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

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

DANCO LABORATORIES, LLC'S MOTION TO DISMISS INTERVENOR-PLAINTIFFS' AMENDED COMPLAINT

Pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(3), and 12(b)(6), Danco Laboratories, LLC moves to dismiss the amended complaint in intervention of Intervenor-States Missouri, Idaho, and Kansas, ECF No. 217. The reasons for dismissal are set forth in the accompanying Memorandum. A proposed order is also attached.

Respectfully submitted this 28th day of January, 2025,

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CERTIFICATE OF SERVICE

I certify that on January 28, 2025, 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.

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth

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

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INTRODUCTION

Two years ago, a group of anti-abortion associations and doctors led by the Alliance for Hippocratic Medicine sued FDA over its regulation of mifepristone. The Supreme Court unanimously rejected the Alliance Plaintiffs' lawsuit, concluding that they "lack standing to challenge FDA's actions." *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 374 (2024). The Alliance Plaintiffs voluntarily dismissed their case as a result. The States of Missouri, Kansas, and Idaho, which intervened in the Alliance Plaintiffs' now-dismissed suit, apparently believe they can nonetheless continue this litigation and have filed an amended complaint. Multiple independent grounds compel dismissal of the Intervenor States' lawsuit.

First, and most obviously, the States of Missouri, Kansas, and Idaho lack venue in the Northern District of Texas. Neither the States nor the federal defendants reside in this district, and none of the States' claims arose in this district. Without any plausible basis for venue, the States' amended complaint should be dismissed.

Second, this Court lacks jurisdiction over the States' claims. The States, as intervenors, cannot continue to pursue a jurisdictionally defective lawsuit that has since been dismissed. The States also lack standing, an independent reason their amended complaint must be dismissed. Their alleged economic injuries simply repeat the same attenuated theory of injury the Supreme Court rejected in *Alliance for Hippocratic Medicine*—just with another link of increased state Medicaid expenses at the end of an already attenuated chain. The States' alleged sovereign injuries are similarly not cognizable and attempt to skirt the well-established prohibitions on *parens patriae* suits against the federal government. And the States' supposed injuries based on population counts would blow open the courthouse doors to any State that claims some action by the federal government may incidentally affect its population count—an all-consuming version of Article III standing that the Supreme Court has firmly rejected.

Finally, other threshold grounds bar review of the States' complaint. The States have not administratively exhausted their claims, and their challenge to FDA's 2016 changes is time-barred. Because their claims cannot proceed, the States' amended complaint should be dismissed.

BACKGROUND

A. Factual Background

2000 Approval. Danco, a small pharmaceutical company incorporated in Delaware, holds the NDA for Mifeprex (mifepristone) Tablets for use in a regimen with misoprostol for the medical termination of intrauterine pregnancy. FDA first approved Mifeprex in 2000. ECF No. 217-1, Exhs. 16, 17, 18 (App. 408-428). FDA imposed certain use restrictions with that approval, which were deemed a Risk Evaluation and Mitigation Strategy (REMS) by the 2007 amendments to the Food, Drug, and Cosmetic Act. *See* 73 Fed. Reg. 16,313 (Mar. 27, 2008).

2016 Changes. In 2015, Danco submitted a supplemental NDA (sNDA) to modify certain aspects of Mifeprex's prescribing information and REMS. *See* ECF No. 217-2, Exh. 23 (App. 511-519). FDA approved these changes in 2016, after considering dozens of studies reporting the outcomes for tens of thousands of women under various combinations of the proposed changes and 15 years of data reflecting the drug's safety profile. *See* ECF No. 217-1, Exh. 2 (App. 8-36); *See* ECF No. 217-2, Exh. 23 (App. 511-519).

In 2019, the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians filed a citizen petition asking FDA to "restore and strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000." ECF No. 217-3, Exh. 29 (App. 606, 631) (2019 citizen petition). They also asked FDA to "retain the Mifeprex [REMS], and to continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber." *Id.* (App. 606).

FDA denied the petition in December 2021, in a 40-page response addressing in detail the petitioners' alleged concerns. ECF No. 217-3, Exh. 34 (App. 648-688). No States were party to that petition, and the Intervenor States did not file their own citizen petition.

2021 Nonenforcement Decisions and 2023 REMS. During the COVID-19 public health emergency, the American College of Obstetricians and Gynecologists urged FDA to suspend enforcement of the in-person dispensing requirement for mifepristone because it unnecessarily put patients and providers at risk of COVID-19, delayed time-sensitive healthcare, and served "as a barrier to accessing this safe, effective medication." ECF No. 217-3, Exh. 31 (App. 640). FDA evaluated that issue, including by analyzing medical literature, postmarketing adverse-event reporting from earlier in the pandemic, and information about deviations or noncompliance events associated with the REMS. ECF No. 217-3, Exh. 32 (App. 644-645). FDA found no indication that forgoing the in-person dispensing requirement increased adverse events. *Id.* FDA's April 2021 response letter therefore stated the agency would exercise enforcement discretion as to that requirement during the public health emergency. *Id.* The States did not file a citizen petition challenging this action.

FDA came to the same conclusion in its December 2021 response to the 2019 citizen petition, which challenged certain of the 2016 changes. Based on the evidence, FDA concluded that "mifepristone may be safely used without in person dispensing," ECF No. 217-3, Exh. 34 (App. 675), and that in-person dispensing was "no longer necessary to ensure that the benefits of the drug outweigh the risks," *id.* (App. 673). FDA relied on safety data from the nonenforcement period, which showed "no indication" that suspending the in-person dispensing requirement "contributed to" adverse events. ECF No. 217-3, Exh. 32 (App. 645). FDA also pointed to three studies permitting pharmacy dispensing by mail and five studies allowing clinic dispensing by

mail, all of which supported the conclusion that mifepristone remains safe and effective without mandatory in-person dispensing. ECF No. 217-3, Exh. 34 (App. 678-682).

Based on its analysis, FDA directed Danco to submit an sNDA proposing modifications to the REMS to remove the in-person dispensing requirement. Danco complied, and FDA approved Danco's sNDA in January 2023. ECF No. 217-1, Exh. 3 (App. 37-211). The States did not file a citizen petition challenging this action.

B. Procedural History

In November 2022, the Alliance Plaintiffs—a group of doctors and medical associations opposed to the use of Mifeprex and all forms of abortion—brought an APA suit challenging FDA's 2000 approval of Mifeprex, FDA's 2016 changes to the labeling, and FDA's 2021 nonenforcement decisions, and asked the District Court to preliminarily enjoin those FDA actions. ECF No. 1. Danco moved to intervene, which this Court granted. ECF Nos. 19, 33.

In response to the Alliance Plaintiffs' motion for a preliminary injunction, ECF No. 6, the Court entered an order stating that it would stay the effective date of the challenged FDA actions, ECF No. 137, which the Supreme Court later stayed pending appeal, *Danco Lab'ys, LLC v. Alliance for Hippocratic Med.*, 143 S. Ct. 1075 (2023). In June 2024, the Supreme Court unanimously held that the Alliance Plaintiffs "lack standing to challenge FDA's actions." *Alliance for Hippocratic Med.*, 602 U.S. at 374. The Supreme Court rejected every one of the Alliance Plaintiffs' theories of standing as a matter of law, holding that (1) federal conscience protections mean that the Alliance Plaintiffs "cannot show" that FDA's actions will cause any conscience injury, *id.* at 390; (2) "the law has never permitted" plaintiffs "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; (3) plaintiffs cannot invoke third-party standing if they have "not suffered and would not suffer an injury

themselves," *id.* at 390 n.3; and (4) an organizational plaintiff cannot "spend its way into standing simply by expending money to gather information and advocate against the defendant's action," *id.* at 394.

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 lacked 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 the deadline to respond to the States' complaint 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 States moved for leave to file an amended complaint. ECF No. 195. Danco and FDA opposed that motion and also moved to dismiss the Alliance Plaintiffs' complaint and the States' complaint. ECF Nos. 196, 197, 198, 199, 200, 201. The Alliance Plaintiffs then filed a Notice of Voluntary Dismissal, dismissing without prejudice "all claims brought in their Complaint as to all defendants." ECF No. 203 at 1; *see* ECF No. 206.

This Court granted the States' motion for leave to amend, highlighting the "high standard for denying leave to amend" and recognizing that "venue remains disputed here." ECF No. 215 at 3. The Court accordingly denied Danco's and FDA's motions to dismiss the States' original complaint as moot, noting that "[r]enewed motions to dismiss" the forthcoming amended

complaint would provide a better chance for the parties to "focus their arguments." *Id.* at 3-4. That same day, the States docketed their amended complaint and exhibits. ECF No. 217.

Danco's motion to dismiss the amended complaint follows. *See also* ECF No. 219 (FDA motion to dismiss the States' amended complaint).

STANDARD OF REVIEW

On a Rule 12(b)(3) motion to dismiss for lack of venue, "the burden of proving that venue is proper [is] on the plaintiff." *Freedom Coal. of Drs. for Choice v. CDC*, No. 2:23-cv-00102, 2023 WL 9105435, at *2 (N.D. Tex. Nov. 3, 2023) (Kacsmaryk, J.) (citation omitted). "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) (citations and quotation marks omitted). A Rule 12(b)(6) motion to dismiss on statute-of-limitations grounds is appropriate "where it is evident from the plaintiff's pleadings that the action is barred and the pleadings fail to raise some basis for tolling or the like." *Jones v. Alcoa, Inc.*, 339 F.3d 359, 366 (5th Cir. 2003).

ARGUMENT

I. Missouri, Idaho, And Kansas Plainly Lack Venue In The Northern District Of Texas.

The States of Missouri, Kansas, and Idaho do not have venue to pursue their claims in the Northern District of Texas. The federal venue statute offers three bases for venue, and the States check none of those boxes. Nor can the States piggyback on the residency of the Alliance Plaintiffs, who are nonparties over which this Court never had jurisdiction. Dismissal is warranted on this threshold defect. *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)).

A. The States' Amended Complaint Fails To Plausibly Allege Venue.

In lawsuits against federal officials and agencies in their official capacities, venue is proper in a district where "(A) a defendant in the action resides, (B) a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (C) the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e). The three States rightly do not assert venue based on the parties' residences. No party on either side of the "v" in the States' amended complaint resides in this district. *See id.* § 1391(e)(1)(A), (C). The federal defendants reside in Washington, D.C. or the District of Maryland, where their offices are located and official duties performed. *See Holloway v. Gunnell*, 685 F.2d 150, 153 n.3 (5th Cir. 1982) ("Where a public official is a party to an action in his official capacity he resides in the judicial district . . . where he performs his official duties." (citation omitted)); *see* ECF No. 217 ¶¶ 43-47. And the States of Missouri, Kansas, and Idaho obviously do not reside in Texas. *Cf. Atlanta & F. R. Co. v. W. Ry. Co. of Ala.*, 50 F. 790, 791 (5th Cir. 1892) (noting that a State's residence is limited to "the boundaries of the state").

The States' sole asserted basis for venue is § 1391(e)(1)(B), on the grounds that "a substantial part of the facts, events or omissions giving rise to the claims occurred in this district." ECF No. 217 ¶ 34. But no well-pled facts support that assertion. Just the opposite: Even on the States' telling, the events "giving rise" to their APA challenges to FDA's 2016, 2021, and 2023 decisions occurred within their own borders or in Washington, D.C. or Maryland, where the federal defendants sit—not in Texas. *See id.* ¶¶ 757-762, 768-782.

It is irrelevant whether the States filed suit "in the same district and division in which an action involving the same subject matter is already pending." *Id.* ¶ 35. That once-pending suit was jurisdictionally deficient and was voluntarily dismissed before the States' amended complaint was docketed. *See* ECF Nos. 203, 217. A Rule 41(a)(1)(A)(i) "voluntary dismissal without

prejudice leaves the situation as if the action had never been filed"; "the action is no longer pending in the court and no further proceedings in the action are proper." *Long v. Bd. of Pardons & Paroles of Tex.*, 725 F.2d 306, 307 (5th Cir. 1984) (citation omitted); *see also* ECF No. 215 at 4 (noting that the States' lawsuit is "the one complaint remaining").

Moreover, the mere fact that other litigants once sued over some of the same agency decisions "itself did not give rise to the [States'] claims" under the APA. *LaCombe v. Walt Disney Parks & Resorts U.S., Inc.*, No. 2:18-cv-07689, 2019 WL 13248968, at *3 (E.D. La. May 1, 2019). To determine venue, a court "looks to the defendant's conduct and where that conduct took place," not whether someone else ever sued over the defendant's conduct. *Turentine v. FC Lebanon II LLC*, No. 3:22-cv-01625, 2022 WL 16951647, at *2 (N.D. Tex. Nov. 15, 2022); *see also Career Colls. & Sch. of Tex. v. Dep't of Educ.*, No. 4:23-cv-00206, 2023 WL 2975164, at *2 (N.D. Tex. Apr. 17, 2023) ("The plain text 'events or omissions giving rise to the claim' implicates 'the' parties bringing the claim and not 'a' generalized burden on non-parties."); *Jenkins Brick Co. v. Bremer*, 321 F.3d 1366, 1371 (11th Cir. 2003) ("Only the events that directly give rise to a claim are relevant."). And here, it is undisputed that all of those events occurred outside this district.

Without any plausible basis to assert venue here, the States' suit should be dismissed. When "venue is improper," "the case *must* be dismissed or transferred under § 1406(a)." *Atl. Marine Const. Co. v. U.S. Dist. Ct. for W. Dist. of Tex.*, 571 U.S. 49, 56 (2013) (emphasis added); *accord* 28 U.S.C. § 1406(a). Dismissal rather than transfer is appropriate here, in light of the States' standing and other threshold problems and the lack of prejudice to the States from having to refile their suit in a proper venue, especially where the States have not identified a preferred alternative. *See Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-00156, 2024 WL

3741510, at *8 (S.D. Ohio Aug. 8, 2024) (dismissing for improper venue rather than transferring because "the remaining Plaintiff's standing is questionable").

B. The States Cannot Establish Venue Based On The Residency Of Nonparties Over Whom This Court Lacks Jurisdiction.

The States have previously suggested that they do not need to establish venue because they can borrow the venue of the Alliance Plaintiffs, some of which claimed to reside in this district. *See* ECF No. 202 at 8-9; ECF No. 1 ¶ 31. That is wrong. The States cannot borrow the venue of one-time litigants over which this Court does not have jurisdiction. *See infra* pp. 10-13.

A tidal wave of authority confirms the opposite is true: When the venue-creating party or claim is dismissed, the court must dismiss or transfer any remaining claims for improper venue if a venue objection was preserved.[1] Without their own plausible claim to venue, the States cannot proceed in this district.

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[1] *Miller v. Albright*, 523 U.S. 420, 427 (1998) (plurality op.) (after sole Texas plaintiff was dismissed, "venue in Texas was therefore improper" for remaining noncitizen plaintiff); *Merchs. Fast Motor Lines, Inc. v. ICC*, 5 F.3d 911, 914, 921-922 (5th Cir. 1993) (venue improper for remaining nonresident petitioner where court lacked jurisdiction over resident petitioner); *Ga. Republican Party v. SEC*, 888 F.3d 1198, 1205 (11th Cir. 2018) (after dismissing resident petitioner, venue was "clearly not . . . appropriate" for remaining nonresident petitioners); *Clark & Reid Co. v. United States*, 804 F.2d 3, 5 (1st Cir. 1986) (same); *Immigrant Assistance Project of Los Angeles Cnty. Fed'n of Lab. (AFL-CIO) v. INS*, 306 F.3d 842, 867-868 & n.20 (9th Cir. 2002) (essential for court to have jurisdiction over "the only plaintiff" on whom "venue . . . could be based"); *Cameron v. Thornburgh*, 983 F.2d 253, 257 (D.C. Cir. 1993) (venue improper where venue-creating claim "had become moot, and appellant could not fit his [remaining] claim under the general venue provisions"); *Associated Gen. Contractors of Am., Inc. v. Fed. Acquisition Regul. Council*, 720 F. Supp. 3d 461, 472-474 (W.D. La. 2024) (courts "must determine whether venue is proper" for remaining plaintiffs following dismissal of resident plaintiffs); *Stewart v. Tex. Tech Univ. Health Scis. Ctr.*, No. 5:23-cv-00007, __ F. Supp. 3d __, 2024 WL 4996604, at *23 (N.D. Tex. July 17, 2024) (after severing improperly joined defendant, "venue is no longer proper" for suit against remaining defendant); *Dayton Area Chamber of Com.*, 2024 WL 3741510, at *1, 7-9 (venue no longer proper after court dismissed venue-creating plaintiffs); *Kruse v. Wells Fargo Home Mortg., Inc.*, No. 1:02-cv-03089, 2006 WL 1212512, at *8 (E.D.N.Y. May 3, 2006) ("[W]hen the original plaintiffs upon whose claims jurisdiction and venue are based are dismissed from the case, plaintiffs must offer independent grounds for venue," and "[h]ere, the dismissal of the original named plaintiffs requires intervenors to provide some basis for venue, which they have

II. This Court Lacks Jurisdiction Over The States' Claims.

A. The States Cannot Piggyback On A Dismissed And Jurisdictionally Defunct Lawsuit.

Precedent from the Supreme Court, the Fifth Circuit, and every other Circuit is clear: An intervenor's "participatory rights remain subject to the intervenor's threshold dependency on the

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failed to do."); *Kansas v. Garland*, No. 2:24-cv-00088, 2024 WL 2384611, at *1 (E.D. Ark. May 23, 2024) ("Because no [remaining] Plaintiff with standing resides in this district, venue is improper."); *Missouri v. Dep't of Educ.*, No. 2:24-cv-00103, 2024 WL 4374124, at *4 (S.D. Ga. Oct. 2, 2024) ("Georgia cannot provide the proper venue for suit because a plaintiff that lacks standing cannot create venue where it would not otherwise exist."); *Godspower v. CoreCivic*, No. 3:23-cv-00399, 2023 WL 6612456, at *1, 5 (M.D. Tenn. Oct. 10, 2023) ("Plaintiff fails to state a claim against six of the seven Defendants, including all Defendants that make venue technically proper in this judicial district," such that "[v]enue is no longer proper here."); *Bishop v. Pane*, No. 1:22-cv-03003, 2023 WL 11915421, at *2 (N.D. Ga. Mar. 8, 2023) (dismissal for failure to state claim against three defendants meant "venue would be improper in this district" for the "only remaining defendant"), *report and recommendation adopted*, 2023 WL 11915424 (N.D. Ga. Mar. 30, 2023); *United States ex rel. Switzer v. Wood*, No. 2:18-cv-08118, 2023 WL 6370917, at *4 (C.D. Cal. May 16, 2023) ("venue is no longer proper" after severing actions); *Decastro v. Bank OZK*, No. 4:21-cv-01194, 2022 WL 4086682, at *3 (E.D. Ark. Sept. 6, 2022) (where claim establishing the "only basis for venue" was dismissed, "venue is no longer appropriate"); *Ctr. for Biological Diversity v. Spellmon*, No. 4:21-cv-00047, 2022 WL 3541879, at *3-4 (D. Mont. Aug. 18, 2022) (where "the only Montana-resident Plaintiff[ ] cannot establish standing," "the District of Montana does not represent an appropriate venue"); *Keane v. Velarde*, No. 3:20-cv-00977, 2021 WL 4248896, at *5-6 (D. Conn. Sept. 17, 2021) (venue improper for remaining litigants after dismissing "the only party residing in Connecticut"); *Couch v. Appling ITF*, No. 5:19-cv-00209, 2019 WL 3936448, at *3 (M.D. Ga. Aug. 20, 2019) ("If the GDC is dismissed, venue would no longer be proper in this district: Plaintiff's remaining claims involve events occurring in the Southern District of Georgia, and all remaining named parties appear to be located there."); *Daker v. Bryson*, No. 5:16-cv-00538, 2017 WL 11457276, at *5 (M.D. Ga. June 8, 2017) ("With the dismissal of these Defendants, venue is no longer proper in this district"), *modified*, 2017 WL 3584910 (M.D. Ga. Aug. 17, 2017); *United States ex rel. Polukoff v. St. Mark's Hosp.*, No. 3:12-cv-01277, 2016 WL 1449219, at *2, 4 (M.D. Tenn. Apr. 13, 2016) ("Without HCA, Inc. as a party, venue in the Middle District of Tennessee is no longer proper."); *Ghaffari v. Wells Fargo Bank. N.A.*, 6 F. Supp. 3d 24, 30 (D.D.C. 2013) ("venue is no longer proper here since its only basis was this Court's original jurisdiction over" claims that were dismissed); *Webber v. Norwalk*, No. 2:05-cv-04219, 2007 WL 7698736, at *10 (D. Ariz. Feb. 8, 2007) (dismissing for improper venue where "there is no Plaintiff with both standing to sue and Arizona residency remaining in this case"); *Jackson v. Leake*, No. 1:05-cv-00691, 2006 WL 2264027, at *3, 10 (M.D.N.C. Aug. 7, 2006) ("In the absence of the District Attorney . . . , none of the Defendants reside in the Middle District of North Carolina and therefore venue is not proper in the Middle District."); *Inst. of Certified Pracs., Inc. v. Bentsen*, 874 F. Supp. 1370, 1372 (N.D. Ga. 1994) ("plaintiff cannot manufacture venue" by relying on venue of party over whom court lacks jurisdiction).

original parties' claims," *Harris v. Amoco Prod. Co.*, 768 F.2d 669, 675 (5th Cir. 1985), and the intervenor therefore "must abide the fate of that suit," *U.S. ex rel. Tex. Portland Cement Co. v. McCord*, 233 U.S. 157, 163-164 (1914). That is doubly fatal here, where the Supreme Court unanimously held that the original "plaintiffs lack standing to challenge FDA's actions," *Alliance for Hippocratic Med.*, 602 U.S. at 374, and where the original plaintiffs have voluntarily dismissed.

It is blackletter law that "[a]n existing suit within the court's jurisdiction is a prerequisite of an intervention." *Harris*, 768 F.2d at 675 (quoting *Kendrick v. Kendrick*, 16 F.2d 744, 745 (5th Cir. 1926)). Intervention "presuppose[s] an action duly brought," *McCord*, 233 U.S. at 163, so if "the party on whose side the intervenor intervened" lacks standing, an intervenor cannot "keep the case alive." *Sierra Club v. Babbitt*, 995 F.2d 571, 574 (5th Cir. 1993) (citation and brackets omitted). The Supreme Court's decision that the Alliance Plaintiffs "lack standing to challenge FDA's actions," *Alliance for Hippocratic Med.*, 602 U.S. at 374, means that the Alliance Plaintiffs never had the requisite interest necessary to invoke this Court's jurisdiction. *See Carney v. Adams*, 592 U.S. 53, 60 (2020) ("standing is assessed at the time the action commences"). And without jurisdiction, the States as intervenors cannot keep the case alive. *See also*, *e.g.*, *Summit Off. Park, Inc. v. U.S. Steel Corp.*, 639 F.2d 1278, 1282 (5th Cir. 1981).

The Alliance Plaintiffs' voluntary dismissal separately requires dismissal of the States' complaint for lack of jurisdiction. A "voluntary dismissal without prejudice under Rule 41(a) leaves the situation as if the action never had been filed," *Long*, 725 F.2d at 307 (citation omitted), such that "the district court's interlocutory orders [a]re vacated," *Marex Titanic, Inc. v. Wrecked & Abandoned Vessel*, 2 F.3d 544, 547 (4th Cir. 1993); *see also In re Piper Aircraft Distrib. Sys. Antitrust Litig.*, 551 F.2d 213, 219 (8th Cir. 1977) (Because "[t]he effect of a voluntary dismissal without prejudice is to render the proceedings a nullity and leave the parties as if the action had

never been brought," "[i]t carries down with it previous proceedings and orders in the action, and all pleadings, both of plaintiff and defendant, and all issues, with respect to plaintiff's claim." (citation omitted)).

Orders granting intervention are interlocutory, *see* Wright & Miller, 7C Fed. Prac. & Proc. § 1923 (3d ed. June 2024 update), and are accordingly voided by voluntary dismissals without prejudice under Rule 41(a)(1)(A)(i). As a result of the Alliance Plaintiffs' dismissal, "the court loses jurisdiction over the litigation," *Qureshi v. United States*, 600 F.3d 523, 525 (5th Cir. 2010), including the States' intervening complaint. *See, e.g.*, *TT Boat Corp. v. M/V Pelican Magic*, No. 97-cv-562, 1997 WL 900853, at *2 (M.D. Fla. Nov. 13, 1997) ("The entire cause of action was due to be dismissed, including any intervening claims [plaintiff-intervenor] had or intended to file."); *Providence Health Ctrs., Inc. v. Matthews*, 81 F.R.D. 537, 538 (D.R.I. 1979) (similar).[2]

The States have not satisfied the sole exception for an intervenor to proceed when the original suit was not jurisdictionally valid and has been dismissed. That would require the States to have "met the requirements that a plaintiff must satisfy—*e.g.*, filing a separate complaint and properly serving the defendants." *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31*, 585 U.S. 878, 890 (2018). 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"

[2] The Fifth Circuit has suggested that intervenors could continue a plaintiff's original "jurisdictionally and procedurally proper suit that [was] dismissed voluntarily" pursuant to a Rule 41(a)(1)(A)(ii) *stipulated* dismissal *with* prejudice, *Sommers v. Bank of Am., N.A.*, 835 F.3d 509, 513 n.5 (5th Cir. 2016), which necessarily depends on the court's jurisdiction to resolve issues between the parties. The same is not true, however, of a Rule 41(a)(1)(A)(i) *notice* of dismissal *without* prejudice. *Odle v. Flores*, 705 F. App'x 283, 285 (5th Cir. 2017) (Graves, J., concurring in rehearing denial).

basis for their action, *Arkoma Assocs. v. Carden*, 904 F.2d 5, 7 (5th Cir. 1990),[3] meaning that the intervenor's suit "satisfies by itself the requirements of jurisdiction and venue," Wright & Miller § 1918. For the reasons already explained, *supra* pp. 6-9, the venue defect in the States' amended complaint prevents it from being treated as if it were "the operative complaint in a new lawsuit." *Janus*, 585 U.S. at 890.

B. The States Lack Standing.

Now that the original plaintiffs have dismissed their complaint, the three States must independently ground their claims in Article III's case-or-controversy requirement. That means the States must establish "(i) that [*they*] 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) (emphasis added). The three States must make this showing "for each claim that they press against each defendant, and for each form of relief that they seek"—including claims the original plaintiffs had raised. *See Murthy v. Missouri*, 603 U.S. 43, 61 (2024) (citation and quotation marks omitted). The States must also establish standing to bring any claims or forms of relief that the original plaintiffs did not.

For each of the States' claims, the result is the same: Missouri, Kansas, and Idaho do not have standing to sue. None of the States' three theories of standing—alleged injuries based on

[3] *See also 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 (3d Cir. 1965); *Atkins v. State Bd. of Educ. of N.C.*, 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 Advocs. 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).

increased Medicaid costs, interference with state law enforcement, and harms to women and fetal life—satisfy Article III's requirements, and all of them conflict with Supreme Court and Circuit precedent. Justice Kavanaugh's unanimous opinion sums it up best: "[T]he federal courts are the wrong forum for addressing the [States'] concerns about FDA's actions." *Alliance for Hippocratic Med.*, 602 U.S. at 396-397. The 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 may "also express their views about abortion and mifepristone to fellow citizens, including in the political and electoral processes." *Id.* at 397. 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 States' amended complaint should be dismissed.

1. The States Cannot Establish Standing Based On Alleged Indirect Costs To State Medicaid Spending.

The States allege that FDA's 2016, 2021, and 2023 actions will cause "economic injury" in the form of increased costs to their Medicaid systems. ECF No. 217 ¶ 593. Relying entirely on speculative statistical probabilities and ignoring their obligation to causally link injury to each specific action they challenge,[4] the States' asserted 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. *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023). Indeed, the Ninth Circuit rejected Idaho's

[4] Dismissal for lack of standing flows from this shortcoming alone. The States do not attempt to separate their alleged economic injuries from each of FDA's 2016, 2021, or 2023 actions from those that would have occurred anyway based on mifepristone's original approval, even though plaintiffs must allege "standing for each claim that they press and for each form of relief that they seek." *TransUnion*, 594 U.S. at 431. That omission is fatal on traceability: "[H]arm from one particular inadequacy in government administration" does not create standing to challenge "*all* inadequacies in that administration." *Lewis v. Casey*, 518 U.S. 343, 357 (1996); *see, e.g.*, *California v. Texas*, 593 U.S. 659, 678-680 (2021) (no standing to challenge minimum-essential-coverage provision of the Affordable Care Act where injuries were caused by other statutory provisions).

attempt to intervene in separate litigation over the mifepristone REMS on exactly these grounds. *Washington v. FDA*, 108 F.4th 1163, 1176 (9th Cir. 2024). "In our system of dual federal and state sovereignty, federal policies frequently generate indirect effects on state revenues or state spending," *Texas*, 599 U.S. at 680 n.3, and government action that is "so far removed from its distant . . . ripple effects" "cannot establish Article III standing," *Alliance for Hippocratic Med.*, 602 U.S. at 383. FDA's 2016, 2021, and 2023 decisions do not regulate Idaho, Missouri, or Kansas, so any alleged impact that FDA's decisions might have on those States' expenditures is therefore indirect, attenuated, and of the type that accompanies virtually any federal policy. *See also Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) (if "peripheral costs imposed on States by actions of the President" "create[d] a cognizable Article III injury for the State to vindicate in federal court," it "would make a mockery of the constitutional requirement of case or controversy" (citation and ellipses omitted)).

The States' theory of standing is simply a reprisal of the similarly capacious—and soundly rejected—"doctor standing" argument made by the Alliance Plaintiffs, 602 U.S. at 391, but with the added link of a state expenditure at the end of the lengthy and attenuated causal chain. The problem, however, is the same: Just as doctors have never been permitted 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.*, States have never been allowed to challenge those changes simply because they may eventually pick up the bill for some of that care. "The causal link between the FDA's regulatory actions" and the alleged increase in Medicaid spending is just "too speculative or otherwise too attenuated to establish standing." *Id.* at 390.

Allowing States, no less than private doctors, "to challenge general safety regulations as unlawfully lax would be an unprecedented and limitless approach and would allow [States] to sue in federal court to challenge almost any policy affecting public health." *Id.* at 391-392. "[V]irtually all drugs come with complications, risks, and side effects," which means that changes in prescription drug guidelines will frequently "yield more visits to doctors to treat complications or side effects." *Id*. at 392. Any State could deploy the rinse-and-repeat formula that Missouri, Kansas, and Idaho debut here to transform those risks into the injury of increased future Medicaid costs. The math is simple: estimate the number of Medicaid-enrolled residents who may be prescribed the drug (based on speculative assumptions about the independent choices of providers and patients not before the court, and without establishing any connection to the particular change at issue), ECF No. 217 ¶¶ 694-695; multiply by the highest potential complication rate in any study (even if many times higher than reflected in the State's own data[5]), *id.* ¶ 691; and declare how

[5] The States' calculation of past economic injury mix and match data sources to maximize their estimates. For example, Missouri's injury calculation starts with the number of Missouri residents that allegedly received medication abortions in each year. ECF No. 217 ¶¶ 422-423, 694. In 2020, the Missouri Department of Health and Senior Services reported that 2,298 residents received medication abortions. *Id.* ¶¶ 422 n.385, 423. That same report counted just 17 complications statewide from medication abortion. *See* 2020 Missouri Vital Statistics, *Table 12C: Post-Abortion Complication Report: Missouri, 2020*, https://perma.cc/D9TX-XHBA. Putting aside that Missouri offers no evidence that these complications involved trips to emergency rooms or any state-funded care, Missouri's own numbers reflect a complication rate of just 0.7%. Instead of consistently using its own data, though, Missouri plucked the 4-6x higher rates from the FDA-approved label, *see* ECF No. 217 ¶ 693, which merely notes that three studies reported "ER visit[s]" of 0%, 2.9%, and 4.6%, but cautions that these data "may not reflect the rates observed in practice," and notes that across all 10 studies referenced in that section of the label, "[s]erious adverse reactions were reported in <0.5% of women," ECF No. 217-1, Exh. 5 (App. 231-234).

Idaho's own data shows an even lower rate complication rate. Idaho's 2020 injury calculation starts with data from its Department of Health and Welfare, which reported 1,102 medication abortions to Idaho residents, ECF No. 217 ¶¶ 428 & n.390, 695, with 889 actually occurring in Idaho, *see* Idaho Dep't of Health & Welfare, *Idaho Vital Statistics, Induced Abortion 2020* at 10, 12, https://perma.cc/8HAM-NN4K. That same Department reported just two instances in 2020

much each complication could cost under the State's Medicaid fee schedule, *id.* ¶¶ 720-721. States need only pick a drug and rinse-and-repeat to create the same economic injury. That would give *every* State—and any other entity that provides health insurance or subsidized medical care—standing "to challenge any FDA decision approving a new drug." *Alliance for Hippocratic Med.*, 602 U.S. at 392.

The States' boundless theory of standing would extend far beyond challenging FDA's decisions; it would sweep up any other agency decision that may affect public health. States like California or New York could sue EPA for "roll[ing] back emissions standards for power plants" on the theory that state Medicaid might spend more on asthma claims. *See id.* at 391. And "there would be no principled way to cabin such a sweeping doctrinal change" to the healthcare context: States could sue federal agencies for rolling back DEI initiatives that the States say require them to spend money to replace, or sue the ATF for "repeal[ing] certain restrictions on guns," on the theory that States will be required to hire more police officers to keep communities safe given the greater prevalence of guns. *See id.* at 391-392. The end result would be that every State would have "standing to challenge virtually every government action that they do not like—an approach to standing that [the Supreme] Court has consistently rejected as flatly inconsistent with Article III." *Id.* at 392. The States' attempt to "create such a novel standing doctrine out of whole cloth" must likewise be rejected. *Id.* at 391.

The States' attempt to manufacture standing fails on another prong: Their alleged injury is not "redressable by a favorable ruling." *Murthy*, 603 U.S. at 57. The States seek to return to the pre-2016 mifepristone labeling, but the 2016 changes made mifepristone even more effective

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where abortion complications were referred to an emergency room or urgent care—a rate of just 0.2%. Idaho Dep't of Health & Welfare, *Idaho Abortion Complication Report 2020* at 6, https://perma.cc/6QDF-R2DU.

and further reduced adverse events. *Compare* ECF No. 28-1, Center for Drug Evaluation and Research, Medical Review(s) of Application Number 020687Orig1s020 at 32 (Mar. 2016) (92% need no intervention under original labeling), *with id.* at 31, 33 (96.1% and 97.4% need no intervention following 2016 changes).[6] Using the States' own speculative and attenuated chain of logic, the marginally less effective rate under the pre-2016 labeling would make it more, not less, likely that women who are prescribed mifepristone may require some additional intervention—and that the States' Medicaid programs would be "injured" under their proposed theory that Medicaid payment equals Article III injury-in-fact. The States will not "benefit in a tangible way from the court's intervention" so much as deepen their own alleged harms. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 n.5 (1998) (citation omitted).

2. Alleged Injuries To The States' Sovereign Interests Are Insufficient.

The States claim to suffer "sovereign injuries" resulting from FDA's interference with their interests in creating and enacting state-law limits on mifepristone. *E.g.*, ECF No. 217 ¶¶ 525, 535. The Supreme Court foreclosed that theory in *United States v. Texas*, 599 U.S. 670 (2023). The Court reaffirmed that alleged underenforcement of federal law did not support a sovereign-harm theory of standing, which would "start the Federal Judiciary down th[e] uncharted path" of adjudicating all sorts of "alleged Executive Branch under-enforcement of any similarly worded laws—whether they be drug laws, gun laws, obstruction of justice laws, or the like." *Id.* at 681.

That is precisely what the States ask for here. On their telling, FDA's deregulatory actions "make[ ] it difficult for state law enforcement to detect and deter state law violations and to give effect to state abortion laws." ECF No. 217 ¶ 548; *see also*, *e.g.*, *id.* ¶ 536 (casting FDA's action as "a practical impediment to on-the-ground compliance with and enforcement of state laws").

[6] Indeed, this improved profile after the REMS changes in 2016 may account for why the States' own data from 2020 reflect lower rates of adverse events. *See supra* p. 16 n.5.

Taking these allegations as true, this type of "sovereign injury" does not confer standing. "Even if the availability of retail and mail-order dispensing does make mifepristone more difficult to police, [courts] have never held that a logistical burden on law enforcement constitutes a cognizable Article III injury." *Washington*, 108 F.4th at 1177.

Missouri, Idaho, and Kansas also claim that FDA has denied them the "benefit" of "the uniform application of federal law and the ability of States to rely on the backdrop of federal law when enacting their own regulations." ECF No. 217 ¶ 556. As an initial matter, this theory cannot be squared with respect to Missouri's recently enacted constitutional amendment recognizing a "fundamental right to reproductive freedom," including "abortion care," Mo. Const. art. I, § 36(2), or with the Kansas Supreme Court's July 2024 holding that abortion is a fundamental right under the Kansas constitution, *Hodes & Nauser, MDS, P.A. v. Kobach*, 551 P.3d 37, 46 (Kan. 2024). Moreover, the States' fear that some litigant may assert a federal preemption claim against one of their state laws proscribing mifepristone access or restricting access to abortion through telemedicine or by other means is wholly speculative. The federal government has not brought a preemption case against the three States (or any State, for that matter). The States also have not alleged a "certainly impending" risk of such a suit; it is merely "speculative whether the Government will imminently target" any of the three States' laws—let alone succeed in such a hypothetical challenge. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013); *see* ECF No. 217 ¶ 577 (confirming that the States will "vigorously dispute" any preemption claims). And the fact that private litigants have challenged *other States'* laws says nothing about the risk of imminent harm to Missouri, Kansas, or Idaho.

Missouri, Kansas, and Idaho further claim standing based on their fears that mifepristone will hurt the health and safety of their citizens, *e.g.*, *id.* ¶ 616, a theory they ground in a so-called

"quasi-sovereign" interest in "protecting [their] citizens," *id.* ¶¶ 38, 40, 42. These allegations are not "concrete, particularized, and actual or imminent," *Clapper*, 568 U.S. at 409, and further run afoul of the established limits on *parens patriae* standing. *See Murthy*, 603 U.S. at 76 ("States do not have standing as *parens patriae* to bring an action against the Federal Government." (citation and quotation marks omitted)). The Fifth Circuit turned back a similar effort to manufacture State standing just last year, when Texas "claim[ed] that it 'ha[d] standing to vindicate its quasi-sovereign interests in its citizens' health and well-being." *Paxton v. Dettelbach*, 105 F.4th 708, 715 (5th Cir. 2024). Rejecting this argument, the Fifth Circuit concluded that the "quasi-sovereign interest" Texas claimed was "wholly derivative of the personal Second-Amendment interests of its citizens and therefore not a valid quasi-sovereign interest at all." *Id.* at 715-716. That holding applies here, too: The States have not shown any injury to their own interests apart from interests that are held by private persons within their borders. The States may "not merely litigate as a volunteer the personal claims of its citizens." *Id.* at 716.

The States likewise cannot establish standing based on interests in promoting citizens' "health and welfare while in state custody or control." ECF No. 217 ¶ 582. Here again, "[t]his argument is a thinly veiled attempt to circumvent the limits on *parens patriae* standing," *Murthy*, 603 U.S. at 76 (citation omitted)—a limit that ensures federal courts hear only those cases that implicate the "judicial Power," U.S. Const. art. III, § 2; *see also Texas*, 599 U.S. at 680 n.3 ("federal courts must remain mindful of bedrock Article III constraints in cases brought by States against an executive agency or officer"). The States do not claim these individuals in their custody or control are unable to sue themselves, further confirming that the States' alleged interests are entirely derivative of these would-be plaintiffs. *See Harrison v. Jefferson Par. Sch. Bd.*, 78 F.4th 765, 773 (5th Cir. 2023) (rebuffing similar theory of standing and observing that "individual

students can sue to get relief from [the] alleged discrimination"). And regardless, FDA's 2016, 2021, and 2023 actions have no effect on parental notification or consent laws.

3. The States' Alleged Injuries To Their Population Interests Do Not Confer Standing.

The States also attempt to generate standing based on a population-loss theory, likening their theory of standing to that of States directly harmed by a census undercount in *Department of Commerce v. New York*, 588 U.S. 752 (2019). *See* ECF No. 217 ¶¶ 417-420. This is the antithesis of "particularized." *Clapper*, 568 U.S. at 410. Were this theory to succeed, any State could beat a path into federal court merely by identifying some federal action that might affect birthrates, life expectancy, or a State's population in some other way. States could argue that everything from the closure of a military base to the loosening of federal firearms laws to more lax air-quality standards could affect a State's total population decades down the road. *Cf. Washington*, 108 F.4th at 1177 (counseling against adopting a theory of State standing that "similarly lacks a limiting principle"); *Alliance for Hippocratic Med.*, 602 U.S. at 392 (refusing "to start the Federal Judiciary down that uncharted path").

III. Other Threshold Grounds Bar The States' Claims.

A. The States Failed To Exhaust Administrative Remedies.

The States' failure to exhaust administrative remedies independently warrants dismissal. Exhausting administrative remedies means that a party has "proceeded through each step of the [agency's] administrative review scheme and received a 'final decision' before seeking judicial review." *Carr v. Saul*, 593 U.S. 83, 88 n.2 (2021). Congress "codified the doctrine of exhaustion of administrative remedies" in the APA by requiring an "aggrieved party" to "exhaust[ ] all administrative remedies expressly prescribed by statute or agency rule." *Darby v. Cisneros*, 509 U.S. 137, 146, 153 (1993); *see also United States v. Menendez*, 48 F.3d 1401, 1411 & n.15 (5th

Cir. 1995). Here, FDA regulations clearly mandate that any request for FDA to "take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a [citizen] petition . . . before any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. § 10.45(b); *see id.* §§ 10.25(a), 10.30. Because the States do not allege that they filed citizen petitions as to any of FDA's decisions the States now challenge, their suit must be dismissed for failure to exhaust administrative remedies. *See Ass'n of Am. Physicians v. FDA*, 358 F. App'x 179, 180-181 (D.C. Cir. 2009) (plaintiffs that failed to file citizen petition challenging FDA's approval of over-the-counter Plan B "failed to exhaust their administrative remedies" and "proffered no legally viable excuse for this failure"); *see also* ECF No. 219 at 12 (collecting cases).

B. The States' Challenge To The 2016 Changes Is Time Barred.

The States' challenge to FDA's 2016 changes fails for yet another reason: It is time-barred. APA challenges "must be brought within six years of the final agency action allegedly causing a plaintiff's injury." *Am. Stewards of Liberty v. Dep't of Interior*, 960 F.3d 223, 229 (5th Cir. 2020); *see* 28 U.S.C. § 2401(a) ("every civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues"). The States' challenge to the 2016 changes first accrued on March 29, 2016—the date FDA approved the challenged changes. *See* ECF No. 217-2, Exh. 23 (App. 513). That means the States had until March 29, 2022 to file their complaint. Yet the States did not seek to intervene in this case until over a year later—on November 3, 2023, *see* ECF No. 151, and their first complaint was not docketed until almost two years after the statute of limitations ran, on January 12, 2024, *see* ECF No. 176. Their challenge to the 2016 changes is accordingly untimely.

CONCLUSION

For the foregoing reasons, and for the reasons in FDA's Brief, ECF No. 219, the Court should grant the motions to dismiss the States' amended complaint.

Respectfully submitted,

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January 28, 2025

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
Jessica L. Ellsworth

CERTIFICATE OF SERVICE

I certify that on January 28, 2025, 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.

/s/ Jessica L. Ellsworth
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