IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION

THE STATE OF MISSOURI, *et al.*, *Intervenor Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.,* *Federal Defendants,* and DANCO LABORATORIES, *et al.*, *Intervenor Defendants.*	No. 4:25-cv-01580-CMS

FEDERAL DEFENDANTS' MOTION TO STAY OR, ALTERNATIVELY, DISMISS

Federal Defendants respectfully move that this Court (1) stay this litigation pursuant to its inherent authority during the pendency of the U.S. Food and Drug Administration's review of the mifepristone Risk Evaluation and Mitigation Strategy, or, alternatively, (2) dismiss the Amended and Supplemental Complaints under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). The grounds for this motion are set forth in the accompanying memorandum.

Intervenor Plaintiffs oppose the relief requested in this motion.

Counsel for Intervenor Defendant Danco Laboratories states: "Danco's position, as detailed in its motion to dismiss, is that the Plaintiff States lack standing and that in the absence of a party with Article III standing, the more prudent course is for the Court to dismiss the action rather than to stay it. If the Court declines to dismiss the case at this time, however, Danco would not oppose Federal Defendants' request for a stay of these proceedings pending the ongoing FDA review."

Counsel for Intervenor Defendant GenBioPro states: "GenBioPro's position, which will be

set forth more fully in GenBioPro's upcoming motion to dismiss, is that Plaintiffs lack standing and have failed to exhaust administrative remedies, and therefore the Court lacks jurisdiction and the case should be dismissed. To the extent the Court declines to dismiss the case at this time, GenBioPro would not oppose Federal Defendants' request for a stay of these proceedings pending the ongoing FDA review."

March 6, 2026

Respectfully submitted,

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

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MEMORANDUM IN SUPPORT OF FEDERAL DEFENDANTS' MOTION TO STAY OR, ALTERNATIVELY, TO DISMISS THE CASE

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INTRODUCTION

Protecting the health and safety of pregnant women is of paramount importance. To that end, on September 19, 2025, the Secretary of Health and Human Services and the Commissioner of Food and Drugs announced that the Food and Drug Administration (FDA) is reviewing the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, a drug approved for medical abortion. Ex. 1 (Sept. 19, 2025 Letter). The Secretary and the Commissioner explained that this review—which will include a study undertaken by FDA itself—is "informed by the lack of adequate consideration underlying prior REMS approvals." *Id.* at 1. FDA's review is rooted in the agency's commitment "to protecting the health and safety of pregnant women" and "ensur[ing] . . . decisions are grounded in Gold Standard Science and rigorous, transparent, and objective evidence." *Id.* at 2.

FDA's decision to review the REMS for mifepristone is consistent with concerns foreshadowed by the Fifth Circuit in *Alliance for Hippocratic Medicine v. FDA*. *See* 78 F.4th 210, 249-51 (5th Cir. 2023), *rev'd on other grounds*, 602 U.S. 367 (2024). Although ultimately reversed on jurisdictional grounds, the Fifth Circuit held that FDA erred in failing to consider the "cumulative effect" of changes, approved in 2016, to the REMS and labeling for mifepristone or "explain[] why it declined to do so." *Id.* at 246. The court also faulted FDA for approving, in 2016, the elimination of a requirement that certified prescribers report nonfatal, serious adverse events without first considering how other changes approved in the same supplement might affect the drug's safety profile. *Id.* at 246-47. And the court held that, in calling for the removal of the requirement that mifepristone be dispensed in person in certain healthcare settings (known as the "in-person dispensing requirement") in December 2021, FDA erroneously "gave dispositive weight to adverse-event data in" FDA's Adverse Event Reporting System despite limitations of that data—including that, since 2016, prescribers were no longer required to report non-fatal serious adverse events to

the sponsors. *Id.* at 249; *see id.* at 250 (faulting FDA's reliance on studies that had "significant limitations" and "did not affirmatively support" eliminating the in-person dispensing requirement).

In deciding to launch a new review of the mifepristone REMS, FDA recognized that mifepristone's conditions of use are a hotly contested legal and scientific issue that has been the subject of litigation for many years. Missouri, Kansas, and Idaho are not the only plaintiffs to have challenged the current conditions of use for mifepristone. Indeed, three other states are challenging either the approval of mifepristone or subsequent actions easing restrictions. *See Louisiana v. FDA*, No. 6:25-cv-1491-DCJ-DJA (W.D. La.) (Louisiana challenging removal of in-person dispensing requirement); *Florida v. FDA*, No. 7:25-cv-126-O (N.D. Tex.) (Florida and Texas challenging, *inter alia*, approval and actions easing REMS restrictions). Still other plaintiffs have challenged the REMS as too restrictive. *Purcell v. Kennedy*, Civ. No. 17-00493 JAO-RT, 2025 WL 3101785, at *28 (D. Haw. Oct. 30, 2025); *Washington v. FDA*, No. 1:23-cv-3026-TOR, 2025 WL 1888794 (E.D. Wash. 2025); *Whole Woman's Health All. v. FDA*, No. 3:23-cv-00019 (W.D. Va.). And aside from court cases, numerous citizen petitions are pending before the FDA—citing voluminous material and seeking mutually inconsistent actions, such as suspending approval of the drug, restoring previous REMS requirements, or eliminating the REMS entirely. *See infra* n.3.

Given this widespread debate over the safety of mifepristone, FDA has concluded that the best path forward is for the agency to undertake its review based on all the evidence before the agency. As noted above, that evidence will include FDA's own study. FDA has emphasized that it "is taking care to do this study properly and in the right way." FDA, Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation (item No. 37).[1] At this time, "FDA continues to work on the collection of the robust and timely data that is

[1] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

necessary for a well-controlled study with adequate statistical power." *Id.* Although studies like these "often take approximately a year or more to conduct," FDA plans to complete the study "sooner than that timeframe." *Id.* Once FDA has analyzed the study data (as well as all other evidence before the agency), it will decide whether "substantive changes to the REMS" are warranted. *Id.*

Missouri, Kansas, and Idaho (Intervenor Plaintiffs) threaten to short-circuit the agency's orderly review and study of the safety risks of mifepristone. They would have this Court set aside the FDA actions modifying the conditions of use (including the REMS) and approving generic equivalents as far back as 2016—without the benefit of FDA's new review of the mifepristone REMS. And Intervenor Plaintiffs' requested relief may prove as unnecessary as it is disruptive, if, for example, FDA ultimately decides that the REMS requirements previously in place must be restored.

Moreover, awarding relief to these Plaintiffs could easily prompt other plaintiffs to seek a conflicting injunction that would sow administrative and judicial chaos. If this Court were to order a change to the REMS, the plaintiffs in *Whole Woman's Health Alliance*, for example, could promptly seek conflicting relief, which would only add to FDA's burden and complicate any future modification efforts if FDA determines that changes are necessary. The prospect of conflicting injunctions is hardly far-fetched. In 2023, minutes after the Northern District of Texas in *Alliance* stayed FDA's approval of mifepristone, the Eastern District of Washington prohibited FDA from altering the status quo in certain States. *Washington v. FDA*, 668 F. Supp. 3d 1125, 1144 (E.D. Wash. 2023), *vacated*, No. 1:23-cv-3026-TOR, 2025 WL 1888794 (E.D. Wash. 2025). Although Intervenor Plaintiffs have (appropriately) not sought preliminary relief, even the ultimate relief they request threatens to spark a judicial tug-of-war.

To prevent that disruption, the Court should exercise its inherent authority to stay this litigation pending the outcome of FDA's review. FDA's review will necessarily result in a new agency decision that could supersede the agency actions that Intervenor Plaintiffs challenge,

obviating any need to consider the merits of Intervenor Plaintiffs' arguments. Any party adversely affected by the new agency decision on mifepristone may seek judicial review at that time. And in the event FDA determines a REMS modification is needed, adherence to FDA's normal process will create far less disruption than the judicially imposed changes sought by Intervenor Plaintiffs. Deferring judicial review until FDA's review is complete also will not prejudice Intervenor Plaintiffs. After all, they waited over seven years to challenge FDA's 2016 action and nearly a year to challenge the 2023 action. Having delayed so long, Intervenor Plaintiffs cannot claim prejudice from the additional time necessary for FDA to complete its ongoing review.

But if the Court does not stay this case, it should be dismissed for several reasons. *First*, although Intervenor Plaintiffs have alleged the challenged actions cause serious harms to women, that does not suffice to establish Article III standing. Missouri, Kansas, and Idaho suffer no sovereign injury because they remain free to make and enforce their pro-life policies after *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022). Nor are Defendants standing in the way of Intervenor Plaintiffs enforcing their abortion laws against out-of-state prescribers of mifepristone. The States' allegations about Medicaid costs rely on an even more attenuated chain of causation that the Supreme Court rejected in *Alliance*. *Second*, even if Intervenor Plaintiffs could overcome the Article III hurdle, Intervenor Plaintiffs failed to administratively exhaust their claims and thus cannot proceed under the Administrative Procedure Act (APA). And *third*, their challenge to FDA's 2016 action is barred by the statute of limitations. For all these reasons, the Court should either stay this case until after FDA completes its review or dismiss it.

BACKGROUND

I. Legal and Factual Background

The Federal Food, Drug, and Cosmetic Act generally prohibits introducing a "new drug" into interstate commerce without FDA approval. 21 U.S.C. § 355(a). In 2000, FDA approved

mifepristone for medical abortion (under the brand name Mifeprex), subject to certain restrictions to assure safe use. *See Alliance*, 602 U.S. at 376; 21 C.F.R. § 314.520.[2] Since 2008, those restrictions have been part of a REMS. *See* Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313, 16314 (Mar. 27, 2008). The two generic equivalents of Mifeprex (approved by FDA in 2019 and 2025) are subject to the same REMS requirements. ECF No. 217 (Am. Compl.) ¶¶ 164-65; ECF No. 281 (Suppl. Compl.) ¶¶ 14-15.

In 2016, FDA approved certain changes to the conditions of use (including the REMS requirements) for mifepristone (the 2016 action). Am. Compl. ¶ 133. The changes included, for example: increasing the gestational age limit from seven weeks to ten weeks; reducing the number of office visits from three to one; allowing non-physician health care providers licensed under state law to prescribe drugs to prescribe mifepristone; and eliminating the requirement that prescribers report non-fatal serious adverse events to the sponsors. *Id.* ¶¶ 135-36.

The in-person dispensing requirement was retained in the 2016 action, but it was eventually removed. In July 2020, a district court preliminarily enjoined enforcement of the in-person dispensing requirement during the COVID-19 pandemic. *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020). The Supreme Court stayed that injunction pending appeal in January 2021. *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021) (mem.). But in April 2021, FDA announced that it would not enforce the in-person dispensing requirement during the COVID-19 public health emergency, and the following month it announced a review of the REMS. *See* Am. Compl. ¶ 170; Pl. Ex. 34 (2021 FDA Letter to AAPLOG, *et al.*) at 5 & 6 n.10.

[2] FDA has separately approved another manufacturer's mifepristone product, Korlym, for the treatment of Cushing's syndrome. Intervenor Plaintiffs do not challenge FDA's actions regarding Korlym, and all references to mifepristone throughout this brief refer to the drug approved for medical abortion (Mifeprex and the approved generic equivalents).

After completing that review, on December 16, 2021, the agency directed the sponsors of the drug to submit supplemental applications proposing to remove the in-person dispensing requirement. *See* Am. Compl. ¶¶ 173-75; 21 U.S.C. § 355-1(g)(4)(B) (authorizing FDA to direct the sponsors of a drug to propose REMS modifications to "ensure the benefits of the drug outweigh the risks of the drug" or "minimize the burden on the health care delivery system of complying with [the REMS]"). The sponsors submitted those applications on June 22, 2022, and FDA approved them on January 3, 2023 (the 2023 REMS Modification).

Today, the agency is once again reviewing the mifepristone REMS. As the Secretary and the Commissioner told 22 state attorneys general on September 19, 2025, FDA's "review of the evidence . . . will contribute to the understanding of the drug's safety profile." Ex. 1. "[T]o determine whether modifications [to the REMS] are necessary," FDA will consider evidence relating to "real-world outcomes" and conduct "a study of the safety of the current REMS." *Id.* In addition, FDA will consider aspects of the 2023 REMS Modification that a court has ordered the agency to reassess, *see Purcell*, 2025 WL 3101785, at *28, as well as numerous citizen petitions that cite voluminous materials and seek competing outcomes.[3]

II. Procedural History

This case began on November 18, 2022 in the Northern District of Texas as *Alliance for Hippocratic Medicine v. FDA*, No. 2:22-cv-223-Z (N.D. Tex). Almost a year later, on November 3, 2023, Missouri, Kansas, and Idaho moved to intervene as plaintiffs. ECF No. 151. In January 2024, while the case was on appeal, the district court (per Judge Kacsmaryk) granted their intervention

[3] The petitions include, but are not limited to, the following: https://www.regulations.gov/document/FDA-2025-P-0377-0001; https://www.regulations.gov/ document/FDA-2025-P-1242-0001; https://www.regulations.gov/document/FDA-2025-P-1576-0001; https://www.regulations.gov/document/FDA-2025-P-2162-0001; https://www.regulations.gov/document/FDA-2025-P-3287-0001; https://www.regulations.gov/document/FDA-2025-P-5434-0001.

motion. The States also sought to intervene in proceedings before the Supreme Court, but that request was denied. *FDA v. All. for Hippocratic Med.*, 144 S. Ct. 997 (Feb. 20, 2024) (mem.). In June 2024, the Supreme Court held that, despite the original plaintiffs' "sincere legal, moral, ideological, and policy objections to elective abortion and to FDA's relaxed regulation of mifepristone," they "failed to demonstrate that FDA's relaxed regulatory requirements likely would cause them to suffer an injury in fact." *Alliance*, 602 U.S. at 396. On remand, the original plaintiffs voluntarily dismissed their complaint, ECF No. 203, but Intervenor Plaintiffs pressed on.

FDA thus moved to dismiss the Intervenor Plaintiffs' Amended Complaint based on improper venue, lack of standing, and failure to exhaust administrative remedies, and because some of their claims were barred by the statute of limitations. ECF Nos. 218, 219. The district court agreed with FDA that, under *Alliance*, the original plaintiffs lacked standing from the outset. ECF No. 273. As a result, the district court held that Intervenor Plaintiffs could not use the original plaintiffs as the basis for establishing venue in the Northern District of Texas. *Id.* Because Intervenor Plaintiffs themselves lacked a basis for establishing proper venue in that district, the court transferred the case to the Eastern District of Missouri. *Id.*

Following transfer, Intervenor Plaintiffs moved for leave to file a supplemental complaint challenging FDA's 2025 approval of a second generic equivalent of Mifeprex. ECF No. 277. The Court granted that motion and directed Defendants to file consolidated responses to the Amended and Supplemental Complaints by March 6, 2026. ECF Nos. 280, 282, 286. In the Amended and Supplemental Complaints, Plaintiffs ask the Court to vacate aspects of the 2016 action, the 2019 and 2025 generic approvals, and the 2023 REMS Modification.

STANDARD OF REVIEW

"[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for

counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). In exercising its "broad discretion to stay proceedings," *Clinton v. Jones*, 520 U.S. 681, 706 (1997), a court "must weigh competing interests and maintain an even balance," *Landis*, 299 U.S. at 254-55; *see also Sierra Club v. U.S. Army Corps of Eng'rs*, 446 F.3d 808, 816 (8th Cir. 2006). "Generally speaking, the Court is to weigh, 'the potential prejudice or hardships to the parties, as well as the interest of judicial economy.'" *Backfisch v. Penske Truck Leasing Co., L.P.*, No. 1:24-cv-213-SNLJ, 2025 WL 3525028, at *1 (E.D. Mo. Dec. 9, 2025) (quotation omitted).

On a Rule 12(b)(1) motion to dismiss, "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). Courts are presumed to "lack jurisdiction unless the contrary appears affirmatively from the record." *Renne v. Geary*, 501 U.S. 312, 316 (1991) (quotation marks omitted). Jurisdiction aside, courts must dismiss claims that are unexhausted or barred by the statute of limitations pursuant to Rule 12(b)(6). *Young v. United States*, No. 4:22-cv-1273-RLW, 2023 WL 6141709, at *1-*2 (E.D. Mo. Sept. 20, 2023); *Chicken v. Becerra*, No. 5:22-cv-5056-RAL, 2023 WL 7386413, at *2 (D.S.D. Nov. 8, 2023).

ARGUMENT

I. The Court Should Stay This Case Pending FDA's Mifepristone REMS Review.

The Court should stay this litigation until after FDA's review of the mifepristone REMS is complete. *Landis*, 299 U.S. at 254-55; *see also Ricci v. Chi. Mercantile Exch.*, 409 U.S. 289, 305 (1973) (upholding stay of judicial proceedings pending completion of agency proceedings). Judicial economy, the prejudice to FDA of moving forward, and the lack of prejudice to Intervenor Plaintiffs from a stay all commend that commonsense result. *See Backfisch*, 2025 WL 3525028, at *1.

The harms of moving forward before FDA's review is complete are manifold. Intervenor Plaintiffs ask the Court to make the very sort of difficult scientific judgments that Congress entrusted to FDA while the agency is considering the same issues. *See Lockhart v. Kenops*, 927 F.2d

1028, 1034 (8th Cir. 1991). Such parallel proceedings would waste judicial resources because FDA's own review may eliminate any need for the Court's. Moreover, if the Court grants the relief Intervenor Plaintiffs seek before FDA's review is complete, it could prompt the sponsors of mifepristone to file supplemental applications seeking modifications to the REMS. This, in turn, would add to the burdens on the agency as it seeks to conduct its own study, review all the evidence before it, comply with the *Purcell* remand, and weigh competing views presented in numerous citizen petitions submitted to FDA. Further complications likely would arise if this Court vacates or enjoins any of FDA's past actions thereby triggering plaintiffs in other mifepristone-related litigation to seek conflicting injunctions. On the other side of the ledger, any claim of prejudice by Intervenor Plaintiffs is belied by their delay in filing suit.

Granting a stay while an agency reviews the matter in litigation is par for the course. *Purcell* (originally *Chelius*) is a case in point. There, the plaintiffs originally challenged the REMS that existed before the 2023 REMS Modification. After FDA announced a REMS review in May 2021, the *Purcell* court stayed the litigation. *See Chelius v. Becerra*, No. 1:17-cv-493-JAO-RT, ECF No. 149 (D. Haw. May 7, 2021) (staying and administratively closing case). The case remained stayed until after the 2023 REMS Modification. *Id.*, ECF No. 158 (D. Haw. Feb. 28, 2023) (reopening case). The Court should take a similar course here to allow FDA to complete its review of the mifepristone REMS.

II. Alternatively, The Court Should Dismiss The Case.

Alternatively, the Court should dismiss this case for three reasons. *First*, the Intervenor Plaintiffs lack Article III standing. *Second*, they failed to administratively exhaust their claims. And *third*, their challenges to the 2016 action are time-barred.

A. The Court lacks subject matter jurisdiction

As Judge Kacsmaryk recognized, "the [o]riginal [p]laintiffs never had a jurisdictionally valid case." ECF No. 273, at 11. Although Judge Kacsmaryk transferred the case without resolving

subject matter jurisdiction, *see* ECF No. 273, at 9, his recognition that standing was absent at the outset dictates that the only proper outcome remains dismissal of Missouri, Kansas, and Idaho's claims. After all, if a court lacks subject matter jurisdiction, "the only function remaining to the court is that of announcing the fact and dismissing the cause." *Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 514 (1868); *see also Muff v. Wells Fargo Bank NA*, 71 F.4th 1094, 1101 (8th Cir. 2023).

But even if the law permitted something other than immediate dismissal, Intervenor Plaintiffs cannot backfill the missing jurisdiction because they too lack standing. "[E]ven if the States as sovereigns are entitled to some undefined 'special solicitude' in the standing analysis, they still must satisfy the basic requirements of Article III standing." *State v. Biden*, 52 F.4th 362, 369 (8th Cir. 2022). That means the States "must demonstrate (i) that [they] ha[ve] suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant[s], and (iii) that the injury likely would be redressed by the requested judicial relief." *Alliance*, 602 U.S. at 380.

Like the original plaintiffs in *Alliance* who lacked standing, Intervenor Plaintiffs "do not prescribe or use mifepristone." *Id.* at 385. Nor do the agency actions they challenge "require[] [them] to do anything or to refrain from doing anything." *Id.* Intervenor Plaintiffs therefore face an uphill battle to establish standing. In addition to showing a cognizable and redressable Article III injury, they must also show that the indirect causal chain between each agency action they challenge and their alleged injury is neither "speculative" nor "attenuated." *Id.* at 383. They have not done so.

1. FDA's actions do not cause "sovereign harm"

Contrary to Intervenor Plaintiffs' contention, the challenged FDA actions do not implicate the States' "sovereign power to enact and enforce their [abortion] laws." Am. Compl. ¶ 527. The Fourth Circuit has held that the mifepristone REMS establishes "a regulatory floor, not a ceiling."

GenBioPro, Inc. v. Raynes, 144 F.4th 258, 274 (4th Cir. 2025).[4] The Federal Government has not taken any position that leaves Missouri, Kansas, or Idaho unable to "regulate abortion for legitimate reasons," including through legislation that furthers a "respect for and preservation of prenatal life at all stages of development." *Dobbs*, 597 U.S. at 300-01.

Intervenor Plaintiffs agree that the mifepristone REMS does not preempt their laws. *See* Am. Compl. ¶ 577. They suggest, however, that the Executive Branch previously contended otherwise. That is incorrect. The public statements Intervenor Plaintiffs identify claimed only that states could not ban mifepristone based on a "disagreement" with FDA's "expert judgment" about "safety and efficacy." *Id.* ¶¶ 250-51. In any event, the Executive Branch now concurs with the Fourth Circuit's view that the mifepristone REMS establishes a regulatory floor, not a ceiling.

Intervenor Plaintiffs' remaining theories of sovereign harm (Am. Compl. ¶¶ 532-53, 554-68, 578-92) all revolve around the idea that FDA's easing of restrictions on mifepristone enables third parties to violate state law. But as the Ninth Circuit recognized when Idaho (among others) tried to assert this theory in a challenge to the 2023 REMS Modification, "even if the availability of retail and mail-order dispensing does make mifepristone more difficult to police," that "logistical burden on law enforcement" does not "constitute[] a cognizable Article III injury." *Washington v. FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024). The Supreme Court, too, rejected a similar makes-state-crime-possible theory in *United States v. Texas*, 599 U.S. 670 (2023). There, a district court found standing in part based on a State's assertion that a federal policy led to individuals "committing[] more crimes" within that State. *Texas v. United States*, 606 F. Supp. 3d 437, 467 (S.D. Tex. 2022). The Supreme

[4] Intervenor Plaintiffs cite district-court decisions from within the Fourth Circuit that pre-date the Fourth Circuit's opinion in *GenBioPro, Inc. v. Raynes* and therefore should receive no weight. *See GenBioPro, Inc v. Sorsaia*, No. CV 3:23-005, 2023 WL 5490179 (S.D. W. Va. Aug. 24, 2023), *aff'd sub nom. Raynes*, 144 F.4th 258; *Bryant v. Stein*, No. 1:23-cv-77, 2024 WL 1886907 (M.D.N.C. Apr. 30, 2024).

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.

Accepting Intervenor Plaintiffs' theory "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." *Washington*, 108 F.4th at 1177. States could challenge the loosening of federal regulations relating to firearms, the environment, banking, or anything else—all on the hypothesis that removing a *federal* restriction on certain activity removes one barrier to third parties violating *state* law restricting that same activity. No case supports that limitless theory of standing.

Most of the cases Intervenor Plaintiffs cite in their Amended Complaint either involve preemption or say nothing about when a State has a sovereign interest sufficient to establish standing under Article III. The only potentially relevant authority cited is *Texas v. United States*, 787 F.3d 733 (5th Cir. 2015), but it cuts squarely against Intervenor Plaintiffs. In *Texas*, the Fifth Circuit found standing based on a "conflict between federal and state law" because a challenged agency action "forced" Texas to choose between incurring costs and changing its laws. *Id.* at 749. Here, by contrast, there is no conflict between federal and state law.

2. The States' alleged pocketbook injuries do not establish standing

The Intervenor Plaintiffs also contend they have standing as payors of Medicaid and other public insurance. Am. Compl. ¶¶ 593-745. As with the sovereign harm theory, the only court to have considered this theory rejected it as too attenuated. *Washington*, 108 F.4th at 1175-76. This Court should do the same. Indeed, the reasoning of *Alliance* compels that conclusion.

Alliance rejected as too attenuated a theory that doctors can "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." 602 U.S. at 391. The States extend that debunked theory a step further, arguing they have standing because the doctors who lack

standing under *Alliance* might pass their costs on to the State through Medicaid. That is illogical. If the chain of causation between the challenged agency action and the doctors' alleged injury is already too attenuated, adding a link (doctors cause Medicaid to incur costs) only weakens it more.

Intervenor Plaintiffs' version of Medicaid-payor standing is just as limitless as doctor standing. So long as the States (through Medicaid) foot the bill for at least one patient, they could challenge *any* federal policy that allegedly caused the visit to the doctor or hospital, including "EPA roll[ing] back emissions standards for power plants," a "federal agency increas[ing] a speed limit from 65 to 80 miles per hour," or the federal government "repeal[ing] certain restrictions on guns." *Alliance*, 602 U.S. at 391. And the logic of this broad theory would apply to "every entity that provides health insurance or subsidized medical care," not just States or Medicaid payors. *Washington*, 108 F.4th at 1176. Article III standing requirements are not so easily brushed aside.

3. The States cannot sue the Federal Government as *parens patriae*

Finally, the Amended Complaint asserts that Intervenor Plaintiffs have standing based on "the loss of fetal life and potential births." Am. Compl. ¶ 746. But the Supreme Court has expressly held that "States do not have standing as *parens patriae* to bring an action against the Federal Government." *Murthy v. Missouri*, 603 U.S. 43, 76 (2024) (quotation marks omitted); *see Haaland v. Brackeen*, 599 U.S. 255, 294-95 & n.11 (2023). Intervenor Plaintiffs baldly assert that "abortions for women" and "decreased births" are "sovereign injur[ies] to the State itself." Am. Compl. ¶ 749. But this is just "a thinly veiled attempt to circumvent the limits on *parens patriae* standing." *Murthy*, 603 U.S. at 76 (quoting *Brackeen*, 599 U.S. at 295 n.11). The Amended Complaint plainly asserts a *parens patriae* theory based on injuries to "the actual or potential population of each state." Am. Compl. ¶ 746; *see Washington*, 108 F.4th at 1178 ("Idaho alleges that elimination of the in-person dispensing requirement will endanger specific pregnant women who take the drug and 'unborn children' subjected to its effects. These allegations concern the well-being of individual citizens—not a

distinct interest of the state as a whole."). No matter how Intervenor Plaintiffs package it, this theory is conclusively disapproved by the Supreme Court.[5]

For similar reasons, Intervenor Plaintiffs cannot rely on purported injuries to their "exercise of state law parental rights for children in state custody[.]" Am. Compl. ¶ 578. To the extent Intervenor Plaintiffs invoke an interest in individuals' "health and welfare while in state custody or control," *id.* ¶ 582, the bar on *parens patriae* standing applies. The theory also fails because, unlike where the challenged federal policy expressly conflicts with state law, *see Deanda v. Becerra*, 96 F.4th 750, 756 (5th Cir. 2024), FDA's challenged actions have no bearing on state parental notification or parental consent laws. At best, the States complain about hypothetical downstream effects of FDA's actions that are too attenuated to provide standing. *See Alliance*, 602 U.S. at 392-93.

B. Intervenor Plaintiffs failed to administratively exhaust their claims

Additionally, the Amended and Supplemental Complaints should be dismissed under Rule 12(b)(6) because Intervenor Plaintiffs failed to first present their arguments to FDA through a citizen petition. *See* 21 C.F.R. §§ 10.25(a), 10.30 (citizen petition process). Courts have dismissed claims that parties failed to 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).

[5] Citing *Department of Commerce v. New York*, 588 U.S. 752, 766-67 (2019), Intervenor Plaintiffs also assert that they "potentially" suffer follow on injuries from a loss of population. But *Department of Commerce* holds only that a State has a cognizable interest in an *accurate* count of its population. *Id.* at 767. It does not permit a State to assert a *parens patriae* theory of standing against the Federal Government under the guise that the policy allegedly threatens the State's population.

Enforcing that requirement is particularly appropriate here for two reasons. First, the exhaustion requirement expressly contemplates raising new evidence and arguments to the agency in the first instance. "An interested person who wishes to rely upon information or views not included in the administrative record shall submit them to [FDA] with a new petition to modify the action under [21 C.F.R.] § 10.25(a)." *Id.* § 10.45(f). And Intervenor Plaintiffs rely on evidence and arguments that were not before the agency during the challenged REMS reviews. *See, e.g.*, Am. Compl. ¶ 66 & nn.8-9; *id.* ¶¶ 300-369 & nn.252-325.

Second, exhaustion will ensure FDA has "an opportunity to correct its own errors." *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975). Indeed, the Secretary and the Commissioner stated that the decision to conduct a study was "informed by the lack of adequate consideration underlying prior REMS approvals," and FDA's new review will follow "Gold Standard Science." Ex. 1. Requiring Intervenor Plaintiffs to file a citizen petition will ensure that any future litigation proceeds with "the benefit of [FDA]'s experience and expertise" and a "record . . . adequate for judicial review." *Weinberger*, 422 U.S. at 765.

C. Challenges to the 2016 Action are time-barred

At the very least, Intervenor Plaintiffs' challenges to the 2016 action (Counts I and IV) are barred by the six-year statute of limitations. 28 U.S.C. § 2401(a). The six-year period begins to run when "the plaintiff suffers the injury required to press her claim in court." *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 811 (2024). According to Intervenor Plaintiffs, they suffered an injury in 2016. *See, e.g.*, Am. Compl. ¶ 605 (alleging the 2016 action caused women to require medical care). Assuming that's true, a straightforward application of § 2401(a) indicates they had to sue by March 2022. Because they did not, the Court should dismiss Counts I and IV as time-barred.

CONCLUSION

For the foregoing reasons, the Court should either stay or dismiss this case.

March 6, 2026

Respectfully submitted,

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EXHIBIT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

September 19, 2025

Dear Attorneys General:

Thank you for your letter of July 31, 2025, regarding the review of mifepristone by the Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services (HHS). We write to provide an update on this review.

As you noted, the FDA first approved Mifeprex (mifepristone) in September 2000 for medical termination of pregnancy (abortion) through seven weeks gestation. In 2016, the FDA extended this window to ten weeks gestation, and relaxed certain other requirements under the drug's Risk Evaluation and Mitigation Strategy (REMS). Most recently, in 2023, the FDA modified the REMS program again by removing the in-person dispensing requirement.

Since its original approval, the FDA has received reports of serious adverse events in patients who took mifepristone. As with all approved drugs, when the FDA receives new information regarding adverse events, the agency reviews the new information and, as appropriate, takes necessary action. The FDA continuously reviews reports of adverse events to determine, among other things, whether they are known risks or whether they are signals of emerging safety concerns.

Under the Food and Drug Administration Amendments Act, the Secretary is authorized to require a REMS when "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a). For drugs that are "inherent[ly] toxic[] or potential[ly] harmful[]," the Secretary "may require that the [REMS] include such elements as are necessary to assure safe use of the drug." *Id.* § 355-1(f)(1). The Secretary is also authorized to require modifications to an existing REMS when he, among other things, "determines that 1 or more goals or elements should be added, modified, or removed from the [current REMS] to … ensure the benefits of the drug outweigh the risks of the drug." *Id.* § 355-1(g)(4)(B).

HHS is committed to studying the adverse consequences reported in relation to mifepristone to ensure the REMS are sufficient to protect women from unstated risks. Therefore, through the FDA, HHS will conduct a study of the safety of the current REMS, in order to determine whether modifications are necessary. HHS's decision to do so is informed by the lack of adequate consideration underlying the prior REMS approvals, and by recent studies raising concerns about the safety of mifepristone as currently administered.

To that end, HHS—through the FDA—is conducting its own review of the evidence, including real-world outcomes and evidence, relating to the safety and efficacy of the drug. Given the 2016 FDA decision to eliminate the REMS requirement for certified prescribers to report non-fatal serious adverse events to the mifepristone sponsors, this review will contribute to the understanding of the drug's safety profile.

Recent studies—such as the study by the Ethics and Public Policy Center (EPPC), which you highlighted in your letter—indicate potential dangers that may attend offering mifepristone without sufficient medical support or supervision. FDA's own data collected between 2000 to 2012 indicated 2,740 adverse events, including 416 events involving blood loss requiring transfusions. Since then, safeguards for women regarding the administration of mifepristone have been significantly reduced.

The concerns you have raised in your letter merit close examination. This Administration will ensure that women's health is properly protected by thoroughly investigating the circumstances under which mifepristone can be safely dispensed.

* * *

HHS and FDA remain committed to protecting the health and safety of pregnant women. This review will help ensure that the FDA's decisions are grounded in Gold Standard Science and rigorous, transparent, and objective evidence.

Thank you again for your continued engagement in this matter. We will keep you informed as the FDA's review of mifepristone progresses.

Sincerely,

/s/

Robert F. Kennedy, Jr.
Secretary

/s/

Martin A. Makary, MD, MPH
Commissioner of Food and Drugs