UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION

FILED
April 10, 2026
KAREN MITCHELL
CLERK, U.S. DISTRICT COURT

STATE OF FLORIDA and STATE OF TEXAS,
Plaintiffs,

v.

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

Case No. 7:25-cv-00126-O

PROPOSED INTERVENOR-DEFENDANT GENBIOPRO, INC.'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS

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INTRODUCTION

For years, the Food and Drug Administration (FDA) has recognized that mifepristone is safe and effective. FDA's regulatory actions regarding mifepristone have been grounded in a substantial body of scientific evidence and expert analysis accumulated over decades. Congress entrusted FDA—not the courts—with responsibility for evaluating that evidence and using it to make scientific judgments about safety and access. Yet Texas and Florida now ask this Court to displace FDA's expert scientific judgment and to invalidate the entire array of FDA's regulatory actions relating to mifepristone, over the last two-and-a-half decades, ranging from its initial 2000 approval of the drug to the drug's governing Risk Evaluation and Mitigation Strategy, known as the "REMS."

This Court should reject that effort at the threshold. The Supreme Court has already held that federal courts are not the proper forum for generalized objections to FDA's alleged under-regulation of a drug—particularly where the asserted injuries depend on attenuated chains of events involving the choices of independent third parties. *FDA v. All. for Hippocratic Medicine*, 602 U.S. 367, 380-83 (2024) (*Alliance*). That unanimous holding forecloses Plaintiffs' similar effort here. FDA's regulatory decisions impose no obligations on Texas or Florida—just as they imposed none on the doctors who challenged these same FDA actions in *Alliance*. Nor do those decisions prevent the States from enforcing their own laws. Plaintiffs' theories instead depend on attenuated theories about how potential choices by third parties might indirectly affect state expenditures or enforcement efforts. If those downstream effects were sufficient to establish standing, there would be no meaningful limit on states' ability to challenge federal policy.

The Complaint suffers from additional threshold defects as well. Texas is precluded from relitigating theories of standing that it has already advanced—and lost—in prior litigation challenging FDA's regulation of mifepristone. And with Texas unable to establish standing, this

case does not belong in this venue even if Florida could establish standing (which it cannot). Florida asserts no basis, and would have no basis, for suing in the Northern District of Texas.

Both States, moreover, seek to bypass mandatory administrative procedures that permit FDA to assess scientific questions and regulatory policy in the first instance. FDA regulations require parties to present such challenges to the agency in the first instance through the citizen-petition process, allowing the agency to bring its expertise to bear on the issues and to evaluate the relevant evidence. Plaintiffs never did so here, even as FDA continues actively to review the mifepristone REMS and consider multiple pending petitions addressing the drug's regulation. And much of the Complaint is untimely: Plaintiffs attempt to challenge agency actions taken in 2000, 2016, and 2019—years or decades before this suit was filed and well outside the six-year statute of limitations governing suits against the federal government.

GenBioPro, Inc. holds an FDA-approved abbreviated new drug application authorizing it to market generic mifepristone—a product that is foundational to its business and an important component of healthcare nationwide. GenBioPro intervened in this action to protect those interests and now asks the Court to dismiss the Complaint.[1]

[1] Because this Court lacks Article III jurisdiction over this case and the States' claims are unexhausted, unripe, and untimely, the proper remedy is dismissal. But to the extent the Court declines to dismiss the case at this time, GenBioPro would not oppose the FDA's request for a stay of these proceedings pending its ongoing review.

BACKGROUND

I. Factual and Regulatory Background

A. FDA's Science-Based Regulation of Mifepristone for 25 Years

2000 Approval and Initial REMS. In 2000, FDA approved mifepristone under the brand name Mifeprex as a safe and effective medication for terminating early pregnancies up to 49 days' of pregnancy. *See* 21 U.S.C. § 355; *Alliance*, 602 U.S. at 375. That approval was accompanied by certain conditions to assure safe use—which, by virtue of the Food and Drug Administration Amendments Act of 2007 (FDAAA), became part of mifepristone's "risk evaluation and mitigation strategy" (or "REMS").

Specifically, in the FDAAA, Congress charged FDA with determining whether a REMS is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). Congress further directed that each REMS must be designed in a manner that "assur[es] access and minimiz[es] burden" on "the health care delivery system." *Id.* § 355-1(f)(2)(D). Drugs "approved before the effective date of [the] Act," like mifepristone, were "deemed to have in effect an approved risk evaluation and mitigation strategy" if they were subject to existing "elements to assure safe use" under certain FDA regulations. Pub. L. No. 110-85, § 909(b)(1), 121 Stat. 951 (2007); *see* 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008). The "elements" for mifepristone at the time included, among other things, requirements that the drug be dispensed in person, under the supervision of a physician with certain qualifications, and that the patient return in person for two follow-up appointments. Compl. ¶ 12; Ex. 18. Mifepristone was initially indicated for pregnancies up to 49 days' gestation. *Id.*

2016 Changes. In 2016, FDA approved several changes to mifepristone's REMS and product label based on a review of more than a decade of safety data and peer-reviewed studies. ECF No. 1-4 at 14-35. The revisions allowed licensed non-physician healthcare providers to

become certified prescribers, and changed the labeling to extend the approved gestational age from 49 to 70 days, and to eliminate two previously required in-person follow-up visits, among other changes. *Id.* at 11, 14; Compl. ¶ 132.

2019 ANDA Approval. In 2019, FDA approved GenBioPro's abbreviated new drug application ("ANDA") to market a generic version of mifepristone. In doing so, FDA determined that generic mifepristone is "bioequivalent" to the reference drug Mifeprex and is therefore safe and effective. 21 U.S.C. § 355(j). The generic product is subject to a single, shared REMS with Mifeprex, sold by Danco Laboratories, LLC. Compl. ¶ 153.

2021 Non-Enforcement Decision. Early in the COVID-19 pandemic, FDA suspended the in-person dispensing requirements for most drugs, but maintained it for mifepristone. *See Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 191-97 (D. Md. 2020). In July 2020, a court required FDA to temporarily suspend the in-person dispensing requirement in response to a lawsuit filed by mifepristone providers, allowing the drug to be mailed to patients. *Id.* at 233. That suspension was in effect for six months, from July 2020 until January 2021, when the Supreme Court stayed the injunction. *See FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).

Based in part on the information gained from the non-enforcement period, in April 2021, FDA exercised its discretion to suspend enforcement of the in-person dispensing requirement during the COVID-19 pandemic. Compl. ¶ 165. FDA also initiated a full review of the mifepristone REMS program. ECF No. 1-3 at 128. After this robust review, FDA in December 2021 announced its determination that the in-person dispensing requirement was not necessary to assure mifepristone's safe use. *Id*. at 165. FDA explained that its decision was based on "a thorough scientific review by [agency] experts," who evaluated data from FDA's assessment

report for the mifepristone REMS, postmarketing safety information, and published scientific studies evaluating different methods for dispensing mifepristone. ECF No. 1-6 at 715.

2023 REMS Modification. In January 2023, FDA issued a new REMS that formally removed the in-person dispensing requirement for mifepristone, confirming that mifepristone, like most drugs, can be used safely when dispensed by mail or at pharmacies. ECF No. 1-3 at 104-06. The 2023 REMS changed some requirements for prescribers, *id.*, and also added a pharmacy certification requirement to, among other things, "ensure[] that pharmacies are aware of and agree to follow applicable REMS requirements." *Id.* at 98. Particularly with those additional certification requirements, FDA determined that the REMS will "continue to ensure that the benefits of mifepristone for medical abortion outweigh the risks." *Id.*

2025 Evita Approval. In September 2025, FDA approved an abbreviated new drug application submitted by Evita Solutions, LLC to market and manufacture generic mifepristone. Compl. ¶¶ 198-99.

B. Plaintiff States' Laws

More than a year after FDA suspended enforcement of the in-person dispensing requirement, the Supreme Court held in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), that there is no federal constitutional right to abortion. *Dobbs* allowed Texas laws that generally prohibit abortions to take effect. *See* Texas Rev. Civ. Stat. Art. 4512.1–4512.6; Tex. Health & Safety Code § 170A. After *Dobbs*, Florida statutes went into effect that prohibit abortions in many cases—but permit them up to a gestational age of six weeks. *See* Fla. Stat. § 390.0111(1). Both Texas's and Florida's abortion laws include additional exceptions, including to save the life of the patient. Compl. ¶¶ 318, 322-23. Both states exclude miscarriage care from the definition of abortion. *See* Tex. Health & Safety Code § 245.002(1)(B); Fla. Stat. § 390.011(1). Mifepristone

thus may be used lawfully for abortions that Texas and Florida laws permit and for non-abortion purposes, including miscarriage management.

C. Ongoing FDA Consideration of Mifepristone

The FDAAA directs FDA to periodically reassess its REMS. *See* 21 U.S.C. § 355-1(d), (g). FDA by regulation has also established a process whereby any interested person can request that the agency "take or refrain from taking any other form of administrative action," 21 C.F.R. § 10.25(a), including actions related to a REMS. The filing of such a "citizen petition" is a prerequisite to judicial review of FDA action. *Id.* § 10.45(b).

FDA is currently evaluating the mifepristone REMS. It has eight mifepristone-related citizen petitions pending before it, including one from GenBioPro that includes comprehensive and up-to-date data demonstrating the safety of mifepristone. *See, e.g.*, GenBioPro, Citizen Petition, FDA-2025-P-2162 (July 7, 2025), https://tinyurl.com/mr3vaj4e. The FDA Commissioner in September also announced that the agency will be conducting further safety studies of the 2023 REMS to "determine whether modifications are necessary." ECF No. 20-1 at 7-8. FDA has recently confirmed its ongoing evaluation in responding to similar litigation challenging FDA's actions, stating that it is undertaking "a new review based on the evidence before the agency," including "FDA's own study." *Id.* at 3. "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.*

II. Procedural History

In November 2022, several doctors and associations challenged virtually every FDA action taken regarding mifepristone, including FDA's initial 2000 approval of the drug, its 2016 changes to the REMS and label, its 2019 approval of GenBioPro's generic mifepristone, and its 2021 non-enforcement of the in-person dispensing requirement. *All. for Hippocratic Med. v. FDA*, 668 F.

Supp. 3d 507, 522-23 (N.D. Tex. 2023). Although the district court granted the requested relief and the Fifth Circuit largely affirmed, those orders were stayed pending appellate review and never took effect. *Danco Lab'ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023) (stay order). Ultimately, the Supreme Court unanimously held that the plaintiffs lacked Article III standing. *Alliance*, 602 U.S. at 374. On remand, Texas and Florida unsuccessfully sought to intervene; the district court held that venue was improper and transferred the case to the Eastern District of Missouri. *Missouri v. FDA*, 2025 WL 2825980, at *12-13 (N.D. Tex. Sept. 30, 2025).

Plaintiffs then filed the Complaint in this case on December 9, 2025. ECF No. 1. FDA filed an unopposed motion for an extension of time to respond to the Complaint on January 30, 2026. ECF No. 18. This Court granted FDA's motion on February 2, 2026, permitting FDA until March 13, 2026, to file their response to the Complaint. ECF No. 19.

LEGAL STANDARD

Under Rule 12(b)(1), dismissal is required if the court lacks subject matter jurisdiction over the action. *Reule v. Jackson*, 114 F.4th 360, 365 (5th Cir. 2024). Plaintiffs have the burden of demonstrating that the court has subject matter jurisdiction, including that the Plaintiffs have standing. *Id*. at 365-67. Under Rule 12(b)(3), once a party moves to dismiss based on improper venue, the plaintiff must "come forward with evidence showing venue is proper." *Perez v. Pan Am. Life Ins. Co.*, 70 F.3d 1268 (5th Cir. 1995) (per curiam). Under Rule 12(b)(6), "where it is evident from the plaintiff's pleadings that the action is [time] barred" dismissal of that claim is proper. *Jones v. Alcoa, Inc.*, 339 F.3d 359, 366 (5th Cir. 2003). The Court must also dismiss any claim which fails to state a claim as a matter of law. *Boudreaux v. Louisiana State Bar Ass'n*, 3 F.4th 748, 753 (5th Cir. 2021).

ARGUMENT

The Complaint fails for multiple independent reasons: Plaintiffs lack standing; their claims are unexhausted and unripe; and their challenges to earlier FDA actions are barred by the statute of limitations.

I. Plaintiffs Lack Article III Standing

Plaintiffs lack Article III standing, which deprives this Court of subject matter jurisdiction. Plaintiffs have not alleged a cognizable injury-in-fact traceable to any of FDA's challenged actions and redressable through the relief sought. Those deficiencies require dismissal of the case. Article III standing is an "essential" and "core component" of the Court's subject matter jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). "Without jurisdiction the court cannot proceed at all in any cause," and "the only function remaining to the court is that of announcing the fact and dismissing the cause." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) (quoting *Ex parte McCardle*, 7 Wall. 506, 514 (1868)); *see also Alliance*, 602 U.S. at 396-97 (directing dismissal of challenge to mifepristone regulations for lack of standing).

A. Texas Is Precluded From Relitigating Theories Of Standing It Has Argued And Lost In Prior Litigation Against FDA

As a threshold matter, Texas is precluded from relitigating its standing to challenge FDA's regulation of mifepristone based on alleged increases in Medicaid spending, purported interference with the State's enforcement of its laws, or asserted harms to women and fetal life. And because Texas lacks standing, there is no basis for venue in this district. *See, e.g.*, *Associated Gen. Contractors of Am., Inc. v. Fed. Acquisition Regul. Council*, 720 F. Supp. 3d 461, 472 (W.D. La. 2024) (when some plaintiffs are "dismissed from the lawsuit for lack of standing, the Court must determine whether venue is proper in this district in their absence").

The doctrine of issue preclusion prohibits "relitigation by a party to a previous action of issues that were actually litigated and decided in that previous action." *Hogue v. Royse City*, 939 F.2d 1249, 1252 n.2 (5th Cir. 1991); *see also, e.g.*, *Robin Singh Educ. Sers. Inc. v. Excel Test Prep Inc.*, 274 F. App'x 399, 404-05 (5th Cir. 2008). The doctrine applies with equal force to jurisdictional holdings: A party may not relitigate "the same jurisdictional issue decided [against it] in a prior case." *Bank of La. v. FDIC*, 33 F.4th 836, 838 (5th Cir. 2022) (emphasis omitted).

That doctrine forecloses Texas from establishing standing here. In *Washington v. FDA*, Texas sought to intervene to defend certain of FDA's restrictions on mifepristone. 108 F.4th 1163, 1174 & n.3 (9th Cir. 2024). In doing so, Texas advanced—and the Ninth Circuit rejected—the same theories of standing the States assert in this case. Specifically, as here, Texas claimed standing to challenge FDA's elimination of the in-person dispensing requirement because the agency's elimination of that requirement would cause Texas "economic injury in the form of increased costs to the state's Medicaid system." *Compare id.* at 1174, *with* Compl. ¶¶ 283-298 (alleging that Texas's "Medicaid reimbursements" for emergency treatment relating to "chemical abortion complications" has "diverted resources from [Texas's] general budget[]"). The Ninth Circuit disagreed, holding that the "causal chain between FDA's regulation of mifepristone" and Texas's theory of economic injury was "too attenuated to establish" standing, and, moreover, that Texas's "alleged uptick in Medicaid costs is exactly the kind of 'indirect effect on state spending' that the Supreme Court has rejected as a basis for standing" in prior cases. *Washington*, 108 F.4th at 1175-76 (quoting *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023)).

The Ninth Circuit similarly rejected Texas's theory—also asserted here—that it had standing because FDA's relaxed regulation of mifepristone interfered with the State's "sovereign interest" in "enact[ing]" and "enforc[ing]" its "own laws regulating chemical abortion." *Compare*

Washington, 108 F.4th at 1176 ("[Texas] alleges an injury to its sovereign interest in enforcing state abortion laws, which make mifepristone illegal to use under most circumstances."), *with* Compl. ¶¶ 305-09, 321-33 (alleging interference with Texas's "sovereign power to enact and enforce regulations on abortion"). And the Ninth Circuit rejected Texas's third theory of standing—its "'quasi-sovereign interest' in maternal health and fetal life"—recognizing that this was just a "thinly veiled attempt to circumvent the limits on *parens patriae* standing." *Compare Washington*, 108 F.4th at 1177-78 (quoting *Murthy v. Missouri*, 603 U.S. 43, 76 (2024)), *with* Compl. ¶¶ 21, 205-82 (alleging that "[a]bortion drugs harm women and girls" and claiming standing to "protect [its] residents"). Because each of Texas's asserted theories of standing was previously litigated and decided against it in *Washington*, the State's attempt to relitigate those exact same issues here must fail.

Without Texas as a proper plaintiff in this action, only Florida remains—meaning that venue is unavailable in this district. *See Associated Gen. Contractors*, 720 F. Supp. 3d at 472; *see Missouri*, 2025 WL 2825980, at *11 (Missouri, Idaho, and Kansas could not establish venue in this district for a similar challenge to FDA's mifepristone-related actions). Plaintiffs' Complaint acknowledges this: their sole asserted basis for venue is that "the State of Texas resides in this judicial district." Compl. ¶ 29. Collateral estoppel is thus reason enough to dismiss this case.

B. Plaintiffs Lack a Cognizable Sovereign Injury Traceable to Any Challenged FDA Action

Texas and Florida cannot establish Article III standing in any event. They assert standing based on a theory of sovereign injury, arguing that the challenged actions "interfere with Plaintiffs' 'sovereign interests in "the power to create and enforce a legal code"' by enabling state-law criminal and civil violations by third parties." Compl. ¶ 327 (quoting *Texas Office of Public Utility*

Counsel v. FCC, 183 F.3d 393, 449 (5th Cir. 1999)). But this "sovereign injury" theory is foreclosed on multiple grounds.

First, precedent forecloses states from using their generalized interests in law enforcement as a means to challenge federal policy. In *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023), the Supreme Court held that Louisiana's and Texas's alleged "sovereign" and economic injuries did not give them standing to challenge a federal policy that they claimed violated federal law. The Court reaffirmed that the underenforcement of federal law does not support a sovereign-harm theory of standing, declining to "start the Federal Judiciary down th[e] uncharted path" of adjudicating "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. And as discussed above, *see supra* pp. 9-10, the Ninth Circuit—applying *United States v. Texas*—rejected a sovereign injury theory materially identical to the one Plaintiffs assert here regarding the mifepristone REMS, holding that "[courts] have never held that a logistical burden on law enforcement constitutes a cognizable Article III injury." *Washington*, 108 F.4th at 1177.

Plaintiffs invoke *Louisiana v. EEOC*, 784 F. Supp. 3d 886 (W.D. La. 2025), as supporting their theory of sovereign injury. Compl. ¶ 327. But in that case, the Court found that the federal action "force[d]" state action "that directly conflict[ed] with the States' own laws and policies" in the State's capacity as an employer. *Louisiana*, 784 F. Supp. 3d at 901. Here, in contrast, the challenged FDA actions do not require Plaintiffs "to do or refrain from doing anything." *Alliance*, 602 U.S. at 374. And as noted, both States permit the use of mifepristone in some circumstances—especially Florida, which permits abortion up to six weeks' gestation. Fla. Stat. § 390.0111(1); *see also supra* p. 5 (describing other exceptions). Given these state-law exceptions, Plaintiffs lack cognizable sovereign interests in banning use of mifepristone within their borders.

Second, even if Plaintiffs had cognizable sovereign injuries, they could not draw the requisite causal link between FDA's actions and those injuries. While Plaintiffs assert that FDA's actions make mifepristone easier to access in their States, both of their laws *permit* using mifepristone in a variety of situations—including, in Florida, up to six weeks without caveats—meaning that any "sovereign injury" depends on independent individuals making "unfettered choices" to violate state law. *Alliance*, 602 U.S. at 383 (citation omitted). For the same reasons, Plaintiffs cannot establish redressability: Even if the challenged FDA actions were vacated, nothing would prevent third parties from continuing to prescribe, distribute, or obtain mifepristone in other jurisdictions or through other lawful channels. And though Plaintiffs challenge the 2000 NDA approval (thereby seeking to remove mifepristone from the market altogether), that particular claim is plainly untimely and thus cannot serve as the basis for Article III jurisdiction. *See infra* pp. 20.

Third, Plaintiffs' related contention that the "purpose" of the 2023 REMS and other challenged actions was to "undermine state abortion laws," *see* Compl. ¶ 89, 328, 352-53, is pure fiction. Of course, none of the challenged FDA actions before *Dobbs*—the 2000 approval, 2016 changes, and 2019 approval—could possibly have been designed to undermine Texas' or Florida's abortion laws. *Contra* Compl. ¶¶ 89, 328. During the nearly two decades during which these actions occurred, abortion was legal in every state under *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 874 (1992), including in Texas and Florida. So too for the removal of the in-person dispensing requirement, which was first effected by court injunction in 2020 (two years before *Dobbs*) and then by FDA in 2021 (more than a year before *Dobbs*). *See supra* pp. 3-5. As FDA's website says expressly, the "Mifepristone REMS Program" was *not* "modified in 2023 in response to" *Dobbs* or any state abortion law. FDA,

Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, Question Nos. 33, 34 (Feb. 2, 2026), https://tinyurl.com/38m6ea9f; *see* ECF No. 1-3 at 129 (FDA's REMS evaluation was initiated "[i]n connection with *Chelius v. Becerra*, [No. 17-cv-00493, (D. Haw.)]"). Since abortion remained legal nationwide in 2021, FDA could not possibly have been motivated by a desire to undermine state abortion laws.

To argue otherwise, Plaintiffs rely on assorted statements by various public officials supporting the goal of ensuring lawful abortion access. None of the statements comes from an FDA official actually responsible for making REMS determinations or approving drug applications. *See* Compl. ¶¶ 8-9, 13, 16, 84, 88-90, 160-163, 177-82. Judicial review of agency action is based on the administrative record generated by the actual decision-makers, not "extrinsic statements" by other Executive Branch actors—particularly statements postdating the relevant decisions. *Trump v. Hawaii*, 585 U.S. 667, 702-04 (2018); *see also, e.g.*, *FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 576-77 (2025) (rejecting allegations of "surreptitious[]" agency action). In any event, none of these statements actually signals an intent to override state law. Plaintiffs' selective quotations are extremely misleading, omitting significant language that undermines their narrative.

For example, quoting a few words from the White House announcement of a 2023 presidential memorandum on reproductive healthcare—which *postdated* the key FDA actions challenged here, including the 2023 REMS—Plaintiffs assert that "President Biden specifically directed HHS Secretary Xavier Becerra to ensure women have 'access' to abortion drugs 'no matter where they live.'" Compl. ¶ 178 (quoting *White House,* Fact Sheet: President Biden to Sign Presidential Memorandum on Ensuring Safe Access to Medication Abortion (Jan. 22, 2023), https://perma.cc/S6R9-AT7W). But far from a binding directive to "ensure [that] women have

'access,'" as Plaintiffs suggest, the Presidential Memorandum merely directed HHS to "*consider* new *guidance*" on mifepristone. Fact Sheet, *supra* (emphasis added). And far from promoting access in instances where it would contravene state law, as Plaintiffs suggest, the guidance the President was calling for would "support patients, providers, and pharmacies who wish to *legally* access, prescribe, or provide mifepristone—no matter where they live." *Id.* (emphasis added); *see* Presidential Mem., *Further Efforts to Protect Access to Reproductive Healthcare Services*, 88 Fed. Reg. 4895, 4896 (Jan. 22, 2023) (directing HHS to "consider … issuing guidance for patients seeking *legal access to mifepristone*, as well as for providers and entities, including pharmacies, that provide reproductive healthcare and seek to *legally prescribe and provide mifepristone* (emphasis added)). Plaintiffs tellingly identify no ensuing HHS "guidance," let alone one imposing the sort of universal mifepristone-"access" mandate they suggest.[2]

Finally, Plaintiffs assert a "quasi-sovereign" theory based on the notion that the challenged actions interfere with the States' rights to regulate and protect their own citizens. Compl. ¶¶ 30, 32, 205-282. This "quasi-sovereign" theory is equally without merit: "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) (quoting *Haaland v. Brackeen*, 599 U.S. 255, 295 (2023)); *see Washington*, 108 F.4th at 1178 (rejecting "thinly veiled attempt to circumvent the limits on *parens patriae* standing" based on similar allegations). Plaintiffs also fail to allege traceability or that the challenged actions affect a "substantial segment" of Texas's and Florida's populations. *See Alfred*

[2] Indeed, it appears that the only relevant guidance issued in the wake of this memorandum was a "remind[er]" to retail pharmacies that, "as recipients of federal financial assistance, [they] are prohibited under law from discriminating on the basis of race, color, national origin, sex, age, and disability in their programs and activities." *Fact Sheet: Biden-Harris Administration Highlights Commitment to Defending Reproductive Rights and Actions to Protect Access to Reproductive Health Care One Year After Overturning of Roe v. Wade* (June 23, 2023),https://tinyurl.com/4e85m8xm.

L. Snapp & Son, Inc. v. Puerto Rico, 458 U.S. 592, 607 (1982). And this theory, just like Plaintiffs' others, was also considered and rejected by the Ninth Circuit in *Washington v. FDA*, *see supra* p. 10.

C. Plaintiffs Lack a Cognizable Economic Injury Traceable to Any Challenged FDA Action

Plaintiffs' theory that FDA's challenged actions "have inflicted concrete economic injury on [Plaintiffs] as the payers and insurers of residents' medical expenses" and the 2021 non-enforcement decision and 2023 REMS modification have caused Plaintiffs "to divert resources to address the explosion of abortion drugs mailed to their residents," Compl. ¶¶ 283, 302, is equally flawed. The Court in *United States v. Texas* rejected the notion that a federal policy's "indirect effects" on "state spending" establishes standing. 599 U.S. at 680 n.3. As the Court explained, "in our system of dual federal and state sovereignty, federal policies frequently generate indirect effects on state revenues or state spending." *Id.* But those "indirect effects" were not adequate to demonstrate standing in *United States v. Texas*, *id.*, and any indirect effect of the challenged actions on Plaintiffs' law enforcement or Medicaid spending is even "far[ther] removed from" the "distant … ripple effects" that the Court found too attenuated in *Alliance*, 602 U.S. at 383.

Indeed, the Ninth Circuit specifically rejected Texas's standing theory based on "downstream medical costs … borne by the state" that purportedly result from the "elimination of the in-person dispensing requirement." *Washington*, 108 F.4th at 1175-76. Allowing such allegations to establish standing "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." *Id.* at 1177.

Plaintiffs also assert that they suffer economic injury from the "expense of investigating, prosecuting, and enforcing" alleged violations of state abortion laws, including costs associated

with investigating out-of-state prescribers and responding to the mailing of abortion drugs. Compl. ¶¶ 299–304. That theory fails for the same reasons as Plaintiffs' Medicaid-cost theory. The investigative and enforcement costs Plaintiffs identify arise only if "independent actors" choose to prescribe, distribute, or use mifepristone in ways that allegedly violate state law—conduct that is neither required nor authorized by FDA's actions. *Alliance*, 602 U.S. at 383. And even if these actions were not independent, recognizing standing on this theory would permit states to challenge any federal policy that even arguably prompts violations of state law or increases the costs of enforcing it. Article III is not so limitless. *See United States v. Texas*, 599 U.S. at 680 n.3; *Alliance*, 602 U.S. at 383, 390-93.

D. Plaintiffs Fall Outside the FDCA's Zone of Interests

Finally, even if Plaintiffs had standing, their claims fail because they do not "fall[] within the 'zone of interests' sought to be protected by the statutory provision whose violation forms the legal basis for [their] complaint." *Louisiana v. United States*, 948 F.3d 317, 321 (5th Cir. 2020) (quotation marks omitted). The FDCA is designed to protect patients by ensuring that drugs are safe and effective—not to protect state interests in regulating abortion or limiting Medicaid expenditures. Because Plaintiffs seek to use the FDCA to vindicate interests unrelated to the statute's purposes, their claims cannot proceed.

II. Plaintiffs' Challenges Are Unexhausted and Not Ripe for Judicial Review

When an "agency rule" requires a party to pursue remedies within the agency as a "prerequisite to judicial review," the party's failure to exhaust those remedies generally requires dismissal. *Darby v. Cisneros*, 509 U.S. 137, 153 (1993). This requirement ensures that agencies have an opportunity to bring their expertise to bear on issues before courts intervene, and prevents the circumvention of agency procedures for resolution of those issues. *Gulf Restoration Network v. Salazar*, 683 F.3d 158, 175 (5th Cir. 2012).

Exhaustion is particularly critical in the context of FDA's regulatory decisions, which, as courts recognize, depend on the agency's "background, competence, and expertise to assess public health." *S. Bay United Pentecostal Church v. Newsom*, 590 U.S. 965, 967 (2020) (Roberts, C.J. concurring). FDA's evaluation of safety and efficacy draws from an array of complex medical evidence—including expert interpretation of clinical-trial data, adverse event reports, and real-world postmarketing studies. And the FDAAA's direction that FDA account for the need to "assur[e] access and minimiz[e] burden" on "the health care delivery system," 21 U.S.C. § 355-1(f)(2)(d), further underscores the delicate balancing that informs FDA's REMS decisions.

FDA's exhaustion requirements preclude judicial review here. Under FDA's regulations, a party typically must file a citizen petition with FDA "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) (citizen petition procedures). FDA regulations also include "an explicit issue-exhaustion requirement," giving the agency "primary jurisdiction to make the initial determination on issues within its statutory mandate." *Indep. Turtle Farmers of La., Inc., v. United States*, 703 F. Supp. 2d 604, 616 (W.D. La. 2010) (quoting 21 C.F.R. § 10.25(b)). Courts have applied these provisions strictly, requiring the filing of a citizen petition and FDA's resolution of that petition as a precondition to judicial review. *See, e.g.*, *Ass'n of Am. Physicians v. FDA*, 358 F. App'x 179, 180-81 (D.C. Cir. 2009) (affirming dismissal where plaintiffs failed to file a "citizen petition with FDA contesting the SNDA approval of Plan B and [ ] proffered no legally viable excuse for this failure"); *Cody Lab'ys., Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011) ("Courts have often dismissed suits against the FDA for failure to utilize the citizen petition procedure."); *Indep. Turtle Farmers,* 703 F. Supp. 2d at 616 (noting the "science has progressed since" FDA's action, but declining to

consider unexhausted issues because "without presentation of arguments to FDA on these issues, [the court is] foreclosed from evaluating them in any substantive capacity").

Under these exhaustion rules, this case cannot proceed. Plaintiffs never filed a citizen petition raising any of the challenged actions, and so FDA could not have reached a "final administrative decision based on" that petition, as FDA's regulations require. 21 C.F.R. § 10.45(b). Indeed, Plaintiffs rely heavily on evidence *postdating* those FDA decisions, *see, e.g.*, Compl. ¶¶ 89, 194 n.136—evidence the agency *could not* have considered it in making those decisions. *See Sierra Club v. FERC*, 827 F.3d 59, 69-70 (D.C. Cir. 2016) (no exhaustion where agency "did not have the opportunity to consider [new objection] in the first instance"). Meanwhile, other parties (including GenBioPro) have played by the rules, submitting a host of petitions seeking a variety of actions from FDA related to mifepristone. *See, e.g.*, GenBioPro, Citizen Petition, FDA-2025-P-2162 (July 7, 2025), https://tinyurl.com/mr3vaj4e. Those petitions allow FDA to do its job of collecting data, assessing stakeholders' interests, and evaluating scientific literature. *See Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997).

While courts have recognized exceptions to the exhaustion requirement if the agency is "powerless to grant the relief requested." *Carr v. Saul*, 593 U.S. 83, 93 (2021), or the agency's decision would "certain[ly]" be adverse, *Tesoro Ref. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009), neither exception applies here. To the contrary, FDA is undertaking a review of mifepristone, and current HHS and FDA leadership have signaled the potential for changes in the drug's status and REMS. *See* Defs.' Mem. Supp. Mot. to Stay at 3, *Louisiana v. FDA*, No. 6:25-cv-1491-DCJ-DJA (Jan. 27, 2026), ECF No. 50-1. For similar reasons, the States' claims challenging the REMS that the agency is currently reconsidering are not ripe; those claims "rest[ ] upon 'contingent future events that may not occur as anticipated, or indeed may not occur at all.'"

Texas v. United States, 523 U.S. 296, 300 (1998); *see Miss. State Democratic Party v. Barbour*, 529 F.3d 538, 547 (5th Cir. 2008) (claims unripe when "[f]urther factual development" would "enhance th[e] case's fitness for judicial review").

III. The Statute of Limitations Bars The States' Challenges to FDA's 2000 and 2019 Approvals and 2016 Changes

The States' claims challenging the 2000 approval, the 2016 changes, and the 2019 ANDA approval must be dismissed because they are time barred. The applicable statute of limitations for suits against the federal government requires a plaintiff to file a complaint "within six years after the right of action first accrue[d]," 28 U.S.C. § 2401(a), *i.e.*, when the "plaintiff is injured by final agency action" and "has a complete and present cause of action," *Corner Post, Inc. v. Board of Governors of Fed. Reserve Sys.*, 603 U.S. 799, 820, 825 (2024). That analysis bars Plaintiffs' challenges here. Specifically, the States' causes of action accrued to challenge FDA's 2000 approval, 2016 changes, and 2019 approval—and the statute of limitations began running—when the challenged action occurred, on September 28, 2000; March 29, 2016; and April 11, 2019, respectively. Therefore, for these claims to be timely, Plaintiffs must have filed complaints challenging these actions by September 28, 2006; March 29, 2022; and April 11, 2025, respectively. Yet Plaintiffs did not file their Complaint challenging each of these actions until December 9, 2025. These claims are time-barred and must be dismissed under Rule 12(b)(6). *Jones*, 339 F.3d at 366.

CONCLUSION

The Court should dismiss the Complaint under Rules 12(b)(1), 12(b)(3), and 12(b)(6).

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Respectfully submitted,

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**Application for admission to the bar of the District Court for the Northern District of Texas pending