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.	Case No. CJ-2017-816 Honorable Thad Balkman

DEFENDANTS' JOINT REPLY IN SUPPORT OF THEIR (1) JOINT MOTION TO DISMISS BASED ON PREEMPTION AND (2) JOINT MOTION TO STAY THIS CASE UNDER THE PRIMARY JURISDICTION DOCTRINE AND THE COURT'S INHERENT AUTHORITY TO STAY PROCEEDINGS

I. INTRODUCTION

The State's claims directly contradict FDA's approval of opioid therapy for long-term treatment of chronic pain. The State's Petition, at its core, seeks to hold Defendants liable for promoting opioid medications for the management of chronic non-cancer pain—the exact purpose for which FDA has approved those medicines. Curiously, the State contends that "Defendants wrongly claim the 'FDA reviewed scientific evidence on using opioids for treating chronic pain, and found that the evidence supported that use.'" Resp.[1] at 15 (quoting Purdue MTD at 9). But FDA, after exhaustive review on multiple occasions, *has* found, and *continues* to find, that opioids can be used to treat chronic pain, including non-cancer pain. Indeed, FDA has repeatedly approved that use, including for all of the extended release long-acting (ER/LA) opioid medications at issue here. And FDA expressly rejected a citizens' petition request by Physicians for Responsible Opioid Prescribing ("PROP Petition") to revoke FDA's approval of opioid medications for the treatment of chronic non-cancer pain and limit those medications to use under 90 days.

Thus, it is the State—which claims that there is no scientific support for long-term use of opioid medications—and not Defendants, that has misapprehended FDA's regulatory decisions, directives, and approved labeling. *See, e.g.*, Pet. ¶¶ 1, 3, 51, 67-69. The State asserts that there is a "***lack*** of evidence supporting the safety and efficacy of the long-term use of opioids." Resp. at 15. However, FDA's approval of the medications for precisely that use belies such an argument. In short, FDA could not have approved the products without "substantial evidence" of efficacy

[1] "Resp." refers to 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.

and safety. *See* 21 U.S.C. § 355(d) (FDA approval requires "substantial evidence that the drug will have the effect it purports or is represented to have"). FDA's response to the PROP Petition supports this conclusion. While FDA agreed that there was an absence of "adequate and well-controlled studies of opioid use longer than 12 weeks,"[2] it declined to limit the use of opioids to that period of time, noting that "[t]here are numerous uncontrolled studies that have evaluated patients on opioids for as long as a year; although some patients drop out of the studies over this period of time, many remain on opioid therapy, which may suggest that they continue to experience benefits that would warrant the risks of opioid use."[3]

The State's Petition presents a straightforward case of preemption. To avoid liability under the State's theories and claims, Defendants would be required to unilaterally change or delete the long-term use indication for their medications or not market them for that FDA-approved use. Therefore, these claims conflict with and are preempted by federal law and should be dismissed. The Supreme Court has expressly rejected as preempted a theory of liability that would effectively require a company to "stop-selling" its FDA-approved medicine to avoid state law liability. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 (2013).

In addition to disregarding FDA's labeling decisions approving long-term use of Defendants' medications, the State asks this Court to decide other complex scientific and health policy issues without the benefit of forthcoming data and FDA guidance. The Court should decline to do so. In the event the Court finds that any of the State's claims are not preempted or otherwise subject to dismissal, it should stay any such claim pending the completion of FDA-mandated post-market studies that are currently evaluating the risks and benefits of long-term

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[2] Ex. 1 at 10.

[3] *Id.* at 10 n.40.

opioid therapy. These studies are expected to "result in the most comprehensive data ever collected in the field of pain medicine," Ex. 6 at 2, and will provide relevant data on the science underlying the State's allegations. Prim. Jur. Mem. at 11-15. This Court thus should stay any remaining claims under the primary jurisdiction doctrine and the Court's inherent authority and allow FDA to complete its review.

II. ARGUMENT

A. All Claims Should be Dismissed Because They Are Preempted.

As Defendants explained in their Motions to Dismiss, courts have repeatedly held that state law claims are preempted 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 evaluating the available data. *See* Joint MTD at 13 (citing cases); Purdue MTD at 8 (citing cases). Under those decisions, unless a plaintiff can show that the manufacturer has obtained "newly acquired information" that would allow it to unilaterally change the label pursuant to the FDCA's "Changes Being Effected" ("CBE") regulations, the plaintiff cannot maintain a claim that a prescription medicine's labeling—or marketing consistent with the labeling—is inadequate or misleading. The State here has not identified, nor could it identify, any "newly acquired information" that would allow Defendants to change the labeling or marketing of their opioid medications under the CBE regulations. Accordingly, the State's claims regarding Defendants' marketing of their opioid medications all are preempted.

Indeed, even if there were new information that might have prompted Defendants to change their marketing—which there is none—Defendants still could establish a conflict preemption defense through "clear evidence that the FDA would not have approved" such a change. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009). As courts have recognized, "the rejection of a citizen petition,"—like FDA's rejection of the PROP Petition's request to limit the duration

and dosing of opioids—can "constitute clear evidence that the FDA would have rejected a manufacturer-initiated change to a drug label." *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir. 2017); *see also Risperdal & Invega Prod. Liab. Cases*, No. BC599531, 2017 WL 4100102, at *11 (Cal. Super. Ct. Mar. 16, 2017) (the "reasons articulated by the FDA in response to the very claims alleged [in the complaint] provide the kind of 'clear evidence' of 'legislative fact' which the U.S. Supreme Court requires before a court can hold that impossibility preemption applies."). The State does not, and cannot, dispute these well-established principles. None of the State's arguments in response can save its claims from preemption.

1. The State Cannot Avoid Preemption Simply Because its Claims Relate to Defendants' Marketing Statements Rather Than the Adequacy of Their Labels.

The State first contends that its state law claims cannot be impliedly preempted because they are not brought as "failure to warn" claims, and because they are based on Defendants' advertising and promotional statements rather than on statements contained in Defendants' FDA-approved labels. Resp. at 13. Neither of these two facts poses a barrier to preemption. Indeed, contrary to the State's contention, several of the cases cited in Defendants' Motions to Dismiss held that preemption applied to claims that were not brought under a "failure to warn" theory, and/or did not directly implicate the adequacy of a drug's label. For example, in *Drager ex rel. Gross v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014), the plaintiff alleged that a drug manufacturer made negligent misrepresentations and fraudulently concealed information about the safety of its product through its promotional and marketing materials. Like the State here, the plaintiff argued that these claims survived preemption because, in its view "the duties imposed by these legal principles [were] unlike state law obligations concerning warnings." *Id.* at 479. The court flatly rejected that argument, finding it "frivolous" and "unavailing." *Id.* Notwithstanding the fact that the plaintiff's negligent misrepresentation and fraudulent

concealment claims were not cast as "failure to warn" claims and related to the manufacturer's marketing materials rather than its labeling, the court found these claims preempted by the FDCA because "[b]oth causes of action [were] premised on the content of statements made by the defendant to the plaintiff," and it would be impossible for the defendant to comply with the FDCA's requirements without subjecting itself to those state law causes of action. *Id.* Similarly, in *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228 (S.D. Fla. 2007), the court held that plaintiffs' marketing claims against Pfizer were preempted where the allegedly improper advertising was based in large part on Lipitor's FDA-approved label. The court explained that:

> [T]he FDA approved Lipitor to reduce the risk of heart attacks in patients . . . with multiple risk factors for coronary heart disease. . . . Accordingly, any advertisements that stated or implied that Lipitor reduced the risk of heart disease or heart attacks simply marketed an approved use for the drug. . . . [T]he alleged advertisements derive from, and largely comport with, the [FDA]-approved label. For this reason, the plaintiffs['] efforts to hold Pfizer liable for the advertisements conflicts with the FDA's jurisdiction over drug labeling, and specifically its approval of Lipitor to reduce the risk of heart disease in some patients. Those claims are therefore preempted by federal law.

Id. at 1234.[4] And in *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378 (6th Cir. 2013), the court directly acknowledged that "advertising and promotional materials are considered labeling, and because labeling is limited by federal law to the information contained in the brand-name drug's labeling," claims based on such materials—including claims that are not brought under a "failure to warn theory"—are preempted. *Id.* at 394 (rejecting, as "unpersuasive," the lower court's

[4] The court in *Prohias* further held that "given the FDA's additional approvals of Lipitor, namely, to reduce the risk of heart attacks in certain patients, Pfizer's . . . advertisements were not misleading as a matter of law. The information included in the labeling of a new drug reflects a determination by the FDA that the information is not 'false or misleading.' Thus, even if the advertisements did not comport precisely with Lipitor's approved label by claiming that Lipitor reduces the risk of coronary heart disease, the alleged advertisements generally comport with the approved label, and are therefore not misleading as a matter of law." 490 F. Supp. 2d at 1235 (citations omitted).

reasoning that breach-of-warranty claims avoid federal preemption to the extent that they are 'not premised on the inadequacy of the label but rather on the product's failure to live up to or conform to its label and advertising'").

Other cases cited in Defendants' Motions to Dismiss are in accord.[5] The State cannot avoid preemption simply by asserting that it "does not make any allegations about what Defendants' labels state or fail to state." Resp. at 14. The State's claims implicate and challenge Defendants' FDA-approved labeling by seeking to hold Defendants liable for marketing an FDA-approved use and for providing the risk information FDA determined is supported for inclusion in the labeling.

2. The State's Allegations Are Preempted Because They Directly Conflict with FDA's Labeling Decisions.

The marketing and promotional statements that the State now challenges are consistent with the labeling and indications 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* Joint MTD at 13-15; Purdue MTD at 6; Ex. 1 at 6-17. Specifically, in responding to the PROP Petition, FDA reviewed whether scientific evidence supports the use of opioids for the treatment of chronic non-cancer pain, and concluded that it did. Ex. 1 at 6-17. FDA explicitly

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[5] *See, e.g., In re Celexa & Lexapro Mkt'g & Sales Practices Litig.*, 779 F.3d 34 (1st Cir. 2015) (consumer fraud claims were preempted); *see also McLaughlin v. Bayer Corp.*, No. CV 14-7315, 2017 WL 697047, at *12-15 (E.D. Pa. Feb. 21, 2017) (recognizing that "[t]o state a misrepresentation claim that was not expressly preempted, Plaintiffs would need to 'allege that Bayer made false or misleading statements in unapproved advertising or other promotional materials that were inconsistent with specific statements in approved FDA materials and that undermined the approved and required statements in those materials'"; concluding that fraudulent misrepresentation claims based on defendant's advertising statements were preempted because they were "completely consistent with statements in FDA-approved materials and do not undermine—or overstate—the approved and/or required statements in those materials" (citations omitted)).

rejected PROP's request for a labeling distinction between use of opioids for cancer-related and non-cancer-related pain, stating its view that "a patient without cancer, like a patient with cancer, may suffer from chronic pain," and that it "knows of ***no physiological or pharmacological basis upon which to differentiate the treatment of chronic pain in a cancer setting or patient from the treatment of chronic pain in the absence of cancer.***" *Id.* at 9. And, "[a]fter a review of the literature cited in the Petition, and an assessment of other relevant information . . . FDA [] determined that ***limiting the duration of use for opioid therapy to 90 days is not supportable.***" *Id.* at 14. In light of these findings, the State's contention that "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," Resp. at 15, is plainly incorrect. Resp. at 15.[6]

FDA's response to the PROP Petition represents "clear evidence" that FDA would not have approved the type of labeling or marketing statements that the State's claims would require Defendants to make in order to avoid being misleading or deceptive. *Cerveny*, 855 F.3d at 1105; *Risperdal*, 2017 WL 4100102, at *11 (where citizen's petition had been denied, finding "clear evidence" that plaintiff's "entire theory" of liability "was not only considered and rejected by the FDA but also rests on information (and allegations) known to the FDA and the medical community. . . . It is not this Court's job to revisit a decision made by the FDA"). The State's claims therefore are preempted by federal law under the Supremacy Clause of the U.S. Constitution.

[6] To the extent the State were to allege that there is "a particular piece or selective slice of data" that FDA may not have seen, this would also be "insufficient to rebut a finding of preemption" where, as here, FDA has generally considered the available data on the risks and benefits of long-term use of opioid medication. *Risperdal*, 2017 WL 4100102, at *9.

B. Any Remaining Claims Should be Stayed Under the Primary Jurisdiction Doctrine.

In the event the Court finds that any of the State's claims are not preempted, they should be stayed under the primary jurisdiction doctrine. As explained in Defendants' Primary Jurisdiction Motion, the primary jurisdiction doctrine applies "whenever enforcement of [a] claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." Prim. Jur. Mot. at 8 (quoting *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63-64 (1956)). Application of the doctrine is particularly appropriate where, as here, a plaintiff challenges the benefits and risks of prescription drugs. *See Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 654 (1973). Because the "[e]valuation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background," such "[t]hreshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand." *Id.* at 653-54 (invoking primary jurisdiction doctrine).

As a California court held in previously staying an action nearly identical to this one, the State's claims that Defendants "downplayed the risks of addiction and touted unsubstantiated benefits of long-term opioid treatment," Resp. at 1, are "convoluted, exacting, expertise driven, issue expanded, [and] nuanced." *People v. Purdue Pharma L.P.*, No. 201400725287, 2015 WL 5123273, at *2 (Cal. Super. Ct. Orange Cty. Aug. 27, 2015). The court held that "[t]he patients, potential patients, and the medical community deserve more" than an effort by the court to decide these medical and scientific issues: "This action could lead to inconsistencies with the FDA's findings, inconsistencies among the States, a lack of uniformity, and a potential chilling effect on the prescription of these drugs for those who need them most." *Id.* In granting a stay, the court noted that it "does not shrink from its responsibilities to handle complex, convoluted

litigation . . . . It does, however, take pause at involving itself in an area which is best left to agencies such as the FDA who are designed to address such issues." *Id.*[7] This Court should do the same.

The State's reliance on an Illinois federal court in a similar case denying a stay on primary jurisdiction grounds is unavailing. *Id.* at 3, 17, 19-20, 23. What the State and the Illinois court both fail to explain is how a court can assess whether a Defendant misstated the relative risks and benefits of long-term opioid use—an issue FDA has addressed already in repeatedly approving that use and requiring specific labeling language about the serious known risks—without countermanding FDA's repeated determinations approving the medications for that use or deciding the disputed scientific questions currently under FDA review. Indeed it cannot.

As it should, FDA has engaged, and continues to engage, in an evaluation of opioid analgesics. *See* Prim. Jur. Mot. at 5-6. The post-market studies presently overseen by FDA will address the very issues on which this litigation turns. *Id.* at 6, 11-15. The State concedes that the post-market studies will "'further the understanding of the known serious risks of opioid misuse, abuse, overdose and death.'" Resp. at 3.[8] And the State agrees that "the issue to be decided by these studies is whether further opioid labeling changes are warranted." *Id.* at 22. The State thus acknowledges that FDA is actively assessing whether Defendants should provide different or additional information to physicians about the risks and benefits of their opioid medications than what the current labeling provides. The State attempts to minimize the ongoing post-market

[7] As noted in Defendants' Primary Jurisdiction Motion, the California court ultimately lifted the stay for the limited purpose of allowing the defendants to submit additional demurrers challenging the sufficiency of the complaint. Briefing is currently underway in the case.

[8] Quoting FDA News Release, "Califf, FDA top officials call for sweeping review of agency opioids policies" (Feb. 4, 2016), available at https://www.fda.gov/newsevents/newsroom/press announcements/ucm484765.htm.

studies by mischaracterizing the Petition, FDA's ongoing investigation, and the governing case law. The Court should reject that effort.

1. The Petition Presents Complex Scientific Issues That Are Best Resolved by FDA.

This lawsuit is not, as the State claims, a routine case of allegedly "fraudulent marketing practices," Resp. at 17, because the science concerning the benefits and risks of chronic opioid therapy is evolving and far from settled. The Court cannot determine whether Defendants misled consumers and doctors by "downplayi[ing] the risks of addiction and tout[ing] unsubstantiated benefits of long-term opioid treatment," as the State urges, *id.* at 1, when scientists and doctors dispute what those benefits and risks are and how they should be weighed. FDA acknowledged the unsettled nature of the science in its 2013 response to the PROP Petition—and again in February 2016—concluding that "more data are needed" about the benefits and risks of long-term opioid use. Ex. 1 at 1; *see also* Ex. 6 at 1.

To resolve the State's claims, the Court and/or trier-of-fact would need to weigh the benefits and risks of chronic opioid therapy. These "complex chemical and pharmacological considerations" are best left to FDA, the expert federal agency charged with making such assessments. *See Weinberger*, 412 U.S. at 653-54. The State is therefore wrong in asserting that the issues presented in this lawsuit are not within the unique expertise or particular discretion of FDA. Resp. at 17-19. Courts routinely invoke the primary jurisdiction doctrine in cases involving false and deceptive marketing where resolution of an issue central to the purported fraud is within the authority of FDA. *See* Prim. Jur. Mot. at 9-10. In fact, in staying a parallel action in deference to FDA, a California court rejected the very argument made by the State here:

> The fundamental premise of the plaintiff's opposition[] (that since this case only deals with false or misleading marketing and therefore that is well within the realm of what a California court should take on under the dictates of the consumer statutes) is incorrect. As the second amended complaint clearly shows, this case is

> about determining what the public and doctors need[] to be told about opioids. That determination necessar[ily] entails much more than determining issues of false and misleading marketing. Underlying every issue here, this case requires this court to become an expert in the field in which it has no expertise. . . .
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> [W]hile it is certainly true that the FDA did not, and will not, rule on the propriety of the marketing which defendants employ, that, once more, is not the issue on this motion. The issue on this motion is what determinations this court will need to make to rule on the propriety of the marketing. All of those determinations fall within the purview of the FDA.

Purdue, 2015 WL 5123273, at *1-2.

The State cites a number of inapposite cases to support its argument that "evaluating materials that market FDA-regulated products does not require the FDA's expertise." Resp. at 17-18. None of those cases required the resolution of disputed scientific issues or had issues presently pending before FDA. Specifically, none of these cases involved situations, like here, where FDA is taking an active role in examining complex scientific issues surrounding balancing the needs of patients for effective pain medication and the potential downsides to those drugs. For example, in *In re Frito-Lay N. Am., Inc. All Nat. Litig.*, No. 12-MD-2413 RRM RLM, 2013 WL 4647512 (E.D.N.Y. Aug. 29, 2013), the court declined to apply the primary jurisdiction doctrine in considering whether a food was deceptively advertised as being "natural" because FDA had explicitly stated that it was "not undertaking rulemaking to establish a definition for 'natural.'" *Id.* at *7. Similarly, in *In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practice Litig.*, 955 F. Supp. 2d 1311 (S.D. Fla. 2013), the court chose not to apply the primary jurisdiction in an area in which "FDA has shown virtually no interest in regulating." *Id.* at 1347-51. The other cases that the State cites applied similar reasoning.[9] FDA's determination of the

[9] *See, e.g., In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. 05-1699 CRB, 2006 WL 2374742, at *12 (N.D. Cal. Aug. 16, 2006) (considering whether advertising statements that contravened findings made by FDA were false and misleading); *Jasper v. MusclePharm Corp.*, No. 14-CV-02881-CMA-MJW, 2015 WL 2375945, at *4 (D. Colo. May *(cont'd)*

risks and benefits of opioid therapy for chronic non-cancer pain will aid the Court and/or trier-of-fact in determining whether any alleged marketing statements (which have not been pled with the requisite specificity) about opioid use for chronic pain were false, thereby enhancing judicial decision-making and efficiency.

The State's attempts to distinguish the cases cited in Defendants' Primary Jurisdiction Motion are similarly unpersuasive. For example, the State argues that the courts' holdings in *Weinberger* and *Imagenetix, Inc. v. Frutarom USA, Inc.*, No. 12-CV-2823-GPC(WMC), 2013 WL 6419674 (S.D. Cal. Dec. 9, 2013), should not apply because those cases involved questions of "whether a product meets FDA regulatory criteria." Resp. at 18-19. And it argues that *Gisvold v. Merck & Co.*, 62 F. Supp. 3d 1198 (S.D. Cal. 2014), is distinguishable because it "relate[d] to the FDA's investigation into future labeling changes." *Id.* at 19. But these are distinctions without a difference. At bottom, each of the State's claims will require a determination of the risks and benefits of opioid medications for the treatment of chronic non-cancer pain. Like the questions of whether a product meets regulatory criteria or should undergo labeling changes, these questions "necessarily implicate[] complex chemical and pharmacological considerations . . . [that are] within the peculiar expertise of" FDA. *Weinberger*, 412 U.S. at 654. The Court thus should "stay[] its hand" pending FDA's consideration of these issues. *Id.*

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15, 2015) (noting that argument for application of primary jurisdiction doctrine was particularly weak because FDA did not have an open investigation into the qualities of the product); *Ivie v. Kraft Foods Glob., Inc.*, 961 F. Supp. 2d 1033, 1045 (N.D. Cal. 2013) (doctrine did not apply because "plaintiff's case does not require this court to determine difficult issues of first impression better left to the FDA's expertise, but instead only requires the application of well-understood FDA regulations directly on point"); *Zapka v. Coca-Cola Co.*, No. 99 C 8238, 2001 WL 1558276, at *6 (N.D. Ill. Dec. 5, 2001) (declining to apply doctrine to case calling for a determination of whether defendant's representation regarding the ingredients in its soda were literally false, without requiring reference to FDA findings or determinations).

2. The Issues Raised in the Petition Are Within FDA's Administrative Discretion and Are Currently Pending Before FDA.

Courts frequently apply the primary jurisdiction doctrine where the issues raised in an action are pending before an administrative agency. *See* Prim. Jur. Mot. 8-10 (citing cases). The State's suggestion that no relevant issues are presently before FDA because FDA has ruled on the PROP Petition, Resp. at 20, is simply wrong. Courts do not require that a formal petition be pending before the agency in order to invoke the primary jurisdiction doctrine. *See, e.g., Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760-62 (9th Cir. 2015) (affirming lower court's invocation of primary jurisdiction doctrine where it appeared that "new guidance would be forthcoming," despite lack of formal proceedings); *Belfiore v. Proctor & Gamble Co.*, 311 F.R.D. 29, 79 (E.D.N.Y. 2015) (staying case in favor of FTC's primary jurisdiction where FTC was conducting an informal inquiry into defendant's labeling and had entered a draft consent order with another manufacturer). FDA's ruling on the PROP Petition demonstrates that FDA has exercised—and continues to exercise—its jurisdiction over opioid medications through labeling modifications, mandated post-market safety studies, and changes to Risk Evaluation and Mitigation Strategy (REMS) prescriber education materials. Ex. 1 at 6-8, 10. FDA has ordered the post-market studies to "determine whether additional action needs to be taken." *Id.* at 10-11. Also wrong is the State's suggestion that the studies have "no bearing on Defendants' prior conduct," and will—at most—lead to future labeling changes. Resp. at 21, 22-23. The information the studies will provide regarding the meaning and context of Defendants' alleged previous statements, whether the information predates or postdates those statements, will benefit the Court and/or trier-of-fact.

3. Staying This Case in Deference to FDA's Ongoing Inquiry Will Serve the Purposes of the Primary Jurisdiction Doctrine.

Because the post-market studies will provide important, additional data about the risks and benefits of long-term opioid treatment that are at the heart of this case, staying this action will advance the purpose of the primary jurisdiction doctrine. The stay will not only enhance judicial decision-making and efficiency by allowing the Court to take advantage of FDA's expertise, as discussed above, but will also ensure uniform application of regulatory laws by avoiding determinations inconsistent with those of FDA and other states. *See United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64-65 (1956), *Williams Pipe Line Co. v. Empire Gas Corp.*, 76 F.3d 1491, 1497 (10th Cir. 1996).

The State simply is incorrect that there is no risk of inconsistent determinations. A determination that Defendants' marketing of opioids for chronic non-cancer pain was fraudulent would be flatly inconsistent with an FDA finding that opioids are safe and effective for chronic non-cancer pain, based on forthcoming post-market studies. As the California court recognized when staying a parallel action, "[t]his action could lead to inconsistencies with the FDA's findings, inconsistencies among the States, a lack of uniformity, and a potential chilling effect on the prescription of these drugs for those who need them most." *Purdue*, 2015 WL 5123273, at *2.[10]

The State argues that adjudication of this case does not "risk inconsistency in the regulation of business entrusted to the FDA" because "[t]he State's claims are brought solely

[10] Even if FDA later determines that the science does not support some of the challenged representations, the State still would need to establish that Defendants knew any such representation was false when made, or recklessly made any such representation without knowledge of its truth or falsity. *See, e.g., Bowman v. Presley*, 2009 OK 48, ¶ 13, 212 P.3d 1210, 1218 (among other elements, fraud claim requires "a false material misrepresentation . . . which is either known to be false or is made recklessly without knowledge of the truth").

under Oklahoma law" and, in the State's view, "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." Resp. at 22-23 (citing *Edwards v. Basel Pharm.*, 1997 OK 22 ¶ 17, 933 P.2d 298, 302, and *Wyeth*, 55 U.S. at 574). The State has it wrong. The State's claims under Oklahoma law all turn on whether Defendants' alleged statements regarding the risks and benefits were false and misleading. To adjudicate those claims, the Court would first be required to determine the benefits and risks of opioid pain medications—issues that are uniquely within FDA's realm of expertise, and which FDA has examined and continues to examine. A finding by this Court as to whether Defendants misrepresented the risks and benefits of opioid medications would risk inconsistency with the results of the FDA-mandated post-marketing studies, and with other state and federal courts considering the same issues. The mere fact that the State's claims are brought under Oklahoma law does not eliminate that risk.

The State further argues that there is no risk of inconsistent rulings because "[t]his 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." Resp. at 23. To support this proposition, the State cites *Frydman v. Portfolio Recovery Assocs., LLC*, No. 11 CV 524, 2011 WL 2560221, at *6 (N.D. Ill. June 28, 2011). Resp. at 23 ("[A]ny change in the [agency] rules . . . would apply prospectively, eliminating the danger of inconsistent rulings."). But *Frydman* did not involve claims, like those asserted here, that statements consistent with existing agency rules were false or misleading. Here, although any changes to FDA's labeling requirements would only apply prospectively, the results of the ongoing FDA studies are important to ensure that the Court does not render findings inconsistent with the outcome of

these comprehensive studies and the determinations rendered by FDA. Staying this case under the primary jurisdiction doctrine would allow the Court to avoid the risk of making findings inconsistent with those of the FDA pending outcome of these studies.

C. The Court Should Stay This Proceeding Pursuant to Its Inherent Authority.

For all the reasons discussed above, the Court should also stay any claims it finds not to be preempted pursuant to its inherent authority. This case is anything but routine. The public health issues bound up in the Petition's allegations are "of extraordinary public moment," directly affecting "the public welfare," and should be decided by FDA experts before this case proceeds. *Landis v. N. Am. Co.*, 299 U.S. 248, 256 (1936).

Staying this case would promote the policies articulated in *Landis* by permitting the FDA-mandated studies to provide critical facts about scientific issues that are "great in their complexity, [and] great in their significance." *Id.* The public's right to access an important class of drugs, challenged here, exemplifies an issue of "extraordinary public moment" that merits a stay under *Landis*. *Id.* Indeed, another court has already concluded that the outcome of parallel litigation would directly affect "the public's right to access this apparently important set of [opioid] drugs" and could lead to "a potential chilling effect on the prescription of these drugs for those who need them most." *Purdue*, 2015 WL 5123273, at *2. A stay, moreover, would provide an "economy of time and effort for [the Court], for counsel, and for litigants." *Landis*, 299 U.S. at 254. As described above, litigating this case now would require this Court and/or trier-of-fact to judge complex medical and pharmacological issues—all while FDA itself evaluates the very same issues. Because the post-market studies will provide data critical to evaluating the challenged statements, and awaiting their outcome will help avoid "inconsistencies with the FDA's findings . . . [and] among the States," *Purdue*, 2015 WL 5123273, at *2, a stay will promote "the public welfare," *Landis*, 299 U.S. at 256. Even if the FDA-mandated studies "may

not settle every question of fact and law" presented by the Petition, they would "in all likelihood . . . settle many and simplify them all." *Id.*

The State argues that a stay would "unnecessarily delay this case and prejudice the State" and its residents who are experiencing opioid addiction. Resp. at 24. But the interests at issue here are not one-sided. They instead implicate—in FDA's words—a "difficult balancing act" between "two complementary principles": first, the government's fight against opioid misuse and, second, the need to "protect the well-being of people experiencing the devastating effects of acute or chronic pain." Ex. 3 at 1. The State gives short shrift to the latter concern.[11]

The State's claims are based on its assertion that opioids are too addictive and inappropriate for long-term use to treat chronic non-cancer pain. *See, e.g.*, Pet. ¶ 3, 68-69. The outcome of this case, therefore, will directly affect thousands of Oklahoma residents dealing with chronic pain and has the potential to create inconsistences—both with FDA and among the states—adversely affecting millions of pain patients across the country. A decision by this Court on the State's claims would short-circuit FDA's current examination of whether the risks of opioids outweigh their benefits in the treatment of chronic pain. The Court should not risk making findings inconsistent with those of the expert federal agency actively addressing these

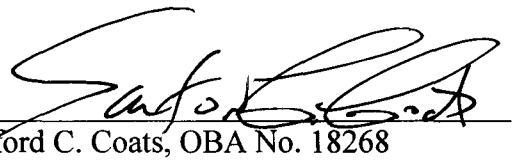
[11] The State also argues that "it would be highly prejudicial to prevent the State of Oklahoma from fully developing the facts surrounding the allegations in the Petition" because doing so would "cause Oklahoma to fall behind" other states and Attorneys General to whom Defendants have agreed to provide discovery. Resp. at 25. But the State provides no explanation for why it would be disadvantaged by having to wait to conduct discovery until after FDA has completed its studies. Nor does it provide any explanation for why this Court should consider the fact that discovery has been allowed in other forums in assessing the merits of a stay here. In particular, the State's argument regarding discovery does not address the risk of inconsistent rulings that would arise if a stay were not issued. It also ignores the unnecessary burden that would be imposed on Defendants if discovery were allowed to proceed prior to the completion of the post-marketing studies.

issues. As the California court succinctly put it: "The patients, potential patients, and the medical community deserve more." *Purdue*, 2015 WL 5123273, at *2.

III. CONCLUSION

For the reasons set forth above and in Defendants' Joint Motion to Dismiss, Purdue's Motion to Dismiss, and Defendants' Primary Jurisdiction Motion, the Court should dismiss the State's claims as preempted by federal law, or, in the alternative, stay any remaining claims under the primary jurisdiction doctrine and the Court's inherent authority to stay proceedings.

Respectfully submitted,

By: 

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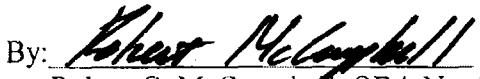
By: 

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