IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WITCHITA FALLS DIVISION

THE STATE OF FLORIDA, *et al.*, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants.*	No. 7:25-cv-00126-O

DEFENDANTS' MOTION TO STAY OR, ALTERNATIVELY, TO DISMISS

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 Complaint 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.

March 13, 2026

Respectfully submitted,

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CERTIFICATE OF CONFERENCE

Pursuant to Local Rule 7.1(b), I hereby certify that I exchanged emails with Plaintiffs' counsel (Samuel Elliott, David Dewhirst, Jeffrey DeSousa, Katherine Pitcher, Jonathan Voos, Jason Muelhoff, Amy Hilton, and Camryn Sutton) on multiple dates (January 29, 2026, January 30, 2026, February 6, 2026, February 12, 2026, March 10, 2026, March 11, 2026, and March 13, 2026) regarding Defendants' stay request. I also conferred with Samuel Elliott via phone on March 10. Because Plaintiffs would not agree to the stay as requested, they oppose the motion to stay.

/s/ Noah T. Katzen
NOAH T. KATZEN

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

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

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 supplemental application 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. Florida and Texas are not the only plaintiffs to have challenged the current conditions of use for mifepristone. Indeed, four other states are challenging FDA actions approving changes to the conditions for use (including the REMS) for mifepristone. *See Missouri v. FDA*, No. 4:25-cv-1580-CMS (E.D. Mo.) (Missouri, Idaho, and Kansas challenging actions in 2016 and 2023); *Louisiana v. FDA*, No. 6:25-cv-1491-DCJ-DJA (W.D. La.) (Louisiana challenging approval of action removing in-person dispensing requirement in 2023). 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 a new review based on 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.[1] At this time, "FDA continues to work on the collection of the robust and timely data that is 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.*

Florida and Texas (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 2000 approval of mifepristone and subsequent actions modifying the conditions of use (including the REMS) and approving generic equivalents—all without

[1] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (item No. 37) (accessed Mar. 13, 2026).

the benefit of FDA's new review of the mifepristone REMS. And if FDA ultimately decides to change course, judicial relief may prove equally unnecessary and disruptive.

Moreover, awarding relief to these States could easily prompt other plaintiffs to seek a conflicting injunction that would sow administrative and judicial chaos. If this Court were to set aside mifepristone's approval or 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 Plaintiffs have (appropriately) not sought preliminary relief, 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, which could, in turn, obviate the need to consider some or all of Plaintiffs' claims. Any party adversely affected by the new agency decision on mifepristone may seek judicial review at that time. And in the event FDA determines some kind of change is needed, adherence to FDA's normal process will create far less disruption than the judicially imposed changes sought by Plaintiffs.

Deferring judicial review until FDA's review is complete will not prejudice Plaintiffs. After all, they waited 25 years to challenge the approval of mifepristone, nearly ten years to challenge FDA's 2016 action, seven years to challenge approval of the first generic equivalent, and nearly three years to challenge the elimination of the in-person dispensing requirement. Having delayed so long, Plaintiffs cannot seriously claim prejudice from the additional time necessary for FDA to complete its ongoing review.

But if the Court does not stay this case, then it should dismiss the Complaint for several reasons. First, although Plaintiffs have alleged the challenged actions cause serious harms to women, that does not suffice to establish *the States'* Article III standing. Florida and Texas 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 Florida and Texas enforcing their abortion laws against out-of-state prescribers of mifepristone. The States' allegations about Medicaid costs rely on the same attenuated chain of causation that the Supreme Court rejected in *Alliance for Hippocratic Medicine*.

Second, even if Plaintiffs could overcome the Article III hurdle, they failed to administratively exhaust their claims and thus cannot proceed under the Administrative Procedure Act (APA). And *third*, their challenges to FDA's actions in 2000, 2016, and 2019 are 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

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. Compl. ¶¶ 153, 199.

In 2016, FDA approved certain changes to the conditions of use (including the REMS requirements) for mifepristone (the 2016 action). ECF No. 1 (Compl.) ¶ 132. 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. *See* Compl. ¶ 14.

[2] FDA has separately approved another manufacturer's mifepristone product, Korlym, for the treatment of Cushing's syndrome. 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).

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.); Compl. ¶¶ 155-58. 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* ECF No. 1-6, Pl. Ex. 35 (2021 FDA Letter to AAPLOG, *et al*.) at 5 & 6 n.10.

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* Compl. ¶¶ 174-75; 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). Compl. ¶ 184 & n.123.

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]

On December 9, 2025, Plaintiffs filed this suit challenging (1) FDA's initial approval of mifepristone in 2000, (2) the 2016 action, (3) the 2023 REMS Modification, and (4) FDA's approval of generic equivalents in 2019 and 2025.[4]

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

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[3] The petitions include, but are not limited to, the following (all accessed January 27, 2026): https://www.regulations.gov/document/FDA-2025-P-0377-0001 (American College of Obstetricians and Gynecologists, et al.); https://www.regulations.gov/document/FDA-2025-P-1242-0001 (James D. Brinkruff, MD); https://www.regulations.gov/document/FDA-2025-P-1576-0001 (Andrew Joy Campbell, Attorney General of Massachusetts and the Attorneys General for 3 other states); https://www.regulations.gov/document/FDA-2025-P-2162-0001 (GenBioPro, Inc.); https://www.regulations.gov/document/FDA-2025-P-3287-0001 (Nick Brown, Attorney General of Washington and the Attorneys General for 18 other states); https://www.regulations.gov/document/FDA-2025-P-5434-0001 (Students for Life of America); https://www.regulations.gov/document/FDA-2025-P-5436-0001 (Students for Life of America); and https://www.regulations.gov/document/FDA-2025-P-5437-0001 (Students for Life of America).

[4] On August 25, 2025, Florida and Texas sought to intervene in *Missouri v. FDA*, which was then before the Northern District of Texas. On September 30, 2025, that court transferred the case to the Eastern District of Missouri and denied the motion to intervene as moot. *Missouri v. FDA*, 2:22-cv-223-Z, ECF No. 273, at 27 (N.D. Tex. Sept. 30, 2025).

(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. In particular, a court must balance "the harm of moving forward" against "the harm of holding back" when determining whether to grant a stay of proceedings. *Ali v. Quarterman*, 607 F.3d 1046, 1049 (5th Cir. 2010).

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).

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). The rationale for deferring judicial review is simple: the "harm of moving forward" with judicial review of FDA's actions outweighs the "harm of holding back." *Ali*, 607 F.3d at 1049.

The harms of moving forward before FDA's review is complete are manifold. Plaintiffs ask the Court to make the very sort of difficult scientific judgments that Congress entrusted to FDA while the agency is conducting its review of mifepristone. *See Sierra Club v. EPA*, 939 F.3d 649, 680 (5th Cir. 2019). Such parallel proceedings would

waste judicial resources because FDA's own review may eliminate any need for the Court's review (or substantially narrow it). Moreover, if the Court grants relief Plaintiffs seek, for example, the reimposition of the in-person dispensing requirement, 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 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 Plaintiffs is belied by their delay in filing suit. *Cf. Gonannies, Inc. v. Goupair.Com, Inc.*, 464 F. Supp. 2d 603, 609 (N.D. Tex. 2006) (observing that delay in seeking judicial relief can undermine claim of urgency). Indeed, one of the agency actions they challenge is more than a quarter-century old.

Granting a stay while an agency reviews the matter in litigation is par for the course. *Purcell* 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).[5] The case remained stayed until after the 2023 REMS Modification. *Id.*, ECF No.

[5] *Chelius* was later renamed *Purcell v. Kennedy*.

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 Complaint

If the Court does not stay this case, it should dismiss the Complaint for three reasons. First, Plaintiffs lack Article III standing. Second, they failed to administratively exhaust their claims. And third, their challenges to FDA's actions in 2000, 2016, and 2019 are time-barred.

A. Plaintiffs lack standing

The federal "judicial Power" is limited to "Cases" and "Controversies." U.S. Const. art. III. "A proper case or controversy exists only when at least one plaintiff establishes that she has standing to sue." *Murthy v. Missouri*, 603 U.S. 43, 57 (2024) (alterations and quotation marks omitted). To have standing, "a plaintiff must demonstrate (i) that she has 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, Florida and Texas "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.* 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 Plaintiffs' contention, the challenged FDA actions do not implicate the States' "sovereign power to enact and enforce regulations on abortion." Compl. ¶ 305. 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).[6] The Federal Government has not taken any position that would leave Florida or Texas 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; *see also* Compl. ¶¶ 306-09 (asserting legitimate interests in regulating abortion).

Florida and Texas do not contend FDA's actions actually preempt their laws; rather, they vaguely assert the agency's actions "threaten" to do so. *Id.* ¶¶ 328, 337-38, 349, *see also id.* ¶ 350 (alleging a "risk of preemption"). Plaintiffs suggest that the Executive Branch previously contended that the 2023 REMS Modification preempts their laws. Compl. ¶ 328. Not so. The public statements Plaintiffs identify claimed only

[6] 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). And far from suggesting that the REMS preempts state law, the Ninth Circuit expressed skepticism of the argument and ultimately declined to consider it. *Satanic Temple v. Labrador*, 149 F.4th 1047, 1053 n.6 (9th Cir. 2025) ("Though TST argues that [the REMS] allows nurse practitioners to prescribe abortifacients even if they are not licensed in the state, it is unclear whether [the] REMS would preempt Idaho state law, as TST had argued to district court but does not raise on appeal.").

that states could not ban mifepristone based on "disagreement" with FDA's "expert judgment" about "safety and efficacy." *Id.* ¶ 196. 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.

Notwithstanding the lack of preemption, Florida and Texas contend that FDA's actions "enabl[e] state-law criminal and civil violations by third parties." *Id.* ¶ 327. But as the Ninth Circuit recognized when Texas (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 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 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 state standing. Indeed, Plaintiffs' cited authorities confirm that sovereign-harm standing requires a conflict between state and federal law. *See Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015) (holding that DAPA "impos[es] substantial pressure on" States "to change their laws"); *Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015) (holding that DAPA created a "conflict between federal and state law" because it "forced" Texas to choose between incurring costs and changing its laws); *Louisiana v. EEOC*, 705 F. Supp. 3d 643, 661 (W.D. La. 2024) (finding standing "because the abortion accommodation mandate forces the *States* Plaintiffs to provide (and fund) accommodations for elective abortions that directly conflict with the States' own laws and policies"). Because no conflict exists here, Plaintiffs suffer no sovereign injury.

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

Plaintiffs also contend they have standing as Medicaid payors. Compl. ¶¶ 285-296. 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. Plaintiffs 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.

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's standing requirements are not so easily brushed aside.

The same is true of the States' contention that they have standing to challenge the 2023 REMS Modification because they are "forced to divert resources to address the explosion of abortion drugs mailed to their residents by abortionists." Compl. ¶ 299. As *Alliance* explained, a plaintiff "that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money." 602 U.S. at 394; *see also Clapper v. Amnesty Int'l*, 568 U.S. 398, 415-16 (2013) (holding that a plaintiff lacking an Article III injury cannot create that injury through expenditure of

resources). Because FDA's actions cause the States no sovereign injury, *see supra* pp. 12-14, any expenditures to avoid that alleged injury do not establish an Article III injury.

B. The States failed to administratively exhaust their claims

Alternatively, the Complaint should be dismissed under Rule 12(b)(6)[7] because 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).

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 Plaintiffs rely on evidence and arguments that were not before the

[7] *See Whitehead v. Zurich Am. Ins. Co.*, 348 F.3d 478, 481 (5th Cir. 2003) ("[A] case may be dismissed without prejudice for failure to exhaust administrative remedies under Rule 12(b)(6).").

agency during any of previous REMS reviews. *See, e.g.*, Compl. ¶ 208 (citing a 2025 study).

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 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. The States' challenges to FDA's 2000, 2016, and 2019 actions are time-barred

At the very least, Plaintiffs' challenges to the approval of mifepristone in 2000 (Count I), the 2016 action (Count II), and the approval of the first generic in April 2019 (Count IV) are barred by the six-year statute of limitations. 28 U.S.C. § 2401(a); *Alliance*, 78 F.4th at 242-45 (holding that a 2022 challenge to the 2000 approval was time-barred). 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 Plaintiffs, they suffered an injury sufficient to give them standing at the time of each challenged agency action. *See* Compl. ¶¶ 295-96 (alleging that the 2000 approval and 2016 action each caused emergency room visits leading to Medicaid costs). Assuming that's true, Plaintiffs cannot challenge any agency action before December 9, 2019. Because the 2000 approval, 2016 action, and 2019 generic approval

were all earlier than that date, the Court should dismiss as time-barred Counts I and II, as well as the portion of Count IV that targets the 2019 generic approval.

CONCLUSION

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

March 13, 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