UNITED STATES DISTRICT COURT
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.*	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

PLAINTIFFS STATE OF LOUISIANA AND ROSALIE MARKEZICH'S MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR PRELIMINARY RELIEF UNDER 5 U.S.C. § 705

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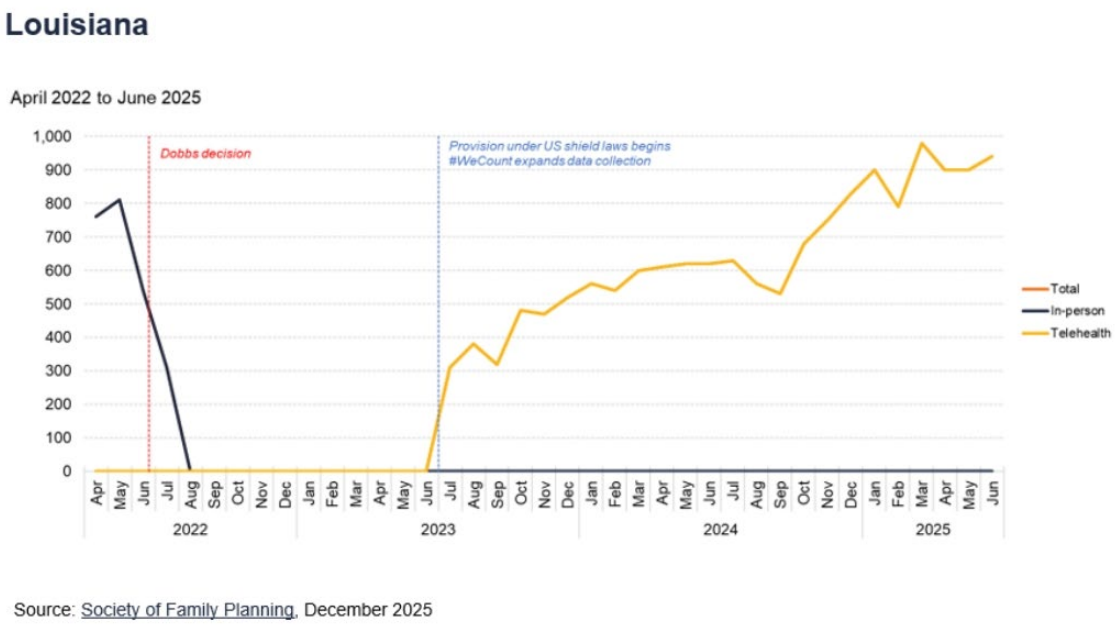
INTRODUCTION

This case presents one of the most profoundly important issues threatening Louisiana's sovereignty, its values, and its people. In *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the Supreme Court "expressly returned the issue [of abortion] to the States." *Louisiana v. EEOC*, 784 F. Supp. 3d 886, 905 (W.D. La. 2025). States, like Louisiana, had laws on the books that sprang into effect broadly prohibiting abortion unless necessary to save the mother's life. President Biden knew this. So he ordered his administration to end-run *Dobbs* by finding every possible means to facilitate abortion in pro-life states. Relevant here, his Food and Drug Administration (FDA) carried out that directive by promulgating a Risk Evaluation and Mitigation Strategy for the abortion drug mifepristone (the 2023 REMS). The 2023 REMS removed a longstanding in-person dispensing requirement. Why? So doctors in states like New York and California could prescribe and mail FDA-approved mifepristone into pro-life states, causing abortions that otherwise would not occur.

The results are sobering. Hundreds of mifepristone-induced abortions are occurring in Louisiana *every month*. Until now, available data suggested that 800 abortions in December 2024 were a high watermark. ECF 1-2 at PowerPoint slide 35. But that number was a floor. As of about a week ago, new data show that the monthly number often crested 900, and reached nearly 1,000, in 2025:



Source: Society of Family Planning, December 2025

Ex. 1, #WeCount Report April 2022 to June 2025 (Dec. 9, 2025), perma.cc/AYJ2-FYJ2; Ex. 2, #WeCount Report Summary Slides with National and 51 State-Level Findings April 2022 to June 2025 (Dec. 9, 2025), perma.cc/83U9-TC79; Ex. 3, Abigail R. A. Aiken et al., Research Letter, *Provision of Abortion Medications Using Online Asynchronous Telemedicine Under Shield Laws in the US*, 334(15) JAMA 1388 (Oct. 21, 2025), https://doi.org//10.1001/jama.2025.11420; Ex. 22, New Decl. at 1–2.

That is why this case is so important. Plaintiffs are the State of Louisiana and Rosalie Markezich, a Louisiana resident whose ex-boyfriend ordered mifepristone from a California doctor, received it by mail, and coerced Rosalie to take it, ending her baby's life. This lawsuit challenges the 2023 REMS as unlawful under the Administrative Procedure Act (APA) and seeks to vacate the 2023 REMS to restore the in-person dispensing requirement. There is no serious question that the 2023 REMS is unlawful. Secretary Robert F. Kennedy, Jr., and FDA Commissioner Martin A. Makary both admit that there was a "lack of adequate consideration" of the safety risks "underlying the prior REMS approvals," including the decision to "remov[e] the in-person dispensing requirement." ECF 1-110 at 2. And in fact, two Fifth Circuit panels have addressed this problem, holding—in suits filed by doctors and medical associations—that the 2023 REMS is likely unlawful. *See All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725, at *17–18 (5th Cir. Apr. 12, 2023) (*Alliance I); All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 249–51 (5th Cir. 2023) (*Alliance II*), *rev'd and remanded on other grounds*, 602 U.S. 367 (2024) (*Alliance*). The Supreme Court later reversed, solely on the ground that those plaintiffs lacked Article III standing—but the Court thought it was "not clear that no one else would have standing." *Alliance*, 602 U.S. at 396.

The only real question in this case, therefore, is whether Plaintiffs have standing to challenge the 2023 REMS, which the Fifth Circuit already determined is likely unlawful. They unquestionably do. Most notably, this is a smoking-gun case where the public record reflects the Biden Administration's avowed intent to "interfere[ ] with [pro-life] States' abilities to enforce their laws and implement the chosen public policies of their citizens"—by unlawfully removing the in-person dispensing requirement for the sole purpose of allowing out-of-state doctors to facilitate illegal mail-order abortions in pro-life states like Louisiana. *Louisiana*, 784 F. Supp. 3d at 897 (citation modified).

It is difficult to imagine a federal action that is more "destructive of state sovereignty," *id.* at 901 (citation modified), particularly one that ends the lives of hundreds of unborn Louisiana children, like Rosalie's, every month. On top of that, Louisiana has suffered, and continues to suffer, a classic pocketbook injury from the 2023 REMS in the form of hundreds of thousands of dollars in increased Medicaid costs attributable to mifepristone-induced abortions that have required emergency care—costs that would not be incurred but for the 2023 REMS.

This case is hard to swallow because of its egregious facts—but it is easy to resolve on the merits and standing. As the Fifth Circuit previously directed, the proper route is to enter a preliminary stay of the 2023 REMS under 5 U.S.C. § 705 and ensure that the "in-person dispensing requirements, and FDA's obligation to enforce them, will continue to apply." *Alliance II*, 78 F.4th at 254.

BACKGROUND

A. "The Louisiana Legislature has expressly set forth the State's policy with respect to abortion." *Louisiana*, 784 F. Supp. 3d at 895 n.10. The State's policy is "that every unborn child is a human being from the moment of conception"—and accordingly, the Legislature has "declare[d] that the longstanding policy of this state [is] to protect the right to life of every unborn child from conception." *Id.* (quoting La. R.S. 40:1061.1). Following *Dobbs*, Louisiana law "prohibits all abortions except those that are determined to be medically necessary to prevent the death or substantial risk of death of the mother," with other narrow exceptions. *Louisiana*, 784 F. Supp. 3d at 895 n.10 (citing La. R.S. 40:1061, 14:87.7, 14:87.8.1). Relevant here, that includes a prohibition on abortion "by means of an abortion-inducing drug." La. R.S. 14:87.9.

Stunningly, however, hundreds of abortions occur every month in Louisiana. That is the direct and intended consequence of a drug war authorized by President Biden's FDA. The same day the Supreme Court decided *Dobbs*, President Biden announced a whole-of-government attack on states that choose to ban or otherwise restrict abortion. In particular, he identified "threats from state officials saying they will try to ban or severely restrict access to medication for reproductive health care." ECF 1-47 at 3. He followed that up with Executive Order No. 14,076 of July 8, 2022, Protecting

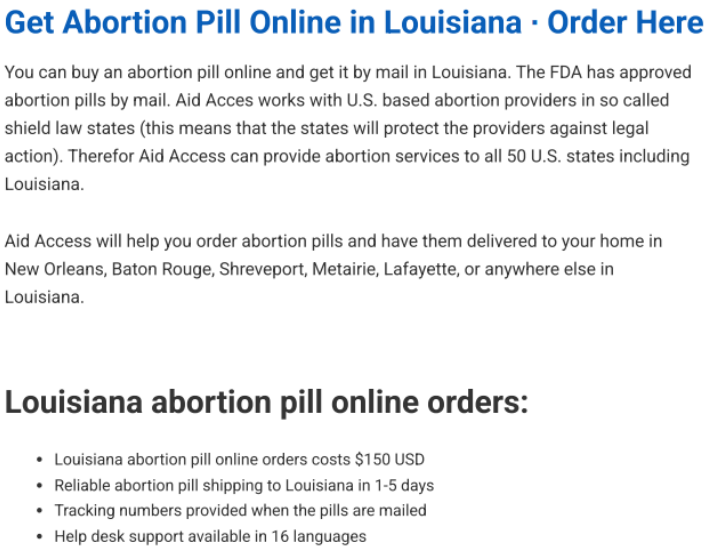
Access to Reproductive Health Care Services, 87 Fed. Reg. 42053 (July 13, 2022), which promised "abortion care, including medication abortion"—"especially for those who live in States that are banning or severely restricting abortion care." ECF 1-44 at 2; *see* ECF 1-45 (Executive Order No. 14,079 of Aug. 3, 2022, Securing Access to Reproductive and Other Healthcare Services, 87 Fed. Reg. 49505 (Aug. 11, 2022), challenging "the continued advancement of restrictive abortion laws in States across the country" and announcing a policy to protect "medication abortions").

Abortion "medication" is code for the FDA-approved abortion drug mifepristone. President Biden "directed the Secretary of Health and Human Services" (and thus FDA) "to identify all ways to ensure that mifepristone is as widely accessible as possible ... *including when prescribed through telehealth and sent by mail*." ECF 1-47 at 3 (emphasis added); ECF 1-60 at 2–3 (President Biden's fact sheet claiming that "states may not ban mifepristone" and promising "to allow mifepristone to continue to be prescribed by telehealth and sent by mail"). That directive was significant because, until the COVID-19 pandemic, FDA required mifepristone to be dispensed in person; in 2021, the Biden FDA cited its enforcement discretion to temporarily "not enforce the in-person dispensing requirement" and thereby facilitate "the dispensing of mifepristone through the mail" (the 2021 Non-Enforcement Decision). *See Alliance II*, 78 F.4th at 222, 226 (citation modified). In the wake of *Dobbs*, that temporary position gave way to the Biden Administration's vow that it would "ensure every American has access to ... medication abortion." ECF 1-48 at 2. "[W]e will double down," then-Secretary Becerra said, "and use every lever we have to protect access to abortion care." *Id.*; *see also* ECF 1-49 at 2, 4; ECF 1-61 at 4, 7; *accord* ECF 1-59 at 2 ("Since *Dobbs*, HHS has worked to protect and expand access to reproductive care amidst unprecedented efforts by Republican officials at the national and state level to restrict access to abortion[.]"). Fulfilling that promise, the Biden FDA issued the 2023 REMS in January 2023, ECF 1-3 at 2; ECF 1-50 at 9, 16, which permanently "formalize[d] the removal of the in-person dispensing requirement," "allow[ing] mifepristone to be prescribed remotely and sent via mail." *Alliance II*, 78 F.4th at 226; *accord Alliance I*, 2023 WL 2913725, at *2; Ex. 21, Francis Decl. ¶ 19.

B. That targeted assault on pro-life states worked as intended. While in-person abortions virtually vanished from Louisiana, mifepristone-induced abortions—authorized by out-of-state

doctors mailing FDA-approved mifepristone—skyrocketed. Said one mifepristone mailer: "We really don't change things unless we're legally required to." ECF 1-106 at 2. "We're confident people in … every state … will still be able to get abortion pills by mail," said another. *Id.* at 3.

To carry out this plan, organizations like AidAccess.org have blanketed the Internet with order forms for FDA-approved mifepristone, ECF 1-71, extolling the ease with which New York and California doctors may inject pills into locales from Baton Rouge to Lafayette:



Get Abortion Pill Online in Louisiana · Order Here

You can buy an abortion pill online and get it by mail in Louisiana. The FDA has approved abortion pills by mail. Aid Acces works with U.S. based abortion providers in so called shield law states (this means that the states will protect the providers against legal action). Therefor Aid Access can provide abortion services to all 50 U.S. states including Louisiana.

Aid Access will help you order abortion pills and have them delivered to your home in New Orleans, Baton Rouge, Shreveport, Metairie, Lafayette, or anywhere else in Louisiana.

Louisiana abortion pill online orders:

- Louisiana abortion pill online orders costs $150 USD
- Reliable abortion pill shipping to Louisiana in 1-5 days
- Tracking numbers provided when the pills are mailed
- Help desk support available in 16 languages

When Louisiana filed this suit, the available data showed a monthly abortion rate that fluctuated between 300 and 600, with an apparent high watermark of just over 800 abortions in December 2024 alone. ECF 1-2 at 36. Last week, however, new data revealed that 800 mifepristone-induced abortions per month was *the minimum* in Louisiana in 2025; more frequently, that monthly number was approximately 900, and nearly 1,000 in March 2025. Ex. 2, #WeCount Report Summary Slides, *supra* pp. 1–2; Ex. 22, New Decl. at 1–2.

There are real women and real-world harms behind those numbers. *See, e.g.*, Ex. 23, Parise Decl. ¶¶ 8–13, 15–16, 17–20; Ex. 18, Voltz Decl. ¶¶ 8–12; Ex. 19, Richard Decl. ¶¶ 2–9; Ex. 24, Sikes Decl. ¶¶ 2–8 (testifying to dozens of women who took or received mifepristone from out-of-state prescribers). Just take Plaintiff Rosalie Markezich, who did not want an abortion. ECF 1-92 at ¶ 16. She told her then-boyfriend that she wanted to raise their unborn baby. *Id.* ¶¶ 5, 11. Yet he went online

in late 2023, filled out a form with her information, gave her money to pay a California doctor through Venmo, and had the drug mailed to her Louisiana home. *Id.* ¶¶ 7, 8, 9. She pleaded, "Don't make me do this." *Id.* ¶ 11. But he grew angry and volatile, and Rosalie was so terrified that she thought taking the drugs was her only route to safety. *Id.* ¶¶ 12, 13. She ended up on a bathroom floor for an hour, and then a garage floor, as she began bleeding—an unspeakable experience that continued "for about a week" and "still haunts [her]." *Id.* ¶¶ 14, 15, 18. She mourns her child. *Id.* ¶ 17.

Rosalie is not alone. Consider the well-known story of Margaret Carpenter, a New York doctor who mailed mifepristone to a Louisiana woman who forced the drug on her pregnant teenage daughter. ECF 1-4, 1-83 to 1-86. The teen faced a medical emergency alone at home, called 911, and was rushed to the hospital in an ambulance after delivering a dead fetus. ECF 1-86. Or, consider data from the Louisiana Department of Health showing that over $92,000 in Medicaid dollars were paid for emergency room care and hospitalization resulting from just *two* mifepristone-induced abortions in 2025. Ex. 20, Willis Decl. ¶¶ 11–12. And these instances are just two examples of many women believed to have suffered similar adverse events requiring emergency medical care at Louisiana hospitals, paid for by Louisiana Medicaid. *Id.* ¶ 13.

These stories are not just disturbing but entirely predictable. That is because, as the Fifth Circuit previously held, the federal government's "own documents" show that "emergency room care is statistically certain" in mifepristone cases. *Alliance I*, 2023 WL 2913725, at *10. For example, FDA's own mifepristone label warns that roughly 1 in 25 (or 4% of) women who take mifepristone *as directed* will end up in the emergency room. ECF 1-9 at 8–9, 16; Ex. 21, Francis Decl. ¶¶ 30–31. And this was *before* the Biden Administration removed the requirement for an initial in-person visit—the only opportunity to screen for dangerous conditions like ectopic pregnancy, to accurately assess gestational age, to screen for coercion and trafficking, and to ensure informed consent. Ex. 21, Francis Decl. ¶¶ 22–28, 41, 49. The label also features a black box warning that mifepristone can cause "[s]erious and sometimes fatal infections and bleeding," and mifepristone can cause other problems warranting emergency attention. ECF 1-9 at 2; Ex. 21, Francis Decl. ¶¶ 31–32, 38, 42–48. What's more, there is good reason to believe that the emergency-room-visit and hospitalization rate is at least as high as

11%, Ex. 21, Francis Decl. ¶ 34—and FDA's own data demonstrates that dispensing mifepristone by mail exacerbates that rate. *See* ECF 1-13 at 2; Ex. 4, Robin Wallace et al, *P040 - Expanding Access to Abortion with Mifepristone and Misoprostol Through 84 Days Estimated Gestational Duration*, 151 Contraception 111117 (Nov. 2025), perma.cc/KXC7-9TFA; *see also* ECF 1-50 at 75; ECF 1-10 at 34–35. It is thus unsurprising that the flood of mifepristone into Louisiana under the 2023 REMS is directly resulting in life-threatening harm to Louisiana women and babies, as well as identifiable sovereign and monetary harms to Louisiana itself.

C. Because of the seriousness of this issue, Louisiana has expended substantial time and resources attempting to stop the mailing of mifepristone into the State. Among Louisiana's efforts are outstanding arrest warrants for Dr. Carpenter and the California doctor Rosalie's ex-boyfriend engaged, Dr. Remy Coeytaux. ECF 1-84; ECF 1 at 46, ¶ 159. But, as predicted, governors in states like New York and California have pursued every avenue available to thwart pro-life states from stopping the mifepristone flood. New York Governor Kathy Hochul, for example, refused to extradite Dr. Carpenter: "Let me be clear: we will never comply with Louisiana's extradition request. Not now, not ever." ECF 1-90. New York and other states have also passed aggressive "shield" laws that, among other things, permit doctors and clinics to omit identifying information from pill bottles—so that a pill bottle with mifepristone can arrive in Louisiana without indicating who sent it. *See, e.g.*, Ex. 5, *Governor Newsom Signs New Landmark Laws to Protect Reproductive Freedom, Patient Privacy Amid Trump's War on Women*, Gov. Gavin Newsom (Sep. 26, 2025), perma.cc/SB5E-V4QB (California law giving doctors "the option to prescribe abortion care medication to patients anonymously"). The stated intent: to prevent pro-life states from stopping the importation of abortion drugs.

Because of those difficulties, Louisiana and Rosalie tried a different tack on September 19, 2025, when they filed a motion to intervene in the still-pending *Alliance* litigation. *See* Rosalie Markezich and the State of Louisiana's Motion for Leave to Intervene and Memorandum in Support, *Missouri v. FDA*, No. 22-cv-223 (N.D. Tex. Sep. 19, 2025), ECF 264, 265. Following the Supreme Court's decision in *Alliance*, the states of Kansas, Idaho, and Missouri moved to intervene in the *Alliance* district court to continue the litigation—and Louisiana and Rosalie sought to join that fight.

On September 30, 2025, however, the *Alliance* district court transferred the case to the Eastern District of Missouri and denied Louisiana and Rosalie's intervention motion as moot. *Missouri v. FDA*, No. 22-cv-223, 2025 WL 2825980, at *1 (N.D. Tex. Sep. 30, 2025). Four business days later, Louisiana and Rosalie filed their Complaint in this Court. ECF 1. They seek a stay of the unlawful 2023 REMS that causes irreparable harm to Louisiana and its citizens every day.

The importance of a preliminary stay of the 2023 REMS has become blindingly clear in recent days. Under pressure from pro-life states and advocates, Secretary Kennedy announced on September 19, 2025, that, "through the FDA, HHS will conduct a study of the safety of the current REMS, in order to determine whether modifications are necessary." ECF 1-110 at 2. Yet on December 8, 2025, it was publicly reported that FDA Commissioner Marty Makary "has told agency officials to delay [a] safety review [of mifepristone] until after the midterm elections." Ex. 6, *US FDA Has Delayed Abortion Pill Safety Study, Bloomberg News Reports*, Reuters (Dec. 8, 2025, at 14:23 PT), perma.cc/DH8S-89TM. He later admitted that study data has not yet been acquired. Ex. 7, Elizabeth Troutman Mitchell, *EXCLUSIVE: Makary Responds to Report Saying He Slow-Walked Abortion Pill Safety Review*, Daily Signal (Dec. 9, 2025), perma.cc/AXP5-XTYS. In other words, FDA will not consider taking action on the 2023 REMS until 2027 at the earliest. And if FDA attempts to rescind or modify the 2023 REMS, the governing statutory framework imposes a timeline of nearly a year before that action could take effect. *See* 21 U.S.C. ¶ 355-1. So absent preliminary relief in this case, Louisiana and its citizens face the prospect of unbounded and illegal mifepristone-induced abortions for at least two more years if not longer. That is untenable. Preliminary relief is essential.

LEGAL STANDARD

Under the APA, Plaintiffs request a stay of the 2023 REMS or, alternatively, a preliminary injunction against Defendants' enforcement of the 2023 REMS. 5 U.S.C. § 705 (a court may stay an agency action "to the extent necessary to prevent irreparable injury"); Fed. R. Civ. P. 65. Plaintiffs are entitled to relief pending review if they show "(1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable harm if the injunction does not issue, (3) that the threatened

injury outweighs any harm that will result if the injunction is granted, and (4) that granting the injunction is in the public interest." *Clarke v. Commodity Futures Trading Comm'n*, 74 F.4th 627, 640–41 (5th Cir. 2023); *see Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1143–44 (5th Cir. 2021) (applying these factors to relief under the APA's Section 705).

ARGUMENT

I. The Stay Factors Are Easily Satisfied, as the Fifth Circuit Already Has Held.

A. Plaintiffs Are Likely to Succeed on the Merits.

Start with the merits—which two Fifth Circuit panels already have assessed and decided in Plaintiffs' favor. *See Alliance I*, 2023 WL 2913725, at *17–18; *Alliance II*, 78 F.4th at 249–51.[1] That is because the 2023 REMS is plainly unlawful for two reasons. *First*, as both panels held, the 2023 REMS is likely arbitrary and capricious and amounted to an abuse of discretion because it has no reasonable or reasoned scientific basis. 5 U.S.C. § 706(2)(A). *Second*, as Judge Ho explained in *Alliance II*, the 2023 REMS is "not in accordance with law" because it authorizes the mailing of abortion drugs, which is prohibited by federal law. 78 F.4th at 267 (Ho, J. concurring in part and dissenting in part) (quoting 5 U.S.C. § 706(2)(A); citing 18 U.S.C. § 1462(c)). For either or both of these reasons, Plaintiffs here—like the plaintiffs in the *Alliance* litigation—are likely to succeed on the merits.

1. The 2023 REMS is arbitrary and capricious (Count I).

Arbitrary-and-capricious review "has serious bite." *Louisiana v. Dep't of Energy*, 90 F.4th 461, 470 (5th Cir. 2024) (citation modified). It "requires that agency action be reasonable and reasonably explained," meaning that the agency "has reasonably considered the relevant issues and reasonably explained the decision." *Wages & White Lion*, 16 F.4th at 1136 (citation modified). "[B]are

[1] As the Complaint explains, ECF 1 at 48 n.200, the Fifth Circuit in *Alliance II* technically considered the 2021 Non-Enforcement Decision, not the 2023 REMS. But, as Chief Judge Elrod explained, the 2023 REMS "formaliz[ed]" the 2021 Non-Enforcement Decision and, in fact, that formalization kept the case alive since "[t]he decision that FDA made in 2021 … remains in force" through the 2023 REMS. 78 F.4th at 248. Because "the effect" of both the 2021 Non-Enforcement Decision and the 2023 REMS "is the same," the Fifth Circuit's analyses in *Alliance I* and *Alliance II* directly govern the 2023 REMS. *Id.*; *see supra* p. 4.

acknowledgement" of concerns and "conclusory statements" are "no substitute for reasoned consideration." *Louisiana*, 90 F.4th at 473. And when an agency changes its position, the agency must "recognize[ ] the change, reason[ ] through it without factual or legal error, and balance[ ] all relevant interests affected by the change," *id.* at 469, including reliance interests on the longstanding prior policy. *Wages & White Lion*, 16 F.4th at 1139.

In the 2023 REMS, FDA removed the in-person dispensing requirement with no legitimate justification for doing so. *Alliance I*, 2023 WL 2913725, at *17–18; *Alliance II*, 78 F.4th at 249–51. FDA's decision was based on two things: (a) an allegedly small number of adverse event reports in FDA's Adverse Event Reporting System (FAERS) database and from the drug sponsors; and (b) a review of the scientific literature. ECF 1-10 at 23. As discussed further below, all this was nonsense, not least because FDA elsewhere admitted that FAERS data is not reliable for purposes of evaluating safety and the scientific literature was inadequate. Indeed, Secretary Kennedy and Commissioner Makary have admitted that there was a "lack of adequate consideration" of the safety risks "underlying the prior REMS approvals," including the decision to "remov[e] the in-person dispensing requirement." ECF 1-110 at 2; *see* ECF 1-108 ("The Biden administration removed mifepristone's in-person dispensing rule without studying the safety risks."); Ex. 8, Ian Lopez, *RFK Jr. Says Biden 'Twisted the Data' on Abortion Pill Safety,* BL (Sep. 4, 2025, at 12:45 ET), perma.cc/ST5H-94H6 ("We know that during the Biden administration, they actually twisted the data, to bury one of the safety signals, a very high safety signal, around 11%, so we're going to make sure that that doesn't happen anymore."); Ex. 9, U.S. Senator Bill Cassidy, M.D. (@SenBillCassidy), X (Dec. 12, 2025, at 13:05 PT), perma.cc/LR7T-9UZT (archived Dec. 13, 2025). That admission, combined with the *Alliance I* and *Alliance II* decisions, makes for an easy merits determination in Plaintiffs' favor.

a. FAERS Data. Start with the FAERS data from 2020 and 2021 that FDA invoked. ECF 1-10 at 25. This is difficult to recount with a straight face. *Alliance I*, 2023 WL 2913725, at *17. FDA had already told the public that FAERS data was not a reliable source for the number of adverse events. That is, in part, because the "[r]ates of occurrence [for an adverse event] cannot be established with [FAERS] reports." ECF 1-52 at 5. Because reporting is voluntary, "FDA does not receive reports for

every adverse event ... that occurs." ECF 1-52 at 5. FDA even cautions on its website that (i) "[t]he number of suspected reactions in FAERS should not be used to determine the likelihood of a side effect occurring"; and (ii) "FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population." *Id.* at 3. Summarizing the utility (or lack thereof) of the data, FDA has said that "the FAERS data by themselves are not an indicator of the safety profile of the drug." *Id.* at 5. Just last week, Commissioner Makary dismissed the quality of this mifepristone data, saying, "There are studies that are done using adverse events, self-reported data. But that data's not very good.... When you do a study based on self-reported data, you're not capturing a lot of the data that you wanna know in a study." Ex. 10, Video posted by Elizabeth Mitchell Troutman (@TheElizMitchell), X, at 02:02–2:19 (Dec. 9, 2025, at 14:56 PT), perma.cc/Q9CV-8FDN.

This defect alone drives a stake through the 2023 REMS. As the Fifth Circuit reasoned, because FAERS does not accurately reflect the number of adverse events and does not indicate mifepristone's safety profile, FDA's reliance on it was plainly arbitrary and an abuse of discretion. *Alliance II*, 78 F.4th at 250. Indeed, "FDA's decision to rely so heavily on data from FAERS 'runs counter to' the critical limitations associated with that data." *Id.*

But there is more: The deficiencies in the FAERS data *are of FDA's own making*. FDA had removed the requirement that abortion prescribers report serious adverse events other than death to FDA—this stripped the FAERS database of actual reporting of non-fatal adverse events. ECF 1-11 at 5–10, 28. Faced with that fact, the Fifth Circuit expressed disbelief that, "[a]fter eliminating th[e] adverse-event reporting requirement [in 2016], FDA turned around in 2021 and declared the absence of non-fatal adverse-event reports means mifepristone is 'safe.'" *Alliance I*, 2023 WL 2913725, at *17. "This ostrich's-head-in-the-sand approach is deeply troubling," it said, "especially on a record that, according to [FDA's] own documents, necessitates a REMS program, a 'Patient Agreement Form,' and a 'Black Box' warning." *Id.* "And it suggests FDA's actions are well outside the zone of reasonableness." *Id.* (citation modified). For those reasons, the Fifth Circuit emphasized that "[i]t's unreasonable for an agency to eliminate a reporting requirement for a thing and then use the resulting

absence of data to support its decision"—and thus "it [is] unlikely that plaintiffs' arbitrary-and-capricious challenges will fail on the merits." *Id.* at *17–18; *accord Alliance II*, 78 F.4th at 249–50.

Perhaps sensing this problem, FDA also considered adverse event data submitted by the drug manufacturers. But that data "was exactly the same as the data FDA obtained from FAERS," *Alliance II*, 78 F.4th at 250, suffered from the same flaws, and thus provided no independent justification for removing the in-person dispensing requirement. *See* ECF 1-10 at 28. And that was damning: "If anything, the fact that [mifepristone's manufacturer] submitted identical data tends to confirm the assertion that FDA lacked sufficient information[.]" *Alliance II*, 78 F.4th at 250.

As this straightforward analysis shows, Secretary Kennedy and Commissioner Makary were exactly right to admit that there was a "lack of adequate consideration" of the safety risks surrounding the decision to "remov[e] the in-person dispensing requirement." ECF 1-110 at 2. On the FAERS ground alone, Plaintiffs are all but certain to succeed on their challenge to the 2023 REMS—just as *Alliance I* and *Alliance II* held.

b. Scientific Literature. To add "extra icing on a cake already frosted," *Yates v. United States*, 574 U.S. 528, 557 (2015) (Kagan, J., dissenting), the 2023 REMS is independently arbitrary and capricious because no scientific literature actually "supported" removing the in-person dispensing requirement. *Alliance I*, 2023 WL 2913725, at *17; *see Alliance II*, 78 F.4th at 250 ("The second defect ...is that it relied on various literature relating to remote prescription of mifepristone—despite FDA's admission that the literature did not affirmatively support its position.").

FDA admitted that the studies it considered were "not adequate on their own to establish the safety of ...dispensing mifepristone by mail." ECF 1-10 at 36; *cf.* 21 U.S.C. § 355(d)(1) (directing FDA to reject drug applications that "do not include adequate tests"). The most FDA could say was that "the literature was only 'not inconsistent with [its] conclusion.'" *Alliance II*, 78 F.4th at 250; ECF 1-10

at 29. FDA thus conceded that "the studies neither confirmed nor rejected the idea that mifepristone would be safe if the in-person dispensing requirement were removed." *Alliance II*, 78 F.4th at 250.[2]

That makes this an extraordinarily easy arbitrary-and-capricious case: "Especially in light of the unreliability of the adverse-event data, it was not reasonable for FDA to depend on the published literature to support its decision." *Id.* "Courts must set aside agency action," the Fifth Circuit summed up, "where there are shortcomings in the agency's explanations or where no record evidence affirmatively makes' the agency's case." *Id.* (citation modified). "That is the case here":

> In the face of concededly limited data, and lacking more probative information from prescribers, FDA fell back on studies that were merely 'not inconsistent' with its intended conclusion. It did not refer to any literature that affirmatively supported the notion that mifepristone would remain safe and effective even without the in-person dispensing requirement.

Id. at 250–51. Accordingly, Plaintiffs "are likely to succeed in showing that [the 2023 REMS] violated the APA." *Id.*

2. The 2023 REMS violates the Comstock Act (Count II).

Although the Court need not proceed further, Judge Ho identified in *Alliance II* a separate reason why the 2023 REMS is unlawful—namely, that the 2023 REMS violates the Comstock Act and thus is not in accordance with law. *See Alliance II*, 78 F.4th at 267–70 (Ho, J., concurring in part and dissenting in part); *id.* at 251 n.8 (maj. op.) (declining to consider this issue); *see also Alliance I*, 2023 WL

[2] Two aspects of those studies warrant additional emphasis. *First*, it is not hard to see why FDA carefully qualified its statements about them—as the Fifth Circuit explained, "FDA recognized many significant limitations" in the studies, including that they could not be "generalize[d]" to the general United States population. *Alliance II*, 78 F.4th at 250. *Second*, if anything, the studies actually showed *increased* risk of harm from removing the in-person dispensing requirement. FDA admitted that "the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic." ECF 1-10 at 35. And in fact, the studies showed that as many as 1 in 8 women would need unplanned medical care if the in-person dispensing requirement were eliminated. *Id.* at 33–34. FDA's only response to these alarming figures was a nonanswer: that "there are no apparent increases in *other* significant adverse events related to mifepristone use." *Id.* at 36 (emphasis added). FDA never explained why the high rates of emergency-room visits were not themselves red flags. Nor did it identify what other serious adverse events it had in mind. Those defects, too, mean the 2023 REMS is well "outside the zone of reasonableness." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 428 (2021).

2913725, at *20–21 (all but agreeing on the violation of the Comstock Act yet determining that the panel "need not definitively interpret the Comstock Act to resolve this stay application").

Through the Comstock Act, Congress prohibited the use of the mail or "any express company or other common carrier or interactive computer service" for "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion." 18 U.S.C. §§ 1461–62. And FDA cannot authorize conduct that violates federal law. "The Administrative Procedure Act requires federal courts to set aside federal agency action that is 'not in accordance with law,' 5 U.S.C. § 706(2)(A)—which means, of course, *any* law, and not merely those laws that the agency itself is charged with administering." *FCC v. Next Wave Pers. Commc'ns, Inc.*, 537 U.S. 293, 300 (2003). Thus, under the plain terms of the Act, "the mailing of abortifacient drugs" is illegal, as is "us[ing] the internet to ship or receive abortifacients." *Alliance II*, 78 F.4th at 267 (concurring in part and dissenting in part). The 2023 REMS thus "violates the Comstock Act" because it "authorizes the dispensing of mifepristone 'through the mail ... or through a mail-order pharmacy.'" *Id.*

To date, FDA's sole defense has been to "argue that the Comstock Act does not mean what it says." *Alliance I*, 2023 WL 2913725, at *21. Yet as Judge Ho explained, the 2023 REMS is "precisely what the Comstock Act prohibits." *Alliance II*, 78 F.4th at 268 (concurring in part and dissenting in part). Indeed, whereas the 2021 Non-Enforcement Decision was only temporary, the 2023 REMS "doubles down on this violation by permanently eliminating the in-person dispensing requirement" and thus permitting doctors and others to "ship mifepristone to its users." *Id.* That is a direct violation of federal law. And thus, there can be no question that the 2023 REMS violates the APA.

B. The Remaining Stay Factors Favor Plaintiffs.

As the *Alliance II* panel determined, the remaining stay factors also favor a stay of the 2023 REMS. "[N]either FDA nor the public has any interest in enforcing a regulation that violates federal law"—and there is no dispute that the 2023 REMS violates federal law. *Id.* at 251 (maj. op.). "In this regard, the government/public-interest analysis collapses with the merits." *Id.* And because Plaintiffs "are likely to succeed on their claims as to" the 2023 REMS, "[i]t follows that FDA and the public will not be injured by an order staying th[at] likely unlawful action[ ]." *Id.* at 251–52. Indeed, that is

especially so because "the public interest is disserved by a drug that does not afford adequate protections to its users," which is the case here since FDA promulgated the 2023 REMS "without sufficient consideration of the effects those changes would have on patients." *Id.* at 253.

With nothing on FDA's side of the ledger, the mountain of irreparable harm to Plaintiffs carries the day. That includes hundreds of thousands of dollars in Medicaid costs that Plaintiff Louisiana is currently incurring due to the influx of mifepristone-induced abortions resulting in emergency room visits. *See infra* Section II.A(2). Those "[m]onetary harm[s] cannot be remedied where, as here, the defendant[s] [are] entitled to sovereign immunity." *Alliance II*, 78 F.4th at 251 (citing *Wages & White Lion*, 16 F.4th at 1142). Those "economic injuries" are thus, by definition, "irreparable." *Id.*; *accord Louisiana v. EEOC*, 705 F. Supp. 3d 643, 653 (W.D. La. 2024) (collecting cases). But "more fundamental" is irreparable harm in the form of the 2023 REMS's "interfere[nce] with [Louisiana's] ability to enforce [its] laws and implement the chosen public policies of [its] citizens." *Louisiana*, 705 F. Supp. 3d at 653. As discussed above and below, *see infra* Section II.A, the avowed purpose of the 2023 REMS was to override pro-life states' chosen public policies—to facilitate the mailing of FDA-approved mifepristone into those states so that abortion may persist with impunity. Louisiana suffers irreparable sovereign harm from that gambit every time an unborn Louisiana child loses her life through an illegal, mifepristone-induced abortion. "Because the principles of federalism afford the states a sovereign interest in creating and enforcing their own laws and public policy, [Louisiana] clearly" faces ongoing, irreparable harm from the 2023 REMS. *Louisiana*, 705 F. Supp. 3d at 654; *id.* at 663 (finding Article III standing and irreparable harm "[f]or the same reasons").

On top of this, the current and future harm for the unborn lives at stake is obvious. A life hanging in the balance presents perhaps "the most irreparable of harms." *Barr v. Lee*, 591 U.S. 979, 986 (2020) (Sotomayor, J., dissenting from vacatur of stay). Because Louisiana has a "legitimate interest[ ]" in the "preservation of prenatal life," *Dobbs*, 597 U.S. at 301—and because Louisiana law expressly protects "every unborn child [as] a human being from the moment of conception," *Louisiana*, 784 F. Supp. 3d at 895 n.10—there can be no question that the public interest favors staying the 2023 REMS and preventing the termination of these lives. The same goes for women like Rosalie who find

themselves in unspeakable situations where they are forced to end their babies' lives—and for women who willingly take the drug but wind up in an emergency room fighting for their own lives. These tragedies are possible only because the 2023 REMS authorizes the mailing of FDA-approved mifepristone into Louisiana. Thus, again, there can be no question that a stay is in the public interest.

C. A Universal § 705 Stay Is the Proper Preliminary Remedy.

1. Because the preliminary-relief factors are satisfied, the only remaining question is the proper form of preliminary relief. The Fifth Circuit spoke to that issue, too, in *Alliance II*, holding that a universal stay under 5 U.S.C. § 705 was warranted. The Fifth Circuit reached that conclusion by focusing on vacatur—the default relief in an APA action, which "effectively rescinds the unlawful agency action." *Alliance II*, 78 F.4th at 254. The Fifth Circuit explained that, "[i]n the same way that a preliminary injunction is the temporary form of a permanent injunction, a stay is the temporary form of vacatur." *Id.* Vacatur is a "'less drastic remedy'" than an injunction "because vacatur does not order the defendant to do anything; it only removes the source of the defendant's authority." *Id.* (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010); *accord Louisiana*, 784 F. Supp. 3d at 910 (an injunction "is neither required nor permitted" if vacatur is "sufficient to address the injury" (citation modified)). And "[k]eeping with the preliminary-permanent injunction analogy," a stay (rather than a preliminary injunction) is the least drastic temporary remedy because it simply "temporarily voids the challenged authority." *Alliance II*, 78 F.4th at 254.

Applying these principles, the *Alliance II* court held that the "appropriate form of relief" was a universal § 705 stay. *Id.* "Practically speaking," that meant FDA-approved mifepristone and its generic equivalent would be distributed "under the conditions that were in effect before" the challenged agency action. *Id.* FDA actions in 2016 also were at issue in *Alliance II*, and so the stay there returned FDA to pre-2016 conditions. *Id.* That meant "[t]he in-person dispensing requirements, and FDA's obligation to enforce them"—which existed before the stayed 2021 Non-Enforcement Decision and 2023 REMS—"will continue to apply." *Id.* The Fifth Circuit also made clear that this universal stay was preferable to a preliminary injunction because "a stay does not actively prohibit conduct, and so does not carry the same threat of contempt." *Id.*

The same route is appropriate here. A universal § 705 stay of the 2023 REMS is the least drastic remedy. Granting such relief would simply mean that the in-person dispensing requirement that existed for well over a decade before the 2021 Non-Enforcement Decision and 2023 REMS "will continue to apply." *Id.* The Court need only cite *Alliance II* to say as much.

2. The Supreme Court's recent decision on universal *injunctions* in *Trump v. CASA, Inc.*, 606 U.S. 831 (2025), has no bearing here. That is because the injunctions at issue in *CASA* were for strictly *equitable* relief—so a federal court's authority to issue universal injunctions was necessarily bounded by inherent and historical limitations on the courts' "equitable authority" "under the Judiciary Act of 1789." *Id.* at 841 & n.4; *see id.* (emphasizing that *CASA* "rests solely" on that specific statutory authority). By contrast, a § 705 remedy under the APA is *legal* relief authorized by Congress to temporarily address invalid agency actions. *See, e.g.*, *Griffin v. HM Fla.-ORL, LLC*, 144 S. Ct. 1, 2 n.1 (2023) (Kavanaugh, J., statement respecting the denial of application) (The APA "empower[s] the judiciary to act directly against the challenged agency action."). Thus, even after *CASA*, "[u]niversal remedies under the APA ... remain within Article III limits because they are legal, not equitable, remedies created by Congress." Ex. 11, T. Elliot Gaiser et al., *The Truth of Erasure: Universal Remedies for Universal Agency Actions*, U. Chi. L. Rev. Online (Aug. 28, 2024), at *11, perma.cc/Y4C6-G7ZX.

That is especially so because, as this Court has recognized, "[i]t is [ ] clear that the scope of ultimate relief under Section 706 is not party-restricted, but rather directs federal courts to wholly 'set aside' unlawful agency action." *Louisiana*, 784 F. Supp. 3d at 910 (citing *Career Colls. & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024)). Because a § 705 stay is "the temporary form of vacatur," *Alliance II*, 78 F.4th at 254, a § 705 stay likewise is not party-restricted. Accordingly, the Court need only enter the same universal § 705 stay of the 2023 REMS that the *Alliance II* Court entered to resolve the case at this preliminary stage.

II. Plaintiffs Have Article III Standing.

The only remaining question is whether Plaintiffs here, unlike the *Alliance* plaintiffs, have Article III standing to challenge the 2023 REMS. "For the same reasons" they have established irreparable harm, they have Article III standing. *Louisiana*, 705 F. Supp. 3d at 663. A plaintiff has

standing when she shows "(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." *Alliance*, 602 U.S. at 380. Plaintiffs have suffered sovereign, pocketbook, and bodily harms from the 2023 REMS's authorization of mail-order abortions occurring in Louisiana. Those injuries are directly traceable to—and indeed are the intended consequence of—FDA's removal of the in-person dispensing requirement. And those injuries are redressable by a decision vacating the 2023 REMS. This easily satisfies Article III standing.

A. The 2023 REMS Causes Plaintiffs' Current and Future Injuries in Fact.

Start with injury-in-fact and causation, which, in this case, go hand-in-hand. In *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025), the Supreme Court addressed a suit where "regulated third parties not before the court" would "likely react to the government regulation ... in predictable ways that will likely cause ... the plaintiff's injury." *Id.* at 112 (citation modified). In such suits, the plaintiff, though technically not a regulated entity, nonetheless "might be considered an object of the [ ] regulation[ ]"—and thus, the plaintiff's Article III standing is obvious. *Id.* at 114–15. That is especially so where the plaintiff's injuries are, in fact, "the whole point of the regulation[ ]." *Id.*

That is the case here. Following *Dobbs*, President Biden knew that pro-life states like Louisiana would prohibit abortion with narrow exceptions. So, through the 2023 REMS, his FDA eliminated the in-person dispensing requirement for mifepristone in an avowed effort to generate mail-order abortions in pro-life states. The direct "objects" of that agency action include mifepristone-prescribing doctors in states like New York and California—"regulated parties not before the court" who are acting "in predictable ways" by prescribing and mailing mifepristone into pro-life states to cause illegal abortions. *Id.* That is not just the predictable consequence of the 2023 REMS but "the whole point" of it: to override the sovereign prerogatives of pro-life states by "ensur[ing] that mifepristone is as widely accessible as possible," "including when prescribed through telehealth and sent by mail." ECF 1-47 at 3. And thus, pro-life states like Louisiana are the "object of the regulation[ ]." *Diamond*, 606 U.S. at 115. Indeed they are the true "targets." *Id.* at 120.

Given this, there is no question that Plaintiffs have suffered Article III injuries caused by the 2023 REMS. Two injuries are most obvious. First, Louisiana has suffered and will continue to suffer quintessential sovereign harms. Second, the State has endured and will continue to endure classic monetary harm. For these reasons, Plaintiffs satisfy the injury-in-fact and traceability requirements.

1. The 2023 REMS causes sovereign harm by facilitating illegal abortions in Louisiana.

It is difficult to imagine a federal action that is more "destructive of state sovereignty" than the 2023 REMS. *Louisiana*, 784 F. Supp. 3d at 901 (citation modified). "Generally, states have an interest in 'the exercise of sovereign power over individuals and entities within the relevant jurisdiction—this involves the power to create and enforce a legal code, both civil and criminal.'" *Louisiana*, 705 F. Supp. 3d at 653. Central among the sorts of "federal intrusions" sufficient to give a state standing is "federal interference with the enforcement of state law." *Id.* (citation modified). "Because a state alone has the right to create and enforce its legal code, only the state has the kind of direct stake necessary to satisfy standing in defending the standards embodied in that code." *Id.* (citation modified).

So it is here. As this Court recently recounted, the people of Louisiana, "through the democratic process, have unambiguously expressed their opposition to purely elective abortions by passing laws prohibiting the same." *Id.*; *accord Louisiana*, 784 F. Supp. 3d at 901. That policy is "expressly set forth" in Louisiana law. *Louisiana*, 784 F. Supp. 3d at 895 n.10. And that law protects "every unborn child ... from the moment of conception" as "a legal person." La. R.S. 40:1061.1(A)(1). Abortion is prohibited except if "determined to be medically necessary to prevent the death or substantial risk of death of the mother," with other narrow exceptions. *Louisiana*, 784 F. Supp. 3d at 895 n.10.

This case presents extreme "federal interference" with Louisiana's enforcement of that policy. President Biden's—and his FDA's—avowed purpose in promulgating the 2023 REMS was to override that policy in all pro-life states that sought to "ban or severely restrict access to medication for reproductive health care" after *Dobbs*. ECF 1-47 at 3; ECF 1-59 at 2; *see supra* pp. 3–4 (cataloguing

statements from the Biden Administration). "[S]tates may not ban mifepristone," President Biden threatened before promising "to allow mifepristone to continue to be prescribed by telehealth and sent by mail." ECF 1-60 at 2–3. Nobody pretended otherwise, including Senator Elizabeth Warren and her Democrat colleagues who demanded the 2023 REMS. The 2023 REMS was a direct response to pro-life states' "new restrictions" and a belief that "it is more important than ever [to] take immediate steps to expand access to medication abortion ... *across the nation*." Ex. 12, Letter from Elizabeth Warren et al. to FDA (Nov. 18, 2022), perma.cc/Y6RB-XDPT (emphasis added).

It is no wonder then that the 2023 REMS has functionally overridden Louisiana's pro-life laws, just as the Biden Administration intended. Freed from the in-person dispensing requirement, faceless doctors from states like New York and California are prescribing and mailing mifepristone into Louisiana with impunity—to the tune of 800, 900, and now 1,000 abortions a month. *See supra* pp. 1–2, 4–5. Each abortion is an independent violation of Louisiana law. *Supra* p.3 (collecting statutes). Each life lost is an independent abrogation of Louisiana's legislative policy to protect "every unborn child ... from the moment of conception." La. R.S. 40:1061.1(A)(1). Again, it is difficult to imagine a scheme that is more destructive of Louisiana's sovereignty—and that is a quintessential injury-in-fact. And Louisiana's defense of its sovereignty has itself resulted in monetary harm and depletion of resources, including through investigations of and warrants for Dr. Carpenter and Dr. Coeytaux regarding their violations of Louisiana's law.

Though Defendants themselves are not directly mailing mifepristone into Louisiana, the 2023 REMS makes this assault on pro-life states possible. But for the 2023 REMS, out-of-state doctors could not—without violating federal law—mail FDA-approved brands of mifepristone into Louisiana. That was "the entire purpose" of the 2023 REMS, *Diamond*, 606 U.S. at 112: to remove the in-person dispensing requirement so that it may be "sent by mail." ECF 1-47 at 3. Nor is it an answer to say that the 2023 REMS "is not the sole cause of the State's injury." *Texas v. United States*, 50 F.4th 498, 519 (5th Cir. 2022). Article III does not impose a "sole cause" standard. There is no question that the 2023 REMS "has exacerbated" Louisiana's injury, and "[t]hat is sufficient" for standing. *Id.* The 2023 REMS is why a flood of mifepristone-induced abortions are occurring in a state that bans

them—and indeed, that is why the Biden Administration "target[ed]," *Diamond*, 606 U.S. at 120, pro-life states in this way. That is a clear example of "federal interference with the enforcement of state law." *Louisiana*, 705 F. Supp. 3d at 653.[3]

2. The 2023 REMS causes pocketbook harm by directly increasing Louisiana's Medicaid costs.

Louisiana also suffers basic pocketbook injuries from the 2023 REMS: the loss of hundreds of thousands of dollars paid through Louisiana Medicaid for care related to FDA-approved mifepristone. Economic losses are "obvious" harms, *TransUnion LLC v. Ramirez*, 594 U.S. 413, 425 (2021), because "[m]onetary costs are of course an injury," *United States v. Texas*, 599 U.S. 670, 676 (2023). Even "one dollar's worth of harm" counts. *Id.* at 688 (Gorsuch, J., concurring); *accord Tex. Corn Producers v. EPA*, 141 F.4th 687, 696–97 (5th Cir. 2025) (same). As the Fifth Circuit has repeatedly held, increased Medicaid costs due to a federal agency action are plainly "a pocketbook-injury." *E.g.*, *Texas v. United States*, 126 F.4th 392, 408, 413 n.26, 414–15 (5th Cir. 2025) (citing *Texas*, 50 F.4th 498); *accord id.* at 411 n.22 (collecting cases). In one case, the Fifth Circuit explained that because Texas had to provide Medicaid services to illegal aliens covered by the challenged Deferred Action for Childhood Arrivals (DACA) program, that program increased the Medicaid costs that Texas had to cover. *Texas*, 126 F.4th at 408 (citation modified); *Texas*, 50 F.4th at 517–18. Those increased costs constituted "an 'injury in fact.'" *Id.* (quoting *Texas*, 50 F.4th at 519).[4]

All the same here. Under the Medicaid statute, Louisiana is required to cover medical assistance for eligible pregnant women, including inpatient and outpatient hospital services. *See* 42 U.S.C. § 1396d(a)(viii); *id.* § 1396d(a)(1), (2); *see also Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 363 (2025) (citation modified) ("Congress created Medicaid in 1965 to subsidize state efforts to

[3] The Biden Administration said that the 2023 REMS preempts Louisiana's laws on abortion. *See* ECF 1, ¶¶ 116–19; ECF 1-61 at 8. That view is dead wrong. *See GenBioPro, Inc. v. Raynes*, 144 F.4th 258 (4th Cir. 2025). But any purported preemption would independently give Louisiana standing. *Louisiana*, 705 F. Supp. 3d at 653 (citing federal preemption of state law as a basis for a state's standing).

[4] In the *Texas* litigation, the Fifth Circuit emphasized that this standing analysis holds regardless of whether Texas was entitled to "special solicitude" in the standing analysis. 126 F.4th at 414. Here, as there, Plaintiff Louisiana does not need "special solicitude" to establish standing.

provide healthcare to families and individuals whose income and resources are insufficient to meet the costs of medical services."). Louisiana "must" pay at least some of the total Medicaid costs, *id.* § 1396a(a)(2), while the federal government will pay between 50% and 83%, *id.* § 1396d(b).

The 2023 REMS is undoubtedly imposing a Medicaid burden on Louisiana. *First*, President Biden's FDA believed that "state actions" restricting abortion would "be felt most acutely by underserved communities, including those with low incomes"—thus, FDA envisioned that the 2023 REMS would particularly benefit low-income individuals. ECF 1-61 at 7–8. *Second*, as the Fifth Circuit previously held, the federal government's "own documents" show that "emergency room care is statistically certain" in mifepristone cases. *Alliance I*, 2023 WL 2913725, at *10. In fact, the FDA label states that roughly 1 in 25 (or 4% of) women who receive an in-person visit with a medical provider and take mifepristone *as directed* will end up in the emergency room. ECF 1-9 at 8–9, 16. The label even features a black box warning that mifepristone can cause "[s]erious and sometimes fatal infections and bleeding" requiring ER care. *Id.* at 2. Real-world data suggest that the emergency-room-visit and hospitalization rate may be as high as 11%—plus dispensing mifepristone by mail could raise that rate even higher. *See* ECF 1-13 at 2; Ex. 4, Wallace et al., *supra*, at 111117; ECF 1-10 at 34–35; *see also* ECF 1-50 at 75 ("[T]he literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic[.]"). And that was *before* the Biden Administration ended the in-person requirement—removing the sole opportunity to screen women for an ectopic pregnancy and verify gestational age. *See* Ex. 21, Francis Decl. ¶¶ 22–23, 41.

These basic facts demonstrate the increased Medicaid costs imposed on Louisiana by the 2023 REMS. Take March 2025, for example, when roughly 1,000 mail-order abortions occurred in Louisiana. *Supra* pp. 1, 5. FDA's own label concedes that at least 40 (4%) of those abortions resulted in emergency room visits—and the actual number of emergency room visits and hospitalizations may be as high 110 (11%). Further, according to the federal government, the women involved most likely have low incomes and thus are almost certainly are on Medicaid. *See* Ex. 22, New Decl. at 2–3. So in March 2025 alone, Louisiana faced increased Medicaid costs for many—if not most—of the 40 to 110 mifepristone-induced abortions that required emergency-room visits and hospitalizations.

This is not hypothetical—this is real world "commonsense economic[s]." *Diamond*, 606 U.S. at 116. As a supporting declaration shows, the Louisiana Department of Health has identified over $92,000 in Medicaid costs incurred for emergency room care and hospitalization required because of just two mifepristone-induced abortions in 2025. Ex. 20, Willis Decl. ¶¶ 11–12. And those costs are just the tip of the iceberg, underscoring that the hundreds of mifepristone-induced abortions that are occurring every month in Louisiana are leading directly to increased Medicaid costs for Louisiana. *See id.* ¶¶ 10, 13–15*; see also, e.g.*, Ex. 23, Parise Decl. ¶¶ 14–16; Ex. 19, Richard Decl. ¶¶ 7–8 (attesting that Louisiana women on Medicaid have been rushed to emergency rooms due to adverse events caused by mifepristone); *see also* ECF 1-14 at 4 (Medicaid-specific study finding significantly higher ER-visit acuity following chemical abortion). As of January 1, 2023 (the most recent data of its kind available), 534,294 women from ages 15 to 44 were enrolled in Louisiana Medicaid and 538,139 women from ages 15 to 44 were recipients of Louisiana Medicaid. Ex. 20, Willis Decl. ¶ 6. And women on Medicaid are more likely to get abortions than women who are not enrolled. Ex. 22, New Decl. 2–3.

To be sure, it is difficult to quantify *the full extent* of this monetary harm. The data Louisiana receives is almost certainly an underrepresentation of the actual state costs incurred due to the illegal importation of mifepristone. *See* Ex. 20, Willis Decl. ¶¶ 14–15. Women may not admit that they took the drug, and they may present at the emergency room with an apparent miscarriage (which Louisiana Medicaid covers) after they have ingested mifepristone. *See, e.g.*, Ex. 23, Parise Decl. ¶¶ 15–17; Ex. 21, Francis Decl. ¶ 37; Ex. 20, Willis Decl. ¶ 14. But whether Louisiana's harm is tens of thousands of dollars or millions of dollars, nobody can dispute that Louisiana's financial harm is more than zero. *Cf. Texas*, 50 F.4th at 517–18 ("The record does not indicate precisely what portion of all costs for illegal aliens is spent on DACA recipients, but no one disputes that some are."). That is all that is necessary to "demonstrat[e] injury in fact" directly caused by the 2023 REMS. *Id.* at 517.[5]

[5] For this Court to have jurisdiction, only Louisiana needs standing. *See Town of Chester v. Laroe Ests., Inc.*, 581 U.S. 433, 438–41 (2017). But Rosalie also has standing because FDA turned a blind eye to women like her. If FDA had never authorized mail-order abortion drugs, Rosalie's then-boyfriend could not have ordered FDA-approved abortion drugs and coerced her to take the drugs against her

B. These Injuries Are Redressable by a Favorable Decision.

For the same reasons, a decision from this Court vacating the 2023 REMS would redress these injuries. As the Fifth Circuit explained, vacating the 2023 REMS means that "[t]he in-person dispensing requirements, and FDA's obligation to enforce them, will continue to apply." *Alliance II*, 78 F.4th at 254. With the in-person dispensing requirement restored, FDA would not authorize doctors in States like New York and California to prescribe and mail mifepristone into pro-life states like Louisiana—and without that flood of mifepristone, Louisiana's monthly average of nearly 1,000 abortions per month will come crashing down.[6] That, in turn, would redress the harms above.

As to the monetary harms from increased Medicaid costs, common sense dictates that as the number of mifepristone-induced abortions decreases, so too will the number of Medicaid-implicated emergency room visits caused by such abortions. *See* Ex. 20, Willis Decl. ¶ 15. As a result, Louisiana's increased Medicaid burden will be alleviated. That was precisely the Fifth Circuit's reasoning embraced in *Texas*, when it said that Texas's increased Medicaid costs "would be partially alleviated if DACA were enjoined." 126 F.4th at 413.

Likewise, as to Louisiana's sovereign harms, it is obvious that, if mailing mifepristone into Louisiana becomes no longer authorized by FDA again (as before the 2023 REMS), the number of

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will. ECF 1-92 at ¶¶ 5–16. The doctor who sent the drugs could prescribe them because FDA had authorized it. *See* Ex. 13, Aria Bendix, *Why Abortions Rose After* Roe *Was Overturned*, NBC News (Nov. 26, 2:00 PT), perma.cc/QP3F-U82N (describing how Dr. Remy Coeytaux partners with A Safe Choice to dispense FDA-approved mifepristone); Ex. 14, Complaint, *Rodriguez v. Coeytaux*, No. 3:25-cv-00225, (S.D. Tex. July 20, 2025), ECF 1 to 1-2 (describing how Dr. Remy Coeytaux partners with Aid Access to dispense FDA-approved mifepristone); Ex. 15, Notice of Cease and Desist from Ken Paxton, Att'y Gen. of Tex., to Remy Coeytaux (Aug. 14, 2025), perma.cc/P7NE-7RTH (same). Rosalie's bodily injury, pain and suffering, mental anguish, and her lost child are thus injuries-in-fact for standing. *Rideau v. Keller Indep. Sch. Dist.*, 819 F.3d 155, 163 (5th Cir. 2016). Rosalie should never be subject to mail-order abortion-drug coercion again—and she is entitled to relief to protect herself and her future children.

[6] Under the pre-2023 REMS, sponsors of mifepristone were required to "[e]nsure that their mifepristone [wa]s available to be dispensed to patients only in clinics, medical offices and hospitals," Ex. 16, FDA, REMS Single Shared System for Mifepristone 200MG (May 2021), perma.cc/W522-9F7G, or they risked severe "enforcement action[s] such as product seizure, injunction or civil money penalties," Ex. 17, *REMS Compliance Program*, FDA (Sep. 22, 2022), perma.cc/KE9P-UKGU. Noncompliant prescribers would face decertification and lose access to mifepristone. *Id.*

mifepristone-induced abortions in Louisiana will dramatically decrease. So too the number of independent violations of Louisiana law, thereby mitigating the ongoing destruction of Louisiana's sovereignty.

It is no answer to say that, even if the in-person dispensing requirement were restored, rebellious doctors could choose to violate federal law and continue mailing mifepristone into Louisiana. *Diamond* squarely forecloses that reasoning. As the Court recognized, "the fact that a regulation was designed to produce a particular effect on the market ordinarily means that the likely result of vacating the regulation would be to reduce that effect on the market." 606 U.S. at 117. The same principle applies here: The 2023 REMS was designed to facilitate mail-order abortions in pro-life states. Accordingly, vacating the REMS would have "the likely result of ... reduc[ing] that effect," if not eliminating it entirely, in pro-life states. *Id.*

One final note underscores the strength of Plaintiffs' redressability argument here: The emergence of shield laws designed to permit anonymous mailing of mifepristone into pro-life states is unquestionably a problem for pro-life states attempting to enforce their policies and laws. But those shield laws are meaningless unless such mailing is FDA-approved to begin with. Staying the 2023 REMS, and thereby restoring the in-person dispensing requirement, would ensure that such mailing is unauthorized and unlawful, leaving no role for shield laws. In that way, staying this concededly unlawful agency action is perhaps the most important step toward restoring Louisiana's and all other pro-life states' sovereignty. In a world where the prevailing sentiment among pro-abortion advocates is to thumb their noses at pro-life laws—"'We really don't change things unless we're legally required to,'" ECF 1-106 at 2—a stay (and then vacatur) of the 2023 REMS is necessary.

CONCLUSION

The Court should stay the 2023 REMS under 5 U.S.C. § 705 and direct that "[t]he in-person dispensing requirement[ ], and FDA's obligation to enforce [it], will continue to apply." *Alliance II*, 78 F.4th at 254. In the alternative, Plaintiffs request a preliminary injunction under 5 U.S.C. § 705 against FDA's enforcement of the 2023 REMS.

Respectfully submitted this 17th day of December, 2025.

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