

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS  
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC	)	
MEDICINE, <i>et al.</i> ,	)	
	)	
Plaintiffs,	)	
	)	Case No. 2:22-cv-00223-Z
v.	)	
	)	
U.S. FOOD AND DRUG	)	
ADMINISTRATION, <i>et al.</i> ,	)	
	)	
Defendants.	)	
	)	
	)	

**States’ Response in Opposition to Defendants’ Motion to Hold in Abeyance**

Defendants ask this Court to hold the States’ intervention motion in abeyance until as late as June 2025<sup>1</sup> and to extend substantially Defendants’ deadline to respond to the States’ motion. Neither request is warranted.

First, judicial efficiency is best served by getting to the merits of FDA’s conduct quickly, not (as FDA suggests) by litigating the matter in piecemeal fashion in different suits in different forums. FDA’s principal argument in its certiorari petition asks the Court to vacate the preliminary injunction for lack of standing. If the Supreme Court were to do so before intervention, the parties would be forced to engage in an entire new round of litigation on the same issues. Ensuring appellate courts can fully resolve the merits more quickly would be much more efficient.

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<sup>1</sup> If the Supreme Court grants certiorari after mid-January, it will not hear the case until October 2024 or later, absent an expediting order.

Second, there is no need for such an extensive delay to respond to a simple intervention motion. While Defendants bemoan the “close to 700 pages” of exhibits submitted by the States, they fail to inform this Court that nearly all of that is identical to material submitted by the private plaintiffs. Of the 41 exhibits the States filed, only 6 are new, several of those 6 are fewer than 3 pages long, and the longest of them is just 20 (double-spaced) pages of substance. Similarly, the substantive arguments in the complaints are the same—except the States bring fewer arguments. The complaints materially differ only with respect to the theories of standing. To the extent any extension is needed at all, an extension to shortly after Thanksgiving should be more than sufficient for FDA to respond to a simple intervention motion.

### **Argument**

#### **I. The Court should reject the request to hold the intervention motion in abeyance.**

Defendants argue that holding the intervention motion in abeyance is necessary because Supreme Court proceedings that they speculate might occur “may obviate the States’ motion and at the very least may shed light on how the motion should be resolved.” Mot. at 3. Neither argument is persuasive.

##### **A. Supreme Court review would not “obviate the States’ motion.”**

The request for abeyance rests on three speculative assumptions. Defendants say the Court should hold the intervention motion in abeyance because (1) the Supreme Court might grant their petition for certiorari, (2) the Supreme Court might rule in their favor on standing, and (3) the Supreme Court might not consider the standing of the States. If the Supreme Court does all three of these things, they say,

this Court will have to dismiss or transfer. It is far from clear that Defendants' speculation about the first three things is warranted, but even if it were, their conclusion does not follow.

Defendants say that a party cannot intervene absent "an existing suit within the court's jurisdiction." Mot. at 4 (quoting *Harris v. Amoco Prod. Co.*, 768 F.2d 669, 675 (5th Cir. 1985)). That is true enough. But that is true here. There is no dispute that the States have sought to intervene in "an existing suit." This Court and two different panels of the Fifth Circuit have all concluded that there is jurisdiction because the private plaintiffs have standing. That jurisdictional ruling governs the current motion to intervene.

Unable to dispute this, Defendants press a novel theory: if the Supreme Court later decides the private plaintiffs lack standing, that ruling would *retroactively* invalidate an order granting intervention. Mot. at 4. But intervention is "judged as of the time the motion [i]s ruled upon." *Equal Empl. Opportunity Comm'n v. United Air Lines, Inc.*, 515 F.2d 946, 950 (7th Cir. 1975). And in any event, if this Court grants intervention and the Supreme Court later grants certiorari, then the Supreme Court may well consider the States' standing given the well-established rule that only "one plaintiff" need have standing for a suit to proceed. *Biden v. Nebraska*, 143 S. Ct. 2355, 2365 (2023).

But even under Defendants' (speculative) assumption that the Supreme Court would decline to consider the States' standing, Defendants fail to cite even a single case adopting their novel theory that a valid intervention order can become invalid

retroactively if the initial plaintiffs are later held to lack standing. They rely on a quote from Wright & Miller and a Supreme Court case on which Wright & Miller relies. Mot. at 4 (citing 7C Charles A. Wright et al., Federal Practice & Procedure § 1917 (3d ed. Apr. 2023)). But Wright & Miller relies on *Mattice v. Meyer*, which held that “there was no basis for intervention” when the *original suit* had already been dismissed. 353 F.2d 316, 318–319 (8th Cir. 1965). Similarly, in the Supreme Court case, the court stated that an “intervention could not cure th[e] vice in the original suit.” *United States ex rel. Texas Portland Cement Co. v. McCord*, 233 U.S. 157, 163–164 (1914). But the intervenor there had voluntarily “dismissed his intervention,” and the “vice” in that original suit was a statutory prohibition against *any* private plaintiff bringing an action at the time the plaintiffs brought theirs (within six months of completing of the contract at issue). *Id.* at 159, 163–64. In other words, intervention “could not cure th[e] vice in the original suit” because the intervenor also could not have sued at the time. *Id.*

Defendants also rely on *Fuller v. Volk*, 351 F.2d 323 (3d Cir. 1965), but that case undermines their position. *Fuller* found that the initial plaintiffs lacked standing, but the court did *not* reverse the prior order granting intervention. Rather, the court simply held intervenors could not cure the jurisdictional defect of the initial plaintiffs, who had failed to meet an amount-in-controversy threshold, because separate claims could not be “aggregated in order to obtain the requisite jurisdictional amount in controversy.” *Id.* at 327–28. In fact, the court permitted the intervening plaintiffs to continue their suit—because intervenors had a separate basis for

jurisdiction—to “avoid the senseless delay and expense of a new suit, which at long last will merely bring the parties to the point where they now are.” *Id.* at 329 (citation and internal quotation marks omitted).

The States do not dispute that intervention would be improper if this Court had already dismissed the action of the private plaintiffs (as in *Mattice*) or if a statutory prohibition barred the States filing this suit in November 2022 alongside the private plaintiffs (as in *McCord*). But neither is true here. Because this Court has already ruled that the private plaintiffs have standing, there is no impediment to intervention.

Defendants’ novel rule would simply impose “the senseless delay and expense of a new suit, which at long last will merely bring the parties to the point where they now are.” *Fuller*, 351 F.2d at 329 (citation and internal quotation marks omitted). If the Supreme Court ruled against the private plaintiffs on standing (while declining to consider State standing), and if this Court did not permit the States to intervene, that would simply delay resolution. The parties would be forced to begin anew. The States and private plaintiffs could file a new, joint complaint, relying on the “one plaintiff” rule for standing. The private plaintiffs could even submit new affidavits to cure whatever standing problem the Supreme Court might identify. But this would all be less efficient.

For that reason, Defendants’ complaints about venue and exhaustion are wholly without merit.<sup>2</sup> Defendants assert (at 5) that the States could not proceed in

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<sup>2</sup> Defendants also say the States have made no attempt to explain how the

this venue without the private plaintiffs and that the States did not exhaust claims before the FDA. But the States would not necessarily sue by themselves. The private plaintiffs have consented to the intervention motion, so there is no reason to suspect they would oppose submitting a joint complaint with the States. That would cure the purported defects raised by Defendants, and it would be permissible under the “one plaintiff” rule of standing because the States plainly have standing.

Even if the private plaintiffs chose not to bring a new complaint with the States, Defendants arguments would fail. The private plaintiffs adequately explain why exhaustion is not required at all under the Administrative Procedure Act. *See* ECF 120 at 13. But even if it were ordinarily required, FDA already rejected the private plaintiffs’ petitions, and the Supreme Court “has consistently recognized a futility exception to exhaustion requirements.” *Carr v. Saul*, 141 S. Ct. 1352, 1361 (2021). Earlier this year, a federal court determined that exhaustion was not required in a similar suit against FDA. *Washington v. FDA*, No. 1:23-cv-3026, ECF 80, at 17 (April 7, 2023, E.D. Wa.).

Venue is no different. Defendants assert that this Court would have to dismiss for lack of venue if the Supreme Court determined that the private plaintiffs lack standing and if the Supreme Court declined to consider whether the States have standing. Not so. This Court could permit the private plaintiffs to remain in the suit

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States’ challenge to FDA’s 2016 actions comply with the 6-year statute of limitations. Mot. at 5. But as FDA well knows, FDA’s own regulations say that an agency action is not final (and the statute of limitations does not begin to run) until FDA denies a citizen petition. 21 C.F.R. § 10.45(b). With respect to the 2016 policies, that did not occur until 2021, just two years ago.

under the “one plaintiff” rule of standing if this Court determined that the States have standing. And even if this Court dismissed the private plaintiffs, venue is not jurisdictional, 28 U.S.C. § 1406(b), so the Court—in light of the amount of time this Court has already expended on this case—could maintain the action even if venue would have been improper had the States brought this suit on their own at the outset. Indeed, *Wright & Miller* is directly against Defendants on this point. Where “jurisdiction in the main action is premised on a federal question” or “a particular claim or party is so closely related to the original action that it can be considered ancillary,” *Wright & Miller* explains, “venue objections should not be entertained.” *Wright & Miller* § 1918.

**B. Holding the motion in abeyance would risk imposing unnecessary delay.**

Contrary to Defendants’ suggestion that holding the intervention motion in abeyance could increase judicial efficiency, the opposite is true. As stated more fully in the States’ suggestions in support of their intervention motion, Defendants’ principal argument in front of the Supreme Court is that the private plaintiffs lack standing. If the Supreme Court were to agree and vacate the preliminary injunction, only judicial inefficiency would result.<sup>3</sup> The States (perhaps with the private plaintiffs joining on remand) would assert the same merits arguments that this Court and the Fifth Circuit have already accepted, and Defendants would have to appeal

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<sup>3</sup> Even if the Supreme Court affirmed on the merits, it might limit the relief to the named parties, consistent with the criticism of some jurists against orders that issue relief beyond the named parties. *E.g., Trump v. Hawaii*, 138 S. Ct. 2392, 2424–29 (2018) (Thomas, J., concurring). If that occurred, the States would likewise be forced to litigate anew.

again to the Supreme Court to address the merits. Defendants are thus quite wrong to assert (at 6) that holding the motion in abeyance will not prejudice the States.<sup>4</sup> Defendants say the States can avoid all this by “fil[ing] their own suit” now rather than intervening, Mot. at 6, but that would only force Defendants to defend in multiple locations rather than in one consolidated proceeding.

On the flipside, holding the intervention motion in abeyance carries no efficiency benefits. The States seek intervention, and have directly asserted a right to intervene. It is only responsive pleadings to the intervention motion and related matters (like this abeyance motion) that Defendants would need to submit. Defendants briefly speculate (without elaboration) that the Supreme Court—if it grants certiorari—“may shed light” on the issues related to intervention. Mot. at 3. But any “light shed” would not make it inefficient to grant intervention. To the contrary, if the Supreme Court affirmed the preliminary injunction, that would apply to the States as parties. And if the Supreme Court reversed on the merits, that too would apply to the States. Either way, intervention increases efficiency.

In the end, FDA’s request leads toward only one result: enabling FDA to persist with an unlawful scheme as long as possible. This Court and two panels of the Fifth Circuit have held FDA’s actions to be unlawful. Here, the judicial inefficiency FDA

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<sup>4</sup> In a preview of their future opposition to the intervention motion, Defendants suggest (at 6) that the States delayed too long in filing their motion. But as the States explained in that motion, many events occurred just this summer that revealed distinct harms to the States posed by FDA’s unlawful activities. ECF 152 at 3–6. And the Fifth Circuit did not affirm this Court’s order until about two months before the States moved to intervene.



seeks simply means more time FDA can violate the law. FDA has no legitimate interest in persisting with unlawful policies.

**II. The Court should reject the request for an extended response time.**

Also unavailing is Defendants' request for a substantial extension of time to respond to the intervention motion. The States have agreed to a reasonable extension past the Thanksgiving holiday, but anything beyond that is excessive. An excessive delay could in fact create the exact inefficiency situation Defendants press for above if the Supreme Court grants certiorari before this Court is able to decide the intervention motion. As of right now, the Supreme Court can consider the petition for certiorari as early as December 8.

Defendants' request is especially unwarranted because the only new material relates to State standing; the States press the same arguments (minus one) on the merits as the private plaintiffs pressed and this Court adopted. Defendants provide nothing to suggest otherwise.

For example, Defendants say that the complaint is 105 pages and that the exhibits are almost 700 pages, but they fail to mention that the complaint presses no new substantive claims (it differs with respect to theories of standing), and nearly all of the exhibits are identical. The complaint brings fewer arguments than the private plaintiffs' complaint (the States do not press the challenge to the 2000 approval of mifepristone), but it presses no new arguments, only new standing analysis. In any event, there is an order staying the deadline to answer, ECF 143, so any differences between the complaints are irrelevant to whether Defendants need an extension.

The same is true with the exhibits attached to the complaint. Defendants complain that these 41 exhibits amount to nearly 700 pages, but they fail to disclose that 35 of the 41 exhibits are identical to exhibits filed by the private plaintiffs.<sup>5</sup> Just 6 exhibits are new. These exhibits are short. Indeed, only one exceeds 10 pages, and several are between 1 and 3 pages. The longest is just 20 pages (excluding the bibliography and CV). And all these exhibits go to the basic issue of standing.

Finally, Defendants complain (at 7) that if the States needed two months to prepare for intervention, Defendants should be given a similar amount of time to oppose intervention. But preparing to intervene requires substantially more work than writing a simple response in opposition to intervention, which can be done in a matter of days. To intervene, the States had to get up to speed with all the intricacies of this case, identify and retain experts, locate relevant agency data, obtain declarations, write a complaint, and finally write a motion to intervene—all while dealing with extraordinarily busy caseloads. The only thing Defendants must do is draft a short response brief in opposition to intervention, which should take a fraction of time.

### **Conclusion**

For the foregoing reasons, the Court should deny Defendants' motion.

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<sup>5</sup> In a substantial understatement, Defendants acknowledge (at 6) only that “some” of the material submitted by the States is identical to material previously submitted by the private plaintiffs.

Dated: November 14, 2023

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on November 14, 2023, a true and accurate copy of the foregoing document was filed electronically (via CM/ECF) and served on all counsel of record.

*/s/ Joshua M. Divine*

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