

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

Alliance for Hippocratic Medicine, *et al.*,

Plaintiffs,

and

State of Missouri, *et al.*,

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

**DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO DISMISS,**  
**AND IN OPPOSITION TO INTERVENOR-PLAINTIFFS'**  
**MOTION FOR LEAVE TO AMEND**

**TABLE OF CONTENTS**

INTRODUCTION.....1

BACKGROUND .....1

LEGAL STANDARD.....3

ARGUMENT.....4

    I.    Plaintiffs’ Complaint Must Be Dismissed Because the Supreme Court Held  
          that They Lack Standing.....4

    II.   The States’ Complaint Must Likewise Be Dismissed .....7

        A.   The States Cannot Intervene in a Lawsuit That Was Never Jurisdictionally  
            Proper .....7

        B.   The States’ Complaint Cannot Proceed as an Independent Suit Before this  
            Court Because, Among Other Reasons, the States Lack Venue.....9

    III.  The States’ Request for Leave to Amend Should Be Denied for Futility .....14

CONCLUSION.....14

**TABLE OF AUTHORITIES**

**Cases**

*Aetna Cas. & Sur. Co. v. Hillman*,  
796 F.2d 770 (5th Cir. 1986).....8

*Alliance for Hippocratic Med. v. U.S. Food & Drug Admin.*,  
117 F.4th 336 (5th Cir. 2024)..... 2, 3

*Alliance for Hippocratic Medicine v. FDA*,  
78 F.4th 210 (5th Cir. 2023).....2

*Associated Gen. Contractors of Am., Inc. v. Fed. Acquisition Regul. Council*,  
720 F. Supp. 3d 461 (W.D. La. 2024).....10

*ATK Launch Sys., Inc. v. EPA*,  
651 F.3d 1194 (10th Cir. 2011).....9

*Atl. Marine Const. Co. v. U.S. Dist. Ct. for W. Dist. of Texas*,  
571 U.S. 49 (2013) .....11

*Bigham v. Envirocare of Utah, Inc.*,  
123 F. Supp. 2d 1046 (S.D. Tex. 2000) .....10

*Career Colls. & Schs. of Texas v. Dep’t of Educ.*,  
2023 WL 2975164 (N.D. Tex. Apr. 17, 2023).....10

*Chavez v. First Nat’l Bank of S. Afr.*,  
2015 WL 13036708 (W.D. Tex. Nov. 24, 2015).....14

*Chevron U.S.A. Inc. v. EPA*,  
45 F.4th 380 (D.C. Cir. 2022).....9

*Clapper v. Amnesty Int’l USA*,  
568 U.S. 398 (2013) .....6

*DaimlerChrysler Corp. v. Cuno*,  
547 U.S. 332 (2006) .....3

*Dayton Area Chamber of Com. v. Becerra*,  
2024 WL 3741510 (S.D. Ohio Aug. 8, 2024),  
appeal filed, No. 24-3868 (6th Cir. Oct. 8, 2024) .....13

*Disability Advocates, Inc. v. N.Y. Coal. for Quality Assisted Living, Inc.*,  
675 F.3d 149 (2d Cir. 2012) .....7

*Ex parte McCordle*,  
7 Wall. 506 (1868).....4

*Federal Recovery Services, Inc. v. United States*,  
72 F.3d 447 (5th Cir. 1995) ..... 8, 9

*Food & Drug Admin. v. Alliance for Hippocratic Med.*,  
602 U.S. 367 (2024) ..... *passim*

*Fuller v. Volk*,  
351 F.2d 323 (3d Cir. 1965) ..... 7

*Ga. Republican Party v. SEC*,  
888 F.3d 1198 (11th Cir. 2018) ..... 13

*Hamilton v. Duke Energy Bus. Servs., LLC*,  
2023 WL 2332248 (S.D. Tex. Mar. 1, 2023) ..... 14

*Harris v. Amoco Prod. Co.*,  
768 F.2d 669 (5th Cir. 1985) ..... 7

*Hines v. Stamos*,  
111 F.4th 551 (5th Cir. 2024) ..... 9

*In re Horseshoe Ent.*,  
337 F.3d 429 (5th Cir. 2003) ..... 12

*In re LimitNone, LLC*,  
551 F.3d 572 (7th Cir. 2008) ..... 9

*In re Volkswagen of America, Inc.*,  
545 F.3d 304 (5th Cir. 2008) ..... 12

*Inst. of Certified Pracs., Inc. v. Bentsen*,  
874 F. Supp. 1370 (N.D. Ga. 1994) ..... 13

*Jenkins Brick Co. v. Bremer*,  
321 F.3d 1366 (11th Cir. 2003) ..... 10

*Kansas v. Garland*,  
2024 WL 2384611 (E.D. Ark. May 23, 2024) ..... 13

*Kendrick v. Kendrick*,  
16 F.2d 744 (5th Cir. 1926) ..... 7

*Lujan v. Defs. of Wildlife*,  
504 U.S. 555 (1992) ..... 6

*Marucci Sports, LLC v. Nat’l Collegiate Athletic Ass’n*,  
751 F.3d 368 (5th Cir. 2014) ..... 4

*Miller v. Albright*,  
523 U.S. 420 (1998) .....12

*Missouri v. Dep’t of Educ.*,  
2024 WL 4374124 (S.D. Ga. Oct. 2, 2024).....12

*Nat’l Distillers & Chem. Corp. v. Dep’t of Energy*,  
487 F. Supp. 34 (D. Del. 1980).....13

*Renne v. Geary*,  
501 U.S. 312 (1991) .....3

*Steel Co. v. Citizens for a Better Env’t*,  
523 U.S. 83 (1998) .....4

*Summit Off. Park, Inc. v. U.S. Steel Corp.*,  
639 F.2d 1278 (5th Cir. 1981).....8

*Total Safety U.S., Inc. v. Rowland*,  
2014 WL 4693114 (E.D. La. Sept. 22, 2014).....14

*United States ex rel. Tex. Portland Cement Co. v. McCord*,  
233 U.S. 157 (1914) ..... 7, 9

*Walters v. Edgar*,  
163 F.3d 430 (7th Cir. 1998).....8

*Woodke v. Dahm*,  
70 F.3d 983 (8th Cir. 1995).....10

**Statutes**

28 U.S.C. § 1391(e) .....12

28 U.S.C. § 1391(e)(1)(B) .....9

28 U.S.C. § 1391(e)(1)(C) .....9

28 U.S.C. § 1406(a) .....11

**Rules**

Fed. R. Civ. P. 12(b)(1)..... 3, 14

Fed. R. Civ. P. 12(h)(3).....3

**Other Authorities**

7C Charles A. Wright et al., Federal Practice & Procedure § 1917 (3d ed. June 2024).....7

7C Charles A. Wright et al., Federal Practice & Procedure § 1918 (3d ed. June 2024)..... 9, 12

7C Charles A. Wright et al., Federal Practice & Procedure § 3815 (3d ed. June 2024).....13

## **INTRODUCTION**

Four months ago, the Supreme Court unanimously held that the Plaintiffs in this case “lack standing to challenge FDA’s actions.” *Food & Drug Admin. v. Alliance for Hippocratic Med.*, 602 U.S. 367, 374 (2024). Based on that conclusion, this Court is required to dismiss Plaintiffs’ Complaint for lack of jurisdiction. Nothing in the Supreme Court’s decision was tentative or preliminary. Instead, the Court’s decision rested on legal flaws inherent in Plaintiffs’ theories of standing. Thus, binding Supreme Court precedent compels dismissal of Plaintiffs’ Complaint for lack of subject-matter jurisdiction.

Once Plaintiffs’ Complaint is dismissed, the separate Complaint filed by the three Intervenor States—the States of Missouri, Idaho, and Kansas (“the States”)—must likewise be dismissed. The Fifth Circuit has squarely held that intervention requires a jurisdictionally proper suit. Because this Court never had jurisdiction over Plaintiffs’ claims, it could not obtain jurisdiction over the States’ claims. And this Court cannot allow the States’ claims to continue as an independent suit because (among other reasons) the States plainly cannot establish venue here: the States of Missouri, Idaho, and Kansas do not reside in—and have no plausible connection to—the Northern District of Texas. Because venue is improper in this District, that defect precludes the States’ Complaint from proceeding. Consequently, this Court must dismiss (or transfer) the States’ Complaint as well and deny leave to amend their Complaint as futile.

## **BACKGROUND**

Plaintiffs here are doctors and medical associations opposed to the use of the drug mifepristone, and they seek to challenge certain regulatory actions taken by the U.S. Food and Drug Administration (“FDA”) with respect to that drug. ECF No. 1 ¶¶ 32-40.<sup>1</sup> On April 7, 2023, in

---

<sup>1</sup> FDA has approved mifepristone, in a regimen with misoprostol, for the termination of early intrauterine pregnancy. FDA has separately approved another manufacturer’s mifepristone

response to Plaintiffs' motion for preliminary injunction, ECF No. 6, this Court entered an order staying the effective date of the challenged FDA actions. ECF No. 137. In August 2023, the Fifth Circuit vacated in part and affirmed in part that order, *Alliance for Hippocratic Medicine v. FDA*, 78 F.4th 210 (5th Cir. 2023), and the Supreme Court granted certiorari. While Supreme Court proceedings were pending, this Court allowed the States of Missouri, Kansas, and Idaho to intervene in this action. ECF No. 175.

In June 2024, the Supreme Court held that Plaintiffs "lack standing to challenge FDA's actions." *Alliance*, 602 U.S. at 374. "Under Article III of the Constitution, a plaintiff's desire to make a drug less available *for others* does not establish standing to sue." *Id.* And although Plaintiffs advanced "several complicated causation theories" to "try to establish standing," the Supreme Court held that "none of the theories suffices[.]" *Id.* at 385-86. Because "the plaintiffs have failed to demonstrate that FDA's relaxed regulatory requirements likely would cause them to suffer an injury in fact," the Court explained, the "federal courts are the wrong forum for addressing the plaintiffs' concerns about FDA's actions." *Id.* at 396-97. 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." *Id.* at 397. Accordingly, the Supreme Court "reverse[d] the judgment of the U. S. Court of Appeals for the Fifth Circuit and remand[ed] the case for further proceedings consistent with this opinion." *Id.*

The Fifth Circuit thereafter issued its mandate in September 2024. In a short per curiam opinion accompanying the mandate, the Fifth Circuit noted that the Supreme Court "reversed our judgment and held that the Plaintiffs lack standing to challenge several FDA actions." *Alliance for Hippocratic Med. v. U.S. Food & Drug Admin.*, 117 F.4th 336, 340 (5th Cir. 2024) (per curiam). The

---

product, Korlym, for the treatment of Cushing's syndrome. Plaintiffs do not challenge FDA's actions regarding Korlym.

Fifth Circuit therefore vacated the district court's order and "remand[ed] for further proceedings consistent with the Supreme Court's opinion." *Id.* In a concurring opinion, Judge Ho agreed that was the proper course because "[t]he Supreme Court has now held that Plaintiffs lack standing." *Id.* at 342 (Ho, J., concurring).

The parties then filed a Joint Status Report in this Court regarding further proceedings. ECF No. 191. Defendants and Intervenor-Defendant explained that, following the Supreme Court's decision, this case should be over and both Plaintiffs' and the States' Complaints should be dismissed. *See id.* ¶¶ 3-4. Plaintiffs and Intervenor-Plaintiffs disagreed, *id.* ¶ 5, and the States indicated that they intended to move for leave to amend their Complaint, *id.* ¶ 6.

The States have now moved for leave to amend. ECF No. 195. Defendants oppose that motion as futile and concurrently seek dismissal of both Plaintiffs' and the States' Complaints. Dismissal of Plaintiffs' Complaint is the only course "consistent with the Supreme Court's opinion," *Alliance*, 117 F.4th at 340, given the Supreme Court's unequivocal holding that Plaintiffs lack standing. And dismissal or transfer of the States' Complaint is required because venue is improper in this District. Nothing in the States' proposed amendments can cure that fundamental defect in their Complaint.

### **LEGAL STANDARD**

"[T]he party asserting federal jurisdiction when it is challenged has the burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006). Federal courts presume that they "lack jurisdiction unless the contrary appears affirmatively from the record." *Renne v. Geary*, 501 U.S. 312, 316 (1991) (quotation marks omitted). And under Rule 12 of the Federal Rules of Civil Procedure, "[i]f the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action." Fed. R. Civ. P. 12(h)(3); *see also* Fed. R. Civ. P. 12(b)(1). Leave to amend is properly

denied where “allowing an amendment would be futile.” *Marucci Sports, LLC v. Nat’l Collegiate Athletic Ass’n*, 751 F.3d 368, 378 (5th Cir. 2014).

## ARGUMENT

### **I. Plaintiffs’ Complaint Must Be Dismissed Because the Supreme Court Held that They Lack Standing**

Upon review of the Fifth Circuit’s judgment regarding this Court’s April 7 Order, the Supreme Court held that “the plaintiffs lack standing to challenge FDA’s actions.” *Alliance*, 602 U.S. at 374. That holding requires this Court to dismiss their Complaint for lack of standing. *See 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, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.” (quoting *Ex parte McCordle*, 7 Wall. 506, 514 (1868))).

Plaintiffs have suggested that the Supreme Court’s holding does not control the outcome at this stage of litigation because their “evidentiary burden” was different when they sought preliminary relief. *See* ECF No. 191 ¶ 5. This Court should reject Plaintiffs’ invitation to ignore binding Supreme Court precedent. The Supreme Court’s decision does not permit a different conclusion about Plaintiffs’ standing at *any* stage of litigation because the Court unequivocally held as a matter of law that Plaintiffs “lack standing to challenge FDA’s actions,” 602 U.S. at 374—not that they merely failed to show a likelihood of success with respect to standing or sufficiently prove their theories of injury. The Supreme Court’s reasoning as to why Plaintiffs lack standing was rooted in *legal* conclusions, and nothing about those conclusions was tentative or equivocal.

The Court’s opinion catalogues Plaintiffs’ standing theories, walks through each one, and explains that “none of the theories suffices to establish Article III standing” because they all have fatal legal flaws. *Id.* at 386. First, the Court addressed Plaintiffs’ principal legal theory: that the plaintiff doctors “may be required—against their consciences—to render emergency treatment

completing the abortions or providing other abortion-related treatment.” *Id.* at 387. The Court rejected this theory, holding that “the plaintiffs have not shown—and cannot show—that FDA’s actions will cause them to suffer any conscience injury.” *Id.* at 390 (emphasis added). As the Court explained, Plaintiffs’ theory fails not only “as a matter of fact,” but also “as a matter of law” because “federal conscience laws definitively protect doctors from being required to perform abortions or to provide other treatment that violates their consciences.” *Id.* at 387-88.

Next, the Court addressed the doctors’ claimed “monetary and related injuries that they will suffer as a result of FDA’s actions—in particular, diverting resources and time from other patients to treat patients with mifepristone complications; increasing risk of liability suits from treating those patients; and potentially increasing insurance costs.” *Id.* at 390. “To begin with,” the Court characterized those injuries as “lack[ing] record support” and “highly speculative.” *Id.* But the Court did not rest on those deficiencies alone. Instead, it emphasized that Plaintiffs’ theory also fails as a matter of law: “In any event, and perhaps more to the point, the law has never permitted doctors to challenge the government’s loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors’ offices with follow-on injuries.” *Id.* at 391. The Court emphatically declined “to invent a new doctrine of doctor standing,” the consequences of which would be “flatly inconsistent with Article III.” *Id.* at 392; *see also id.* at 393 n.5 (explaining how “[t]his Court has repeatedly rejected” arguments that doctors “can sue in a representative capacity to vindicate their patients’ injuries or potential future injuries” when the doctors have not themselves suffered an injury in fact).

Finally, the Court addressed the standing of the plaintiff medical associations. Although those associations claimed that “FDA has impaired their ability to provide services and achieve their organizational missions,” the Court held that this theory “does not work to demonstrate standing.” *Id.* at 394 (quotation marks omitted). In particular, “an organization that has not suffered a concrete

injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action." *Id.*; *see also id.* at 395 ("FDA's actions relaxing regulation of mifepristone have not imposed any [legally cognizable] impediment to the medical associations' advocacy businesses."). And "even if no one would have standing" to challenge FDA's actions, the proper result would be for Plaintiffs to "present their concerns and objections to the President and FDA in the regulatory process, or to Congress and the President in the legislative process." *Id.* at 396-97. But "the federal courts are the wrong forum for addressing the plaintiffs' concerns about FDA's actions." *Id.* All of those holdings are definitive legal conclusions that were not tentative or otherwise preliminary.

Separately, Plaintiffs have suggested that dismissal is unwarranted because, in their view, the Supreme Court "rejected Defendants' request 'to remand with instructions that the case be dismissed or transferred to an appropriate venue.'" ECF No. 191 ¶ 5 (quoting Reply Brief of the United States, Nos. 23-235, 23-236, 2024 WL 1158797, at 14 n.3 (U.S. filed Mar. 15, 2024)). The Supreme Court's decision to follow the ordinary remand process can hardly be characterized as a decision to allow Plaintiffs' claims to proceed when, as just discussed, everything else in the opinion makes abundantly clear that Plaintiffs lack standing. *Cf. Lujan v. Defs. of Wildlife*, 504 U.S. 555, 578 (1992) (holding that plaintiffs "lack standing" and therefore "revers[ing]" and "remand[ing] for proceedings consistent with this opinion"); *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 422 (2013) (same).

Ultimately, the Supreme Court held that "the plaintiffs lack standing to challenge FDA's actions." *Alliance*, 602 U.S. at 374. The Supreme Court's decision, and the legal holdings on which the Court relied, leave no room for a different conclusion at any stage of litigation and under any burden of proof. Plaintiffs' Complaint must therefore be dismissed.

## II. The States' Complaint Must Likewise Be Dismissed

Once Plaintiffs' Complaint is dismissed for lack of subject-matter jurisdiction, binding precedent confirms that the States' Complaint must likewise be dismissed. Because Plaintiffs lacked standing from the outset, there was never a jurisdictionally valid lawsuit in which the States could intervene. Nor can the States' Complaint proceed as an independent suit, given that (among other reasons) venue is improper in this District.

### A. The States Cannot Intervene in a Lawsuit That Was Never Jurisdictionally Proper

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)). “Indeed, this rule is so deeply entrenched in our jurisprudence that it is an axiomatic principle of federal jurisdiction in every circuit to have addressed the question.” *Disability Advocates, Inc. v. N.Y. Coal. for Quality Assisted Living, Inc.*, 675 F.3d 149, 160-61 (2d Cir. 2012) (collecting cases). For similar reasons, “[i]ntervention cannot cure any jurisdictional defect that would have barred the federal court from hearing the original action.” 7C Charles A. Wright et al., *Federal Practice & Procedure* § 1917 (3d ed. June 2024); *see also, e.g., United States ex rel. Tex. Portland Cement Co. v. McCord*, 233 U.S. 157, 163-64 (1914) (holding that “the cause of action had not accrued to the creditors who undertook to bring the suit originally,” and “[t]he intervention [of a party with a proper claim] could not cure this vice in the original suit”); *Fuller v. Volk*, 351 F.2d 323, 328 (3d Cir. 1965).

Because Plaintiffs lack standing, this Court lacks jurisdiction over Plaintiffs' Complaint, and the States cannot rely on intervention to overcome this Court's lack of jurisdiction. Indeed, almost a century of Fifth Circuit precedent confirms as much. *See, e.g., Kendrick*, 16 F.2d at 746 (“The intervening petition being merely a contrivance between friends for the purpose of founding a

jurisdiction which otherwise would not exist, the device cannot be allowed to succeed.” (quotation marks omitted)).

These principles are so fundamental that, even outside the intervention context, the Fifth Circuit has routinely emphasized that jurisdiction cannot be created through the addition of other parties. In *Federal Recovery Services, Inc. v. United States*, 72 F.3d 447 (5th Cir. 1995), for example, the Fifth Circuit held that Rule 15 could not be used to fix a jurisdictional defect by substituting a new party, regardless of whether the Rule 15 request was made before dismissal: “In short, regardless of when the district court actually determines it lacks subject matter jurisdiction over the original plaintiff, Rule 15 does not allow a party to amend to create jurisdiction where none actually existed.” *Id.* at 453 (cleaned up); *see also, e.g., Aetna Cas. & Sur. Co. v. Hillman*, 796 F.2d 770, 776 (5th Cir. 1986) (“The citizenship of a party at the *commencement* of the action is controlling for purposes of determining diversity jurisdiction and subsequent actions do not affect the court’s jurisdiction. Jurisdiction cannot be created retroactively by substituting a diverse claimant for a nondiverse party.” (citations omitted)); *Summit Off. Park, Inc. v. U.S. Steel Corp.*, 639 F.2d 1278, 1282 (5th Cir. 1981) (“where a plaintiff never had standing to assert a claim against the defendants, it does not have standing to amend the complaint and . . . substitut[e] new plaintiffs, a new class, and a new cause of action”); *cf. Walters v. Edgar*, 163 F.3d 430, 432-33 (7th Cir. 1998) (holding “federal jurisdiction never attached” if “plaintiffs never had standing to bring this suit,” a failure that cannot be cured through addition of new parties).

It is therefore irrelevant that this Court previously granted the States’ intervention motion prior to the Supreme Court’s decision. That decision now confirms that no federal court *ever* had Article III jurisdiction over Plaintiffs’ claims. *See Alliance*, 602 U.S. at 374. And because Plaintiffs’ Complaint must be dismissed for lack of subject-matter jurisdiction, so too must the States’ Complaint, because otherwise—even assuming *arguendo* the States could establish jurisdiction for

their claims—that would impermissibly “allow a party . . . to create jurisdiction where none actually existed.” *Fed. Recovery Servs.*, 72 F.3d at 453; *see also Tex. Portland Cement Co.*, 233 U.S. at 163-64 (“[I]ntervention could not cure this vice in the original suit.”).

**B. The States’ Complaint Cannot Proceed as an Independent Suit Before this Court Because, Among Other Reasons, the States Lack Venue**

The States’ Complaint likewise cannot proceed independently. When an original suit is dismissed for lack of jurisdiction, the only way an intervenor’s complaint may still be allowed to proceed “as if it were a separate suit” is when “the intervenor’s claim . . . satisfies by itself the requirements of jurisdiction *and venue*.” Wright & Miller, *Federal Practice & Procedure* § 1918 (emphasis added). Putting aside other problems with the States’ standing and the merits of their claims, it is clear that the States may not proceed with this case because venue is improper in this District. None of the States of Missouri, Idaho, or Kansas has any plausible connection to the Northern District of Texas.<sup>2</sup>

1. It is beyond dispute that the States of Missouri, Idaho, and Kansas do not reside in the Northern District of Texas. *See* 28 U.S.C. § 1391(e)(1)(C) (allowing civil actions against the United States in any district in which “the plaintiff resides if no real property is involved in the action”). Instead, the States claim that venue exists in this District pursuant to 28 U.S.C. § 1391(e)(1)(B) on the ground that “a substantial part of the facts, events or omissions giving rise to the claims occurred in this district[.]” States’ Compl. (ECF No. 176) ¶ 35; *see also* States’ Prop. Am. Compl.

---

<sup>2</sup> This venue defect is a threshold, non-merits basis for dismissal, which this Court may address without first considering jurisdiction. *See, e.g., Chevron U.S.A. Inc. v. EPA*, 45 F.4th 380, 385 (D.C. Cir. 2022); *ATK Launch Sys., Inc. v. EPA*, 651 F.3d 1194, 1200 (10th Cir. 2011); *In re LimitNone, LLC*, 551 F.3d 572, 576-77 (7th Cir. 2008); *see also Hines v. Stamos*, 111 F.4th 551, 564 (5th Cir. 2024) (recognizing that “a federal court has leeway to choose among threshold grounds for denying audience to a case on the merits,” such as “granting *forum non conveniens* dismissals before addressing other jurisdictional issues” (quotation marks omitted)).

(ECF No. 195-1) ¶ 34. But none of the “facts, events or omissions” giving rise to the States’ claims—much less a substantial part—occurred in the Northern District of Texas.

In general, venue under § 1391(e)(1)(B) is analyzed based on where the defendant’s allegedly unlawful actions occurred, not where plaintiffs might feel the effects of those actions. *See, e.g., Jenkins Brick Co. v. Bremer*, 321 F.3d 1366, 1372 (11th Cir. 2003) (asking first “[w]hat acts or omissions by [the defendant] ‘gave rise’ to [the plaintiff’s] claim?”); *Woodke v. Dahm*, 70 F.3d 983, 985 (8th Cir. 1995) (“[B]y referring to ‘events or omissions giving rise to the claim,’ Congress meant to require courts to focus on relevant activities of the defendant, not of the plaintiff.”); *Bigham v. Envirocare of Utah, Inc.*, 123 F. Supp. 2d 1046, 1048 (S.D. Tex. 2000) (“In determining whether or not venue is proper, the Court looks to the defendant’s conduct, and where that conduct took place. Actions taken by a plaintiff do not support venue.” (citation omitted)).

Here, none of the challenged actions occurred in the Northern District of Texas. The States seek to challenge FDA’s regulatory actions, and FDA is headquartered in Silver Spring, Maryland. The challenged actions did not occur in, and have no plausible connection to, the Northern District of Texas. *Cf. Associated Gen. Contractors of Am., Inc. v. Fed. Acquisition Regul. Council*, 720 F. Supp. 3d 461, 473 (W.D. La. 2024) (venue was lacking in challenge to agency action because “the events giving rise to the PLA Rule took place where EO 14,063 and the Final Rule were both drafted and enacted, that is, in Washington, D.C.”).

Nor would venue be proper even if it were determined by where the States feel the effects of the challenged policies. The States have not identified any way in which they feel the alleged effects of FDA’s actions in the Northern District of Texas. And even when courts have relied upon the effects of a challenged agency action to establish venue, they have still required “that a party bringing the claim must be present in the district or division in some real capacity and burdened by the unlawful rule.” *Career Colls. & Schs. of Texas v. Dep’t of Educ.*, 2023 WL 2975164, at \*3 (N.D. Tex.

Apr. 17, 2023). The States of Missouri, Idaho, and Kansas simply do not have any meaningful presence in the Northern District of Texas.

Of course, the conclusion that venue is improper in this District does not itself preclude the States from filing suit in a proper forum. Particularly now that Plaintiffs' Complaint must be dismissed for lack of standing, there is no basis for the sovereign States of Missouri, Idaho, and Kansas to seek to litigate their claims in this forum, as opposed to the Federal courts located in their home jurisdictions or where Defendants are headquartered. To the extent that the States' claims may proceed at all, therefore, those claims must be adjudicated by courts with proper venue—not in a forum that has no conceivable connection to any of the remaining parties or claims in this case.

2. The States have previously raised various theories as to why this Court should ignore the venue statute's requirements. None of the States' arguments has merit.

First, the States have asserted that “[v]enue is not jurisdictional,” Brief of Amici Curiae States of Missouri, Idaho, and Kansas, Nos. 23-235, 23-236, 2024 WL 948009, at \*25 (U.S. filed Feb. 29, 2024), thereby implying that this Court could simply ignore the United States' venue objection. But the States cite no authority allowing a court to ignore a timely raised venue objection, and doing so would be contrary to the venue statute itself, which speaks in mandatory terms. *See* 28 U.S.C. § 1406(a) (“The district court of a district in which is filed a case laying venue in the wrong division or district *shall* dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought.” (emphasis added)). As the Supreme Court has explained:

When venue is challenged, the court must determine whether the case falls within one of the three categories set out in § 1391(b). If it does, venue is proper; if it does not, venue is improper, and the case *must be dismissed or transferred* under § 1406(a).

*Atl. Marine Const. Co. v. U.S. Dist. Ct. for W. Dist. of Texas*, 571 U.S. 49, 56 (2013) (emphasis added).

The Fifth Circuit has likewise explained that timely raised venue objections should be given “a top

priority” in the handling of a case. *In re Horseshoe Ent.*, 337 F.3d 429, 433 (5th Cir. 2003); *cf. In re Volkswagen of America, Inc.*, 545 F.3d 304 (5th Cir. 2008) (en banc). Contrary to the States’ suggestion, then, neither the venue statute nor precedent allows a court simply to ignore a timely venue defense.

Next, the States have previously argued that “when a particular claim or party is so closely related to the original action that it can be considered ancillary . . . venue objections should not be entertained.” Reply in Supp. of Intervention (ECF No. 172) at 7 (quoting Wright & Miller, Federal Practice & Procedure § 1918). In making this argument, however, the States misconstrue the relevant passage in Wright & Miller. Specifically, the States quote from a portion discussing principles that apply when there is a “main action” and “jurisdiction in the main action is premised on a federal question[.]” Wright & Miller, Federal Practice & Procedure § 1918. But here, there is no “main action” because Plaintiffs’ Complaint must be dismissed for lack of jurisdiction, as discussed above. And in the scenario relevant here—*i.e.*, when there is no longer a main action, and the States are asserting an independent right to pursue their claims in this Court—the very same section of Wright & Miller makes clear that proper venue is mandatory: “[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*.” *Id.* (emphasis added). Because the States cannot plausibly satisfy venue here, their suit cannot continue in this Court.

The States have also argued that, even if Plaintiffs lack standing, the States can still rely on those same Plaintiffs to satisfy venue. *See, e.g.*, Reply in Supp. of Intervention (ECF No. 172) at 7. But the law is clear that a party who lacks standing cannot be the basis for satisfying venue. *See Miller v. Albright*, 523 U.S. 420, 426-27 (1998) (op. of Stevens, J.) (“[T]he District Court concluded that Mr. Miller did not have standing and dismissed him as a party. Because venue in Texas was therefore improper, see 28 U.S.C. § 1391(e), the court transferred the case[.]”); *Missouri v. Dep’t of Educ.*, 2024 WL 4374124, at \*4 (S.D. Ga. Oct. 2, 2024) (“Without standing, Georgia cannot provide the proper

venue for suit because a plaintiff that lacks standing cannot create venue where it would not otherwise exist.”); *Kansas v. Garland*, 2024 WL 2384611, at \*1 (E.D. Ark. May 23, 2024) (“Because no Plaintiff with standing resides in this district, venue is improper.”); *Dayton Area Chamber of Com. v. Becerra*, 2024 WL 3741510, at \*8 (S.D. Ohio Aug. 8, 2024) (similar), *appeal filed*, No. 24-3868 (6th Cir. Oct. 8, 2024); *see also, e.g., Ga. Republican Party v. SEC*, 888 F.3d 1198, 1205 (11th Cir. 2018); *Inst. of Certified Pracs., Inc. v. Bentsen*, 874 F. Supp. 1370, 1372 (N.D. Ga. 1994); *Nat’l Distillers & Chem. Corp. v. Dep’t of Energy*, 487 F. Supp. 34, 36-37 (D. Del. 1980); Wright & Miller, *Federal Practice & Procedure* § 3815. The States’ limitless theory would allow any plaintiff to manufacture venue for any case in any District simply by adding parties who have no Article III standing (or even an interest in the case) but who happen to reside in the plaintiff’s preferred District. That is not the law, and this Court should not endorse such an approach.

Finally, the States argue that “if there were a venue issue . . . the States could easily cure it[.]” ECF No. 191 ¶ 5. But apparently that is not the case; the States have known about the United States’ venue objection for almost a year, *see* ECF No. 155 at 4, and they have had four months since the Supreme Court’s decision to evaluate how to proceed in light of that objection, but they have now filed a motion for leave to amend that adds no new parties and relies on the same basis for venue as their original Complaint. *Compare* States’ Compl. (ECF No. 176) ¶ 35, *with* States’ Prop. Am. Compl. (ECF No. 195-1) ¶ 34; *see also* Part III, *infra*. Sophisticated litigants like the three Intervenor States do not need, and would not be entitled to, a third bite at the apple to try to justify why their lawsuit should proceed in this forum. In any event, a hypothetical ability to cure a venue defect in the future does not save the States’ *current* Complaint from dismissal or transfer, given the mandatory command of § 1406(a).

Accordingly, the States’ Complaint should be dismissed or transferred to a District where venue would be proper—*i.e.*, the District of Columbia, the District of Maryland, the Western

District of Missouri, the District of Idaho, or the District of Kansas. In any scenario, however, the States cannot proceed in the Northern District of Texas, a District that has no plausible connection to the States of Missouri, Idaho, and Kansas or their claims in this case.

### **III. The States' Request for Leave to Amend Should Be Denied for Futility**

Relatedly, the States' motion for leave to amend should be denied as futile. Again, setting aside the other jurisdictional and merits defects in the States' proposed pleading, nothing in the States' proposed Amended Complaint alters the conclusion that venue in this District is improper. The Intervenor-States are still the States of Missouri, Idaho, and Kansas, *see* States' Prop. Am. Compl. (ECF No. 195-1) ¶¶ 38-42, and those States still do not have any relevant connection to the Northern District of Texas.

Courts routinely deny leave to amend when a proposed pleading would not cure a venue defect. *See, e.g., Hamilton v. Duke Energy Bus. Servs., LLC*, 2023 WL 2332248, at \*4 (S.D. Tex. Mar. 1, 2023) ("Plaintiff's additional factual allegations fail to cure any of the venue issues . . . so granting leave to amend would be futile."); *Chavez v. First Nat'l Bank of S. Afr.*, 2015 WL 13036708, at \*4 (W.D. Tex. Nov. 24, 2015) ("Plaintiff's amendment would be futile because this Court is not an appropriate venue."); *Total Safety U.S., Inc. v. Rowland*, 2014 WL 4693114, at \*8 (E.D. La. Sept. 22, 2014) (denying leave to amend because "venue in the Eastern District is futile"). Similarly, here, the States' motion for leave to amend should be denied because their proposed Amended Complaint does not (and cannot) cure the lack of venue in this District.

### **CONCLUSION**

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(3), Plaintiffs' Complaint (ECF No. 1) should be dismissed for lack of subject-matter jurisdiction; the States' current Complaint (ECF No. 176) should likewise be dismissed or transferred for lack of venue; and the States' motion for leave to amend (ECF No. 195) should be denied for futility.

November 1, 2024

Respectfully submitted,

BRIAN M. BOYNTON  
Principal Deputy Assistant Attorney General

ERIC B. BECKENHAUER  
JULIE STRAUS HARRIS  
EMILY NESTLER  
Assistant Directors

*/s/ Daniel Schwei*  
DANIEL SCHWEI  
Special Counsel  
CHRISTOPHER A. EISWERTH  
KATE TALMOR  
Trial Attorneys  
Federal Programs Branch  
Civil Division  
U.S. Department of Justice  
1100 L St., NW  
Washington, DC 20005  
202-305-8693  
daniel.s.schwei@usdoj.gov

BURDEN WALKER  
Acting Deputy Assistant Attorney General

AMANDA N. LISKAMM  
Acting Director

HILARY K. PERKINS  
Assistant Director

NOAH T. KATZEN  
Trial Attorney  
Consumer Protection Branch

*Counsel for Defendants*