Petition on September 10, 2013, granting it in part and denying it in part. *See* Mot. to Stay, Exhibit 1, p. 1 (PROP Response).

In resolving the PROP Petition, the FDA acknowledged a basic fact that Defendants cannot dispute: "***Opioids [] have grave risks, the most well-known of which include addiction, overdose, and even death***." *Id.*, p.2 (emphasis added). The FDA further stated that the already-existing classification of opioid drugs (Schedule II) "reflects a finding that most opioid drugs have 'high potential for abuse' and that '[a]buse of the drug . . . may lead to severe psychological or physical dependence.'" *Id.*, pp. 2–3. In the PROP Response, the FDA further concluded that important safety labeling changes were needed for extended-release/long-acting ("ER/LA") opioids. *Id.*, p.1. The FDA stated that the labeling changes set forth in the PROP Response would "help more effectively communicate ***the serious risks of misuse, abuse, neonatal opioid withdrawal syndrome (NOWS), addiction, overdose, and death***" associated with the use of ER/LA opioids. *Id.*, p. 2 (emphasis added). Among the labeling changes, the FDA struck language from the label permitting the use of opioids for "moderate" pain and indicated that opioids were appropriate only when other treatments had been tried and failed. *Id.*, p. 9.

Although the FDA declined to implement PROP's requested dosage and duration labeling changes, the FDA agreed with PROP that "adverse effects and substance abuse of opioids occur at high doses" and "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." *Id.*, p. 12. Likewise, the FDA found that the literature cited as support for imposing a maximum duration of 90 days for continuous daily use showed "high rates of addiction . . . concerning enough to require further exploration in postapproval studies." *Id.*, p. 16.

In addition to the labeling changes, the FDA also directed opioid manufacturers to conduct studies and clinical trials to further assess the "***known serious risks of misuse, abuse, addiction, hyperalgesia, overdose, and death***" associated with the long-term use of ER/LA opioid

analgesics. *Id.*, p. 10 (emphasis added). The FDA noted that these additional studies were compelled "in light of the serious risks of ER/LA opioids, and the totality of available data . . . ." *Id.*, p. 11. The FDA anticipates that the additional studies will be completed sometime in 2018. *Id.*

C. Recent FDA Actions and CDC Guidelines

Since the FDA's resolution of the PROP Petition, the nation-wide opioid epidemic has worsened, necessitating further action by the FDA. As with the PROP Response, the FDA's ongoing actions emphasize the gravity of the opioid epidemic while making clear the risks posed by opioids are well established. For example:

- In February 2016, incoming FDA Commissioner Dr. Robert Califf "called for a far-reaching action plan to reassess the agency's approach to opioid medications" "in response to the opioid abuse epidemic . . . ."[5] In developing this new plan, the FDA recognized the "***known serious risks of opioid misuse, abuse, overdose and death***" and their impact on "the lives of so many people who are struggling under the weight of this terrible crisis."[6]

- In March 2016, the FDA announced compulsory class-wide safety labeling changes for immediate-release (IR) opioid pain medications.[7] Among the changes, the FDA required a new boxed warning "about ***the serious risks of misuse, abuse, addiction, overdose and death***."[8] The FDA made these labeling changes as part of its "continuing effort to educate prescribers and patients about the potential risks related to opioid use . . . ."[9]

- In June 2017, FDA Commissioner Scott Gottlieb announced an increased effort "to identify what additional and more forceful steps the FDA can take, on top of the vigorous work the agency is already doing, to address the crisis of opioid addiction."[10]

- In August 2017, Commissioner Gottlieb released an update about the FDA's evaluation of opioid medications approved to treat cough in children.[11] As part of these efforts, "the FDA announced required changes in April 2017 to the labeling of prescription codeine products

---

[5] *Id.* at n.3, *supra.*
[6] *See id.* at n.3, *supra* (emphasis added).
[7] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm (last visited October 18, 2017).
[8] *Id.* at n.7, *supra* (emphasis added).
[9] *Id. at* n.7, *supra.*
[10] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562961.htm (last visited October 18, 2017).
[11] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm572466.htm (last visited October 18, 2017).

in order to help better protect children from ***serious risks associated with these opioid medications***, including life-threatening respiratory depression and death."[12]

In March of 2016, the Centers for Disease Control and Prevention ("CDC") released a "Guideline for Prescribing Opioids for Chronic Pain" to "chart a safer, more effective course."[13] In releasing its guidelines, the CDC stated: "***The science of opioids for chronic pain is clear***: for the majority of patients, ***the known, serious, and too-often fatal risks far outweigh the unproven and transient benefits.***"[14] The CDC summarized its assessment of opioid data as follows:

- ***No evidence shows a long-term benefit of opioids*** in pain and function versus no opioids for chronic pain with outcomes examined at least one year later (with most placebo-controlled randomized trials ≤6 weeks in duration).
- ***Extensive evidence shows the possible harms of opioids*** (including opioid use disorder, overdose, and motor vehicle injury).
- Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm.

Mot. to Stay, Exhibit 18, p. 15 (emphasis added) (CDC Guidelines). Based on these findings, the CDC set forth twelve guidelines for prescribing opioids for chronic pain. The guidelines provide recommendations including that "nonopoioid pharmacologic therapy [is] preferred for chronic pain" and that "clinicians should discuss with patients known risks and realistic benefits of opioid therapy . . . ." *Id.*, p. 16. The FDA has expressed its support for the CDC's guidelines.[15]

In light of the foregoing, Defendants' suggestion that more research is necessary to establish that opioids pose serious risks is baseless. The recent findings of the FDA and CDC do

---

[12] *Id.* at n.11, *supra* (emphasis added).
[13] http://www.nejm.org/doi/full/10.1056/NEJMp1515917#t=article (last visited October 27, 2017) (CDC announcement of the guidelines in the New England Journal of Medicine).
[14] *Id.* at n.13, *supra* (emphasis added).
[15] *Id.* at n.3, *supra* ("The FDA's call to action is also supportive of the Centers for Disease Control and Prevention's current work on guidelines for prescribing of opioids for the treatment of chronic pain outside of end of life care.").

not affect this Court's jurisdiction in any way; rather, they further indict Defendants *past* marketing behavior—which is what this case is about.

III. ARGUMENT AND AUTHORITIES

The issue in this case is whether Defendants' past marketing misrepresented the risks, benefits, and superiority of opioids to treat pain—a determination this Court and a jury are well-equipped, and entitled, to make. No FDA labeling regulation, past or future, is dispositive of this issue. Accordingly, Defendants' joint motion to dismiss based on preemption, Purdue's motion to dismiss based on preemption, and Defendants' joint motion to stay under the primary jurisdiction doctrine or the court's inherent power to manage its docket must be denied.

A. Defendants' Joint Motion to Dismiss and Purdue's Individual Motion to Dismiss Based on Preemption Should Be Denied

Defendants mischaracterize the State's allegations and the FDA's actions to argue that the State's state law claims are preempted by federal law. Defendants contend that implied "impossibility" preemption applies because it would be impossible for Defendants to comply with a state law duty (*i.e.*, a jury verdict) to modify its opioid labeling without violating federal regulations. Purdue MTD at 6; Jt. MTD at 12. This argument is misplaced for two reasons. First, none of the State's claims question the content of Defendants' labels, nor does the State allege that the labels must be revised to avoid liability under state law. Thus, nothing in the State's claims would prevent Defendants from complying with federal law. Second, the FDA's labeling decisions regarding opioids have no bearing on Defendants' prior conduct and knowledge and whether—in spite of the labeling—Defendants misrepresented the risk of addiction and touted unsubstantiated benefits of long term opioid treatment. Because the State's claims do not prevent Defendants from simultaneously complying with state and federal laws, there is no preemption.

1. Legal Standards

Defendants assert a form of implied conflict preemption known as impossibility preemption.[16] Under impossibility preemption, state law is preempted only where a private party cannot comply with both state and federal law. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009). It is a demanding defense—requiring a drug manufacturer to establish by "clear evidence" that the FDA "would have prohibited" the manufacturer from adding a stronger warning. *Id.* at 573. Stated differently, a district court must decide whether "clear evidence" exists that, at the time of the plaintiff's injury, had the manufacturer proposed a change to its label under the changes being effected ("CBE") regulations, the FDA nonetheless would have rejected that proposal. *Id.* If so, compliance with both state law duties and FDA regulations is impossible, and the plaintiff's claim is preempted. *Id.* at 571.

Two principles guide the preemption analysis under the Supremacy Clause: (1) "the purpose of Congress is the ultimate touchstone," and (2) the presumption "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 565.

a. Congress Did Not Intend for the FDA To Completely Preempt State Law Claims Related to Prescription Drugs

In *Wyeth*, the seminal preemption case involving state common law claims against prescription drug manufacturers, the Supreme Court analyzed the legislative history behind the United States Federal Food, Drug, and Cosmetic Act ("FDCA") and found that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. The Court added:

---

[16] The defense of impossibility preemption assumes a plaintiff is alleging the defendant should have provided a better or different warning on their label, a much different case than this one.

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, see § 2, 90 Stat. 574 (codified at 21 U.S.C. § 360k(a)), Congress has not enacted such a provision for prescription drugs. *See Riegel*, 552 U.S., at 327 ("Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.")

Id. at 574. The FDA's silence is significant.

"When the FDA believes that its regulations preempt state law it says so. The FDA has been silent with respect to the preemption of lawsuits challenging false claims in prescription drug advertisements. This silence suggests the FDA does not intend its review of promotional materials to preempt false advertising claims." *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699 CRB, 2006 U.S. Dist. LEXIS 95500, at *71 (N.D. Cal. 2006).

b. There is a Strong Presumption that State Law Claims are Not Preempted

Adding to the difficulty of Defendants' impossibility preemption defense, the United States Supreme Court has instructed that there is a strong presumption against preemption. Courts must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth*, 555 U.S. at 565 (internal quotations omitted). As the Supreme Court explained in *Medtronic, Inc. v. Lohr*:

> Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are primarily, and historically, matters of local concern, the States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.

518 U.S. 470, 475 (1996).

In *Wyeth*, the Supreme Court added that state law claims are an important complement to the FDA's regulation of prescription drugs:

> In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. . . . Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

555 U.S. at 578–79. The strong presumption against federal preemption equally applies here.

2. Impossibility Preemption Does Not Apply—There is No Direct Conflict Between the State's Claims and the FDA's Regulations of Opioids

a. The State Does Not Allege a Claim for Failure to Warn

Defendants mischaracterize the State's claims as alleging a "failure to warn" in a thinly-veiled attempt to fit their preemption argument. Indeed, every case cited in support of Defendants' preemption arguments is based on such a claim, and, thus, are inapposite.[17]

In *Seufert v. Merck Sharp & Dohme Corp.*, for example, the plaintiff was severely injured from taking the prescription drugs Onglyza and/or Kombigylze. 187 F. Supp. 3d 1163, 1165 (S.D. Cal. 2016). The plaintiff sued the manufacturer for failing to adequately warn of the risks of pancreatic cancer associated with the drugs. *Id.* Defendants argued that the claim was preempted because, based on the FDA's prior investigations into the specific issue implicated by plaintiff's claims, it would have been impossible to reference pancreatic cancer in drug labeling and still comply with FDA regulations. *Id.* at 1166. The Court agreed, finding clear evidence that the FDA would have rejected a pancreatic cancer labeling change. *Id.* at 1173.

[17] Defendants incorporate identical string cites into their respective briefs. *See* Purdue MTD at 8; Jt. MTD at 13. All seven of these cases involve preemption of state law claims against drug manufacturers for failure to warn resulting from inadequate *labeling*. Thus, none are applicable here.

Here, no such conflict or "impossibility" exists. The State does not make any allegations about what Defendants' labels state or fail to state, or that Defendants need to change their label to avoid liability under state law. Rather, the State's claims are based on Defendants' deceptive marketing of opioids, which differed from—and often conflicted with—the language on their drugs' labels. The Supreme Court has made it clear that federal law does not preclude a plaintiff from asserting claims of fraud or false advertising of prescription drugs and that the types of claims that the State brings offer a layer of consumer protection that complements FDA regulation. *Wyeth,* 555 U.S. at 578–579. Because nothing in the Petition prevents Defendants from simultaneously complying with state and federal law, there is no preemption.

b. The State's Allegations Do Not Conflict with the FDA's Labeling Decisions

Defendants wrongly assert that the State's claims should be preempted because they conflict with prior FDA labeling decisions. *See* Purdue MTD at 9-11; Jt. MTD at 14-15. To prevail, Defendants would have to show not only that their labeling met federal requirements, but that it was impossible for them to simultaneously comply with the state consumer protection laws. *See In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 376 (E.D.N.Y. 2010) ("[E]ven if the statements met the FDA's threshold requirements, they could still be misleading under state law consumer protection statutes."). Defendants cannot show this.

Defendants' argument is based in part on the partial grant of the PROP Petition on July 25, 2012, discussed above. *See* Purdue MTD at 9-11; Jt. MTD at 14-15. However, this argument too is falsely premised upon Defendants' mischaracterization of the State's claims. Because the State does not challenge Defendants' labeling, decisions by the FDA related to labeling cannot conflict with the State's claims. That is the end of the inquiry.

However, even if evidence of the FDA decisions were proper or relevant, nothing in the PROP Petition supports Defendants' assertion that the FDA has determined that opioids are safe for long-term use in the treatment of chronic pain. Defendants wrongly claim the "FDA reviewed scientific evidence on using opioids for treating chronic pain, and ***found that the evidence supported that use***." Purdue MTD at 9 (emphasis added); Jt. MTD at 14 ("the FDA recently reviewed whether scientific evidence supports the use of opioids for the treatment of chronic pain, ***and the agency concluded that it did***." (emphasis added)). Defendants blatantly distort the facts. The cited document actually states that the "FDA is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks." Mot. to Stay, Exhibit 1, p. 10 (PROP Response). Moreover, when combined with the FDA's direction that Defendants conduct studies to assess the impact of increased dosage and duration, it demonstrates the ***lack*** of evidence supporting the safety and efficacy of the long-term use of opioids. *See id.*

Defendants' other references to FDA-approved labeling (for example, Defendants' assertion that certain labels describe "Pseudoaddiction" or "Risks of Addiction and Long-Term Opioid Use") are irrelevant for the same reasons.

Because the State's claims do not preclude Defendants from complying with FDA labeling regulations and state law, there is no preemption.

B. Defendants' Joint Motion to Stay Based on the Primary Jurisdiction Doctrine or the Court's Inherent Power Should Be Denied

Defendants improperly ask the Court to stay this case under the primary jurisdiction doctrine or, alternatively, under its inherent power to manage its docket. The primary jurisdiction doctrine does not warrant a stay in this case. As set forth herein, the issues in this case: (1) are routinely decided by courts and juries; (2) do not require scientific judgments reserved for or before

the FDA; and (3) do not risk inconsistent determinations. For these same reasons, a stay is not warranted under the Court's inherent power to manage its own docket.

1. Legal Standards

The Oklahoma Supreme Court has indicated that discretionary deferral to an agency under the primary jurisdiction doctrine may be warranted in certain situations. *See Davis v. GHS HMO, Inc.*, 2001 OK 3, ¶27, 22 P.3d 1204, 1213. While the Oklahoma Supreme Court has not analyzed the factors that would make such a decision appropriate, the Tenth Circuit provides that the prudential form of the primary jurisdiction doctrine "require[s] [the district court] to consider whether the issues of fact in the case: (1) are not within the conventional experience of judges; (2) require the exercise of administrative discretion; or (3) require uniformity and consistency in the regulation of the business entrusted to the particular agency." *Crystal Clear Communs., Inc. v. Sw. Bell Tel. Co.*, 415 F.3d 1171, 1179 (10th Cir. 2005).

In considering whether to invoke the doctrine, the district court is not required to defer factual issues to an agency under the doctrine of primary jurisdiction if those factual issues are of the sort that the court routinely considers. *Marshall v. El Paso Nat. Gas Co.*, 874 F.2d 1373, 1377 (10th Cir. 1989) (citing *United States v. Zweifel*, 508 F.2d 1150, 1156 (10th Cir.), *cert. denied*, 423 U.S. 829 (1975)). "The courts should be reluctant to invoke the doctrine of primary jurisdiction, which often, but not always, results in added expense and delay to the litigants. Primary jurisdiction should not be applied where the litigation is identical to disputes normally resolved by the courts." *Pace Membership Warehouse, Inc. v. U.S. Sprint Commc'ns Co. Ltd. P'ship*, No. 90-F-2121, 1991 U.S. Dist. LEXIS 19788, at *3–4 (D. Colo. Feb. 8, 1991) (citations and quotations omitted).

Moreover, Oklahoma courts "have the power to facilitate and expedite causes before it so long as the reasonable exercise of these inherent powers do not prejudice the rights of the parties

involved." *Tr. Co. v. Jage (In re Wallace)*, 2009 OK 34, ¶7, 219 P.3d 536, 538. "[T]he suppliant for a stay must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to some one else." *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936).

2. The Issues of Fact in This Case Are Within the Conventional Experience of the Court

The State is not asking the Court to resolve or interpret any FDA regulation or standard. Rather, the core questions for this Court arise under state statutes and common law and relate to Defendants' fraudulent marketing practices. "[T]he standards to be applied in an action for fraudulent misrepresentation are within the conventional competence of the courts, and the judgment of a technically expert body is not likely to be helpful." *Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290, 305–06 (1976) (primary jurisdiction doctrine inapplicable to fraudulent misrepresentations by airline, even though Civil Aeronautics Board had statutory authority to investigate whether the airlines had engaged in deceptive practices).

This principle applies equally to products regulated by the FDA, including opioids. Under facts substantially similar to those at issue here, the Northern District of Illinois denied defendants' request to invoke primary jurisdiction, holding that courts are equipped to adjudicate whether "defendants deliberately misrepresented the risks, benefits, and superiority of opioids when marketing them to treat chronic pain . . . ." *City of Chi.*, 211 F. Supp. 3d at 1065 (declining to invoke the primary jurisdiction doctrine where defendant opioid manufacturers argued that the FDA's ongoing studies compelled deference to the FDA). Indeed, courts across the country hold

that evaluating materials that market FDA-regulated products does not require the FDA's expertise.[18]

None of the cases Defendants rely upon support their primary jurisdiction argument. In *Weinberger v. Bentex Pharmaceuticals, Inc.*, the Supreme Court applied the primary jurisdiction doctrine because the case required a determination of whether a drug was "new" within the meaning of the Food, Drug, and Cosmetic Act ("FDCA"). 412 U.S. 645, 653–54 (1973); *see also Imagenetix, Inc. v. Frutarom USA, Inc.*, No. 12-CV-2823, 2013 U.S. Dist. LEXIS 173193, at *10–13 (S.D. Cal. Dec. 9, 2013) (applying the primary jurisdiction doctrine because the issue underlying plaintiff's breach of warranty claims was whether a probiotic product was a drug or a

[18] *See, e.g., In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699, 2006 U.S. Dist. LEXIS 95500, at *73–74 (N.D. Cal. Aug. 16, 2006) ("Plaintiffs' false advertising claims do not implicate the primary jurisdiction doctrine . . . The issue is whether contrary to the FDA's findings, Pfizer nonetheless falsely claimed that Celebrex was superior. Courts and juries frequently decide similar false advertising claims."); *In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practice Litig.*, 955 F. Supp. 2d 1311, 1349 (S.D. Fla. 2013) ("Plaintiffs' claims rest on the determination of whether [Defendant's] brain health representations on its products' labeling, in its advertisements, and on its website are false and/or misleading . . . . This is not a technical area in which the FDA has greater technical expertise than the courts — as every day courts decide whether conduct is misleading." (citations, quotations, and formatting omitted)); *Jasper v. Musclepharm Corp.*, No. 14-cv-02881, 2015 U.S. Dist. LEXIS 64588, at *12 (D. Colo. Apr. 9, 2015) ("[T]he question isn't whether the product itself burns fat . . . but whether the product labeling would lead the reasonable consumer to think that it does. This is not a question of arcane scientific expertise properly deferred to the FDA; it is a routine question of tort law."); *In re Frito-Lay N. Am., Inc.*, No. 12-MD-241, 2013 U.S. Dist. LEXIS 123824, at *27 (E.D.N.Y. Aug. 29, 2013) ("This case is far less about science than it is about whether a label is misleading, and the reasonable-consumer inquiry upon which some of the claims in this case depends is one to which courts are eminently well suited, even well versed." (quotations omitted)); *Ivie v. Kraft Foods Global*, 961 F. Supp. 2d 1033, 1045 (N.D. Cal. Jun. 28, 2013) ("The FDA's expertise is not necessary to determine whether the labels are misleading, and the reasonable consumer determination and other issues involved in this lawsuit are within the expertise of the courts to resolve." (quotations and formatting omitted)); *Zapka v. Coca-Cola Co.*, Case No. 99 C 8238, 2001 U.S. Dist. LEXIS 20155, at *16 (N.D. Ill. Dec. 3, 2001) ("[W]hile the FDA has specialized expertise in the branding and labeling of food and drinks, it does not have specialized expertise in the marketing or advertising of food and drinks. Therefore, a referral to the FDA is inappropriate, and the Court will not dismiss the instant action.").

dietary supplement within the meaning of the FDCA). In *Gisvold v. Merck & Co.*, the Southern District of California applied the primary jurisdiction doctrine because the FDA had issued a proposed rule "on [the] very issue" to be decided by the court. 62 F. Supp. 3d 1198, 1204 (S.D. Cal. 2014).

These cases are inapposite because the State's claims here do not involve whether a product meets FDA regulatory criteria or relate to the FDA's investigation into future labeling changes. *See City of Chi. v. Purdue Pharma L.P.*, No. 14-cv-4361, 2015 U.S. Dist. LEXIS 60587, at *15–16 (N.D. Ill. May 8, 2015) (distinguishing *Weinberger* and *Imagenetix*).

Rather, the State alleges Defendants deliberately sought to circumvent the FDA's regulations by promoting the use of opioids through unbranded advertising disseminated by doctors and entities controlled by Defendants. *See* Pet. ¶¶58–66. Defendants' argument would require ***any*** action challenging deceptive or misleading statements made about prescription drugs to be referred to the FDA, regardless of whether the FDA had the power to review the statements in the first instance. Likewise, Defendants' argument would foreclose the adjudication of false marketing claims anytime the FDA was collecting data regarding a drug at issue for any reason—even where, as here, the FDA study was commissioned to evaluate *strengthening* drug restrictions in response to an epidemic relating to Defendants' own products.

3. The Issues of Fact in This Case Do Not Require the Exercise of Administrative Discretion

Defendants wrongly assert that the State's claims require resolution of issues currently before the FDA. The basis for Defendants' argument is the partial grant of the PROP Petition. Mot. to Stay, pp. 4–7. As described below, the FDA's actions in response to the PROP Petition show there is no issue before the FDA that in any way affects this Court's jurisdiction.

First, the PROP Petition does not warrant invoking the primary jurisdiction doctrine because it does not address the State's allegations. The allegations in the State's Petition involve Defendants' deceptive ***marketing*** of opioids. *See, e.g.*, Pet. ¶¶ 4–5. On the other hand, the PROP Petition sought to change drug ***labeling***. *See* Mot. to Stay, Exhibit 2, p. 1 (PROP Petition) ("By implementing the label changes proposed in this petition, FDA has an opportunity to reduce harm caused to chronic pain patients as well as societal harm caused by diversion of prescribed opioids."). The issue in this case is not whether opioids are labeled appropriately, but whether they are marketed truthfully—an issue distinct from the language on the drugs' labels. Pet. ¶¶ 67, 70. Thus, the PROP Petition and the FDA's response do not concern the core allegations of the Petition. *See City of Chi.*, 211 F. Supp. 3d at 1065.

Second, the PROP Petition does not warrant invoking the primary jurisdiction doctrine because it has been resolved by the FDA. Where there is no relevant agency determination pending, there is no matter to defer to the agency. *See RJB Gas Pipeline Co. v. Colo. Interstate Gas Co.*, 1989 OK CIV APP 100, ¶29, 813 P.2d 1, 6 ("Although courts may at times defer a decision in an area of the law in which a governmental agency exercises a particular expertise, in the instant case, there is no matter the trial court could have deferred. The FERC had already set the rates for gathering."); *Reid v. Johnson & Johnson*, 780 F.3d 952, 966 (9th Cir. 2015) (denying motion to refer to FDA because "[t]he FDA has already addressed some issues that McNeil identifies as requiring further regulatory review"). The FDA ruled on the PROP Petition over four years ago, declining to implement certain labeling changes and granting others. *See* Mot. to Stay, Exhibit 1, pp. 1, 6, 11 (PROP Response). Because the FDA already made its labeling determination in response to the PROP Petition, it cannot be a basis for invoking the primary jurisdiction doctrine.

Likewise, studies commissioned by the FDA that *may* lead to further strengthening of drug labels do not warrant deference to the FDA. The outcomes of these studies will have no bearing on Defendants' *prior* conduct and knowledge relating to their deceptive marketing—*i.e.*, the issues in this case. Additionally, far from conflicting with the State's allegations, the FDA's response to the PROP Petition and additional investigation fully align with the State's claims.

The FDA may order post-marketing studies in three circumstances: (1) to assess known serious risk; (2) to assess signals of serious risk; or (3) to identify an unexpected serious risk. 21 U.S.C. § 355(o)(3)(A). Here, the FDA required post-marketing studies "to assess the ***known*** serious risks of misuse, abuse, hyperalgesia, addiction, overdose and death" associated with opioids. Mot. to Stay, Exhibit 1, p. 10 (PROP Response). Accordingly, the additional studies were not ordered to evaluate a potential risk or identify risks of opioids—they were ordered to further study the ***known*** risks. These risks have been well-known for decades, but Defendants ignored them in their marketing. Accordingly, the ongoing FDA studies will not impact or conflict with the allegations in the Petition. *In re 5-Hour Energy Mktg. & Sales Practices Litig.*, No. MDL 13-2438, 2014 U.S. Dist. LEXIS 149732, at *38–39 (C.D. Cal. Sep. 4, 2014) ("[T]he mere existence of an agency investigation does not weigh in favor of a referral under the primary jurisdiction doctrine. Defendants have not made any showing that the litigation of this case would conflict with the FDA's investigation. In the absence of such a showing, there is no reason to think that this case will interfere with the FDA's uniform administration of federal labeling laws.").

Finally, Defendants' attempt to match cherry-picked terms from the Petition to cherry-picked language from approved FDA labeling and ongoing studies is misguided and does not alter the result here. *See* Mot. to Stay, pp. 13–15 (discussing "function", "risk of addiction", and "pseudoaddiction"). Referring to FDA-approved labeling, for example, Defendants' assertions

that certain labels describe pseudoaddiction, are irrelevant. Again, the State's claims are not about whether Defendants properly labelled their drugs. Rather, the State specifically alleges that Defendants' deceptive conduct often *contradicted* their own labels. Pet. ¶¶ 67, 70. Even if the State's claims were about labeling, *approved* labels are not a pending issue before the FDA that could warrant stay of this case. *See RJB Gas Pipeline*, 1989 OK CIV APP 100, ¶29, 813 P.2d at 6. The language Defendants highlight related to ongoing studies is equally misleading. *See* Mot. to Stay, pp. 12–15. Again, the issue to be decided by these studies is whether further opioid labeling changes are warranted, which is not an issue raised by the Petition.

4. The Issues of Fact in This Case Do Not Risk Inconsistency in the Regulation of Business Entrusted to the FDA

The State's claims are brought solely under Oklahoma law and seek remedies that only Oklahoma courts can provide, including restitution, civil penalties, and abatement—specifically: (1) declarations that Defendants have violated the Oklahoma Consumer Protection Act, the Oklahoma Medicaid Program Integrity Act, and the Oklahoma Medicaid False Claims Act; (2) full restitution as permitted under these Acts; (3) actual damages as permitted under these Acts; (4) abatement of public nuisance; (5) injunction as permitted under these Acts; (6) punitive Damages; and (7) attorneys' fees and expenses. Pet. § VII (Prayer for Relief). As discussed at length above, these determinations do not relate to labeling and are not affected by any decision pending before the FDA. Defendants have not and cannot claim that the FDA can provide the relief the State seeks.

The Oklahoma Supreme Court and United States Supreme Court are clear that the FDA's power to regulate drug labels does not displace state law:

> It has long been the concern of this state to protect the health and safety of its citizens. The Supreme Court has recognized that state concern is warranted and permitted. It is the widely held view that the FDA sets minimum standards for drug

> manufacturers as to design and warnings. We conclude that compliance with these minimum standards does not necessarily complete the manufacturer's duty. The common law duty to warn is controlled by state law. Even the FDA agrees, as noted by the FDA Commissioner who observed that civil tort liability for failure to warn is governed by state law.

Edwards v. Basel Pharm., 1997 OK 22, ¶ 17, 933 P.2d 298, 302 (citations omitted); *see also Wyeth*, 555 U.S. at 574 (2009) (Congress's decision not to provide a private right of action under the FDCA recognizes "that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings."). The same is true here. The FDA has no expertise to lend in applying Oklahoma law to determine whether Defendants' marketing scheme was deceptive or misleading or how the opioid Oklahoma epidemic created by Defendants' deceptive marketing scheme should be abated.

Likewise, the Court's determinations have no relationship to any decisions the FDA may make in the future regarding opioid labels. This Court's determination of Defendants' culpability for historical deceptive marketing of opioids does not conflict with the FDA's assessment of opioid labeling in 2018 and beyond. *See Frydman v. Portfolio Recovery Assocs., LLC*, 2011 U.S. Dist. LEXIS 69502, at *17 (N.D. Ill. June 28, 2011) ("[A]ny change in the [agency] rules . . . would apply prospectively, eliminating the danger of inconsistent rulings.").

The role of the Court in determining the state law claims before it and the role of the FDA in assessing labeling requirements do not overlap in this case. Accordingly, the need for "uniformity and consistency in the regulation of business" does not justify application of the doctrine of primary jurisdiction here. *See City of Chi.*, 211 F. Supp. 3d at 1065 ("[T]he Court is not being asked to adjudicate whether opioids are appropriate for the treatment of chronic, non-cancer pain or whether defendants' drugs' labels are accurate, but whether defendants deliberately

misrepresented the risks, benefits, and superiority of opioids when marketing them to treat chronic pain . . . ."). Thus, there is no potential for inconsistent results in this case.

5. The Court Should Not Stay This Action Under Its Inherent Authority

A court may stay a case in order to facilitate and expedite the causes before it. *See Tr. Co. v. Jage (In re Wallace)*, 2009 OK 34, ¶7, 219 P.3d at 538. In exercising that power, the court must not prejudice the rights of a party. *Id.* Further, "the suppliant for a stay must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to someone else." *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936). Here, a stay will unnecessarily delay this case and prejudice the State. In contrast, Defendants fail to identify any hardship or inequity they would suffer in going forward with the case.

Defendants provide no reason why the Court should exercise its discretionary authority and stay this case. As set forth above, the FDA's investigation is directed at labeling, not the deceptive marketing claims at issue here. The additional study of known opioid risks to inform potential labeling changes does not conflict with the State's false marketing and public nuisance claims (or any others). There is no outcome of the FDA studies that could dispose of this case. There is simply nothing pending before the FDA that will affect the claims raised in this litigation. In short, neither the Court nor the parties would gain anything at all from a stay of this litigation. Just the opposite is true.

Defendants fail to address the prejudice to the State if its claims are stayed while the FDA completes its supervision of clinical studies. These clinical studies may, at most, result in changes to the labels of ER/LA opioids at some unknown point in the *future*. In the meantime, Oklahoma residents will continue to die, and the financial burden on the State will continue to rise.

Additionally, given the expansive and intensifying investigations by state and federal authorities, to whom Defendants have indicated they are providing information, it would be highly prejudicial to prevent the State of Oklahoma from fully developing the facts surrounding the allegations in the Petition. For example, recent press releases indicate that, as part of the ongoing investigation by a coalition of 41 Attorneys General into whether manufacturers have engaged in unlawful practices in the marketing and sale of opioids, the attorneys general are using a variety of legal means—including subpoenas for documents and testimony—to help determine what role drug manufacturers played in creating or prolonging the opioid epidemic.[19] In fact, the working group of Attorneys General already have served subpoenas requesting information from five major opioid manufacturers who are Defendants in this case, including Janssen, Allergan, Purdue Pharma and Teva.[20] These Defendants have indicated they will comply with the subpoenas, and likely will be required to provide documents and information pre-suit.[21] And, some states have tolling agreements with one or more Defendants that allow discovery. Accordingly, every day this case is stayed would cause Oklahoma to fall behind.

This Court is equipped to address the State's claims. It should do so without delay.

IV. CONCLUSION

The issue in this case is whether Defendants' past marketing misrepresented the risks, benefits, and superiority of opioids to treat pain—a determination this Court and a jury are well-equipped, and entitled, to make. No FDA labeling regulation, past or future, is dispositive of this issue. Accordingly, the Court should deny Defendants' joint motion to dismiss based on

---

[19] https://texasattorneygeneral.gov/news/releases/ag-paxton-announces-ongoing-investigation-to-help-address-the-opioid-crisis (last visited October 18, 2017).

[20] http://www.cnn.com/2017/09/19/health/state-ag-investigation-opioids-subpoenas/index.html (last visited October 18, 2017).

[21] *Id.* at n.20, *supra.*

preemption, Purdue's motion to dismiss based on preemption, and Defendants' joint motion to stay under the primary jurisdiction doctrine or the court's inherent power to manage its docket.

Dated: October 30, 2017

Respectfully submitted,

Michael Burrage, OBA No. 1350
Reggie Whitten, OBA No. 9576
WHITTEN BURRAGE
512 N. Broadway Avenue, Suite 300
Oklahoma City, OK 73102
Telephone: (405) 516-7800
Facsimile: (405) 516-7859
Emails: mburrage@whittenburragelaw.com
rwhitten@whittenburragelaw.com

Mike Hunter, OBA No. 4503
ATTORNEY GENERAL FOR
THE STATE OF OKLAHOMA
Abby Dillsaver, OBA No. 20675
GENERAL COUNSEL TO
THE ATTORNEY GENERAL
Ethan A. Shaner, OBA No. 30916
DEPUTY GENERAL COUNSEL
313 N.E. 21st Street
Oklahoma City, OK 73105
Telephone: (405) 521-3921
Facsimile: (405) 521-6246
Emails: abby.dillsaver@oag.ok.gov
ethan.shaner@oag.ok.gov

Bradley E. Beckworth, OBA No. 19982
Jeffrey J. Angelovich, OBA No. 19981
NIX, PATTERSON & ROACH, LLP
512 N. Broadway Avenue, Suite 200
Oklahoma City, OK 73102
Telephone: (405) 516-7800
Facsimile: (405) 516-7859
Emails: bbeckworth@nixlaw.com
jangelovich@nixlaw.com

Glenn Coffee, OBA No. 14563
GLENN COFFEE & ASSOCIATES, PLLC
915 N. Robinson Ave.
Oklahoma City, OK 73102
Telephone: (405) 601-1616
Email: gcoffee@glenncoffee.com

Tracy Schumacher, OBA No. 15950
Schumacher & Stanley, P.L.L.C.
114 E. Main Stret
Norman, OK 73072
Telephone: (405) 701-1882
Email: tracy@schumacherstanley.com

ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the above and foregoing was mailed, postage prepaid, this 30th day of October 2017 to:

Robert G. McCampbell
Travis V. Jett
GableGotwals
One Leadership Square, 15th Floor
211 North Robinson
Oklahoma City, OK 73102

John H. Sparks
Benjamin H. Odom
Odom, Sparks & Jones, PLLC
HiPoint Office Building
2500 McGee Drive, Ste. 140
Norman, OK 73072

Sanford C. Coats
Cullen D. Sweeney
CROWE & DUNLEVY, P.C.
Braniff Building
324 N. Robinson Ave., Ste. 100
Oklahoma City, OK 73102

Sheila Birnbaum
Mark S. Cheffo
Hayden A. Coleman
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010

Patrick J. Fitzgerald
R. Ryan Stoll
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
155 North Wacker Drive, Ste. 2700
Chicago, Illinois 60606

Steven A. Reed
Harvey Bartle IV
Jeremy A. Menkowitz
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921

Brian M. Ercole
MORGAN, LEWIS & BOCKIUS LLP
200 S. Biscayne Blvd., Suite 5300
Miami, FL 33131

Charles C. Lifland
O'MELVENY & MEYERS LLP
400 S. Hope Street
Los Angeles, CA 90071

Michael Burrage