IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, *ex rel.*, MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, v. PURDUE PHARMA L.P., *et al.*, Defendants.	Case No. CJ-2017-816

DEFENDANTS PURDUE PHARMA L.P., PURDUE PHARMA INC. AND THE PURDUE FREDERICK COMPANY INC.'S NOTICE OF FILING NOTICE OF REMOVAL

TO: The above named Plaintiff, and said Plaintiff's attorney of record:

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YOU, AND EACH OF YOU, WILL TAKE NOTICE, that on the 13th day of June, 2018, Defendants PURDUE PHARMA L.P., PURDUE PHARMA INC. AND THE PURDUE FREDERICK COMPANY INC. filed with the Clerk of the United States District Court for the Western District of Oklahoma, styled *STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA v. PURDUE PHARMA L.P., et al.*, their Notice of Removal, together with copies of all process, pleadings and orders filed in the case or served

upon it in the above-captioned case. A true and correct copy of such Notice of Removal is attached hereto as Exhibit A (without exhibits).

DATED this 13th day of June, 2018.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the above and foregoing was emailed this 13th day of June, 2018 to:

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

(1) STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, v. (1) PURDUE PHARMA L.P.; (2) PURDUE PHARMA, INC.; (3) THE PURDUE FREDERICK COMPANY, INC.; (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.	CIV-18-_____-___

DEFENDANTS PURDUE PHARMA L.P., PURDUE PHARMA INC., AND THE PURDUE FREDERICK COMPANY'S NOTICE OF REMOVAL

Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company (together "Purdue"), by their undersigned attorneys, hereby give notice of removal of this action, pursuant to 28 U.S.C. §§ 1331, 1441, and 1446, from the District Court of Cleveland County, Oklahoma, to the United States District Court, Western District of Oklahoma. As grounds for removal, Purdue states as follows:

PRELIMINARY STATEMENT

Federal question jurisdiction exists in this case because the State's recent Responses and Objections to Purdue Pharma Inc.'s First Set of Interrogatories ("Interrogatory Responses") revealed—for the first time—that the State's lawsuit involves state law claims that are inextricably tied to substantial disputed federal questions. The State's Interrogatory Responses makes clear that the State is attempting to supplant the U.S. Food & Drug Administration's ("FDA") complex regulatory determinations and federal administrative prerogatives with the State's contrary assessment regarding how Defendants' opioids should be regulated, labeled, and marketed. In doing so, the State seeks to use Oklahoma state law to require that Defendants convey ***different*** information about the safety and efficacy of their opioid medications and ***different*** packaging for those medications in Oklahoma than what the FDA has required in Oklahoma and every other state in the country. These requested remedies give rise to federal question jurisdiction pursuant to 28 U.S.C. § 1331 because they require the Court to second guess the FDA by reassessing, reevaluating, and revamping the FDA's prior federal regulatory determinations. *See McKay v. City & Cty. of San Francisco*, 2016 WL 7425927, at *4-5 (N.D. Cal. 2016).

A federal multidistrict litigation ("MDL") has been created in the Northern District of Ohio (before Judge Polster) to coordinate several hundreds of cases involving claims similar to those here. *See In re Nat'l Prescription Opiate Litig.*, MDL No. 2804 (Sept. 25, 2017), Dkt. # 328. Notably, one of the cases currently pending in the MDL, *State of Montana v. Purdue Pharma L.P.*, was originally filed in state court and removed to the District Court of Montana on similar federal question grounds. The State of Montana moved to remand the case and the federal district court in Montana thereafter denied the remand motion without prejudice to renewal, if appropriate, before the MDL court. *State of Montana v. Purdue Pharma L.P.*, No. 1:18-OP-45604-DAP (D. Mont. March 6, 2018), Dkt. 20.

To the extent that the State here moves to remand, this Court should follow the approach taken by the court in *Montana* and deny the motion without prejudice and allow the case to be transferred to the MDL where the remand motion will be heard. Allowing one court to decide the similar jurisdictional questions in *Montana* and this case would serve the interests of both judicial efficiency and consistency.

The grounds for removal are as follows:

1. The State of Oklahoma, through its Attorney General's Office (the "State"), filed this action on June 30, 2017, in the District Court of Cleveland County, Oklahoma. A copy of the Summons, Petition, and all processes, pleadings, and orders served on Purdue are attached hereto as part of Exhibits 5 through 167, and the Cleveland County District Court docket sheet is Exhibit 168.

2. The State alleges that Defendants fraudulently promoted its opioid medications. In addition to seeking damages and civil penalties, the State fleetingly states in its Petition that it seeks an "[i]njunction against Defendants from violating the Oklahoma Consumer Protection Act." Pet. at p. 31 (Prayer for Relief, Section H). Yet the State provided no details concerning the specific injunctive relief that it sought.

3. On April 18, 2018, Purdue Pharma Inc. propounded its First Set of Interrogatories (the "Interrogatories"). Interrogatory No. 1 stated: "Describe the complete public nuisance abatement and the complete injunctive relief that You seek, if any, including in Your description the nature, terms, and scope of the relief sought, any conduct that You seek to prohibit, and any affirmative conduct You seek to compel." Interrogatories at 5 (attached as Exhibit 1).

4. On May 21, 2018, the State responded to the Interrogatories. In response to Interrogatory No. 1, the State stated in relevant part that the "necessary injunctive relief" it seeks includes, but is not limited to, requiring Defendants to both (i) "[a]bid[e] by CDC or other government guidelines related to opioids in all communications (written or oral) with health care providers," and (ii) "[p]ackag[e] prescription opioids in blister packs or other package to limit accelerated use." Resp. to Interrogatories at 46 (attached as Exhibit 2).

5. The State requests that the court order Defendants to make statements, both written and oral, to physicians on an on-going prospective basis about their opioid medications that abide by, *inter alia*, non-binding prescribing guidelines for primary care

clinicians issued by the U.S. Department of Health and Human Services, Centers for Disease Control ("CDC") (hereinafter, "CDC Guidelines"). *Id.* But the CDC has no regulatory authority over Defendants or any prescription medications, including opioid pain medicines. Instead, Congress has mandated that only the FDA has the regulatory authority to determine the safety and efficacy of prescription medications, including exclusive regulatory authority to determine what manufacturers must disclose in product labeling and promotional materials and exclusive ongoing regulatory responsibilities to monitor drugs post-approval. 21 U.S.C. §§ 301, *et seq.*; *id.* § 393(b)(2)(B). The State's requested relief runs counter to the FDA's own assessment and findings concerning Defendants' prescription opioids and their labeling under federal law. The requested relief also impermissibly seeks to confer regulatory jurisdiction on the CDC under the guise of state law, undoubtedly an important federal issue.

6. The State also requests the Court to require Defendants to package their medications in blister packs or other packaging that will limit the amount of medication that can be prescribed at a given time. Once again, the FDA has the exclusive regulatory authority to decide what packaging, such as blister or unit-of-dose packaging, is appropriate and under what circumstances. The federal regulatory scheme recognizes that placing medication in blister packs or other packaging to limit their use can affect the stability of the medication and thus can fundamentally affect the integrity of the medication. In order for a pharmaceutical manufacturer to change its medication packaging, it would be required to submit a Supplemental New Drug Application to the

FDA and obtain prior FDA approval for the change. *See* 21 C.F.R. §§ 314.70(b)(1) & (b)(2)(vi).

7. In order to comply with federal law, and avoid the risk of being held liable for manufacturing an unapproved new drug in violation of federal law, prior FDA approval would be required for a change from bottles to a blister package and stability data sufficient to satisfy the FDA would be required in order to obtain FDA approval. For instance, 21 C.F.R. § 314.70(b)(2)(vi) specifically provides that FDA must approve any "***[c]hanges in a drug product container closure system that controls the drug product delivered to a patient or changes in the type*** (e.g., glass to high density polyethylene (HDPE), HDPE to polyvinyl chloride, vial to syringe) or composition (e.g., one HDPE resin to another HDPE resin) ***of a packaging component*** that may affect the impurity profile of the drug product." (Emphasis added.) So, too, among other things, 21 C.F.R. § 314.50(d)(1)(ii)(a) requires "stability data" to support blister packaging.

8. While the State's Petition purports to contain state law claims only, the State's Interrogatory Responses demonstrate the specific relief the State seeks through this lawsuit—information not otherwise specified in its original pleading—raises substantial federal questions. *See, e.g., Akin v. Ashland Chem. Co.*, 156 F.3d 1030, 1035 (10th Cir. 1998).

9. As we now know through the State's Interrogatory Responses, the State challenges the FDA's determination as to what doctors should be told about the risks and benefits of Defendants' opioid medications, and the FDA's evaluation as to how the

medications should be packaged and dispensed. These claims amount to a "collateral attack on the validity of [a federal agency's] decision," and the State "can only succeed ... if [it] establish[es] that the agency decision was incorrect." *Bader Farms, Inc. v. Monsanto Co.*, 2017 WL 633815, at *3 (E.D. Mo. 2017); *Citizens All. to Save Southline v. Montana Rail Link, Inc.*, 672 F. Supp. 1576, 1579 (D. Mont. 1987). "Under these circumstances," the State's claims "present[] a substantial federal question." *Bader*, 2017 WL 633815, at *3. And because the State would have the court make the CDC Guidelines binding on manufacturers "in all communications (written or oral) with health care providers," the State's claims impermissibly seek to confer regulatory jurisdiction on the CDC to cover ***all*** opioid related communications—when, in reality, Congress gave it no such regulatory power.

10. As such, removal is proper. This Court has original jurisdiction pursuant to 28 U.S.C. § 1331 because there is federal question jurisdiction over the State's claims. Removal is also timely because Purdue filed this Notice of Removal within 30 days from the service of the State's Interrogatory Responses. Under 28 U.S.C. § 1446(b)(3), "a notice of removal may be filed within thirty days after receipt by the defendant, through service or otherwise, of a copy of an amended pleading, motion, order or ***other paper*** from which it may first be ascertained that the case is one which is or has become removable." 28 U.S.C. § 1446(b)(3) (emphasis added). As the Sixth Circuit recognized in *Berera v. Mesa Med. Grp., PLLC*, "'answers to interrogatories' ... may constitute 'other papers' under § 1446(b)(3)." 779 F.3d 352, 365 (6th Cir. 2015) (citation omitted).

11. The Tenth Circuit's decision in *Akin* is instructive. 156 F.3d 1030 (10th Cir. 1998). In *Akin*, defendants removed the case more than 30 days after the initial pleading, but within 30 days of the plaintiff's answer to an interrogatory, which revealed that there was federal question jurisdiction. The plaintiff moved to remand, arguing that removal was untimely. The district court denied the remand motion and the Tenth Circuit affirmed. The Tenth Circuit reasoned that it was "only after receipt of 'other paper'—in this case answers to interrogatories—were defendants provided sufficient notice that" there was a federal question. *Id.* at 1035. "We agree that the initial pleading in this case was ambiguous in that it did not provide unequivocal notice of the right to remove, and that the first clear notice of removability was given in answer to an interrogatory." *Id.* So, too, here.

FEDERAL QUESTION JURISDICTION

12. This Court has "federal question" jurisdiction pursuant to 28 U.S.C. § 1331 and the principles set forth in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005). Under *Grable*, there is federal question jurisdiction over a case involving state-law claims if any of the state-law claims necessarily raises a federal question "actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id.* at 314. This "captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the

experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id.* at 312. As set forth below, the *Grable* requirements are each met here.

A. SUBSTANTIAL FEDERAL ISSUES ARE EMBEDDED IN THE STATE'S CLAIMS

i. The FDA Has Exclusive Authority to Regulate Defendants' Opioid Medications

13. Defendants' opioid medications are subject to extensive regulation by the FDA under the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, and the federal regulations promulgated thereunder. *See* 21 C.F.R. §§ 1.1, *et seq.* The purpose of the FDCA is to establish uniform nationwide standards for the regulation of pharmaceutical medications, in order to "promote" and "protect the public health by ensuring that ... human ... drugs are safe and effective." 21 U.S.C. § 393(b).

14. The FDA must approve any prescription medication before it is marketed or sold. 21 U.S.C. § 355(a). As part of this approval process, the FDCA requires the FDA to ensure that "drugs are safe and effective" for their approved intended uses, *id.* § 393(b)(2)(B), in part by "promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products," *id.* § 393(b)(1). Furthermore, post-approval, the FDA has exclusive regulatory authority to engage in broad post-marketing surveillance and risk assessment programs to monitor and ensure the continued safety of prescription medications. *Id.* §§ 314.80 *et seq.*

15. The FDA has exclusive regulatory authority to determine the precise content of prescription drug labeling (*e.g.*, the instructions, warnings, precautions,

adverse reaction information provided by manufacturers, and marketing materials). 21 U.S.C. §§ 301 *et seq.*; *id.* § 393(b)(2)(B).

16. The Supreme Court has recognized that, under the FDCA and its implementing regulations, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times," while "the FDA retains authority" to approve or reject labeling changes. *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009). The FDA has described the manufacturer's FDA-approved labeling as one of the most important written communications made to physicians.

> Under the [FDCA], FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading. Under the act and FDA regulations, the agency makes approval decisions based not on an abstract estimation of its safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (21 U.S.C. 355(d)).
> ...
> The centerpiece of risk management for prescription drugs generally is the labeling, which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively in accordance with the act. FDA carefully controls the content of prescription drug labeling, because such labeling is FDA's principal tool for educating health care practitioners about the risks and benefits of the approved product to help ensure safe and effective use.

Food and Drug Administration, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934, 3968 (Jan 24, 2006).

17. Once approved, pharmaceutical medications must be promoted and sold consistent with their labeling to ensure the provision of accurate information about the medications' comparative risks and benefits. 21 C.F.R. § 202.1(e)(4). If a pharmaceutical manufacturer's promotional messaging is inconsistent with the safety and risk information contained in the FDA-approved labeling, the prescription medication may be considered misbranded under federal law. 21 U.S.C. § 352. The penalties for selling a misbranded prescription medication are significant and include civil fines, injunctions and seizures, and in some instances, criminal prosecution. 21 C.F.R. §§ 333(b) & 334.

18. The FDA also has exclusive regulatory authority to determine how prescription medications should be packaged. *See* 21 C.F.R. §§ 314.70(b)(1) & (b)(2)(vi). In order to use blister packs for its medication—as the State seeks to compel through a prospective court-ordered injunction—a pharmaceutical manufacturer must seek and obtain FDA approval to do so. As part of its application to the FDA, stability data must be provided to the FDA to permit the FDA to determine that the medication remains safe and effective in that type of packaging, as opposed to another type of packaging, such as bottles. *See* 21 CFR § 314.50(d)(1)(ii)(a). In addition, if a manufacturer were to seek FDA approval to change its packaging, it would also need to submit a Supplemental New Drug Application to the FDA to change the medication's labeling and, again, obtain FDA approval. This is because, among other things, a

medication's labeling must describe how the medication is packaged. *See* 21 C.F.R. § 201.57(c)(17)(i)-(iv).

ii. The State's Allegations and Requested Prospective Injunctive Relief

19. Under the guise of asserting state law claims, the State's Interrogatory Responses make clear that it is directly challenging the FDA's decision under the FDCA to approve Defendants' opioid medications as safe and effective for their indicated uses, as well as the FDA's approval of the labeling for those medications. Through the broad and prospective injunctive relief it seeks, the State attempts to supplant the FDA's regulatory directives about what information Defendants must communicate to doctors and patients about the safety, efficacy, and appropriate prescribing and use of their medications.

a. CDC and Other Governmental Guidelines

20. Specifically, as first revealed in its Interrogatory Responses, the State seeks an order requiring that Defendants "[a]bid[e] by CDC or other government guidelines related to opioids in all communications (written or oral) with health care providers." Ex. 2 at 46. The CDC Guidelines, however, include statements that are inconsistent with the FDA's approval of Defendants' opioid medications.

21. For example, the CDC Guidelines assert that "[w]hen starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of

extended-release/long-acting (ER/LA) opioids." [1] Yet in contrast to the CDC Guidelines, the FDA-approved labeling for some of the Defendants' ER/LA opioid medications (*e.g.*, Purdue's Butrans) expressly provides that doctors may start appropriate patients with these medications at a particular dose.[2]

22. Similarly, the FDA's instructions to physicians on the uses of a product are set forth in the "Indications and Usage" section of the product insert. For example, FDA instructs physicians that "OxyContin is an opioid agonist indicated for pain severe enough to require daily, around-the-clock, ***long-term*** opioid treatment and for which alternative treatment options are inadequate."[3] The CDC Guidelines, however, instruct physicians that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later [and] Extensive evidence shows the possible harms of opioids."[4] The FDA, which has the regulatory oversight, does not agree with CDC's position. For instance, in 2013, the FDA noted that there were numerous studies that suggested that some patients taking

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[1] CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[2] Butrans Labeling § 2.2.

[3] OxyContin Labeling, at 1 (attached as Exhibit 3) (emphasis added).

[4] CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

opioid medications may continue to experience benefits that would warrant the use of opioids for more than 90 days.[5]

23. These examples demonstrate that the CDC Guidelines are in several substantial respects inconsistent with the FDA's approval of Defendants' opioid medications.

24. Putting aside any substantive issues with the CDC's underlying methodology with respect to the prescribing recommendations, the CDC has no legal authority to regulate opioids or communications concerning opioids. Congress has tasked the FDA and ***only*** the FDA with exclusive responsibility for "determin[ing] whether a drug is generally recognized as safe and effective." *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 653-54 (1973).

25. The State nonetheless requests that, under the compulsion of an injunction, the court prospectively order Defendants to abide by, among other things, non-binding CDC guidelines that are directed to primary care clinicians, as well as other unnamed government guidelines, and make representations about the safety and efficacy of its opioid medications that are based on those guidelines. Ex. 2 at 46.

26. The State's attempt to seek relief based on unnamed "other government guidelines" is particularly problematic. This broad description could cover guidelines issued any governmental body—including towns, cities, and counties of other states, as

[5] Letter from the FDA to PROP at 10 n.40 (Sept. 10, 2013), *available at* https://www.regulations.gov/document?D=FDA-2012-P-0818-0793.

well as other states themselves, and other federal agencies. The State's requested relief would frustrate Congress's intent to have a national and uniform regulatory scheme with a cacophony of competing guidelines.

27. As for the CDC, it has no regulatory authority over Defendants or any prescription medications, including opioid pain medicines or over communications between pharmaceutical manufacturers and physicians. Instead, Congress has mandated that only the FDA has the regulatory authority to determine the safety and efficacy of prescription medications, including exclusive regulatory authority to determine what manufacturers must disclose in product labeling and promotional materials and exclusive ongoing regulatory responsibilities to monitor drugs post-approval. 21 U.S.C. §§ 301, *et seq.*; *id.* § 393(b)(2)(B). The State's requested relief runs counter to the FDA's own assessment and findings concerning Defendants' prescription opioids and their FDA-approved labeling under federal law.

28. Not only would requiring Defendants to abide by the CDC Guidelines in terms of what it and cannot say about its opioid medications, under the compulsion of an injunction, be inconsistent with what the FDA has directed Defendants to tell doctors and patients about their medications, but they may also effectively require Defendants to engage in misbranding of its medications in violation of federal law.

b. Packaging

29. Moreover, the State's Interrogatory Responses make clear that it is directly challenging the FDA's authority to decide what type of packaging is appropriate for

Defendants' medications, as it seeks an order requiring Defendants to "[p]ackag[e] prescription opioids in blister packs or other package to limit accelerated use." Ex. 2 at 46.

30. But the FDA has the exclusive regulatory authority to make that decision. For instance, on January 30, 2018, the FDA Commissioner issued a press announcement, noting that the FDA is considering the use of blister packs for immediate release opioid medications:

> We're also actively exploring how we can use changes in packaging as a way to give providers better options for tailoring how much they prescribe to the clinical need. This is especially true when it comes to immediate release formulations of opioid drugs like Vicodin and Percocet, which are typically meant for short-term use.
>
> If more immediate release opioid drugs, in particular, were packaged in three or six-day blister packs; then more doctors may opt for these shorter durations of use. Additionally, provided the FDA concluded that there was sufficient scientific support for these shorter durations of use, this could provide the basis for further regulatory action to drive more appropriate prescribing.[6]

31. Certain Defendants in this action manufacture immediate release formulations of opioid medications. Even if FDA might conclude that such changes in packaging are appropriate for immediate release formulations of opioid medications, Purdue's opioid medications, such as Hysingla, are extended release formulations and, thus, may well be outside the ambit of what FDA determines might be appropriate for

[6] FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to help prevent new addiction, curb abuse and overdose related to opioid products, https://www.fda.gov/NewsEvents/Newsroom/%20PressAnnouncements/ucm594443.htm

immediate release formulations. The difference between immediate and extended release formulations, as recognized by the FDA, shows that the issue is nuanced and subject to the FDA's expert scientific and medical judgment. To the extent it is even appropriate—and certain medical organizations have suggested that it may not be in the interests of their patients—it is not a blunt one-size-fits-all approach, such as that being sought by the State. Nonetheless, through the instant lawsuit, the State seeks to usurp FDA's exclusive regulatory authority in this area through a prospective court-ordered injunction against the Defendants.

iii. The State's Claims Challenge the FDA's Findings and Present Substantial Disputed Federal Questions

32. Federal question jurisdiction exists because the State's claims (1) necessarily raise federal issues; the federal issues are (2) actually disputed and (3) substantial; and (4) this federal forum can capably entertain the issue without disturbing any congressionally approved balance of federal and state judicial responsibilities. *Grable*, 545 U.S. at 314.

33. First, the State's Interrogatory Responses make clear that, at base, the State seeks to directly challenge (1) Congress's decision to grant FDA exclusive authority to regulate prescription opioid medications and communications concerning those medications, (2) the FDA's decision to approve Defendants' opioid medications as safe and effective for certain conditions, (3) the FDA's exclusive authority to dictate the information that a pharmaceutical manufacturer must convey to clinicians and patients concerning the risks and benefits of prescription opioids, and (4) FDA's authority and

decision as to how Defendants' opioid medications should be packaged and, correspondingly, how they should be labeled.

34. Such claims are inextricably intertwined with disputed federal issues. To obtain the injunctive relief that it seeks, the State must establish, *inter alia*, that the FDA failed to perform its regulatory duties to oversee prescription opioids or that the FDA's exclusive authority to dictate the approval, safety, efficacy, labeling, and packaging of prescription medications "may be enjoined because of a state law violation." *Montana Rail Link*, 672 F. Supp. at 1579. Whether federal regulatory bodies fulfill their duties with respect to the entities they regulate is "inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001); *Bader*, 2017 WL 633815, at *3. Furthermore, a federal question arises when, as here, "the remedies [a party] seek[s] require nothing short of a reassessment, reevaluation and revamping of [a federal agency's earlier determination]" because that is "tantamount to asking the Court to second guess the validity of [a federal agency's] decision." *McKay*, 2016 WL 7425927, at *4; *Montana Rail Link*, 672 F. Supp. at 1579.

35. Second, the federal issues raised by the State are undeniably substantial. "A federal issue is substantial" when "plaintiffs' state law claims, if granted the relief requested ... [are] collaterally attacking a final decision of ... [a federal agency]" in a state court. *McKay*, 2016 WL 7425927, at *5. Moreover, there is a strong federal interest in having a federal court decide the federal questions raised by the State's

Interrogatory Responses—whether a party can use state law claims to challenge a federal agency's final determination and whether the FDA complied with its regulatory duties as to Defendants' opioid medications.

36. Third, determination by a federal court of the substantial and disputed federal issues that lie at the heart of this case would not "disturb[] any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 545 U.S. at 314. The State's claims here are not the individual "garden variety" tort actions of the kind that the Supreme Court characterized as leading to a "horde" of filings in federal court. *Id.* at 318. Rather, this is an attempt by the State to use Oklahoma state law claims to seek broad prospective injunctive relief that would, among other things, require Defendants to provide conflicting information about the safety and efficacy of their opioid medications, and package their medications in a manner that is different than what the FDA has determined is appropriate. In essence, the State wants to substitute its judgment for the FDA's expertise and Congressionally-authorized duty to determine the safety, efficacy, and packaging of opioid medications. In doing so, the State would require that Defendants tell healthcare providers and patients different information about their opioid medications in Oklahoma, and package its medications in a different way in Oklahoma, than what the FDA requires in every other state in the country. Such claims necessarily implicate substantial federal questions.

PROPRIETY OF REMOVAL

37. For the foregoing reasons, this Court has jurisdiction over this matter. To the extent that the above bases for federal jurisdiction do not extend to one or more of the State's claims, this Court has supplemental jurisdiction over such claim or claims pursuant to 28 U.S.C. § 1367.

38. All Defendants consent to this Notice of Removal.

39. This Notice is timely, having been filed within 30 days of the State's Interrogatory Responses, which were served on Purdue on May 21, 2018. These responses first demonstrated that federal jurisdiction was present in this case and fall squarely within the "other paper" doctrine set forth in 28 U.S.C. § 1446(b)(3). *See Berera*, 779 F.3d at 365; *Akin*, 156 F.3d at 1035-36.[7]

40. This District Court embraces the District Court of Cleveland County, Oklahoma, where this suit was originally filed. Removal to this District Court is therefore proper. 28 U.S.C. §§ 116(b), 1441(a).

41. Purdue will promptly file a true and correct copy of this Notice of Removal to the District Court of Cleveland County, Oklahoma, in accordance with 28 U.S.C.

[7] On July 24, 2017, the parties to this action entered into a Stipulation that provided in relevant part that Defendants "will not remove the above-captioned case, ***based upon Plaintiff's Original Petition***, to Federal Court." Stipulation ¶ 2 (emphasis added) (attached as Exhibit 4). But this Notice of Removal is based upon the disclosures in the ***State's Interrogatory Responses***, which revealed for the first time the nature and extent of the relief that the State seeks, and is an "other paper" for purposes of 28 U.S.C. § 1446(b)(3).

§1446(d), and serve the State's counsel with a true and correct copy of this Notice of Removal, in accordance with 28 U.S.C. § 1446(d).

42. If the State moves to remand, then this Court should deny the motion without prejudice, allow the case to be transferred to the MDL, where the MDL court will decide similar jurisdictional issues raised by the Montana Attorney General, and allow the MDL court to decide both remand motions simultaneously.

43. Alternatively, if the State challenges the removal of this action, and this Court is inclined to decide the issue, then Purdue respectfully requests the opportunity to conduct discovery or brief any disputed issues and to present oral argument in support of its position that this civil action is properly removable. *See Sizova v. Nat'l Inst. of Standards & Tech.*, 282 F.3d 1320, 1326 (10th Cir. 2002); *Hansen v. United States*, 3 F. App'x 592, 593 (9th Cir. 2001).

WHEREFORE, Purdue notices the removal of this case to the United States District Court for the Western District of Oklahoma, pursuant to 28 U.S.C. §§ 1331, 1441, and 1446.

Dated this 13th day of June, 2018.

Respectfully submitted,

/s/ Sanford C. Coats

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WRITTEN CONSENT OF OTHER DEFENDANTS:

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Watson Laboratories, Inc., Actavis LLC, and
Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

/s/ Robert G. McCampbell
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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the above and foregoing was e-mailed, this 13th day of June, 2018 to:

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