

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

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Plaintiffs,

and

MISSOURI, KANSAS, and IDAHO,
Intervenor-Plaintiffs

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants,

and

DANCO LABORATORIES, LLC,
Intervenor-Defendant.

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

**MEMORANDUM IN SUPPORT OF DANCO'S MOTION TO DISMISS THE
ALLIANCE PLAINTIFFS' COMPLAINT AND THE THREE STATES' COMPLAINT
IN INTERVENTION, AND MEMORANDUM IN OPPOSITION TO THE THREE
STATES' MOTION FOR LEAVE TO AMEND**

INTRODUCTION

Plaintiffs Alliance for Hippocratic Medicine, et al., brought claims that they lack standing to assert. The Supreme Court was unanimous in so holding. *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 374 (2024) (“the plaintiffs lack standing to challenge FDA’s actions”). As a result, the Alliance Plaintiffs’ complaint must be dismissed.

Intervenor-States Missouri, Idaho, and Kansas sought to intervene in the Alliance Plaintiffs’ suit. But intervenors are limited by the suit they seek to join. Indeed, for more than a century, the Supreme Court has held that intervenors “must abide the fate of [the original] suit.” *U.S. ex rel. Texas Portland Cement Co. v. McCord*, 233 U.S. 157, 163-164 (1914). That requires dismissal of the three States’ operative complaint in intervention. Because the Alliance Plaintiffs’ suit was never jurisdictionally valid to begin with, there was no action properly in this Court for the Intervenor-States to insert themselves into, then or now. Nor can the States proceed as if they filed a separate lawsuit: aside from other threshold problems, the Northern District of Texas is plainly an improper venue to hear claims brought by Missouri, Kansas, and Idaho.

For the same reason, the States’ motion for leave to amend their complaint must be denied. Without a jurisdictionally valid suit in which they can file an amended complaint in intervention, the three States’ proposed amendment is futile. It cannot cure the Alliance Plaintiffs’ lack of standing, without which there is no action in which the States can act as intervenors, nor can it cure the three States’ venue problems.

Justice Kavanaugh’s unanimous opinion put it point blank: “[T]he federal courts are the wrong forum for addressing the plaintiffs’ concerns about FDA’s actions.” *Alliance for Hippocratic Med.*, 602 U.S. at 396-397. The Alliance Plaintiffs, and likewise the three States, may still “present their concerns and objections to the President and FDA in the regulatory process, or to Congress and the President in the legislative process” and “also express their views about

abortion and mifepristone to fellow citizens, including in the political and electoral processes.” *Id.* But “under Article III of the Constitution, those kinds of objections alone do not establish a justiciable case or controversy in federal court.” *Id.* at 396.

The Alliance Plaintiffs’ suit must be dismissed, which necessitates dismissing the three States’ complaint in intervention and denying leave to amend.

BACKGROUND

Because this Court is familiar with the underlying facts and procedural history, Danco provides only a brief overview of the relevant points.

Two years ago, the Alliance Plaintiffs filed this action against FDA, alleging the agency acted arbitrarily and capriciously in its regulation of Mifeprex. *See* ECF No. 1. Danco, the manufacturer of Mifeprex, moved to intervene in this litigation, which this Court granted. ECF Nos. 19, 33.

The Court entered a preliminary injunction for the Alliance Plaintiffs, ECF No. 137, which the Supreme Court later stayed pending appeal. After the Fifth Circuit largely affirmed the preliminary injunction, Danco and FDA petitioned the Supreme Court for review, which the Supreme Court granted.

The Supreme Court unanimously held that the Alliance Plaintiffs lack standing to challenge FDA’s regulation of Mifeprex. As the Court explained, “the federal courts are the wrong forum for addressing the plaintiffs’ concerns about FDA’s actions”; instead “[t]he plaintiffs may present their concerns and objections to the President and FDA in the regulatory process, or to Congress and the President in the legislative process.” *Alliance For Hippocratic Med.*, 602 U.S. at 396-397.

While the parties’ certiorari petitions were pending, nearly a year after this suit was filed and after previously participating in the proceedings as amici, Missouri, Kansas, and Idaho moved

to intervene. ECF Nos. 100, 110, 151. Danco and FDA opposed that motion, explaining that if the Supreme Court held that the Alliance Plaintiffs lack standing, it would confirm that there is no jurisdictionally valid case in which the three States could have intervened, rendering any intervention decision both premature and futile. ECF Nos. 153, 154. This Court granted the three States leave to intervene and docketed their complaint in intervention. ECF Nos. 175, 176. By this point, the Supreme Court had granted certiorari, so this Court also stayed Danco's deadline to respond to the complaint in intervention until after the Supreme Court's decision. ECF No. 180. The States then moved to intervene in the Supreme Court; that motion was denied.

Upon remand to this Court following the Supreme Court's decision, the parties filed a joint status report regarding further proceedings in this Court. ECF No. 191. Before the Court addressed that joint status report, the States moved for leave to amend. ECF No. 195.

STANDARD OF REVIEW

“A case is properly dismissed for lack of subject matter jurisdiction when the court lacks the statutory or constitutional power to adjudicate the case.” *Home Builders Ass'n of Miss., Inc. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998). “The burden of proof for a Rule 12(b)(1) motion to dismiss is on the party asserting jurisdiction. Accordingly, the plaintiff constantly bears the burden of proof that jurisdiction does in fact exist.” *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001) (quotation marks and citations omitted).

For a Rule 12(b)(3) motion to dismiss for improper venue, as this Court recently explained, “[t]he Fifth Circuit has not ruled on which party bears the burden on a 12(b)(3) motion, but ‘most district courts within this circuit have imposed the burden of proving that venue is proper on the plaintiff once a defendant has objected to the plaintiff’s chosen forum.’ ” *Freedom Coal. of Drs. for Choice v. CDC*, No. 2:23-CV-102-Z, 2023 WL 9105435, at *2 (N.D. Tex. Nov. 3, 2023)

(Kacsmark, J.) (quoting *Galderma Labs., L.P. v. Teva Pharm. USA, Inc.*, 290 F. Supp. 3d 599, 605 (N.D. Tex. 2017)).

A district court should deny leave to amend where the amended complaint would be futile or, among other things, is unduly delayed, would prejudice the opposing party, or involves a repeated failure to cure deficiencies. *Smith v. EMC Corp.*, 393 F.3d 590, 595 (5th Cir. 2004).

ARGUMENT

I. The Alliance Plaintiffs' Complaint Must Be Dismissed, Ending This Action.

The Supreme Court's unanimous decision in *Alliance for Hippocratic Medicine* compels dismissal of the Alliance Plaintiffs' lawsuit.

As the Supreme Court explained, when an “unregulated plaintiff” asserts standing based on “government regulation of a third-party,” “the plaintiff must show a predictable chain of events leading from the government action to the asserted injury—in other words, that the government action has caused or likely will cause injury in fact to the plaintiff.” 602 U.S. at 384-385. The Supreme Court held that the Alliance Plaintiffs' theories fell short of this standard as a matter of law. The Supreme Court rejected the Alliance Plaintiffs' claim to standing based on a conscience injury, *id.* at 387-389, concluding that “the plaintiffs have not shown—and cannot show—that FDA's actions will cause them to suffer any conscience injury” given conscience protections in federal law, *id.* at 390. The Court also flatly declined to “create” a “novel” “doctor standing” doctrine to allow doctors to challenge an “FDA decision approving a new drug” or other government decisions altering “public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-in injuries.” *Id.* at 391-392. As the Court emphasized, “doctors have never had standing to challenge FDA's drug approvals simply on the theory that use of the drugs by others may cause more visits to doctors.” *Id.* at 392.

The organizational Alliance Plaintiffs also could not “manufacture” organizational standing by “expending money to gather information and advocate against” FDA’s actions. *Id.* at 394. And finally, the Court readily dismissed the Alliance Plaintiffs’ assertions that they could premise standing on their “distress[] by others’ use of mifepristone and by emergency abortions,” or that they could invoke third-party standing even if they had “not suffered and would not suffer an injury themselves.” *Id.* at 390 n.3, 393 n.5. The Court had “repeatedly rejected such arguments” already, and did not hesitate to do so again. *See id.* at 393 n.5.

When plaintiffs lack standing, which is a “bedrock constitutional requirement,” their claims cannot proceed. *See, e.g., id.* at 378 (quoting *United States v. Texas*, 599 U.S. 670, 675 (2023)). It makes no difference that the Supreme Court’s decision was on review of a preliminary injunction. The Supreme Court was clear that the Alliance Plaintiffs’ theories of standing were legally defective to their core—not faulty merely for a failure of proof. That leaves this Court’s “only function” as “announcing th[at] fact and dismissing the cause.” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94 (1998).

II. The Three States’ Operative Complaint In Intervention Must Be Dismissed.

As Intervenors, the three States “must abide the fate of [Plaintiffs’] suit.” *McCord*, 233 U.S. at 163-164. Without a jurisdictionally valid lawsuit in which to intervene, their claims likewise cannot proceed.

It is bedrock law that a party’s “status as an intervenor does not confer standing sufficient to keep the case alive” if “the party on whose side the intervenor intervened” lacks standing in their own right. *Sierra Club v. Babbitt*, 995 F.2d 571, 574 (5th Cir. 1993) (citation, ellipses, and brackets omitted). Intervention “presuppose[s] an action duly brought,” *McCord*, 233 U.S. at 163, so “a person may not intervene if the original, underlying case was jurisdictionally defective,” *Odle v. Flores*, 899 F.3d 344, 348 (5th Cir. 2017) (Graves, J., concurring in denial of rehearing en

banc). Said differently, an intervenor’s “participatory rights remain subject to the intervenor’s threshold dependency on the original parties’ claims,” and it is “well-settled that ‘[a]n existing suit within the court’s jurisdiction is a prerequisite of an intervention, which is an ancillary proceeding in an already instituted suit.’” *Harris v. Amoco Prod. Co.*, 768 F.2d 669, 675 (5th Cir. 1985) (quoting *Kendrick v. Kendrick*, 16 F.2d 744, 745 (5th Cir. 1926)).

This black-letter law is true regardless of whether intervention is granted before or after the original plaintiff is found to lack standing. After all, “a case or controversy can exist only if a plaintiff has standing to sue,” *Texas*, 599 U.S. at 675, and “standing is assessed at the time the action commences,” *Carney v. Adams*, 592 U.S. 53, 60 (2020) (quotation marks and citation omitted). That is why the Fifth Circuit rejects intervention “in a ‘jurisdictionally or procedurally defective’ suit,” *Sommers v. Bank of Am., N.A.*, 835 F.3d 509, 513 n.5 (5th Cir. 2016) (citation omitted), and why, “where a plaintiff never had standing to assert a claim against the defendants, it does not have standing to amend the complaint,” *Summit Off. Park, Inc. v. U.S. Steel Corp.*, 639 F.2d 1278, 1282 (5th Cir. 1981).

Nor can the three States proceed as if they had filed an independent lawsuit, as they previously suggested. ECF No. 156 at 4-5. When there is no jurisdictionally valid suit in which the intervenor could have intervened, it is true that “the 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.” Charles Alan Wright & Arthur R. Miller, 7C Fed. Prac. & Proc. Civ. § 1918 (3d ed.).¹ But—setting aside for now other threshold problems, including standing—it is

¹ Every Circuit agrees that a court may exercise its “discretion to treat an intervention as a separate action” *only* if the intervenors establish “a separate and independent” basis for their action. *Arkoma Assocs. v. Carden*, 904 F.2d 5, 7 (5th Cir. 1990); *see Indus. Commc’ns & Elecs., Inc. v. Town of Alton*, 646 F.3d 76, 79 (1st Cir. 2011); *Disability Advocs., Inc. v. N.Y. Coal. for Quality Assisted Living, Inc.*, 675 F.3d 149, 160-162 (2d Cir. 2012); *Fuller v. Volk*, 351 F.2d 323, 328-329

patently clear that the States of Missouri, Kansas, and Idaho do not have venue to pursue their claims in the Northern District of Texas. *See Sinochem Int’l Co. v. Malaysia Int’l Shipping Corp.*, 549 U.S. 422, 431, 436 (2007) (“a federal court has leeway ‘to choose among threshold grounds for denying audience to a case on the merits’ ” (citation omitted)).

The three States did not attempt to meet their “burden of proof . . . to establish that venue is proper in th[is] district.” *Utah v. Walsh*, No. 2:23-cv-016, 2023 WL 2663256, at *5 (N.D. Tex. Mar. 28, 2023) (Kacsmayk, J.) (citation omitted). No party on either side of the “v” in the three States’ complaint in intervention resides in this district. *See* 28 U.S.C. § 1391(e)(1)(A), (C). The three States’ complaint in intervention asserted that “[v]enue properly lies in this Court . . . because a substantial part of the facts, events or omissions giving rise to the claims occurred in this district.” ECF No. 176 ¶ 35. No well-pled facts support that assertion. Just the opposite: Even on the three States’ telling, the events “giving rise” to their claims occurred within their own borders or in Washington, D.C. or Maryland, where the federal defendants sit—not in Texas. *See* 28 U.S.C. § 1391(e)(1)(B).

The three States’ complaint in intervention alternatively contends that venue in Texas is appropriate given that the Alliance Plaintiffs’ case was filed here. ECF No. 176 ¶ 35. The three States’ theory appears to be that because their claims are allegedly “so closely related to the original action” in which the States intervened, “venue objections should not be entertained.” ECF No. 172 at 12 (quoting *Wright & Miller*, § 1918). But as the very section of *Wright & Miller* that

(3d Cir. 1965); *Atkins v. N.C. Bd. of Educ.*, 418 F.2d 874, 876 (4th Cir. 1969); *Horn v. Eltra Corp.*, 686 F.2d 439, 440 (6th Cir. 1982); *Buckley v. Ill. Jud. Inquiry Bd.*, 997 F.2d 224, 227 (7th Cir. 1993); *Mattice v. Meyer*, 353 F.2d 316, 319 (8th Cir. 1965); *Benavidez v. Eu*, 34 F.3d 825, 829-831 (9th Cir. 1994); *Miller & Miller Auctioneers, Inc. v. G. W. Murphy Indus., Inc.*, 472 F.2d 893, 896 (10th Cir. 1973); *Nat’l Ass’n of State Util. Consumer Advoc. v. FCC*, 457 F.3d 1238, 1250 (11th Cir. 2006), *as modified*, 468 F.3d 1272 (11th Cir. 2006); *Aeronautical Radio, Inc. v. FCC*, 983 F.2d 275, 283 (D.C. Cir. 1993).

they invoke for this proposition explains, that “presupposes the pendency of an action in a court of competent jurisdiction.” Wright & Miller § 1918. Because this Court lacks jurisdiction over the Alliance Plaintiffs’ suit, the three States must independently satisfy venue. *See id.* They cannot.

Nor can the three States mix and match to point to the Alliance Plaintiffs for venue and themselves for standing.² *See* ECF No. 172 at 12. The venue-creating plaintiff *itself* “must have standing.” *Clark & Reid Co. v. United States*, 804 F.2d 3, 5 (1st Cir. 1986). That principle is uncontroversial and routinely applied in dismissing or transferring cases where the venue-creating plaintiff lacks standing. *Cf. Miller v. Albright*, 523 U.S. 420, 427 (1998) (plurality opinion); *see, e.g., Merchants Fast Motor Lines, Inc. v. I.C.C.*, 5 F.3d 911, 920-922 (5th Cir. 1993); *Georgia Republican Party v. Sec. & Exch. Comm’n*, 888 F.3d 1198, 1205 (11th Cir. 2018); *Clark & Reid Co.*, 804 F.2d at 7; *Associated Gen. Contractors of Am., Inc. v. Fed. Acquisition Regul. Council*, No. 6:24-CV-00037, 2024 WL 1078260, at *7 (W.D. La. Mar. 12, 2024); *compare White Hat v. Landry*, 475 F. Supp. 3d 532, 550 (M.D. La. 2020). To hold otherwise would invite endless cycles of attempted venue- or standing-saving interventions, with new parties moving to intervene to try to save deficient suits from dismissal. Such an approach would make a mockery of Article III and statutory venue requirements and “start the Federal Judiciary down [an] uncharted path.” *Alliance for Hippocratic Med.*, 602 U.S. at 392.

² The three States also lack standing, an issue beyond the scope of this motion, which is limited to seeking dismissal of an intervenor’s complaint as a direct consequence of the dismissal of the Alliance Plaintiffs’ jurisdictionally deficient action. Should this Court grant the three States’ motion to amend, Danco reserves the right to move to dismiss the three States’ amended complaint for lack of standing and on any other appropriate grounds.

III. The States' Motion For Leave To Amend Their Complaint Must Be Denied.

The three States' motion for leave to amend must be denied for all the same reasons. Because there is no jurisdictionally valid suit in which the States could have intervened, there is likewise no jurisdictionally valid suit in which to file an amended complaint.

The proposed amended complaint also does not attempt to cure the three States' fundamental venue defect. *See In re Connect Transp., LLC*, 825 F. App'x 150, 155 (5th Cir. 2020) (affirming denial of leave to amend as futile where allegations in proposed amended complaint "do nothing to cure the deficiencies of the first [] complaint"). It just repeats that venue is appropriate "because a substantial part of the facts, events or omissions giving rise to the claims occurred in this district." ECF No. 195-1 ¶ 34. Again, no well-pled factual allegations support that statement. And noting that the Alliance Plaintiffs filed suit here, *id.* ¶ 35, does not help the three States because they cannot piggyback on a suit that is not jurisdictionally valid in its own right. Amendment would accordingly be futile as venue does not properly lie in this district. *See, e.g., Hamilton v. Duke Energy Bus. Servs., LLC*, No. 4:21-CV-4070, 2023 WL 2332248, at *4 (S.D. Tex. Mar. 1, 2023) (denying leave to amend as futile where proposed amended complaint "fail[ed] to cure" lack of venue).

Finally, litigating the fact that this Court never had jurisdiction over this matter has required extensive resources, another reason the States' belated attempt at amendment should be denied. *See, e.g., New Leaf Serv. Conts., Inc. v. Gerhard's Inc.*, No. 3:22-CV-1145-G, 2023 WL 2938241, at *7 n.4 (N.D. Tex. Apr. 13, 2023) (denying leave to amend where defendant already "expended extensive resources" litigating the prior complaint and amendment was "unlikely" to cure jurisdictional defects). That is particularly true where Danco would be forced to expend yet further resources in a forum that plainly lacks venue to hear the three States' claims in the first place.

CONCLUSION

For the foregoing reasons, and for the reasons in FDA's Brief, ECF Nos. 197, 198, the Court should grant Danco's motion to dismiss, dismiss the Alliance Plaintiffs' suit and the three States' complaint in intervention, and deny the three States' motion for leave to amend.

Respectfully submitted,

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November 1, 2024

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with Local Rule 7.2 in that it does not exceed 25 pages.

/s/ Jessica L. Ellsworth
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CERTIFICATE OF SERVICE

I certify that on November 1, 2024, I electronically filed the foregoing using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties of record.

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