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

THE STATE OF LOUISIANA, *et al.*, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants.*	No. 6:25-cv-01491-DCJ-DJA

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO STAY THE CASE AND IN RESPONSE TO PLAINTIFFS' MOTION FOR PRELIMINARY RELIEF

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INTRODUCTION

Protecting the health and safety of pregnant women is of paramount importance. To that end, on September 19, 2025, the Secretary of Health and Human Services and the Commissioner of Food and Drugs announced that the Food and Drug Administration (FDA) is reviewing the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, a drug approved for medical abortion. ECF No. 1-110 (Letter to State Attorneys General (Sept. 19, 2025)). The Secretary and the Commissioner explained that this review—which will include a study undertaken by FDA itself—is "informed by the lack of adequate consideration underlying prior REMS approvals," including a 2023 modification to the mifepristone REMS that approved the removal of an in-person dispensing requirement. *Id.* at 1. FDA's review is rooted in the agency's commitment "to protecting the health and safety of pregnant women" and "ensur[ing] . . . decisions are grounded in Gold Standard Science and rigorous, transparent, and objective evidence." *Id.* at 2.

FDA's decision to review the REMS for mifepristone is consistent with the concerns about removing the in-person dispensing requirement foreshadowed by the Fifth Circuit in *Alliance for Hippocratic Medicine v. FDA*. *See* 78 F.4th 210, 249-51 (5th Cir. 2023), *rev'd on other grounds*, 602 U.S. 367 (2024). Although ultimately reversed on jurisdictional grounds, the Fifth Circuit held that, in calling for the removal of the in-person dispensing requirement in December 2021, FDA erroneously "gave dispositive weight to adverse-event data in [the FDA Adverse Event Reporting System]," despite limitations of that data—including the fact that, as a result of action FDA took in 2016,

the REMS no longer requires prescribers to report non-fatal serious adverse events. *Id.* at 249. The court also faulted FDA's reliance on studies that had "significant limitations" and "did not affirmatively support" eliminating the in-person dispensing requirement. *Id.* at 250.

In deciding to review the REMS for mifepristone, the FDA recognized that the validity of FDA's restrictions on mifepristone is a hotly contested legal and scientific issue that has been the subject of litigation for many years. Louisiana and Ms. Markezich are not the only plaintiffs to have challenged the current requirements for dispensing mifepristone. Indeed, five other states are challenging either the approval of mifepristone or subsequent actions easing restrictions. *See Missouri v. FDA*, No. 4:25-cv-1580-CMS (E.D. Mo.) (Missouri, Idaho, and Kansas challenging actions easing REMS restrictions); *Florida v. FDA*, No. 7:25-cv-126-O (N.D. Tex.) (Florida and Texas challenging approval of mifepristone and actions easing REMS restrictions). Still other plaintiffs have challenged FDA's restrictions as too burdensome. *Purcell v. Kennedy*, Civ. No. 17-00493 JAO-RT, 2025 WL 3101785, at *28 (D. Haw. Oct. 30, 2025) (plaintiffs challenged REMS as too restrictive); *Washington v. FDA*, No. 1:23-cv-3026-TOR, 2025 WL 1888794 (E.D. Wash. 2025) (same); *Whole Woman's Health All. v. FDA*, No. 3:23-cv-00019 (W.D. Va.) (same). And aside from litigation, before the FDA are numerous citizen petitions—citing voluminous material and seeking mutually inconsistent relief, such as suspending approval of the drug, restoring previous REMS requirements, or eliminating the REMS entirely. *See infra* n.3.

Given this widespread debate over the safety of mifepristone, FDA has concluded that the best path forward is for the agency to reconsider the restrictions on mifepristone based on all the evidence before the agency. As noted above, that evidence will include FDA's own study. FDA has emphasized that it "is taking care to do this study properly and in the right way." FDA, Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation.[1] At this time, "FDA continues to work on the collection of the robust and timely data that is necessary for a well-controlled study with adequate statistical power." *Id.* Although studies like these "often take approximately a year or more to conduct," FDA's current plan is to complete the study "sooner than that timeframe." *Id.* And once FDA has analyzed the data from that study (as well as all other evidence before the agency), it will decide whether "substantive changes to the REMS" are necessary. *Id.*

Plaintiffs now threaten to short circuit the agency's orderly review and study of the safety risks of mifepristone by asking this Court for an immediate stay of the 2023 REMS Modification approved three years ago. They would have this Court set aside the 2023 REMS Modification—all without the benefit of FDA's expertise, and even as the agency is already reconsidering the matter in its review. And Plaintiffs' requested relief may prove as unnecessary as it is disruptive, if FDA ultimately decides that the in-person dispensing requirement must be restored.

[1] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (item No. 37) (accessed Jan. 27, 2026).

Moreover, awarding preliminary relief to these Plaintiffs could easily prompt other plaintiffs to seek a conflicting injunction that would sow administrative and judicial chaos. If this Court were to grant Plaintiffs' motion, the plaintiffs in *Whole Woman's Health Alliance* could promptly seek conflicting relief, which would only add to FDA's burden and complicate any future modification efforts. The prospect of conflicting injunctions is hardly far-fetched. In 2023, literally minutes after the Northern District of Texas in *Alliance for Hippocratic Medicine* stayed FDA's approval of mifepristone, the Eastern District of Washington prohibited FDA from altering the status quo in certain States. *Washington v. FDA*, 668 F. Supp. 3d 1125, 1144 (E.D. Wash. 2023), *vacated*, No. 1:23-cv-3026-TOR, 2025 WL 1888794 (E.D. Wash. 2025).

To prevent that disruption, the Court should exercise its inherent authority to stay this litigation pending the outcome of FDA's review of the mifepristone REMS. FDA's review will necessarily result in a new agency decision that could supersede the 2023 REMS Modification, obviating any need to consider the merits of Plaintiffs' arguments challenging the validity of the 2023 REMS Modification. Any party adversely affected by the new agency decision on mifepristone may seek judicial review at that time. And in the event of a further REMS modification, adherence to FDA's normal process will create far less disruption than the abrupt, judicially imposed change sought by Plaintiffs.

Deferring judicial review until FDA's review is complete will not prejudice Plaintiffs. Louisiana waited nearly three years to challenge the 2023 REMS Modification, and Rosalie Markezich does not identify any ongoing or imminent injury from which

she needs relief. Indeed, although Plaintiffs have alleged the 2023 REMS Modification causes serious harms to women, Plaintiffs lack standing to challenge that modification. Louisiana suffers no sovereign injury because it remains free to make and enforce its pro-life policies after *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022). Nor are Defendants standing in the way of Louisiana enforcing its abortion laws against out-of-state prescribers of mifepristone. The State's allegations about Medicaid costs and "quasi-sovereign" interests also do not create any case or controversy between Louisiana and FDA. And the tragic injury that Ms. Markezich alleges she suffered in the past due to the independent actions of her former boyfriend is neither traceable to FDA nor redressable by the prospective relief Plaintiffs seek. For all those reasons, the Court should stay this case until after FDA completes its review of the mifepristone REMS and deny Plaintiffs' motion without prejudice.

BACKGROUND

The Federal Food, Drug, and Cosmetic Act generally prohibits introducing a "new drug" into interstate commerce without FDA approval. 21 U.S.C. § 355(a). In 2000, FDA approved mifepristone for medical abortion, subject to certain restrictions to assure safe use. *See All. for Hippocratic Med.*, 602 U.S. at 376; 21 C.F.R. § 314.520.[2] Since 2008, those restrictions have been part of a REMS. *See* Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for

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

Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313, 16314 (Mar. 27, 2008).

For most of the drug's history, mifepristone's restrictions included an "in-person dispensing requirement," ensuring that the drug could be dispensed only in "clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber." *See, e.g.*, ECF No. 20-16 (REMS Single Shared System for Mifepristone 200MG (May 2021)) at 2. In July 2020, a district court preliminarily enjoined enforcement of the in-person dispensing requirement during the COVID-19 pandemic. *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020). The Supreme Court stayed that injunction pending appeal in January 2021. *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021) (mem.). ECF No. 1 (Compl.) ¶¶ 49-50. But in April 2021, FDA announced that it would not enforce the in-person dispensing requirement during the COVID-19 public health emergency, and the following month it announced it would conduct a review of the REMS. *See* ECF No. 1-10 (2021 FDA Letter to AAPLOG, *et al*.) at 5 & 6 n.10.

On December 16, 2021, the agency directed the sponsors of the drug to submit supplemental applications proposing to remove the in-person dispensing requirement. *See* Compl. ¶ 56; 21 U.S.C. § 355-1(g)(4)(B) (authorizing FDA to direct the sponsors of a drug to propose REMS modifications to "ensure the benefits of the drug outweigh the risks of the drug" and "minimize the burden on the health care delivery system of complying with [the REMS]"). The sponsors submitted those applications on June 22, 2022, and FDA approved them on January 3, 2023, in the 2023 REMS Modification.

Today, the agency is once again reviewing the mifepristone REMS. As the Secretary and the Commissioner told state attorneys general on September 19, 2025, FDA's "review of the evidence . . . will contribute to the understanding of the drug's safety profile." ECF No. 1-110, at 1. "[T]o determine whether modifications [to the REMS] are necessary," FDA will consider evidence relating to "real-world outcomes" and conduct "a study of the safety of the current REMS." *Id.* FDA will also consider aspects of the 2023 REMS Modification that a court has ordered the agency to reassess, *see Purcell*, 2025 WL 3101785, at *28, as well as numerous citizen petitions that cite voluminous materials and seek competing outcomes.[3]

On the same day the Secretary and the Commissioner issued their letter regarding the REMS review, Plaintiffs sought to intervene in *Missouri v. FDA*, No. 2:22-cv-223-Z, ECF No. 264 (N.D. Tex. filed Sept. 19, 2025). That case began in late 2022 styled as *Alliance for Hippocratic Medicine v. FDA* and wound its way to the Supreme Court. *See All. for Hippocratic Med.*, 602 U.S. at 376-77 (discussing procedural history).

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

There, the Supreme Court determined that, despite the original plaintiffs' "sincere legal, moral, ideological, and policy objections to elective abortion and to FDA's relaxed regulation of mifepristone," they "failed to demonstrate that FDA's relaxed regulatory requirements likely would cause them to suffer an injury in fact." *Id.* at 396.

Plaintiffs' attempted intervention was unsuccessful. At the end of September 2025, the Northern District of Texas transferred *Missouri* to the Eastern District of Missouri and denied Plaintiffs' motion to intervene. *Missouri v. FDA*, No. 2:22-cv-223-Z, 2025 WL 2825980, at *13 (N.D. Tex. Sept. 30, 2025).

On October 6, 2025, Plaintiffs filed this suit. Then, Plaintiffs filed a motion for preliminary relief on December 17, ECF No. 20 (Pl. Mot.)—nearly three years after the agency action that they challenge took effect.

STANDARD OF REVIEW

"[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). In exercising its "broad discretion to stay proceedings," *Clinton v. Jones*, 520 U.S. 681, 706 (1997), a court "must weigh competing interests and maintain an even balance," *Landis*, 299 U.S. at 254-55. In particular, a court must balance "the harm of moving forward" against "the harm of holding back" when determining whether to grant a stay of proceedings. *Ali v. Quarterman*, 607 F.3d 1046, 1049 (5th Cir. 2010).

To obtain a preliminary injunction or a stay of agency action under the Administrative Procedure Act, Plaintiffs must show "(1) a substantial likelihood of

prevailing on the merits; (2) a substantial threat of irreparable injury if the injunction is not granted; (3) the threatened injury outweighs any harm that will result to [a] non-movant if the injunction is granted; and (4) the injunction will not disserve the public interest." *Ridgely v. FEMA*, 512 F.3d 727, 734 (5th Cir. 2008); *see also Nken v. Holder*, 556 U.S. 418, 435 (2009); *Texas v. U.S. Dep't of Health & Hum. Servs.*, 770 F. Supp. 3d 940, 947 (E.D. Tex. 2025) ("Courts grant relief under [5 U.S.C.] § 705 based on the traditional four equitable factors for injunctive relief . . . ."). Preliminary relief "should not be granted unless the party seeking it has clearly carried the burden of persuasion on all four requirements." *Dennis Melancon, Inc. v. City of New Orleans*, 703 F.3d 262, 268 (5th Cir. 2012) (quotation marks and citation omitted).

"A preliminary injunction . . . cannot be requested by a plaintiff who lacks standing to sue." *Speech First, Inc. v. Fenves*, 979 F.3d 319, 329 (5th Cir. 2020). "[T]he party asserting federal jurisdiction when it is challenged has the burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006). And courts presume that they "lack jurisdiction unless the contrary appears affirmatively from the record." *Renne v. Geary*, 501 U.S. 312, 316 (1991) (quotation marks omitted).

ARGUMENT

I. The Court Should Stay This Case And Deny Plaintiffs' Motion Pending FDA's Review of The Mifepristone REMS.

The Court should stay further litigation until after FDA's mifepristone REMS review is complete and deny Plaintiffs' motion without prejudice. *Landis*, 299 U.S. at 254-55; *see also Ricci v. Chi. Mercantile Exch.*, 409 U.S. 289, 305 (1973) (upholding stay of

judicial proceedings pending completion of agency proceedings). The rationale for deferring judicial review is simple: the "harm of moving forward" with judicial review of the 2023 REMS Modification outweighs the "harm of holding back." *Ali*, 607 F.3d at 1049. And the same calculus confirms that granting preliminary relief would not be equitable at this time because it would disrupt FDA's ongoing review.

The harms of judicial review before the ongoing agency review is complete are manifold. Plaintiffs ask the Court to make the very sort of difficult scientific judgment about the 2023 REMS Modification that Congress entrusted to FDA while the agency itself is considering the same issues. *See Sierra Club v. EPA*, 939 F.3d 649, 680 (5th Cir. 2019). Such parallel reviews would waste judicial resources because FDA's own review may eliminate any need for the Court's. Moreover, if the Court vacates or stays the 2023 REMS Modification before FDA's review is complete, it could prompt the sponsors of mifepristone to file supplemental applications seeking modifications to the REMS. This, in turn, would add to the burdens on the agency as it seeks to conduct its own study, review all the evidence before it, comply with the *Purcell* remand, and weigh competing views presented in numerous pending citizen petitions. *See supra* pp. 2-3, 7. And on top of all that, granting Plaintiffs interim relief could lead to conflicting injunctions, further complicating FDA's efforts. *See supra* p. 4.

These disruptive effects on FDA's ongoing review also confirm that the balance of the equities and the public interest weigh against Plaintiffs' request. *See Peak v. Dist. of Columbia*, No. 06-cv-0373, 2006 WL 8445985, at *6 (D.D.C. Mar. 20, 2006) ("[I]t is not in the public interest to interrupt the administrative process."). The purpose of

preliminary relief is "to preserve" the existing positions of the parties and thereby "prevent irreparable harm" before the merits are determined. *City of Dallas v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017) (citation omitted). Far from preserving existing positions, preliminary relief would upend the status quo as well as the agency's administrative process.

Indeed, the text of 5 U.S.C. § 705 only underscores why the Court should decline to award preliminary relief. It authorizes the Court "to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. The effective date of the 2023 REMS Modification cannot be "postpone[d]" because it occurred three years ago. *Postpone*, Webster's New International Dictionary 1682 (1928) (def. 1) (defining "postpone" to mean "to defer to a future or later time; to put off; delay"); *Postpone*, Black's Law Dictionary 1389 (3d ed. 1933) ("To put off; defer; delay"); *see also Niz-Chavez v. Garland*, 593 U.S. 155, 160 (2021) (affording "the law's terms their ordinary meaning at the time Congress adopted them"). And none of the relevant definitions of "preserve" suggests relief that would upend a status quo that has existed for three years. *Preserve*, Webster's New International Dictionary 1699 (def. 1 & 3) (defining "preserve" as "[t]o keep or save from injury or destruction," "to guard or defend from evil," "to protect," "to maintain" or "to retain").[4]

[4] Although a Fifth Circuit panel "strongly doubt[ed] that § 705 should be read to impose the limit urged by FDA" here, the court did not reach "a definitive answer on this question." *All. for Hippocratic Med.*, 78 F.4th at 256. In any event, that opinion was later reversed on jurisdictional grounds. The question therefore remains open.

Finally, Plaintiffs' three-year delay in challenging the 2023 REMS Modification weighs against disrupting the status quo at this time. *Parker v. Dacres*, 130 U.S. 43, 50 (1889) (applying "the principle upon which courts of equity uniformly proceed, independently of any statute of limitations, of refusing relief to those who unreasonably delay to invoke their aid"); *see, e.g.*, *Tate v. LeBlanc*, No. 13-1253-P, 2014 WL 6455794, at *2 (W.D. La. Nov. 17, 2014) (finding a delay of "more than one year" sufficient to deny relief). Despite being aware of the 2023 REMS Modification and its alleged consequences since its inception, *see* Amicus Curiae Br. of Mississippi, et al., *Alliance for Hippocratic Medicine v. FDA*, No. 2:22-cv-00223-Z, ECF No. 55-1, at 3 (N.D. Tex. filed Feb. 10, 2023), the State has waited until this past October to seek relief of its own.[5] That there is "no apparent urgency" to Louisiana's request for preliminary relief further indicates that there is little harm in the Court holding back. *Amid, Inc. v. Medic Alert Found. U.S., Inc.*, 241 F. Supp. 3d 788, 821 (S.D. Tex. 2017).

Granting a stay while an agency reviews the matter under litigation is par for the course. *Purcell* is a case in point. There, the plaintiffs originally challenged the REMS that existed before the 2023 REMS modification. After FDA announced a REMS review in May 2021, the *Purcell* court stayed the litigation. *See Chelius v. Becerra*, No. 1:17-cv-

[5] Louisiana cannot excuse its delay based on the district court having granted universal relief in *Alliance for Hippocratic Medicine*. The relief granted in that case never took effect because the Supreme Court stayed it, *FDA v. All. for Hippocratic Med.*, No. 22A902, 143 S. Ct. 1075 (Apr. 21, 2023) (mem.), and ultimately held that the plaintiffs lacked standing, 602 U.S. 367. Even if it were justifiable for Louisiana to refrain from seeking relief until the Supreme Court's ultimate disposition, that does not explain why the State then waited a year and a half to seek preliminary relief.

493-JAO-RT, ECF No. 149 (D. Haw. May 7, 2021) (staying and administratively closing case).[6] The case remained stayed until after the 2023 REMS Modification. *Id.*, ECF No. 158 (D. Haw. Feb. 28, 2023) (reopening case). The Court should take a similar course here to allow FDA to complete its review of the mifepristone REMS.

II. Plaintiffs Would Not Be Prejudiced By A Stay Pending FDA's Review of The Mifepristone REMS Because They Are Not Suffering Ongoing Harm.

Plaintiffs would not be prejudiced by a stay pending FDA's review of the mifepristone REMS because they are experiencing no ongoing harm—much less irreparable harm—caused by FDA's 2023 REMS Modification. In any event, because Plaintiffs lack Article III standing, the Court should deny Plaintiffs' motion for preliminary relief.

The federal "judicial Power" is limited to "Cases" and "Controversies." U.S. Const. art. III. "A proper case or controversy exists only when at least one plaintiff establishes that she has standing to sue." *Murthy v. Missouri*, 603 U.S. 43, 57 (2024) (alterations and quotation marks omitted). To have standing, "a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief." *All. for Hippocratic Med.*, 602 U.S. at 380. Neither Louisiana nor Ms. Markezich satisfies this test.

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

A. Louisiana lacks standing

Like the plaintiffs in *Alliance for Hippocratic Medicine* that lacked standing, Louisiana "do[es] not prescribe or use mifepristone." *Id.* at 385. Nor does the 2023 REMS Modification "require[] [Louisiana] to do anything or to refrain from doing anything." *Id.* The State therefore faces an uphill battle to establish standing: in addition to showing a cognizable and redressable Article III injury, it must also show that the indirect causal chain between the 2023 REMS Modification and the State's alleged injury is neither "speculative" nor "attenuated." *Id.* at 383. Louisiana has not done so.

1. The 2023 REMS Modification does not cause "sovereign harm"

Contrary to Louisiana's contention, the 2023 REMS Modification does not implicate the State's sovereign "power to create and enforce a legal code." Compl. ¶ 111; Pl. Mot. 19. The Fourth Circuit has held that the mifepristone REMS establishes "a regulatory floor, not a ceiling," *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 274 (4th Cir. 2025), and the federal government has not taken any position that would leave Louisiana unable to "regulate abortion for legitimate reasons," including through legislation that furthers a "respect for and preservation of prenatal life at all stages of development," *Dobbs*, 597 U.S. at 300-01.

Recognizing this,[7] Louisiana argues instead that the 2023 REMS Modification has "functionally overridden" state laws by "making it possible" for *others*, especially out-

[7] Louisiana agrees that the REMS does not preempt its laws but contends that the Executive Branch previously suggested otherwise. Pl. Mot. 21 n.3. That is incorrect. The public statements Plaintiffs identify claimed only that states could not ban mifepristone

of-state actors, to violate them. Pl. Mot. 20. However, as the Ninth Circuit recognized, "even if the availability of retail and mail-order dispensing does make mifepristone more difficult to police," that "logistical burden on law enforcement" does not "constitute[] a cognizable Article III injury." *Washington v. FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024).

Furthermore, the Supreme Court rejected a similar makes-state-crime-possible theory in *United States v. Texas*, 599 U.S. 670 (2023). There, a district court found standing in part based on a State's assertion that a federal policy led to individuals "committing[] more crimes" within that State. *Texas v United States*, 606 F. Supp. 3d 437, 467 (S.D. Tex. 2022). The Supreme Court reversed, concluding that "none of the various theories of standing asserted by the States . . . overcomes the fundamental Article III problem with this lawsuit." 599 U.S. at 680 n.3.

Accepting Louisiana's theory "would greatly expand state standing to challenge any federal action that allegedly increases crime or disorder, or imposes indirect compliance costs for state law enforcement." *Washington*, 108 F.4th at 1177. States could challenge the loosening of federal regulations relating to firearms, the environment, banking, or anything else—all on the hypothesis that removing a *federal* restriction on certain activity "mak[es] it possible" for persons to violate *state* law restricting that same activity.

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based on "disagreement" with FDA's "scientific judgment" about "safety and efficacy." ECF Nos. 1-60, 1-61. In any event, the Executive Branch now concurs with the Fourth Circuit's view that the mifepristone REMS establishes a regulatory floor, not a ceiling.

Louisiana's primary authority, *Louisiana v. EEOC*, 784 F. Supp. 3d 886 (W.D. La. 2025), does not support this limitless theory of state standing. That case involved a challenge to a rule that "directly regulated" the State by "mandat[ing]" that it "provide (and fund) accommodations for elective abortions that directly conflict with the States' own laws and policies." *Id.* at 900-01 (citation omitted). Unlike the abortion-accommodation "mandate," the 2023 REMS Modification does not require or forbid Louisiana to do anything. So the "direct[] conflict" that was present in *Louisiana* is absent here. *Id.* at 901 (citation omitted)

Diamond Alternative Energy, LLC v. EPA, 606 U.S. 100 (2025), is even further afield. There, the Court found standing where "government regulation of a business" caused economic injuries "to other linked businesses" in a "chain." 606 U.S. at 117; *see also All. for Hippocratic Med.*, 602 U.S. at 384 ("[W]hen the government regulates (or under-regulates) a business, the regulation (or lack thereof) may cause downstream or upstream economic injuries to *others in the chain*, such as certain manufacturers, retailers, suppliers, competitors, or customers." (emphasis added)). There is no similar "link[]" or "chain" between Louisiana and those regulated by the REMS, *i.e.*, drug manufacturers, prescribers, and pharmacies located throughout the country. Thus, unlike *Diamond Alternative Energy*, Louisiana's causal theory is far too "attenuated" to satisfy Article III. *See id.* at 383.

2. Medicaid-based economic harm is too attenuated to establish standing

Louisiana argues next that it has standing as a Medicaid payor. Pl. Mot. 21-23. As with the sovereign harm theory, the only court to have considered whether a State has

standing to challenge the 2023 REMS Modification based on Medicaid costs rejected that theory as too attenuated. *Washington*, 108 F.4th at 1175-76. This Court should do the same.

Indeed, the reasoning of *Alliance for Hippocratic Medicine* compels that conclusion. There, the Court rejected as too attenuated a theory that doctors can "challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries." 602 U.S. at 391. Louisiana extends that debunked theory a step further. Louisiana argues that it has standing because the very doctors who lack standing under *Alliance for Hippocratic Medicine* can pass their costs on to the State through Medicaid. That is illogical. If the chain of causation between the challenged agency action and the doctors' alleged injury is already too attenuated, adding a link (doctors cause Medicaid to incur costs) only weakens it more.

Plaintiffs' version of Medicaid-payor standing is also just as limitless as doctor standing. So long as the Louisiana (through Medicaid) foots the bill for at least one patient, the State could challenge *any* federal policy alleged to have caused that visit to the doctor or hospital, including "EPA roll[ing] back emissions standards for power plants," "[a] federal agency increas[ing] a speed limit from 65 to 80 miles per hour," and the federal government "repeal[ing] certain restrictions on guns." *All. for Hippocratic Med.*, 602 U.S. at 391. And the logic of this broad theory would apply to "every entity that provides health insurance or subsidized medical care," not just States or Medicaid payors. *Washington*, 108 F.4th at 1176; *see* Pl. Mot. 21 n.4 (conceding that this theory does

not depend on "special solicitude" for States). Article III's limitations are not so easily eviscerated.

Plaintiffs' alleged authority for its Medicaid-payor theory, *Texas v. United States*, 50 F.4th 498, 517-20 (5th Cir. 2022), relied on a much different—and less attenuated—causal chain. It involved a challenge to a policy alleged to increase a State's Medicaid costs by increasing the total number of people on that State's Medicaid rolls. The State's theory did not rely on any supposition that those additional Medicaid enrollees would engage in a particular activity or suffer a particular type of injury. By contrast, Louisiana alleges that the 2023 REMS Modification leads more women who are already on its Medicaid rolls to use a specific drug, which in turn causes some of them to suffer specific types of adverse events, which in turn causes those women to seek medical care, which in turn generates costs that doctors and hospitals then pass on to the State. That is the sort of theory that *Alliance for Hippocratic Medicine* rejected as too attenuated, and so it fails here, too.

3. Louisiana cannot sue the Federal Government as *parens patriae*

Finally, in its Complaint (though not in its motion for preliminary relief), Louisiana asserts standing based on "quasi sovereign" interests in protecting Louisianans. Compl. ¶¶ 120-131. But the Supreme Court has expressly held that "States do not have standing as *parens patriae* to bring an action against the Federal Government." *Murthy*, 603 U.S at 76 (quotation marks omitted); *see also Haaland v. Brackeen*, 599 U.S. 255, 294-95 & n.11 (2023).

Recognizing this, Louisiana eschews the label "*parens patriae*" and disclaims "asserting the rights of its citizens." Compl. ¶ 131. This is just "'a thinly veiled attempt to circumvent the limits on *parens patriae* standing.'" *Murthy*, 603 U.S. at 76 (quoting *Brackeen*, 599 U.S. at 295 n.11). The Complaint plainly asserts a *parens patriae* theory based on "direct injuries to pregnant Louisiana women" and "fatal injuries to [] unborn babies." Compl. ¶ 129; *see Washington*, 108 F.4th at 1178 ("Idaho alleges that elimination of the in-person dispensing requirement will endanger specific pregnant women who take the drug and 'unborn children' subjected to its effects. These allegations concern the well-being of individual citizens—not a distinct interest of the state as a whole."). Whatever label is applied, this theory remains disapproved by the Supreme Court.

B. Ms. Markezich lacks standing

For her part, Ms. Markezich avers standing because her former boyfriend allegedly forced her to take mifepristone to end a pregnancy. Compl ¶¶ 150-59; Pl. Mot. 23 n.5. That past injury (though of course tragic) is not redressable by the prospective relief she seeks. *See All. for Hippocratic Med.*, 602 U.S. at 381 (explaining that a plaintiff seeking "prospective relief" must establish "a sufficient likelihood of future injury"). Seeking to avoid that problem, Ms. Markezich alleges that she "could be placed in the same position for future pregnancies." Compl. ¶ 155. But such speculation (including about the actions of third parties) is insufficient to satisfy the injury-in-fact requirement. *See, e.g.*, *City of L.A. v. Lyons*, 461 U.S. 96, 108 (1983) (finding no case or controversy where it was "no more than speculation to assert" that the plaintiffs "will be" subject to the allegedly unlawful conduct in the future). Also, her theory of causation—that the

2023 REMS Modification is ultimately responsible for Ms. Markezich's boyfriend obtaining mifepristone from an out-of-state prescriber under false pretenses and then coercing her into taking the drug, *see* Compl. ¶¶ 150-52—is exactly the kind of attenuated theory rejected in *Alliance for Hippocratic Medicine*. *See* 602 U.S. at 385-393.

CONCLUSION

For the foregoing reasons, the Court should stay this case pending FDA's review and deny Plaintiffs' motion without prejudice.

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