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

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' MOTION TO DISMISS

Pursuant to Federal Rule of Civil Procedure 12(b), Defendants hereby respectfully move to dismiss the Intervenor States' Amended Complaint (ECF No. 217). Venue in this District is improper, and therefore the States' Amended Complaint should be dismissed, *see* Fed. R. Civ. P. 12(b)(3), or transferred to a District where venue may 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. *See* 28 U.S.C. § 1406(a).

Alternatively, the States' Amended Complaint should be dismissed because this Court lacks Article III jurisdiction over the States' claims; the States failed to administratively exhaust their claims; and the States' challenges to Defendants' 2016 actions are barred by the statute of limitations. *See* Fed. R. Civ. P. 12(b)(1), (6).

The reasons supporting this motion are set forth in the accompanying Memorandum, and a proposed order is attached.

January 18, 2025

Respectfully submitted,

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DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO DISMISS INTERVENOR-PLAINTIFFS' AMENDED COMPLAINT

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INTRODUCTION

In June 2024, the Supreme Court unanimously held that the original 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). The original Plaintiffs have now voluntarily dismissed all of their claims. *See* ECF No. 203. Nonetheless, the three Intervenor States—the States of Missouri, Idaho, and Kansas ("the States")—desire to continue this litigation in this forum, and have now filed an Amended Complaint expanding their claims further. ECF No. 217. The States' Amended Complaint should be dismissed for multiple reasons.

Most obviously, the States of Missouri, Idaho, and Kansas have no plausible connection to the Northern District of Texas. None of those States resides in this District, nor do their claims arise out of events occurring in this District. Accordingly, the States plainly lack venue to pursue their claims here. Consistent with the venue statute's mandatory command, the States' Amended Complaint should either be dismissed or transferred.

Even apart from venue, there are several more reasons why the States' Amended Complaint should be dismissed. First, this Court lacks jurisdiction over the States' claims: the States cannot continue litigating a case that was never jurisdictionally valid and has now been voluntarily dismissed, nor can the States independently establish their own Article III standing. Second, the States did not administratively exhaust any of their claims with FDA, contrary to FDA's mandatory regulations. And third, the States' challenges to FDA's 2016 actions are time-barred because the States first raised their claims more than six years after those actions were finalized. The Court need not address these other issues to the extent it dismisses or transfers this case based on improper venue. Regardless of the specific reasons, however, the States' claims cannot proceed in this Court, and the Amended Complaint should be dismissed or transferred.

BACKGROUND

This case was originally filed by doctors and medical associations opposed to the use of the drug mifepristone, seeking 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.[1] On April 7, 2023, in response to the original 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 the original Plaintiffs "lack standing to challenge FDA's actions." *Alliance*, 602 U.S. at 374.

After the case returned to this Court, the States requested leave to amend their Complaint. ECF No. 195. Defendants opposed and also moved to dismiss both the original Plaintiffs' Complaint and the States' Complaint. *See* ECF No. 197. As to the original Plaintiffs, Defendants argued that the Supreme Court's decision foreclosed their standing, thereby requiring dismissal for lack of jurisdiction. *Id.* at 4-6. As to the States, Defendants argued that their claims could not independently proceed because, among other reasons, the States lacked proper venue in this District, and leave to amend should be denied because nothing in the proposed Amended Complaint altered that conclusion as to venue. *Id.* at 7-14. Rather than respond to that motion to dismiss, the original Plaintiffs filed a Notice of Voluntary Dismissal, dismissing without prejudice "all claims brought in their Complaint as to all defendants." ECF No. 203 at 1.

[1] FDA has approved mifepristone, in a regimen with misoprostol, for the termination of early intrauterine pregnancy. FDA has separately approved another manufacturer's mifepristone product, Korlym, for the treatment of Cushing's syndrome. The States do not challenge FDA's actions regarding Korlym.

On January 16, 2025, this Court granted the States' motion for leave to amend, noting "Rule 15(a)'s high standard for denying leave to amend," and concluding that "venue remains disputed here and should be properly dealt with at a phase where each party may fully argue the issue." ECF No. 215 at 3. Because the Court granted leave to amend, it then denied Defendants' motion to dismiss as moot. *Id.* at 3-4. Later that day, the States formally docketed their Amended Complaint and exhibits. ECF No. 217. Defendants now move to dismiss the States' Amended Complaint.

LEGAL STANDARD

Once a defendant moves to dismiss based on improper venue, the plaintiff has the burden of establishing venue. *See Lawson v. Dep't of Justice*, 527 F. Supp. 3d 894, 896 (N.D. Tex. 2021). Additionally, "the 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).

ARGUMENT

I. The States Plainly Lack Venue in This District

The States of Missouri, Kansas, and Idaho have no cognizable connection to the Northern District of Texas, nor do any of the claims they seek to present in their Amended Complaint. Venue in this District is therefore improper, which requires dismissal (or transfer) pursuant to the venue statute's mandatory command. *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)); *Atl. Marine Constr. Co. v. U.S. Dist. Ct. for W. Dist. of Texas*, 571 U.S. 49, 56 (2013) (when "venue is improper . . . the case must be dismissed or transferred under § 1406(a)").[2]

A. The States of Missouri, Idaho, and Kansas obviously 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' Amended Complaint asserts that venue is proper under 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." Am. Compl. ¶ 34. But none of the "facts, events or omissions" giving rise to the States' claims—much less a substantial part—allegedly 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. *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

[2] 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)).

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 purportedly 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 Tex. v. Dep't of Educ.*, No. 4:23-cv-206-P, 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.

B. The States' Amended Complaint also alleges that "Plaintiff States brought this intervention action in the same district and division in which an action involving the same subject matter is already pending." Am. Compl. ¶ 35. But this allegation is likewise insufficient to support venue. As an initial matter, the other "action involving the same subject matter" was a jurisdictionally invalid suit that is now no longer pending because it has been voluntarily dismissed, making it as if the original Plaintiffs' suit "had never been filed." *Ford v. Sharp*, 758 F.2d 1018, 1023-24 (5th Cir. 1985). Thus, even if it were theoretically possible to establish venue based on similar litigation pending in the same District, that would not help the States here given that the prior litigation no longer exists and is considered to never have existed.

More fundamentally, the venue statute requires that "a substantial part of the events or omissions *giving rise to the claim*" must occur in the chosen forum. 28 U.S.C. § 1391(e)(1)(B) (emphasis added). There is no sense in which events "giving rise to [a] claim" can be said to occur in a forum

simply because a different party pursued similar claims in that forum. Indeed, the States' theory—that the pendency of "an action involving the same subject matter" is sufficient to establish venue, Am. Compl. ¶ 35—is incorrect even with respect to distinct claims in a single action. Courts routinely insist that, even within the same case, "venue must be established for each separate cause of action and for each defendant." *Asevedo v. NBCUniversal Media, LLC*, 921 F. Supp. 2d 573, 589 (E.D. La. 2013); *see also Pierce v. Aircraft Fin. Corp. LLC*, 512 F. Supp. 3d 753, 765 (S.D. Tex. 2021); Fed. R. Civ. P. 19(a)(3) (even when a party is required to be joined in a case, dismissal is mandatory if venue is improper for that party). That requirement is irreconcilable with the States' theory that the pendency of similar claims in a District is sufficient to create venue even as to different claims and different parties.

Moreover, the States' theory would eviscerate the venue statute's requirements—essentially requiring only one plaintiff to satisfy venue in a District, after which any party would then be free to pursue similar claims in that same District, even if the original plaintiff lacked standing or their claims were already dismissed. Parties should not be permitted to satisfy venue in this fashion. Aside from this singular fact—that different parties, at one point in time, pursued similar claims in this District—the States do not identify any meaningful connection between the claims they are pursuing and 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. But there is no basis for the sovereign States of Missouri, Idaho, and Kansas to insist on litigating their claims in this forum, as opposed to the Federal courts in the States' capital cities or where Defendants are headquartered—*i.e.*, the District of Columbia, the District of Maryland, the Western District of Missouri, the District of Idaho, or the District of Kansas. 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 connection to any of the

remaining parties or claims in this case. Accordingly, the States' Amended Complaint should be dismissed for lack of venue, or in the alternative transferred to a court with proper venue.[3]

II. Additional Threshold Reasons Preclude the States from Pursuing Their Claims

The States' lack of proper venue in this District is a sufficient basis for granting this motion. Even apart from venue, however, the States' claims cannot proceed for several more threshold reasons. First, this Court lacks jurisdiction over this matter—both because the States as intervenors cannot continue a matter that was never jurisdictionally valid and has now been voluntarily dismissed, and because the States themselves cannot satisfy Article III standing. Second, the States never administratively exhausted any of the claims they seek to present. And third, the States' challenge to FDA's 2016 actions is outside the statute of limitations—those actions were taken in March 2016, more than six years before the States first sought to present their claims in November 2023.

A. This Court Lacks Jurisdiction Over the States' Claims

1. The States Cannot Continue a Jurisdictionally Invalid Suit That Has Now Been Voluntarily Dismissed

As discussed previously, 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)); *see* ECF No. 197 at 7-9. And following the Supreme Court's decision, there can be no doubt that the original Plaintiffs lacked jurisdiction to bring their

[3] To the extent this case is transferred, Defendants reserve the right to present any and all arguments in opposition to the States' claims, including that each of the Intervenor States lacks standing. As discussed previously, ECF No. 197 at 12-13, venue can be satisfied only by a party with standing, which may further narrow the list of potentially proper venues. Thus, for purposes of judicial efficiency, the Court may prefer to either dismiss the case or transfer to the District of Columbia (where the Department of Health and Human Services is headquartered) or the District of Maryland, to avoid potential further transfers in the event particular States are held to lack standing.

suit. *See Alliance*, 602 U.S. at 374 (holding that "the plaintiffs lack standing to challenge FDA's actions"). Regardless of the States' subsequent intervention, then, this entire matter should be dismissed given that it was never jurisdictionally valid. *See United States ex rel. Tex. Portland Cement Co. v. McCord*, 233 U.S. 157, 163-64 (1914); *Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447, 453 (5th Cir. 1995); *Aetna Cas. & Sur. Co. v. Hillman*, 796 F.2d 770, 776 (5th Cir. 1986); *Summit Off. Park, Inc. v. U.S. Steel Corp.*, 639 F.2d 1278, 1282 (5th Cir. Unit A Mar. 1981).

Dismissal is compelled even more so now that the original Plaintiffs have voluntarily dismissed their suit. Their filing of a Notice of Voluntarily Dismissal immediately "closes the file," and "[t]here is nothing the defendant can do to fan the ashes of that action into life and the court has no role to play." *Am. Cyanamid Co. v. McGhee*, 317 F.2d 295, 297 (5th Cir. 1963); *see also Qureshi v. United States*, 600 F.3d 523, 525 (5th Cir. 2010) ("[I]n the normal course, the district court is divested of jurisdiction over the case by the filing of the notice of dismissal itself."). Again, given that the Notice of Voluntary Dismissal makes it as if "the suit had never been filed," *Ford*, 758 F.2d at 1023-24, the States cannot rely on a prior grant of intervention—in a now-defunct lawsuit—as a basis for continuing to litigate this action. *Cf. Marex Titanic, Inc. v. Wrecked & Abandoned Vessel*, 2 F.3d 544, 547 (4th Cir. 1993) ("When Marex filed its notice of dismissal . . . the action was terminated and the district court's interlocutory orders were vacated."). This entire action should be closed, leaving the States free to pursue their claims elsewhere—not as part of this suit, which was never jurisdictionally valid and has now been voluntarily dismissed.

2. The States Independently Lack Article III Standing

The States also cannot pursue their claims because they cannot establish their own Article III standing. To demonstrate Article III standing, "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v.*

Ramirez, 594 U.S. 413, 423 (2021). And to establish injury in fact, the States are required to show "an invasion of a legally protected interest" that is both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). None of the States' theories here suffices.

First, the States cannot establish a cognizable injury based on their purported health and safety concerns associated with mifepristone. *See, e.g.*, Am. Compl. ¶ 395 ("Many women in Plaintiff States have been harmed by the FDA's deregulation of abortion drugs."). That is nothing more than an attempt at *parens patriae* standing, which the Supreme Court has unequivocally rejected in suits against the federal government. *See, e.g.*, *Murthy v. Missouri*, 603 U.S. 43, 76 (2024) ("States do not have standing as *parens patriae* to bring an action against the Federal Government." (quotation marks omitted)); *Haaland v. Brackeen*, 599 U.S. 255, 294-95 & n.11 (2023).

For similar reasons, the States cannot rely on purported injuries to their "exercise of state-law parental rights for children in state custody[.]" Am. Compl. ¶ 578. Bringing suit against the federal government based on the States' interest in protecting individuals' "health and welfare while in state custody or control," *id.* ¶ 582, is "nothing more a thinly veiled attempt to circumvent the limits on *parens patriae* standing," *Brackeen*, 599 U.S. at 295 n.11. And in any event, the theory fails on its own terms. Unlike in the States' cited authority where the challenged federal policy was determined to expressly conflict with a state parental consent law, *see Deanda v. Becerra*, 96 F.4th 750, 756 (5th Cir. 2024), here FDA's challenged actions have no bearing on state parental notification or parental consent laws. Instead, the States are complaining about hypothetical downstream effects of FDA's actions that are too attenuated to provide standing. *See Alliance*, 602 U.S. at 392-93.

The States also fail to establish that "FDA's actions interfere with Plaintiff States' sovereign interest in the power to create and enforce a legal code." Am. Compl. ¶ 525 (quotation marks omitted). At times, the States' theory of injury appears to be that the challenged FDA actions make

it harder for the States to enforce their own abortion laws. *See, e.g.*, *id.* ¶ 532 ("Plaintiff States are injured as sovereigns by Defendants' intentional enablement of third parties to undermine state law enforcement and to violate state abortion-drug laws."). But that theory cannot be squared with the Supreme Court's decision in *United States v. Texas*, 599 U.S. 670 (2023). There, the district court found state standing based on the assertion that a federal policy led to individuals "committing[] more crimes in Texas." *Texas v. United States*, 606 F. Supp. 3d 437, 467 (S.D. Tex. 2022). The Supreme Court reversed, concluding that "none of the various theories of standing asserted by the States . . . overcomes the fundamental Article III problem with this lawsuit." 599 U.S. at 680 n.3; *see also Washington v. FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024) ("[E]ven if the availability of retail and mail-order dispensing does make mifepristone more difficult to police, we have never held that a logistical burden on law enforcement constitutes a cognizable Article III injury. Holding otherwise would greatly expand state standing to challenge any federal action that allegedly increases crime or disorder, or imposes indirect compliance costs for state law enforcement.").[4]

In other places, the States' theory of injury appears to be that FDA's actions might preempt state abortion laws. *See, e.g.*, Am. Compl. ¶ 569 ("Plaintiffs have a sovereign interest in their laws not being displaced, preempted, or nullified by the federal government."). But the States fail to identify any actual or imminent controversy over whether any of their laws are preempted; they simply point to two district court decisions, involving litigation brought by private parties (not the federal government), addressing West Virginia's and North Carolina's laws. *See id.* ¶¶ 574-76. The States cannot establish standing to challenge FDA's actions based on a concern that someone, at some point, in some other case might invoke FDA's actions as a basis to argue that their laws are

[4] It is also worth noting that the Amended Complaint's discussion of Missouri's abortion laws, *see* Am. Compl. ¶¶ 484-500, is no longer accurate now that Missouri's Constitution has been amended to codify a "fundamental right to reproductive freedom," including "abortion care[.]" Mo. Const. art. I, § 36(2).

preempted. *See also id.* ¶ 577 (confirming that "Plaintiff States will vigorously dispute that their laws are preempted" by FDA's actions); *Bauer v. Texas*, 341 F.3d 352, 358 (5th Cir. 2003) (standing to seek equitable relief cannot be based on a "conjectural, hypothetical, or contingent" dispute; there must be a "real and immediate" controversy over "a definite, rather than speculative threat of future injury").

Next, the States claim that "FDA's decisions to increase access to abortion drugs . . . inflict[] substantial economic injury on Plaintiff States as the payers or insurers of residents' medical expenses." Am. Compl. ¶ 593. But this theory is also irreconcilable with the Supreme Court's decision in *United States v. Texas*, which confirms that when a federal law or policy "has produced only" "indirect effects on state revenues or state spending," the state's claim of economic injury from the federal law or policy is too "attenuated" to satisfy Article III. 599 U.S. at 680 n.3; *see also, e.g.*, *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)); *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) (allowing such "peripheral costs imposed on States by actions of the President" to "create a cognizable Article III injury" would cause state standing to be virtually "boundless," "'mak[ing] a mockery . . . of the constitutional requirement of [a] case or controversy'"); *cf. Alliance*, 602 U.S. at 392 (noting that "virtually all drugs come with complications, risks, and side effects," and rejecting a theory of standing based "simply on the theory that use of the drugs by others may cause more visits to doctors," because that "uncharted path" would "seemingly not end until virtually every citizen had standing to challenge virtually every government action that they do not like").

Finally, the States claim that, as a result of FDA's actions, they have suffered "decreased births in Plaintiff States" which "is a sovereign injury to the State in itself." Am. Compl. ¶ 749. Defendants are unaware of any authority supporting this theory—*i.e.*, that "[e]ach abortion" causes

an Article III injury to the States based on "a loss in potential population or potential population increase." *Id.* ¶ 747. Although States can sometimes 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), that hardly equates to a free-ranging Article III interest to sue over any policy that affects a State's potential future birthrate. That is the type of speculative and attenuated theory of standing that the Supreme Court has repeatedly rejected. Just as "[a]llowing doctors or other healthcare providers to challenge general safety regulations as unlawfully lax would be an unprecedented and limitless approach and would allow doctors to sue in federal court to challenge almost any policy affecting public health," *Alliance*, 602 U.S. at 391-92, the same would be true if States were permitted to sue over any federal policy that might affect their population size. That is not a valid theory of Article III injury, and the States' Amended Complaint cannot proceed for lack of standing.

B. The States Never Exhausted Any of Their Claims

FDA's regulations require that parties administratively exhaust their claims before presenting them in court. *See* 21 C.F.R. §§ 10.45(b), (f), 10.25(a), 10.30. Numerous courts have dismissed claims that parties failed to properly exhaust before FDA. *See, e.g.*, *Ass'n of Am. Physician & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 21-24 (D.D.C. 2008), *aff'd*, 358 F. App'x 179 (D.C. Cir. 2009); *Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302, 303 (9th Cir. 2017); *Cody Lab'ys, Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011); *Dietary Supplemental Coal., Inc. v. Sullivan*, 978 F.2d 560 (9th Cir. 1992); *Holistic Candlers & Consumer Ass'n v. FDA*, 770 F. Supp. 2d 156, 163 (D.D.C. 2011), *aff'd*, 664 F.3d 940 (D.C. Cir. 2012); *Jensen v. Biden*, No. 4:21-cv-5119-TOR, 2021 WL 10280395 (E.D. Wash. Nov. 19, 2021).

Here, the States did not exhaust any of their claims with FDA. The States' Amended Complaint does not contend otherwise, nor does it plead any reasons justifying their failure to

exhaust. The States' failure to administratively exhaust any of their claims warrants dismissal of those claims.

Enforcing FDA's exhaustion requirements is particularly appropriate here. Administrative exhaustion requirements are designed to give the agency "an opportunity to correct its own errors," and "afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975). Here, the States' claims turn on issues that are squarely within the agency's expertise—for example, technical and factual assertions about the overall safety profile of mifepristone, including the particular conditions of use under which mifepristone has been shown to be safe and effective. *See generally* Am. Compl. ¶¶ 6-17, 50-56. Moreover, the States' claims rely on studies and other materials that were not before the agency at the time of the relevant determinations. *See, e.g.*, Am. Compl. ¶¶ 63-64 & nn.5-6 (relying on a declaration dated November 2022); *id.* ¶ 66 & nn.8-9 (relying on a study from April 2024); *id.* ¶ 75 & n.19 (citing news report from October 2022); *id.* ¶¶ 300-369 & nn.252-325 (discussing events occurring in 2023 and 2024, postdating the most recent FDA action the States seek to challenge); *id.* ¶¶ 737-39 & n.500 (citing study from February 2023); *id.* ¶ 744 & n.501 (citing study from May 2019 about mifepristone's effects on rats). Requiring exhaustion here will allow FDA to address these matters in the first instance, thereby applying its expertise and creating an adequate record for judicial review.

The States cannot avoid their obligation to exhaust by invoking the citizen petitions submitted by the original Plaintiffs in this matter. For one thing, those citizen petitions did not exhaust all of the claims that the States now seek to bring—*e.g.*, the original Plaintiffs' citizen petitions did not argue that FDA's actions were unlawfully "enabl[ing] the violation of state laws restricting abortion," Am. Compl. ¶ 761; that FDA's 2016 changes violated the Pediatric Research Equity Act, *id.* ¶ 779; or that there was anything problematic about FDA's April 2019 approval of

the Abbreviated New Drug Application for the generic version of mifepristone, *id.* ¶ 784. The States cannot rely on the original Plaintiffs' citizen petitions to "exhaust" arguments or claims that were never actually raised in those petitions.

More fundamentally, there is no basis for assuming that exhaustion would be pointless simply because the agency responded to similar citizen petitions several years ago. As the D.C. Circuit has explained:

> Where the issue was raised only by parties to another proceeding that took place three years earlier, however, the bounds of vicarious exhaustion have been exceeded. That an agency at one time considers and rejects certain arguments does not mean that the agency can thereafter be bypassed.

Am. Scholastic TV Programming Found. v. FCC, 46 F.3d 1173, 1178 (D.C. Cir. 1995). Disregarding FDA's mandatory exhaustion requirements, simply because different parties raised similar arguments five years ago, would undermine the very purposes of the exhaustion doctrine—depriving FDA of the opportunity to consider the States' evidence and apply its expertise. The States' failure to exhaust any of their claims is an independent reason for dismissal, consistent with the numerous court decisions cited above.

C. The States Cannot Challenge FDA's 2016 Actions Because They Are Outside the Statute of Limitations

Even if venue were proper, and even if the States had standing and were not required to exhaust their claims, at a minimum their challenges to FDA's 2016 actions are time-barred. The applicable statute of limitations required the States to bring their challenges "within six years after the right of action first accrue[d]." 28 U.S.C. § 2401(a). A right of action "first accrues" under the Administrative Procedure Act "when the plaintiff is injured by final agency action." *Corner Post, Inc. v. Bd. of Governors, Fed. Reserve Sys.*, 603 U.S. 799, 804 (2024). So, if the Court concludes—contrary to Defendants' arguments—that the States have standing to challenge FDA's 2016 actions and did not need to exhaust administrative remedies, then their right of action would have "first accrue[d]" on

the date when FDA finalized those actions, which was March 29, 2016. *See* Am. Compl. ¶¶ 132-33. But the States did not move to intervene in this case until more than seven-and-a-half years after that date, on November 3, 2023. ECF No. 151. Therefore, at the very least, the States' challenges to FDA's 2016 actions are untimely.

* * * *

Despite the efforts of the Intervenor States to continue litigating in this forum, there is no basis for continuing this litigation. The Supreme Court unanimously concluded that the original Plaintiffs lacked standing, and those Plaintiffs have now voluntarily dismissed all of their claims. Although this Court previously allowed the States of Missouri, Kansas, and Idaho to intervene, that grant of intervention does not permit the States to continue litigating in a matter that was never jurisdictionally proper. And even if the States could theoretically continue with their claims, the States have no cognizable connection to the Northern District of Texas. Venue is therefore improper in this District, and the States' Amended Complaint should be dismissed or transferred.

CONCLUSION

Pursuant to Federal Rules of Civil Procedure 12(b)(3), the States' Amended Complaint (ECF No. 217) should be dismissed (or transferred) for lack of venue. Alternatively, the States' Amended Complaint should be dismissed for lack of subject-matter jurisdiction or failure to exhaust. At a minimum, the States' challenges to FDA's 2016 actions should be dismissed as time-barred.

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Respectfully submitted,

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