UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, *v.* U.S. FOOD AND DRUG ADMINISTRATION, *et al*., *Defendants*.	Civil Action No. 6:25-cv-01491 Judge: David C. Joseph Mag. Judge: David J. Ayo

PROPOSED INTERVENOR-DEFENDANT GENBIOPRO, INC.'S CONDITIONAL MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY RELIEF

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Other Authorities

INTRODUCTION

The Court should deny the extraordinary relief Plaintiffs seek. The U.S. Food and Drug Administration's ("FDA") decision that mifepristone can be safely dispensed without an in-person clinic visit goes back nearly five years and is grounded in a robust body of scientific evidence. Plaintiffs' request that this Court displace FDA's congressionally assigned role in favor of their own misplaced views of the science defies fundamental precepts of administrative law. It would also have profound nationwide effects sweeping far beyond the purely state-specific interests Louisiana purports to assert. Yet Plaintiffs delayed for years and never brought their request or arguments to FDA itself, and they now seek to press forward despite the fact that FDA is currently conducting its own review and considering similar requests by others.

Plaintiffs' request for relief fails for a host of reasons. For Article III standing, Plaintiffs rely on attenuated theories of sovereign injury and indirect economic injury that falter under directly-on-point Supreme Court precedent. *See FDA v. All. for Hippocratic Med.* ("*AHM*"), 602 U.S. 397 (2024); *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023). Plaintiffs' failure to exhaust administrative remedies independently bars relief and renders their claims unripe.

Nor can Plaintiffs establish any likelihood of success on the merits. The 2023 Risk Evaluation and Mitigation Strategy (or "REMS") (Ex. A) for mifepristone is based on FDA's rigorous, data-based evaluation of the requirements appropriate to promote safe use of the product while fulfilling Congress's direction to appropriately "assur[e] access and minimize[e] [the] burden" on "the health care delivery system." 21 U.S.C. § 355-1(f)(2), (f)(2)(D). After analyzing voluminous data from no fewer than 15 studies evaluating the safety of mifepristone when distributed through pharmacies and by mail, FDA concluded that mifepristone may be safely used without an in-person dispensing requirement. *See, e.g.*, ECF 1-50 at 82-83. Plaintiffs' contention that FDA acted unlawfully in reaching its reasonable, data-backed conclusion fails on its face.

Plaintiffs' suggestion that a 2016 change in FDA's protocol for adverse event reporting by prescribers somehow undermined the integrity of FDA's 2023 findings is also baseless. FDA continues to collect and review adverse event reports relating to mifepristone through multiple

channels, including voluntary physician reports and regular mandatory reporting from manufacturers, just like it does for virtually all other prescription drugs (including many drugs subject to REMS). Plaintiffs' assertion that handling adverse event reporting for mifepristone the same way as it does for other prescription drugs somehow reduced the quality of FDA's adverse event data and hamstrung FDA's later decision-making is meritless.

Nothing in the REMS violates the Comstock Act: FDA neither ships mifepristone itself, nor requires or authorizes anyone else to ship mifepristone in any circumstance that would violate the Comstock Act or any other statute.

Plaintiffs' hyperbolic claims that the REMS was somehow designed to undermine Louisiana's or other states' ability to enforce abortion laws in the wake of *Dobbs* are divorced from reality. It is undisputed that the in-person dispensing requirement was first suspended in 2020, then suspended again by FDA following a review in 2021—all prior to the 2022 *Dobbs* decision. The 2023 REMS simply carried forward that pre-*Dobbs*, evidence-based determination.

In sum, the Court should deny Plaintiffs' baseless request for extraordinary relief that would upend the nearly five-year regulatory status quo.

BACKGROUND

I. Factual and Regulatory Background

A. FDA's Risk Evaluation and Mitigation Strategy (REMS) Program

This case involves FDA's amendment to the conditions for dispensing mifepristone under a "Risk Evaluation and Mitigation Strategy," or REMS. In the Food and Drug Administration Amendments Act of 2007 (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"; if so, FDA must review and approve a plan and conditions to help minimize risks. 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 minimize[s] burden" on "the health care delivery system." *Id.* § 355-1(f)(2), (f)(2)(D). When evaluating whether to impose a REMS on an approved drug, FDA must consider "new safety information," which the statute defines as "information derived from a clinical trial, an adverse

event report, a postapproval study ... , or peer-reviewed biomedical literature; data derived from the postmarket risk identification and analysis system ... ; or other scientific data deemed appropriate by the Secretary." 21 U.S.C. § 355-1(a)(2)(A), (b)(3).

When Congress enacted the FDAAA, mifepristone had been FDA-approved for seven years as a safe and effective medication for terminating pregnancy, subject to certain conditions to assure safe use. ECF 1-11 at 4-5. In the new statute, Congress provided that drugs "approved before the effective date of [the] Act" would be "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), 121 Stat. 951 (2007). FDA identified mifepristone as one of those drugs. *See* 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008). The "elements" in place at the time included allowing dispensing only in a healthcare setting. ECF 1-24 at 2-3.

In 2016, FDA approved a series of changes to mifepristone's REMS and product label based on a review of over a decade of safety and efficacy data, peer-reviewed studies, and professional medical guidelines. ECF 1-11 at 24-26. Changes in the 2016 REMS included allowing licensed, non-physician healthcare providers to be certified prescribers. ECF 1-11 at 26-28.

FDA also rescinded an unusual provision in the mifepristone prescriber agreement that separately required prescribers to report certain adverse events to manufacturers. ECF 1-11 at 26; *see* ECF 1-30 at 8 (requiring that hospitalizations, transfusions, and other serious events be submitted to the manufacturer). Federal law independently requires drug manufacturers to review reports of adverse drug experiences for their products, including from clinical investigations, studies, scientific literature, and prescribers and patients, and to collect and submit that data to FDA in both periodic and annual reports. *See* 21 U.S.C. § 355(k)(1); 21 C.F.R. §§ 314.98, 314.80(b)-(c), 314.81. FDA collects these reports in the FDA Adverse Event Reporting System, "FAERS."[1] In its 2016 changes to the mifepristone REMS, FDA reasoned that because data on

[1] [1] FAERS "supports the FDA's post-marketing safety surveillance program" for all marketed drug products. *FAERS Public Dashboard - FAQ*, FDA, https://tinyurl.com/39uv9hee (last visited Feb. 3, 2026); *see FAERS Public Dashboard*, FDA (Dec. 7, 2023), https://tinyurl.com/53hbtps5.

"serious adverse events other than deaths" would still be included in the FAERS database via the manufacturer's "periodic safety update reports and annual reports to [FDA]," there was no need for a separate, mifepristone-specific channel for prescribers to report non-fatal events. ECF 1-11 at 28. FDA further explained that such additional reporting was unnecessary because the "safety profile" of mifepristone was "essentially unchanged" after fifteen years of reporting, *id.*, with "known risks occurring rarely," *id.* at 26. FDA thus conformed the adverse event reporting requirements for mifepristone to those applicable to the vast majority of approved drugs, which require no such additional reporting.

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). During those six months, FDA observed no impact on patient safety. ECF 1-50 at 45, 61-62.

Based in part on the information gained from the non-enforcement period, in April 2021, FDA exercised its discretion to again suspend enforcement of the in-person dispensing requirement. FDA also initiated a full review of the mifepristone REMS program. ECF 1-50 at 46. In December 2021, FDA announced its determination that the in-person dispensing requirement was not necessary to assure mifepristone's safe use. *Id.* at 45. 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 1-10 at 5, 26-37.

Importantly, an adverse event report does *not* mean the adverse event was *caused* by a drug, but rather that the event occurred "in the course of the use of a drug product." 21 C.F.R. § 314.80(a).

B. Louisiana Law

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 a Louisiana statute that generally prohibits abortions to go into effect. La. Rev. Stat. Ann. § 40:1061. Louisiana law excludes from its definition of "abortion" procedures necessary to prevent a patient's death (or substantial risk of death), to prevent the serious, permanent impairment of a life-sustaining organ, or to terminate certain "medically futile" pregnancies. La. Rev. Stat. Ann. § 14:87.1(1)(b); *see id.* § 40:1061(F). Mifepristone thus may be used lawfully for abortions that Louisiana law permits and for non-abortion purposes, including miscarriage management. *See id.* § 14:87.1(1)(b)(ii); *id.* § 14:87.1(2)(a) (defining "abortion-inducing drugs" as those used "with the intent to cause an abortion").

C. FDA's Approval of the 2023 REMS

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 prescribed safely by telemedicine and dispensed by mail or at pharmacies. ECF 1-50 at 3. The 2023 REMS added new 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." ECF 1-50 at 15. 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.*

The administrative record underlying FDA's 2023 REMS decision, which has been produced in other litigation concerning the mifepristone REMS, shows that the 2023 REMS rested on a robust scientific record. *See* Index to AR, *Washington v. FDA*, No. 23-cv-03026 (E.D. Wash. Sept. 1, 2023), ECF No. 127. FDA's review was grounded in its more than two decades of experience with mifepristone, and its analysis included its 2021 review of published literature, safety information submitted during the COVID-19 pandemic, more than five years of adverse

event data, a separate one-year assessment report for the mifepristone REMS, and information provided by advocacy groups, individuals, and manufacturers. *See, e.g.*, ECF 1-50 at 3, 45. FDA found that all this information supported the safety of the REMS modification. *Id.*

That record included 15 studies evaluating the safety and efficacy of mifepristone when dispensed outside the clinical setting, including by pharmacies and through the mail. ECF 1-50 at 65. These studies, which collectively evaluated outcomes for more than 55,000 individuals, repeatedly showed the safety of the drug was consistent when dispensed across a wide variety of non-clinical settings. *See id.* at 65-77. FDA found there were "no new safety concerns" related to the removal of the in-person dispensing requirement. *Id.* at 63. It therefore concluded that "[r]emoving the in-person dispensing requirement will render the REMS less burdensome to healthcare providers and patients and provided all other requirements of the REMS are met, including the additional requirement for pharmacy certification, the REMS will continue to ensure that the benefits of mifepristone for medical abortion outweigh the risks." *Id.* at 80-81.

D. GenBioPro's Operations Under the 2023 REMS

GenBioPro is a generic mifepristone manufacturers, and the sale of mifepristone represents the majority of its total revenue. Decl. of Evan Masingill ¶ 5. In 2019, FDA approved GenBioPro's amended new drug application to market a generic version of mifepristone. The REMS that was in effect for branded mifepristone (sold by Danco Laboratories, LLC) was re-issued to cover GenBioPro's product. ECF 1-57. Before 2021, GenBioPro shipped its product directly to clinics and hospitals for in-person dispensing. *See id.* ¶ 7. When FDA removed the in-person dispensing requirement in the 2023 REMS, GenBioPro redesigned its supply chain to meet pharmacy demand, *id.* ¶ 8, including through new pharmacy-specific distributor contracts, and by redesigning its logistics framework to incorporate pharmacy distribution, *id.* ¶ 9. Pharmacy sales now represent a substantial portion of GenBioPro's total sales. *Id.* ¶ 10.

E. 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 petition 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 considering 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* Ex. B at 13-14 n.50 (citing 13 studies published after 2021 reaffirming the safety of mifepristone). In addition, FDA recently denied a petition seeking reinstatement of the in-person dispensing requirement, explaining that it needed more time to review the "complex scientific and policy issues" implicated and would instead evaluate these issues "as part of FDA's ongoing regulation of [mifepristone] products." Ex. C at 13 (FDA Letter denying citizen Petition submitted by American Association of Pro-Life Obstetricians & Gynecologists ("AAPLOG")). The FDA Commissioner in September 2025 similarly announced that the agency will be conducting further safety studies of the 2023 REMS "in order to determine whether modifications are necessary." ECF 1-110 at 2.

II. Procedural Background

A. *AHM* Litigation

In November 2022, several doctors and associations challenged virtually every FDA action ever 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 and Fifth Circuit issued orders suspending certain FDA actions involving mifepristone, 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. *AHM*, 602 U.S.at 374.

Three states intervened and, on remand, the case has since been transferred to the Eastern District of Missouri, where it remains pending. Shortly before the transfer, on September 19, 2025,

Plaintiffs here sought to intervene, but the court denied that "belated" request. *Missouri v. FDA*, 2025 WL 2825980, at *11-*12 (N.D. Tex. Sept. 30, 2025).

B. This Lawsuit

Plaintiffs filed suit in October 2025, more than four years after FDA first suspended the in-person dispensing requirement and three years after *AHM* was filed, challenging only the 2023 REMS and focusing on FDA's removal of the in-person dispensing requirement. On December 17, 2025, Plaintiffs filed their motion for preliminary relief. ECF 20; *see* ECF 20-26 ("Mot.").

LEGAL STANDARD

To justify Plaintiffs' request for preliminary relief, they must show "(1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction does not issue, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that granting the injunction is in the public interest.'" *See* Mot. 8-9 (quoting *Clarke v. Commodity Futures Trading Comm'n*, 74 F.4th 627, 640-41 (5th Cir. 2023)); *see Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1135-36 (5th Cir. 2021).

ARGUMENT

I. Plaintiffs Lack Article III Standing

Plaintiffs lack Article III standing, and they are not entitled to preliminary relief. *See AHM*, 602 U.S. 367 (reversing award of preliminary injunctive relief because plaintiffs lacked standing).

A. Louisiana Lacks a Cognizable Sovereign Injury Traceable to the 2023 REMS

Louisiana first asserts Article III standing based on a theory of sovereign injury, arguing that the 2023 REMS "enables third parties to violate Louisiana's pro-life laws, preventing Louisiana from effectively enforcing its prohibition on abortion." Compl. ¶ 109; *see* Mot. 19-21.

Louisiana's sovereign injury theory is precluded by precedent. In *United States v. Texas*, 599 U.S. 670 (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. *Id.* at 680 n.3. 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. Applying *United States v. Texas*, one circuit court rejected an argument materially identical to the one Plaintiffs assert here regarding the mifepristone REMS, holding that, even if "the availability of retail and mail-order dispensing does make mifepristone more difficult to police, [courts] have never held that a logistical burden on law enforcement constitutes a cognizable Article III injury." *Washington v. FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024).

Louisiana relies on *Louisiana v. EEOC*, 784 F. Supp. 3d 886 (W.D. La. 2025), as supporting its theory of sovereign injury. 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. *Id.* at 901. Here, the REMS neither overrides Louisiana laws nor prevents Louisiana from enforcing them. Rather, as in *AHM*, the 2023 REMS does not require Louisiana "to do or refrain from doing anything." *AHM*, 602 U.S. at 374.

Contrary to Plaintiffs' assertion, Louisiana was not the "object" of the 2023 REMS. Mot. 18-19. The REMS does not, in any way, operate to regulate Louisiana. It regulates pharmaceutical manufacturers (and the supply chain) and guides providers' and pharmacies' prescribing and dispensing of mifepristone. *See* 21 U.S.C. § 355-1; Ex. A (2023 REMS). Thus, this case is nothing like *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025), where the Supreme Court noted that private fuel producers "might" be considered the "object" of a state regulation that "explicitly [sought] to restrict the use" of the producers' products. *Id.* at 114-15.

Plaintiffs' contention that "the whole point" of the 2023 REMS was "to override the sovereign prerogatives of pro-life states" after *Dobbs*, Mot. 18 (citation omitted), is pure fiction. The in-person dispensing requirement was first removed by court injunction in 2020 (two years before *Dobbs*) and then voluntarily suspended by FDA in 2021 (more than a year before *Dobbs*). *See supra* § I.A. 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, https://tinyurl.com/38m6ea9f; *see* ECF 1-50 at 46 (FDA's REMS evaluation was initiated "in 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 override the sovereign prerogatives of pro-life states." *Contra* Mot. 18.

To argue otherwise, Plaintiffs rely on assorted statements by various public officials supporting the goal of maintaining lawful abortion access. Mot. 19-20. In addition to postdating the key 2021 determination, none of these statements is by an FDA official responsible for making REMS determinations. *See id.* at 20. Judicial review of agency action is based on the administrative record generated by the decision-makers, not miscellaneous comments by other government actors, particularly those made after the fact. *See FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 576-77 (2025) (rejecting allegations of "surreptitious[]" agency action).

Even if Louisiana had a cognizable sovereign injury, any such injury would be attributable to independent actors, not the 2023 REMS. Louisiana complains that its enforcement is hindered because individuals and organizations have been mailing mifepristone to Louisiana and other states have refused to cooperate with Louisiana's extradition requests. *See, e.g.*, Mot. 18, 20. However, if a party were already mailing mifepristone illegally, Plaintiffs offer no evidence to suggest that individual would be less likely to do so in the absence of the in-person dispensing requirement. Plaintiffs thus cannot avoid the reality that the "unfettered choices made by independent actors not before the courts" break the chain of causation between the 2023 REMS and any sovereign harm to Louisiana. *AHM*, 602 U.S. at 383 (citation omitted).

Louisiana asserts another "quasi-sovereign" standing theory in its Complaint—albeit not its motion for preliminary relief—based on the notion that the REMS interferes with Louisiana's right to regulate and protect its own citizens. Compl. ¶¶ 120-131. 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 n.11 (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 2023 REMS affects a "substantial segment" of Louisiana's population. *See Arizona v. Garland*, 730 F. Supp. 3d 258, 276 (W.D. La. 2024).

B. Louisiana Lacks a Cognizable Economic Injury Traceable to the 2023 REMS

Louisiana's other theory of standing is that FDA's "deregulatory action" "causes Louisiana textbook pocketbook injuries" of "Medicaid-related expenses" and increased payments to public hospitals for the care of patients who have taken mifepristone. Compl. ¶¶ 109, 148-149; *see* Mot. 21-23. This theory is equally flawed, not the least of which because 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 noted, "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 2023 REMS on Louisiana's Medicaid spending is even "far[ther] removed from" the "distant … ripple effects" that the Court found too attenuated in *AHM*, 602 U.S. at 383. For these reasons, one circuit court confronting similar arguments easily rejected other states' standing claims based on allegations of "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.

Plaintiffs rely on *Texas v. United States*, 126 F.4th 392 (5th Cir. 2025). Mot. 21, 24. But in that case, Texas challenged a federal immigration policy, alleging an increase in spending that was directly traceable to the additional *number of non-citizens* who would stay in the state as a result of the challenged policy and who could thus take advantage of state services like Medicaid. *Id.* at 412. Here, in contrast, Louisiana does not contend that the 2023 REMS has any bearing on the number of Medicaid beneficiaries. It instead alleges that, by virtue of the potential for increased mifepristone use in the state, the *amount of money spent* on those individuals will increase. Mot. 22-23. But federal policy on any number of subjects can be "indirect[ly]" traced to increased state spending, from nutrition to pharmaceuticals to tobacco to guns to automobile safety, *see United*

States v. Texas, 599 U.S. at 680-81 & n.3, yet those sorts of indirect contingent economic interests are "too attenuated," and too "far removed" to support standing, *AHM*, 602 U.S. at 383, 390-93.

Louisiana cites specific Medicaid expenditures for emergency care that patients allegedly sought after taking mifepristone. Mot. 23. But Louisiana does not attempt—because it cannot—to tie those expenditures to the challenged FDA action, *i.e.*, FDA's safety determination in the 2023 REMS, as opposed to the mere use of mifepristone, which remains a lawful FDA-approved drug. *Supra* § I.B. Louisiana's economic injury theory is no more availing than its other theories.

C. Ms. Markezich Lacks Standing

Nor does Ms. Markezich have Article III standing. Her alleged past injuries are not redressable through APA claims against FDA seeking prospective relief. *See Lujan v. Defs. Of Wildlife*, 504 U.S. 555, 564 (1992). To the extent she claims to be at risk of suffering similar injury again in the future, such claims are too speculative to support standing. *See City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983); *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (emphasizing that the "purpose" of Article III's "imminence" requirement is to "ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending" (quoting *Lujan*, 504 U.S. at 565 n.2)). Plaintiffs' argument (Mot. 23 n.5) highlights why neither Plaintiff has standing, confirming that any alleged injury necessarily depends on third-party acts—including coercion, abuse, and identity theft by Ms. Markezich's ex-boyfriend, *see* Compl. ¶¶ 150-54—which cannot be legally traced to FDA, *see AHM*, 602 U.S. at 383.[2]

II. Plaintiffs' Challenge Is Unexhausted and Not Ripe for Judicial Review

Even if Plaintiffs had standing, their case cannot proceed because they failed to exhaust administrative remedies and their claims are unripe.

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[2] Plaintiffs also have not shown that they "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, 322 (5th Cir. 2020) (quotation marks omitted). Neither the provisions in 21 USC § 355-1 specifying the factors FDA must consider when adopting or amending REMS, nor the Comstock Act's prohibition on shipping materials for the purpose of unlawful abortion, reveals any intent on the part of Congress to protect state interests in enforcing their own laws or in lowering Medicaid costs.

A. Plaintiffs' Challenge Is Unexhausted

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*, 140 S. Ct. 1613, 1614 (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 minimize[e] burden" on "the health care delivery system," 21 U.S.C. § 355-1(f)(2), 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 generally 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 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, 180-181 (D.C. Cir. 2009) (affirming

dismissal where plaintiffs failed to file a "citizen petition with FDA contesting the SNDA approval of Plan B and [ ] proffer[ing] no legally viable excuse for this failure").[3]

Under these exhaustion rules, this case cannot proceed. Plaintiffs never filed a citizen petition, 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). In fact, the "evidence" Plaintiffs invoke *postdates* the challenged FDA decision, *see* Compl. ¶¶ 38 nn.18-19, nn.20-21, meaning the agency *could not* have considered it in the REMS decision that Plaintiffs now seek to enjoin, *cf. Sierra Club v. FERC*, 827 F.3d 59, 69-70 (D.C. Cir. 2016). 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.*, Ex. B (GenBioPro's Citizen Petition); *see also* ECF 50 at 7 n.3 (Defs.' Br.) (listing citizen petitions). 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).

No exception to exhaustion applies, and Plaintiffs make no attempt to argue otherwise. *See Gardner v. School Bd. Caddo Parish*, 958 F.2d 108, 112 (5th Cir. 1992). FDA plainly is not "powerless to grant the relief requested." *Carr v. Saul*, 593 U.S. 83, 93 (2021). There is no indication that a decision by FDA would "certainly" be adverse. *Tesoro Ref. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009) (futility requires "*certainty* of an adverse decision" (citation omitted)). Rather, as Plaintiffs repeatedly emphasize, FDA is undertaking a review of mifepristone, and current HHS and FDA leadership have signaled uncertainty about the drug's status. *See* ECF 1 ¶ 13; Mot. 2, 8, 10, 11, 12; *see also* Defs.' Br. 3 (noting ongoing review of alleged "safety risks" of mifepristone). Plaintiffs' impatience, Mot. 8, does not grant them a license to bypass a legally required administrative review process.

[3] *See also 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").

B. Plaintiffs' Challenge Is Not Ripe

For similar reasons, Plaintiffs' challenge is not ripe for judicial review. "A claim is not ripe for adjudication if it rests 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). Courts find claims unripe, for example, when "[f]urther factual development" would "enhance th[e] case's fitness for judicial review." *Miss. State Democratic Party v. Barbour*, 529 F.3d 538, 547 (5th Cir. 2008).

Here, there is every reason for FDA's active consideration of the mifepristone REMS, which Plaintiffs acknowledge, Mot. 8, to proceed before court involvement. FDA confirmed as recently as January 16—when it denied without comment a citizen petition requesting that FDA modify the existing REMS—that it needed additional time to review the "complex scientific and policy issues" at the heart of this case, and would do so "as part of FDA's ongoing regulation of [mifepristone] products," Ex. C at 13 (FDA Letter Denying AAPLOG Citizen Petition), a representation it has confirmed in its filings in this Court, *see* Defs. Br. 3, 9-13. There is no basis for short-circuiting that administrative process.

III. Plaintiffs Are Not Likely to Succeed on the Merits for Additional Reasons

A. The 2023 REMS Is Not Arbitrary and Capricious

After ample experience without in-person dispensing during the pandemic, FDA determined that mifepristone—like the vast majority of drugs—could be dispensed without an in-person clinic or office visit. That determination is not arbitrary or capricious by any stretch.

FDA's modification of the REMS in 2023 was "reasonable and reasonably explained," and it easily satisfies the arbitrary-and-capricious standard. *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021); *see* 5 U.S.C. § 706(2)(A). The FDAAA directs FDA to make the "fact-laden" determination, *see Seven Cnty. Infrastructure Coal. v. Eagle Cnty.*, 605 U.S. 168, 183 (2025), of whether the REMS will "ensure the benefits of the drug outweigh [its] risks"; "minimize the burden on the health care delivery system"; and "accommodate different, comparable aspects of the elements to assure safe use for a drug." 21 U.S.C. § 355-1(g)(4)(B). In addition, REMS

elements must not be "unduly burdensome on patient access to the drug," and, "to the extent practicable," must "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2).

FDA's application of those factors easily clears the APA's standard for reasoned decision-making. *See Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 923 (D.C. Cir. 2013) (Kavanaugh, J.) ("[C]ourts must be careful not to unduly second-guess [FDA's] scientific judgments."). In approving the 2023 REMS, FDA relied on multiple, independent lines of evidence. It reviewed more than five years of adverse-event data, comparing periods when the in-person dispensing requirement was enforced with periods when it was not. *Supra* § I.C. Based on FAERS data and adverse event data submitted by Danco and GenBioPro, FDA determined there were "no new safety concerns" related to the removal of the in-person dispensing requirement, and concluded "there does not appear to be a difference in adverse events between [those] periods"—which "suggests that mifepristone may be safely used without an in-person dispensing requirement." ECF 1-50 at 63. FDA also analyzed 15 studies that evaluated the safety and efficacy of mifepristone when dispensed to more than 55,000 patients by a variety of means not involving in-person dispensing in a clinic or hospital, finding that their cumulative results corroborated that removing the in-person dispensing requirement did not pose safety risks. *See* ECF 1-50 at 65-66, 69, 73, 74.[4]

Plaintiffs do not identify any evidence—no clinical trials, adverse event reports, post-approval studies, peer-reviewed literature, or other scientific data—that FDA erred in not considering. Instead, Plaintiffs contend that a change FDA made five years earlier, in 2016, to the adverse event reporting requirements for mifepristone made the FAERS data unreliable. That

[4] The studies supporting mifepristone's safety—including the studies upon which FDA relied and the studies published *after* the 2023 REMS—are all included in GenBioPro's citizen petition and the accompanying appendices. Ex. B at 11 n.35 (collecting and attaching studies FDA relied upon demonstrating safety of mifepristone); *see* Ex. B at 14-15 n.50 (collecting and attaching studies published after December 2021 demonstrating safety of mifepristone when dispensed via telehealth); *see also* Ex. E at 1, 6 (Sophie Dilek *et al.*, *The US Food and Drug Administration's Regulation of Mifepristone*, J. Am. Med. Ass'n (Jan. 12, 2026) (noting medical "consensus" that serious complications with mifepristone "are very rare," and commending FDA's "conservative[e]" and "incremental[]" approach to regulating mifepristone)).

argument is incorrect.[5] FDA's 2016 change simply brought the adverse event reporting for mifepristone closer in line with the protocol applicable to virtually all other prescription drugs, including many drugs with a REMS in place, under which prescribers are permitted (but not required) to report other adverse events. ECF 1-11 at 26-28; 21 C.F.R. § 314.80(c) (imposing reporting requirements on manufacturers but not providers). FDA thus maintained a mifepristone-specific reporting requirement for fatalities, while recognizing that, as with other drugs, "serious adverse events other than deaths" continue to reach FDA through manufacturers' "periodic safety update reports and annual reports." ECF 1-11 at 28; *supra* § I.A. Indeed, manufacturers are required to report *all* adverse events that they receive, including from a variety of different sources that are *not* limited to physician reports. *See* 21 C.F.R. § 314.80(b)-(c). Significantly, adverse event reports are overinclusive by nature: they include *all* adverse experiences when taking a drug and do not incorporate any kind of causation analysis. *See id.* § 314.80(a); *supra* § I.A.

The FAERS database that FDA considered in its assessment incorporates all of this data. *Supra* § I.A; *see* Masingill Decl. ¶ 16. Importantly, the relative numbers of non-fatal adverse events in the FAERS database for years after 2016 are comparable to those for years prior to the 2016 change. And FDA had more than ample post-2016 data to make an apples-to-apples comparison of adverse event reports when in-person dispensing was required versus when it was not. Plaintiffs' suggestion that FAERS data is somehow unreliable without a requirement that physicians report non-fatal adverse events also ignores the reality that most drugs have no such reporting requirement, *see* ECF 1-11 at 28; 21 C.F.R. § 314.80(c), yet Congress still directed FDA to rely on "adverse event reports" as one source of data when making its safety determinations, *see* 21 U.S.C. § 355-1(a)(1)(E), (b)(3); *see also Prometheus Radio*, 592 U.S. at 427 (agency decisions do not require "perfect empirical or statistical data").

[5] Plaintiffs emphasize comments about the FAERS database made by the Fifth Circuit in the *AHM* litigation, Mot. 10-12, but the Supreme Court vacated those Fifth Circuit decisions in their entirety, *AHM*, 602 U.S. at 397. They have no legal effect or precedential value. *See O'Connor v. Donaldson*, 422 U.S. 563, 577 n.12 (1975).

Plaintiffs also latch on to a characterization in FDA's analysis that the literature was "not inconsistent with [FDA's] conclusion" to suggest that the literature does not actually support the 2023 REMS. Mot. 12 (quoting ECF 1-10 at 29). That argument ignores the surrounding context of FDA's analysis. FDA reviewed the results of 15 studies that evaluated medication abortion outcomes for over 55,000 patients, and each study reached the conclusion that dispensing by mail, courier, or through pharmacies was safe and effective. *See* ECF 1-50 at 65-81. The 15 studies did not identify any new or increased risks when mifepristone is dispensed outside a clinic or hospital. *Id.* In particular, the largest study—involving patients in the United Kingdom—found "no significant differences in the rates of reported [serious adverse events]" between patients who received mifepristone by mail or picked it up at pharmacies and those who received it via an in-person physical examination. *Id.* at 74. And four studies evaluating post-telemedicine dispensing by mail in the United States showed "no increased frequency of [serious adverse events]," supporting the "conclusion that dispensing by mail is safe." *Id.* at 80.

FDA thus explained that the studies it examined "generally support a conclusion that dispensing by mail is safe" and "there was no increased frequency of" serious adverse events. *Id.* And those studies' conclusions as to safety fully supported FDA's predictive judgment that "mifepristone will remain safe" without requiring in-person dispensing at a clinic or hospital. *Id.* Any limitations in the specific studies that FDA examined were outweighed by the fact that *all* the studies it examined supported the safety of removing the in-person dispensing requirement, *id.*, and by the fact that FDA imposed *additional* requirements on pharmacies and physicians to ensure compliance with the mifepristone REMS, *id.* at 80-81.

Plaintiffs' reliance on FDA's observation in one subset of studies that "there may be more frequent [emergency department]/urgent care visits related to the use of mifepristone when dispensed by mail," Mot. 13 n.2 (quoting ECF 1-10 at 35), ignores FDA's expert *analysis* of those findings, which confirmed that those same studies "support[ed]" the finding "that dispensing by mail is safe and effective," ECF 1-50 at 80. Indeed, in one of those studies, the author noted that "half of the participants who had an "ED/urgent care visit did not require medical treatment," and

the studies did *not* show an increase in other adverse events. *Id.* In other words, FDA reasonably concluded that the fact that a patient visited a healthcare professional after the termination of a pregnancy did not undermine the robust data showing that the drug is safe. *See id.*

Unable to sustain an arbitrary-and-capricious claim based on the actual administrative record before the agency at the time of its decision, Plaintiffs rely most heavily on post-decision, extra-record evidence. Mot. 6; ECF 20-4 (Wallace Study, published 2025); ECF 1-14 (Studnicki Study, published 2024); ECF 1-13 (Hall Study, published 2025). But in APA cases, the administrative record, *i.e.*, "the decision of the agency and the evidence on which it was based," is "[t]he focal point for judicial review," and courts must not consider "some new record made initially in the reviewing court." *Texas v. EPA*, 156 F.4th 523, 537-38 (5th Cir. 2025).

In any event, Plaintiffs' studies do not support their challenge. Not one of the post-decision extra-record studies on which Plaintiffs rely (Wallace (ECF 20-4), Hall (ECF 1-13), or Studnicki (ECF 1-14)) purports to evaluate the safety of mifepristone as dispensed through pharmacies or by mail, and the results are therefore irrelevant to evaluating FDA's decision to remove the in-person dispensing requirement. The Wallace study suggested that *expanded* use of mifepristone with a specific misoprostol regimen past 77 days of pregnancy may "*increase* access to safe, effective abortion," ECF 20-4 (emphasis added), and therefore undermines Plaintiffs' arguments.

The other two studies do not support Plaintiffs' position either. The Hall publication was a self-published (*i.e.*, non-peer reviewed) report authored by two non-physician, non-medical scientists, which was posted on the website of the advocacy organization the Ethics & Public Policy Center (EPPC). Ex. B at 16-20 (explaining critical methodological problems with EPPC report). Among other flaws, the EPPC report does not even disclose certain of the databases upon which it relies, making it impossible for anyone to assess either the "reliability or relevance of that dataset." *Id.* at 19. EPPC's report adopts a medically unsupported, overbroad definition of "adverse events" that is inconsistent with established standards and captures events like ectopic pregnancies, which are not caused by mifepristone. *Id.* at 17-18. And the Studnicki study similarly adopts a flawed methodology that dramatically overstates the acuity of patients' medical treatment, while

basing its findings and recommendations on the assumption that patients and healthcare workers are regularly acting in "bad faith" and lying about the purpose of the visit. Ex. F at 19-23 (letter from UCLA Law Center for Reproductive Health, Law, and Policy and others explaining methodological flaws in Studnicki study). Plaintiffs' post-2023 sources do not resemble anything close to the kind of methodologically sound studies upon which FDA relies.

To the extent Plaintiffs rely on alleged new "evidence" adduced since 2023, they are urging the Court to reach a scientific conclusion on the disputed rates (and types) of hospitalization based on pharmacy versus clinic prescriptions of mifepristone before the agency has even completed its review of that evidence. Even if Plaintiffs' post-decision, extra-record evidence were somehow fit for consideration in this APA case, the Court would also be required to consider the bevy of post-2023 studies *confirming* the safety of mifepristone when dispensed through certified pharmacies. *See* Ex. B at 14-15 n.50 (collecting 13 peer-reviewed studies published since December 2021 supporting safety of dispensing of mifepristone outside the clinic setting). Plaintiffs make no effort to account for that evidence, and the very premise of their request for this Court to assess complex scientific evidence on a cold record in the first instance turns administrative law on its head.

Plaintiffs also rely on extra-record statements by various public officials. None of these statements is part of the administrative record, and none is even by an FDA decision-maker responsible for the decision to remove the in-person dispensing requirement. *See supra* § I.A (noting removal of requirement was made prior to *Dobbs*). As for the recent comments by Defendants Kennedy and Makary, Mot. 10, if anything, those comments support letting FDA's review run its course to consider the post-2023 evidence in the first instance. They do not render FDA's earlier analysis and decisions arbitrary and capricious, and they provide no basis for finding Plaintiffs likely to succeed on the merits of their APA claim challenging the 2023 REMS.

B. The 2023 REMS Is Not Contrary to Law

Plaintiffs are also wrong that the 2023 REMS is somehow contrary to the Comstock Act.

While the Comstock Act restricts shipping of items "intended for producing abortion," 18 U.S.C. §§ 1461, 1462, it has long been construed as applicable only to *knowingly* shipping such

items for the purpose of *illegal* abortions, *see United States v. One Package*, 86 F.2d 737, 739-40 (2d Cir. 1936) (L. Hand, J., concurring); *Youngs Rubber Corp. v. C.I. Lee & Co.*, 45 F.2d 103, 108 (2d Cir. 1930); *Davis v. United States*, 62 F.2d 473, 475 (6th Cir. 1933); *Application of the Comstock Act to the Mailing of Prescription Drugs that Can Be Used for Abortions*, 46 Op. O.L.C. __ (Dec. 23, 2022), https://www.justice.gov/olc/opinion/file/1560596/dl ("OLC Opinion"). By repeatedly amending the statute against that judicial backdrop without changing it to reject that construction, Congress has ratified that interpretation. *See* OLC Opinion, *supra*, at 13; *Texas Dep't of Hous. & Cmty. Affairs v. Inclusive Cmtys. Project*, 576 U.S. 519, 536 (2015).

Under the 2023 REMS, FDA does not ship mifepristone at all, let alone knowingly ship it for the purpose of illegal abortions. In the principal case Plaintiffs rely on, it was the Federal Communication Commission's own action—its revocation of a broadband license—that violated a Bankruptcy Code provision prohibiting such revocations. *FCC v. Next Wave Pers. Commc'ns, Inc.*, 537 U.S. 293, 300 (2003). Here, in contrast, there is no plausible theory that by adopting the 2023 REMS, FDA somehow engaged in illegal shipping under the Comstock Act.[6]

Nor does the 2023 REMS compel or authorize anyone else to violate the Comstock Act. FDA's remit under the FDAAA is narrow and technical: to determine whether various conditions, including the requirement of in-person dispensing, are appropriate in light of the dual criteria of "assur[ing] safe use" while "not be[ing] unduly burdensome on patient access." 21 U.S.C. § 355-1. In the 2023 REMS, FDA determined based on overwhelming data that continuing the in-person dispensing requirement was unnecessary for safe use and would impede patient access. FDA's scientific judgment based on its evaluation of those criteria neither required, nor purported to permit, anyone to knowingly ship mifepristone for the purpose of illegal abortions. Plaintiffs'

[6] Plaintiffs rely on a concurrence to support their novel interpretation of the Comstock Act. Mot. 13-14 (citing *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 267-69 (5th Cir. 2023) (Ho., J., concurring in part)). Among other issues, that concurrence (which was not joined by any of the other five circuit judges involved in the decisions in the *AHM* litigation) does not cite *Next Wave* or its progeny and fails to explain how *FDA* somehow acted contrary to the Comstock Act.

claim that the 2023 REMS is unlawful under the Comstock Act is therefore wholly lacking in merit, and Plaintiffs have no possibility—much less a likelihood—of succeeding on it.

IV. Plaintiffs Have Not Demonstrated Irreparable Harm

Plaintiffs have not shown the irreparable harm necessary for preliminary relief. Initially, Plaintiffs' extreme delay in seeking relief (nearly three years after the 2023 REMS was adopted, and more than four years from when the in-person dispensing requirement was originally lifted in 2021) belies their assertion of the kind of irreparable harm that would entitle them to the relief they seek. Indeed, the *AHM* district court denied Plaintiffs' "belated" request for intervention in that case, where three other states moved to intervene nearly two years before this case began. *Missouri*, 2025 WL 2825980, at *11-*12. And even after filing this lawsuit, Plaintiffs waited an inexplicable 72 days before moving for preliminary relief. "[A] party requesting a preliminary injunction must generally show reasonable diligence," *Benisek v. Lamone*, 585 U.S. 155, 159 (2018), and courts have denied preliminary relief based on delays measured in just weeks or months, *see Gonannies, Inc. v. Goupair.Com, Inc.*, 464 F. Supp. 2d 603, 609 (N.D. Tex. 2006) (collecting cases).[7]

As Plaintiffs' own delay vividly illustrates, their alleged injuries are not, in fact, irreparable. Even if Louisiana's payment of past Medicaid-related costs might suffice for standing purposes (it does not), it still would fail to satisfy the much heavier "burden of showing that the circumstances justify" the "extraordinary remedy of injunction." *Nken v. Holder*, 556 U.S. 418, 428, 434 (2009). At most, Plaintiffs' argument is that the REMS "could" cause Louisiana to incur expenses for Medicaid patients in the future. Mot. 22. They do not and cannot quantify those expenditures,

[7] Plaintiffs' request for a "stay" under 5 U.S.C. § 705 is improper. That statute authorizes courts to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of [judicial] review." To "postpone" means to "defer," "put off," or "delay." *See Black's Law Dictionary* 1389 (3d ed. 1933). The 2023 REMS has been in effect for years; it cannot sensibly be "postpone[d]." Nor would relief "preserve" the status quo; it would upend it. *Preserve*, Webster's New International Dictionary 1699 ("[t]o keep or save from injury or destruction," "to guard or defend from evil," "to protect," "to maintain" or "to retain"). As for Plaintiffs' request for traditional injunctive relief, the Fifth Circuit has admonished against allowing "one district court [to] make a binding judgment for the entire country," especially when "many states [ ] have not brought suit" and may have "accepted and even endorsed" the federal policy. *Louisiana v. Becerra*, 20 F.4th 260, 263-64 (5th Cir. 2021).

predict when they will occur, or link them causally to the 2023 REMS itself, as opposed to the independent acts of third parties.

Louisiana also bases irreparable harm on its theory that the REMS prevents it from enforcing its abortion laws. But the REMS neither overrides Louisiana law nor prevents Louisiana from enforcing it. Louisiana continues to prohibit the use of mifepristone for many purposes and retains its existing enforcement tools; any frustration Plaintiffs experience results from the actions of third parties not before this Court (and certainly not FDA). Unlike cases such as *Planned Parenthood of Greater Texas Surgical Health Services v. Abbott*, 734 F.3d 406 (5th Cir. 2013), no Louisiana statute is enjoined by the REMS, *see id.* at 419 (staying injunction of statute pending appeal because "[w]hen a statute is enjoined, the State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its laws").

Regardless, even if Louisiana were correct that the REMS precludes it from enforcing its law (it is not), "the inability to assert" a state interest in enforcement of the law "during the pendency of litigation" is not, without more, an irreparable injury. *Texas v. Ysleta del Sur Pueblo*, 2018 WL 1566866, at *13 (W.D. Tex. Mar. 29, 2018) (denying Texas's motion for preliminary injunction against conduct that allegedly prevented enforcement of gaming laws). The 2023 REMS neither prohibits Louisiana from enforcing its laws nor removes any law-enforcement tools that Louisiana seeks to use for that enforcement. *See id.* Accordingly, as in *Ysleta del Sur Pueblo*, "[t]he Court can make a decision later that would be just as effective as a decision now." *Id.*

V. The Balance of the Equities and Public Interest Militate Against Relief

In considering whether to grant preliminary relief, courts also must account for the harms an injunction (or stay) would impose on parties and non-parties, as well as the public interest. *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021); *SO Apartments, LLC v. City of San Antonio*, 109 F.4th 343, 353 (5th Cir. 2024) (considering interests in public health, safety, and welfare in balancing the harms). Here, those harms are concrete, profound, and irreparable.

There is no doubt that suspending the 2023 REMS would cause immediate and irreparable harm to GenBioPro. Mifepristone accounts for the majority of the company's revenue, and sales

through pharmacy distribution that would be cut off by a stay are a substantial portion of that revenue. Masingill Decl. ¶¶ 5, 10. The preliminary order Plaintiffs seek would undo the months of significant work by GenBioPro to establish a new pharmacy distribution framework in reliance on the 2023 REMS. *Id.* ¶¶ 9, 13-15. It would also create significant confusion, conceivably even compelling GenBioPro to revert to an obsolete regulatory regime, *see id.* ¶¶ 12, 15, and potentially halting distribution of the product entirely, *see* Ex. G ¶ 15 (Decl. of J. Woodcock, Principal Deputy Comm'r of FDA, in Supp. of Stay Application, *FDA v. AHM*, No. 22A902 (U.S. Apr. 14, 2023)). Compliance with any such regulatory regime would fundamentally disrupt the company's compliance and distribution framework, requiring significant time and expense to unwind the very distribution network that GenBioPro created in reliance on the 2023 REMS. Masingill Decl. ¶¶ 9, 12-15. Moreover, all those efforts would be unnecessary and irreparable if the "preliminary" relief is found unwarranted following full adjudication or on appeal. *Id.* ¶¶ 7, 11, 13-15.

The acute disruption to access to mifepristone that would result from suspending the 2023 REMS would also run counter to the public interest. Louisiana seeks relief to address what it alleges are harms to its interests *in Louisiana*—one of 50 states. But the nationwide relief it seeks reaches far beyond Louisiana's borders and would affect countless non-party providers and patients, severely undermining the provision of health care in the states that take less restrictive approaches to abortion than Louisiana. *See* Ex. H at 9-11, 19-20 (Am. College of Obstetricians & Gynecologists' citizen petition detailing benefits of expanding access to abortion, as well as harms from curtailing such access). The very data on which Plaintiffs rely to assert injury to Louisiana shows that in the first half of 2025, 27% of all abortions nationwide were provided via telehealth, constituting a significant portion of the abortion services in states where abortion is more broadly permitted than it is in Louisiana. ECF 20-1 at 2.

Even if mifepristone could still be permissibly shipped to providers for in-clinic dispensing if the Court entered the requested relief, the requested relief would serve a significant blow to

abortion access in non-party states, harming people nationwide.[8] Many patients around the country will be forced to travel long distances to healthcare settings to obtain mifepristone in-person, with long waits at clinics overrun with patients whose pharmacy access has been restricted by judicial order, and supply-chain disruptions may even cause a lapse in the availability of mifepristone. *See* ECF 1-50 at 58-59 (noting increase in prescribers based on removal of in-person dispensing requirement).[9] Still other patients may seek procedural abortions or even be forced to carry pregnancies to term against their will if access is restricted. *See, e.g.*, Ex. H at 9-11, 19-20.

In sum, this Court should not upend the status quo with its own nationwide regulatory regime that would harm public and private interests in the 49 states that are not a party to this suit.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' motion for preliminary relief.

[8] *See, e.g.*, Ex. I at 2-6 (letter from University of Chicago professors detailing public health harms resulting from restricted access to abortion, including increased infant deaths and worse maternal health outcomes); Ex. J at 1-2 (letter from Boston University's School of Law's Program on Reproductive Justice and other groups detailing the link between restricting abortion access and incidents of inter-partner violence); Ex. K (letter from Legal Voice and other groups explaining that restricting abortion access puts "intimate partner violence survivors at risk").

[9] *See* Ex. B at 11 n.35, 21 n.76 (collecting authorities showing public health benefits of abortion, including, Leah Koenig *et al.*, *The role of telehealth in promoting equitable abortion access in the United States: spatial analysis*, 9 JMIR Public Health Surveillance e45671 (2023); and Erica Chong *et al.*, *Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic*, 104 Contraception 43, 44 (2021)).

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Respectfully submitted,

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