

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION**

State of Missouri, *et al.*,

Intervenor-Plaintiffs,

v.

Case No. 2:22-cv-00223-Z

U.S. Food and Drug Administration, *et al.*,

Defendants,

Danco Laboratories, LLC,

Intervenor-Defendant,

and

GenBioPro, Inc.,

Intervenor-Defendant.

DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

The three Intervenor-Plaintiff States—the States of Missouri, Idaho, and Kansas (“the States”)—do not dispute that their claims have no connection to the Northern District of Texas and that, if the States were to file their own suit in this District, that suit could not proceed due to improper venue. To justify continued litigation here, the States instead rely on the original plaintiffs’ lawsuit seeking to challenge FDA’s actions. But the Supreme Court unanimously concluded that those plaintiffs lacked standing, and they have now voluntarily dismissed all of their claims. The States therefore cannot rely on those plaintiffs to satisfy venue requirements, which are mandatory and require dismissal (or transfer) here. None of the States’ arguments in their opposition, ECF No. 228, warrants a different result, either as to venue or the other threshold bases for dismissal.

ARGUMENT

I. The States Cannot Satisfy Venue By Relying On Now-Dismissed Claims Over Which This Court Never Had Jurisdiction

The States do not dispute that their Amended Complaint, standing alone, does not establish venue in this District. *See* Defs.’ MTD (ECF No. 219) at 4-5. Instead, they contend that “[b]ecause venue was valid when the States intervened, it has been satisfied.” Opp’n at 6. Essentially, the States argue that they can piggyback on the original *Alliance* plaintiffs’ venue, notwithstanding that those plaintiffs were held to lack standing and have now voluntarily dismissed their claims. As explained previously, that approach is contrary to binding precedent requiring a jurisdictionally valid suit with proper venue for an intervenor to continue litigating in the original forum. *See* MTD at 5-8.

The States’ response relies heavily on the Fifth Circuit’s decision in *Harris v. Amoco Production Co.*, 768 F.2d 669 (5th Cir. 1985), which recognized that there are some “circumstances in which an intervenor can continue to litigate after dismissal of the party that originated the action.” *Id.* at 676. But *Harris* itself makes plain that intervenors can continue only if the district court properly had jurisdiction over the initial suit. *See id.* at 675 (“[I]t is equally well-settled that ‘an existing suit within

the court’s jurisdiction is a prerequisite of an intervention, which is an ancillary proceeding in an already instituted suit.” (quoting *Kendrick v. Kendrick*, 16 F.2d 744, 745 (5th Cir. 1926)); see also *id.* at 680 (allowing suit to continue “[w]here a solid basis for jurisdiction exists”). Here, of course, the Supreme Court has already confirmed that this Court lacked jurisdiction over the original plaintiffs’ claims, which means that the States’ reliance on *Harris* fails at the outset.

The States try to get around the Supreme Court’s holding in *Alliance* by arguing that the original plaintiffs “*did* have standing when they first brought their suit,” and those plaintiffs only lost standing after a purported change in position before the Supreme Court. Opp’n at 3-4, 8. But as discussed previously, that argument fails for several reasons. See ECF No. 211 at 3-6. For one thing, the original plaintiffs have now voluntarily dismissed their claims—effectively making it as if this case, and the States’ prior intervention, never occurred. See *Ford v. Sharp*, 758 F.2d 1018, 1023-24 (5th Cir. 1985); *Marex Titanic, Inc. v. Wrecked & Abandoned Vessel*, 2 F.3d 544, 547 (4th Cir. 1993). Because the original plaintiffs’ suit was effectively never filed, the States cannot rely on any purported jurisdiction in the original suit to justify adjudication of the States’ claims in this forum.

Moreover, as a factual matter, Defendants did not switch positions before the Supreme Court. See ECF No. 211 at 4. And legally, the Supreme Court made clear that the correct interpretation of federal conscience laws eliminated any threat of injury. See *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 387 (2024). The States offer no authority for their theory that the assertion of an incorrect legal argument in unrelated briefing creates temporary Article III injury until the law’s correct meaning is clarified.

Most fundamentally, the States’ position confuses standing with mootness. The Supreme Court’s conclusion that “the plaintiffs lack standing to challenge FDA’s actions,” *id.* at 374, necessarily means that the original plaintiffs *never* had standing to pursue their claims. See *Davis v. Fed. Election Comm’n*, 554 U.S. 724, 734 (2008) (“[T]he standing inquiry remains focused on whether the

party invoking jurisdiction had the requisite stake in the outcome when the suit was filed.”); *Friends of the Earth, Inc. v. Laidlaw Env't Serns. (TOC), Inc.*, 528 U.S. 167, 189-92 (2000). Indeed, the Supreme Court’s decision in *Alliance* itself makes clear that no court ever had jurisdiction over the original plaintiffs’ claims. *See* 602 U.S. at 379 (a plaintiff without standing cannot “get in the federal courthouse door”); *id.* at 396-97 (“[T]he federal courts are the wrong forum for addressing the plaintiffs’ concerns about FDA’s actions.”); *cf. Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94 (1998) (“Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law[.]”). Thus, this case is wholly unlike *Harris*, because there was never a jurisdictionally proper suit before this Court in which the States could intervene. *Cf. Lujan v. Defs. of Wildlife*, 504 U.S. 555, 571 n.4 (1992) (Scalia, J., plurality op.) (explaining that additional parties, “by later participating in the suit,” could not create “jurisdiction[] that did not exist at the outset”).¹

The States further misconstrue *Harris* by suggesting that the decision allows courts simply to ignore non-jurisdictional defects in intervenors’ suits. *See* Opp’n at 7. In *Harris*, the Fifth Circuit allowed the EEOC to continue litigating as an intervenor even after the original plaintiffs settled, but only after conducting a lengthy examination of the Title VII statutory scheme, *see* 768 F.2d at 676-81, and determining that Title VII’s procedural requirements were not intended to frustrate EEOC’s ability to pursue claims as an intervenor. *See id.* at 681 (“[N]othing in the statute suggests that a valid intervention by the Commission, once present, need be dispelled; indeed, the scheme as a whole compels the reverse.”). Here, however, the relevant frameworks—*i.e.*, the venue statutes and the

¹ The States’ other cited authorities similarly require that intervention be in a “jurisdictionally and procedurally proper suit.” *Sommers v. Bank of Am., N.A.*, 835 F.3d 509, 513 n.5 (5th Cir. 2016). And the Fifth Circuit has suggested that *Sommers* should be read to allow, at most, intervention in certain cases after stipulated dismissals, but not after unilateral dismissals without prejudice as occurred here. *See Odle v. Flores*, 899 F.3d 344, 346 (5th Cir. 2017) (Graves, J., concurring in rehearing denial); *id.* at 352 (Jones, J., dissenting from rehearing denial). Ultimately, the States fail to cite any authority endorsing what they are attempting here—to continue litigating claims in an improper venue, even after the original plaintiffs were held to lack standing and voluntarily dismissed their claims under Rule 41(a)(1)(A)(i).

Federal Rules of Civil Procedure—compel the opposite conclusion, namely that intervenors must be dismissed if they are unable to establish proper venue. The venue statute speaks in mandatory language, *see* 28 U.S.C. § 1406(a) (courts “shall dismiss” or transfer any case with improper venue), and defendants are entitled to assert improper venue as a defense, *see* Fed. R. Civ. P. 12(b)(3). Moreover, courts have repeatedly held that only a party with Article III standing can satisfy venue. *See* ECF No. 197 at 12-13 (collecting cases). The States’ position—that intervenors can rely on the original plaintiffs to establish venue, even if those original plaintiffs lacked standing and have dismissed their claims—is irreconcilable with these authorities.

Contrary to the States’ suggestion (Opp’n at 9), it makes no difference whether the original plaintiffs’ lack of standing is determined by a district court or on appeal. If anything, a binding Supreme Court decision regarding the original plaintiffs’ lack of standing makes it even *more* inappropriate to rely on those same plaintiffs to establish venue. Regardless, venue is lacking here even under the States’ theory—*i.e.*, “the plaintiff with venue” was “conclusively determined to lack standing at the outset” of the case, Opp’n at 9, because the Supreme Court’s decision confirming that lack of standing was issued before any Defendant filed a response to the Complaints. Indeed, the States themselves, when seeking to intervene, characterized this case as being “in its earliest stages.” ECF No. 172 at 8. The States cannot now argue that the Supreme Court’s decision came too late for Defendants to raise their venue objections through a timely Rule 12 motion.

The States also continue to distort Wright & Miller as supporting their ability to proceed without satisfying venue. *See* Opp’n at 10. That treatise is explicit: “[T]he court has discretion to treat the intervenor’s claim as if it were a separate suit and may entertain it if it satisfies by itself the requirements of jurisdiction *and venue*.” Wright & Miller, Federal Practice & Procedure § 1918 (3d ed. Apr. 2025) (emphasis added). That straightforward statement cannot be reconciled with the States’ interpretation—that venue is irrelevant as long as federal-question jurisdiction exists. Opp’n at 10.

To the contrary, the passage in Wright & Miller on which the States rely addresses venue objections when the main action remains pending:

[S]upplemental jurisdiction may be utilized over an intervenor's claim in cases in which *jurisdiction in the main action* is premised on a federal question. Thus, it seems clear, applying the principle noted at the outset, that the intervenor's claim also would be supplemental (or ancillary) for venue purposes and venue objections should not be entertained *in this situation*.

Wright & Miller § 1918 (emphases added). The reference to supplemental jurisdiction highlights that the main action must still be pending. Supplemental jurisdiction is available only in a “civil action of which the district courts have original jurisdiction,” 28 U.S.C. § 1367(a), and here jurisdiction never existed (as confirmed by the Supreme Court's decision), and certainly does not exist now that the original plaintiffs have voluntarily dismissed their claims. The States cannot rely on any notion of “supplemental venue” here, therefore, given that there is no longer any “main action” pending that would satisfy venue.

In any event, even the States' interpretation of Wright & Miller underscores that their claims cannot proceed. The States acknowledge that, pursuant to Wright & Miller, venue objections are permitted in “cases involving gamesmanship (where a party seeks to cure the jurisdiction of another party)[.]” Opp'n at 10. Of course, that was the very premise of the States' intervention motion here—*i.e.*, because Defendants “attack[ed] the [original] plaintiffs' theories of standing,” the States sought to “press sovereign and economic harms that cannot be asserted” by those plaintiffs” so that “this Court . . . can more cleanly get to the merits” of the plaintiffs' claims. Intervention Mot. (ECF No. 152) at 1. In other words, the States sought to intervene for the purpose of rehabilitating the original plaintiffs' lack of standing. The States' own filings thus confirm the potential for gamesmanship and the resulting need for rigorous enforcement of the venue statute's requirements.

The States also cannot satisfy venue simply by pointing to past litigation proceedings occurring before this Court and the Fifth Circuit. Opp'n at 11. The venue statute requires that a

party's *claims* have substantial connection to the chosen forum. 28 U.S.C. § 1391(e)(1). The litigation itself cannot serve as the requisite link to the forum, because then a plaintiff would always satisfy venue based solely on the act of filing their claims in a particular court. Aside from this litigation, the States do not dispute that their claims have no connection to the Northern District of Texas.

Finally, the States err in suggesting that Defendants are “asking this Court to revisit its earlier intervention decision,” and thus must show that the earlier decision was “clearly erroneous.” Opp’n at 8-9. Defendants’ motion does not request that this Court reconsider its prior Order granting intervention, ECF No. 175, nor does the motion argue that the Court erred in its analysis of the Rule 24 intervention factors. Instead, Defendants invoke Rule 12 to argue that the States’ Amended Complaint must be dismissed. The motion therefore *assumes* the States’ status as independent parties with their own Complaint; it does not seek to relitigate the intervention decision itself. Tellingly, the States do not point to any specific aspect of the Court’s intervention decision that they believe conflicts with (let alone forecloses) Defendants’ current Rule 12 motion.

At bottom, the States cannot keep alive a lawsuit in which the original plaintiffs were held to lack standing, those plaintiffs have now voluntarily dismissed their claims, and the States’ own claims have no connection to this District. The States are free to pursue their claims in a District where venue is proper, *see* MTD at 6-7, but the States’ claims before this Court must be dismissed or transferred pursuant to the venue statute’s mandatory command.

II. The States’ Amended Complaint Fails for Additional Threshold Reasons

Even apart from improper venue, the States’ Amended Complaint here should be dismissed for additional threshold reasons. The States lack Article III standing; they failed to exhaust their claims; and their challenge to FDA’s 2016 actions is outside the six-year statute of limitations.

A. The States Lack Article III Standing

The States do not dispute that, in order to continue with their claims, they must satisfy

Article III's requirements. *Cf.* Opp'n at 7 (acknowledging that intervenors cannot proceed if there is "a *jurisdictional* reason to dismiss"). Their claimed injuries here, however, fail to satisfy Article III.

Sovereign Harms. The States first contend that "FDA's actions directly interfere with the States' ability to create and enforce a legal code." *Id.* at 12. But the States still fail to identify any actual or imminent controversy over whether any of their laws are preempted. Indeed, the States "vigorously dispute that their laws are preempted," Am. Compl. (ECF No. 217) ¶ 577, and they concede that "no party" in this case has "challenged the States' laws on preemption grounds." Opp'n at 13. They contend that nothing requires "the States . . . to wait" until such a preemption dispute occurs, *id.*, but that is exactly what Article III requires. *See Alliance*, 602 U.S. at 381 ("the injury must be actual or imminent, not speculative"). It would be a remarkable expansion of standing to allow a State to challenge federal agency action based solely on an abstract concern that some other party, at some point in time, in some other case might invoke the agency's action as a basis to argue for preemption. *Cf. Tex. Cent. Bus. Lines Corp. v. City of Midlothian*, 669 F.3d 525, 536 (5th Cir. 2012) ("Though the parties continue to disagree over whether the ICCTA preempts the City's floodplain ordinance, this is little more than 'an abstract dispute about the law' without an existing or impending violation of the ordinance." (quoting *Alvarez v. Smith*, 558 U.S. 87, 93 (2009))); *see also Harrison v. Jefferson Par. Sch. Bd.*, 78 F.4th 765, 770-72 (5th Cir. 2023).

The States also contend that FDA's actions have made it easier for individuals "to evade state laws." Opp'n at 14. But even assuming that were true, the mere fact that someone might violate state law "does not by itself injure the government in an Article III way." *Harrison*, 78 F.4th at 771 (quoting *Saginaw Cnty. v. STAT Emergency Med. Servs., Inc.*, 946 F.3d 951, 956 (6th Cir. 2020)). As the Ninth Circuit has explained, a "cognizable interest in the preservation of sovereign authority . . . does not convey standing to challenge federal action that affects state law enforcement indirectly, by making violations of state law more difficult or costly to detect." *Washington v. FDA*, 108 F.4th

1163, 1176 (9th Cir. 2024); *see also United States v. Texas*, 599 U.S. 670, 680 n.3 (2023).

The States also invoke a claimed “interest in the standards that FDA establishes” because they “rely on the backdrop of federal law when enacting their own regulations.” Opp’n at 15. This highly abstract interest would give states Article III standing to challenge *any* FDA policy (or that of any other federal agency), and therefore cannot be correct. Similarly, the States fail to cite any precedent supporting their theory that they can sue over any policy that affects their potential future birthrate, *id.* at 16, which is fundamentally different than allowing states to sue based on direct economic losses stemming from inaccurate population counts of existing persons, *see Dep’t of Commerce v. New York*, 588 U.S. 752, 767-68 (2019); *cf. Alliance*, 602 U.S. at 391-92 (criticizing an “unprecedented and limitless approach” that would allow litigants to “challenge almost any policy affecting public health”). Thus, the States’ claimed sovereign injuries all fail.

Economic Harms. For many of the same reasons, the States cannot rely on incidental, downstream economic costs allegedly stemming from FDA’s failure to regulate others more stringently. Those are exactly the type of “indirect effects on state revenues or state spending” that are too “attenuated” to satisfy Article III. *Texas*, 599 U.S. at 680 n.3; *see also Washington*, 108 F.4th at 1176 (“[A]n alleged uptick in Medicaid costs is exactly the kind of indirect effect on state spending that the Supreme Court has rejected as a basis for standing.” (cleaned up)). Otherwise, any state would be free to challenge the approval of any drug based on concerns about paying to treat side effects of that drug. *Cf. Alliance*, 602 U.S. at 392 (rejecting a theory of standing that would “essentially allow any doctor or healthcare provider to challenge any FDA decision approving a new drug”); *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) (questioning “what limits on state standing remain” if “any federal regulation of individuals through a policy statement that imposes peripheral costs on a State creates a cognizable Article III injury for the State to vindicate in federal court”).

Just as in *Texas*, the States here cannot challenge FDA’s alleged under-regulation of third

parties based on indirect monetary costs they claim to suffer. The States assert (Opp’n at 19) that their standing is no different than the “insurance organizations” that brought suit in *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983). Whatever the standing of private companies, however, there is no history of states being able to sue the Federal Government based on downstream economic harms. *Cf. Wyoming v. Oklahoma*, 502 U.S. 437, 448 (1992) (“Courts of Appeals have denied standing to States where the claim was that actions taken by United States Government agencies had injured a State’s economy and thereby caused a decline in general tax revenues.”). In any event, a reduction in automobile safety standards has a far more direct economic impact on automobile insurance companies than the States’ claimed costs here, none of which is inherently tied to the particular agency actions being challenged.

B. The States Failed to Exhaust Any Claims

The States do not dispute that they never exhausted any of their claims. Instead, they reject the notion that there is an “exhaustion requirement,” Opp’n at 23, wholly ignoring the numerous authorities dismissing claims brought by parties that similarly failed to exhaust. *See* MTD at 12. The States contend that exhaustion is required only if the agency action is inoperative while the administrative process is ongoing, Opp’n at 23, but that applies only to administrative appeals—*i.e.*, “an appeal to superior agency authority,” 5 U.S.C. § 704—not when a party has failed to initiate agency review in the first instance as required by agency regulations. 21 C.F.R. § 10.45.

The States again invoke *Harris* to contend that intervenors can piggyback on the original plaintiffs’ exhaustion of their claims. Opp’n at 23. Unlike the Title VII scheme in *Harris*, however, FDA’s statutory scheme here would plainly be frustrated by allowing intervenors to raise new arguments, based on new evidence, that FDA has not previously had the opportunity to consider. *Cf.* 21 C.F.R. § 10.45(f). And the States do not dispute that they seek to rely on numerous studies that were never presented to the agency. *See* MTD at 13. Thus, there is no basis for excusing

exhaustion here, contrary to FDA’s mandatory regulations and the one-sided weight of authority upholding the exhaustion requirement in this highly technical statutory scheme.

C. At A Minimum, the States’ Challenge to the 2016 Actions Is Untimely

At a minimum, the States’ challenge to FDA’s 2016 actions is time-barred because the States sought to intervene more than six years after FDA finalized those actions. The States once again invoke *Harris* to argue that statutes of limitations are irrelevant, Opp’n at 21, but the Fifth Circuit has made clear that, once a plaintiff files a notice of voluntary dismissal, the prior suit does not toll the statute of limitations. *Ford*, 758 F.2d at 1024. If a plaintiff cannot rely on its own prior suit to extend the statute of limitations, *id.*, surely intervenors cannot do so, contrary to the States’ suggestion here, *see* Opp’n at 21 (“The States satisfy the statute of limitations because the original plaintiffs did.”).

The States’ other arguments are equally unavailing. Even before the Supreme Court’s decision in *Dobbs*, nothing prevented the States from attempting to bring APA claims challenging the scope of FDA’s authority or its decisionmaking. Opp’n at 22. The States are thus dissimilar from the plaintiff in *Corner Post*, which “did not exist” at the time the challenged regulation was adopted. *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 806 (2024). And even if the States think they have suffered multiple injuries, Opp’n at 22, the statute of limitations begins to run when “the right of action *first* accrues,” 28 U.S.C. § 2401(a) (emphasis added), which here was 2016. Finally, FDA’s response to the 2019 citizen petition did not reopen the 2016 actions (even assuming that doctrine is valid) because FDA’s response simply upheld the 2016 actions. Thus, at a minimum, the States’ challenge to the 2016 actions is time-barred.

CONCLUSION

Regardless of the merits of the States’ claims, the States cannot proceed in this Court. The States’ Amended Complaint should be dismissed or transferred for lack of venue.

May 5, 2025

Respectfully submitted,

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