No. 26-30203

In the United States Court of Appeals for the Fifth Circuit

STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL ; ROSALIE MARKEZICH,
Plaintiffs-Appellants

v.

FOOD & DRUG ADMINISTRATION ; MARTY MAKARY, COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION ; RICHARD PAZDUR, IN HIS OFFICIAL CAPACITY AS DIRECTOR, CENTER FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMINISTRATION ; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES ; ROBERT F. KENNEDY, JR., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellees

v.

DANCO LABORATORIES, L.L.C. ; GENBIOPRO, INCORPORATED,
Intervenors-Appellees

On Appeal from the United States District Court
for the Western District of Louisiana
No. 6:25-cv-01491-DCJ-DJA, Hon. David C. Joseph

MOTION FOR § 705 STAY OR INJUNCTION PENDING APPEAL

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Louisiana, et al. v. Food and Drug Administration, et al.

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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The State of Louisiana

Rosalie Markezich

Defendants-Appellees:

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U.S. Department of Health and Human Services

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Intervenors-Appellees:

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GenBioPro, Inc. (GenBioPro represents that its parent company is Xenia Holdco LLC, and there is no publicly held corporation that owns 10% or more of GenBioPro's stock.)

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MOTION

Under Federal Rules of Appellate Procedure 8 and 27, Plaintiffs-Appellants the State of Louisiana and Rosalie Markezich move the Court for a stay under 5 U.S.C. § 705 pending appeal or, alternatively, an injunction pending appeal. The subject of the stay or injunction is the U.S. Food and Drug Administration's (FDA) "2023 agency action removing the in-person dispensing requirement for the abortion drug, mifepristone," also known as the "2023 REMS." Ex. A (Dist.Ct.Op.) at 1.[1]

Although a movant "ordinarily" must first seek relief pending appeal in the district court, Fed. R. App. P. 8(a)(1), that is not the case where such a formal request would be futile, *see, e.g.*, *Simon v. City & Cnty. of San Francisco*, 135 F.4th 784, 815 n.22 (9th Cir. 2025); *In re Flint Water Cases*, 960 F.3d 820, 825 (6th Cir. 2020). That is the situation here, as the district court has both (a) denied the precise preliminary relief Plaintiffs now seek from this Court and (b) stayed the lawsuit, preventing any further proceedings below.

[1] The Intervenors oppose this relief and intend to respond; the Federal Defendants intend to respond.

STATEMENT

For decades, FDA closely regulated the abortion drug mifepristone. One such regulation was an in-person dispensing requirement, which, among other things, ensured that a woman was operating free from coercion and that mifepristone would not pose a unique danger to her health.

In 2023, however, the Biden Administration changed mifepristone's Risk Evaluation and Mitigation Strategy (REMS) to remove the in-person dispensing requirement. The Biden Administration's avowed purpose was to undermine *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215, 232 (2022). Fearing that pro-life states would provide strong protections for unborn babies and their mothers after *Dobbs*, the Biden Administration sought to ensure that prescribers outside those states (say, in New York and California) could still effectuate abortions in pro-life states. The key to that scheme was the 2023 REMS: the permanent removal of the in-person dispensing requirement, which allowed the "dispensing [of] mifepristone through the mail ... or through mail-order pharmacy" into pro-life states. Dist.Ct.Op.6 (citation omitted). The net result is that some 1,000 Louisiana babies are

illegally aborted using FDA-approved mifepristone every month. Dist.Ct.Op.24.

In this case, Louisiana and one of its citizens—Rosalie Markezich, who was coerced to take mifepristone to abort a baby she wanted—have sued for vacatur of the 2023 REMS under the Administrative Procedure Act (APA).[2] *See* Dist.Ct.ECF.1 (complaint). Louisiana has sought a stay of the 2023 REMS under 5 U.S.C. § 705 or a preliminary injunction against its enforcement. *See* Dist.Ct.ECF.20-26 (preliminary-relief motion); Dist.Ct.ECF.111 (preliminary-relief reply). FDA has refused to defend the 2023 REMS. Ex. B (Tr.) at 35 ("We're not taking a position on any merits issue with respect to this motion."). In fact, FDA's position is that the 2023 REMS reflects a "lack of adequate consideration," Dist.Ct.Op.28 (citation omitted), and that the "Biden [A]dministration removed mifepristone's in-person dispensing rule without studying the safety risks," Dist.Ct.ECF.1 at 4 (citation omitted).

There is virtually no question that the 2023 REMS is unlawful under basic APA review. Two panels of this Court already have said as

[2] Because the district court focused its analysis on Louisiana, *see* Dist.Ct.Op.25 n.15, 26 n.16, this motion likewise focuses on Louisiana.

much, criticizing FDA's "ostrich's-head-in-the-sand approach" and twice upholding a § 705 stay of the 2023 REMS. *All. for Hippocratic Med. v. FDA* (*Alliance I*), 2023 WL 2913725, at *17 (5th Cir. Apr. 12, 2023); *All. for Hippocratic Med. v. FDA* (*Alliance II*), 78 F.4th 210, 249–51 (5th Cir. 2023).[3] (The Supreme Court later reversed that stay solely on standing grounds. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367 (2024).) The district court below similarly agreed that "Plaintiffs are likely to succeed on the merits of their 2023 REMS challenge." Dist.Ct.Op.28.

There is also virtually no question that Louisiana has standing to sue and is suffering irreparable harm. Here, too, the district court below agreed that, "[b]y permitting medical providers to prescribe mifepristone remotely, the 2023 REMS facilitates the distribution of mifepristone into Louisiana," causing illegal abortions in Louisiana. *Id.* "Louisiana suffers sovereign harm each time [its] laws are circumvented," the court explained, and "[n]o remedy at law can redress that sovereign harm." *Id.*

[3] As the district court explained, the *Alliance II* Court technically considered a 2021 Nonenforcement Decision, not the 2023 REMS; however, "the *Alliance II* court described the 2023 REMS as merely a 'final form of a previous, identical policy,' removing mifepristone's in-person dispensing requirement"—*i.e.*, the 2021 Nonenforcement Decision. Dist.Ct.Op.27. So the Court's reasoning directly maps onto the 2023 REMS as well.

Further, Louisiana suffers unrecoverable (due to FDA's sovereign immunity) "financial injury" given the economic costs of this scheme. *Id.* The "same facts" that establish Louisiana's standing also "establish irreparable harm." *Id.*

Because the district court correctly concluded that Louisiana (a) is likely to succeed in this challenge to the 2023 REMS and (b) suffers irreparable harm every day that the 2023 REMS remains in effect, preliminary relief is plainly warranted. *See, e.g.*, *United States v. Abbott*, 110 F.4th 700, 706 (5th Cir. 2024) (en banc) ("The first factor—likelihood of success on the merits—is 'the most important.'"); *Moore v. Tangipahoa Par. Sch. Bd.*, 507 F. App'x 389, 399 (5th Cir. 2013) (likelihood of success on the merits and irreparable harm are "the most important" preliminary-relief factors). But, in a strange turn of events, the court denied Louisiana's relief and imposed an *indefinite* stay under the heading "Balance of Harms/Public Interest." Dist.Ct.Op.28.

The district court erred in denying relief. Consider just two reasons why: (1) while Louisiana is suffering irreparable harm, the district court identified no irreparable harm from entering a § 705 stay, which means the balance favors Louisiana; and (2) this Court already held that the

public has no interest in the illegal 2023 REMS, FDA and the public "will not be injured by" a § 705 stay, and "the public interest is disserved by a drug that does not afford adequate protections to its users." *Alliance II*, 78 F.4th at 251–53. A § 705 stay is warranted.

The only thing that has changed since *Alliance II* is that FDA has now proclaimed for over a year that it will "study" and "review" the 2023 REMS. But when pressed by the district court in February 2026, FDA said (a) "I don't have a timeline I can give Your Honor," (b) some part of the review (but "*not* the whole review") might be complete by 2027, and (c) FDA "can't talk specifically about what they are doing" but they are somewhere "in the data collection phase of the study." Tr.33–34; *accord* Dist.Ct.ECF.20-26 at 8. In other words, as of February 2026 (and still today[4]), FDA did not even have the data sufficient to conduct a review.

The district court nevertheless relied on FDA's purported study to deny preliminary relief to Louisiana and then indefinitely stay this lawsuit to see what, if anything, comes of the supposed review.

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[4] Remarkably, the day after the decision below, FDA (non)updated its website to say that, "[a]s of April 2026," FDA *still* does not have sufficient data for its "saftey [sic] study on mifepristone." *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. Food & Drug Admin., perma.cc/4TMY-SWYQ.

This motion challenges the denial of preliminary relief (rather than the stay decision). For there is no justification—given Louisiana's, FDA's, and the district court's agreement that the 2023 REMS is unlawful—for forcing Louisiana to suffer ongoing irreparable harm unless and until FDA decides what it wants to do (or not do) with the 2023 REMS at some unidentified future date. (The district court has requested only a status update in six months.) Such a result flips the APA on its head—the whole point of which is to ensure timely judicial review and vacatur of unlawful agency actions. *See* § 705 ("Relief pending review").

Each month that passes is not just time lost; it is some 1,000 Louisiana lives lost. For these reasons, the Court should enter the same § 705 stay it upheld in *Alliance I* and *Alliance II* or, alternatively, enjoin enforcement of the 2023 REMS pending appeal.

JURISDICTIONAL STATEMENT

On April 7, the district court issued its decision denying Plaintiffs' motion for preliminary relief and granting the Federal Defendants' motion to stay the case. Ex. A. The State appealed that ruling the next day. Dist.Ct.ECF.269. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1).

STANDARD OF REVIEW

Plaintiffs request a stay of the 2023 REMS or, alternatively, a preliminary injunction pending appeal. *See* 5 U.S.C. § 705; Fed. R. Civ. P. 65. Plaintiffs thus "must show '(1) a strong likelihood of success on the merits; (2) irreparable injury in the absence of an injunction; (3) that the balance of hardships weighs in their favor if injunctive relief is granted; and (4) that the public interest favors such relief.'" *Vapor Tech. Ass'n v. Graham*, 167 F.4th 302, 305 (5th Cir. 2026) (citation omitted); *see Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1143–44 (5th Cir. 2021) (applying these factors under § 705). The first two are the "most important." *Abbott*, 110 F.4th at 706; *Moore*, 507 F. App'x at 399. This Court applies a "sliding-scale" approach to these factors, such that Plaintiffs' strong showing on one or more factors requires only "some" showing on the others. *TitleMax of Tex., Inc. v. City of Dallas*, 142 F.4th 322, 328–29 (5th Cir. 2025).

ARGUMENT

The issue before this Court is remarkably narrow because the district court resolved nearly the entire preliminary-relief analysis in Plaintiffs' favor. *First*, the district court concluded—as two panels of this Court concluded—that Plaintiffs are likely to succeed in their APA

challenge to the 2023 REMS. *Second*, the district court concluded that Louisiana not only has standing but is suffering irreparable harm every day that the 2023 REMS remains in effect.

That leaves only the *third* issue: whether the equities and public-interest inquiries, which merge in this context, *see Nken v. Holder*, 556 U.S. 418, 435 (2009), somehow override Louisiana's entitlement to preliminary relief and warrant an indefinite stay of this litigation while Louisiana undisputedly continues to suffer irreparable harm. They do not. The proper course is to enter preliminary relief, just what this Court preserved in *Alliance I* and *Alliance II*.

I. AS THIS COURT AND THE DISTRICT COURT HAVE CONCLUDED, PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS.[5]

A. The 2023 REMS Is Unlawful.

Start with the merits analysis that this Court has twice conducted—and in which the district court concurred. Arbitrary-and-capricious review "requires that agency action be reasonable and reasonably explained," meaning that the agency "has reasonably

[5] Given current space constraints, this analysis is necessarily more abbreviated than the analyses preserved below and in this Court's prior decisions. *See* Dist.Ct.ECF.20-26 at 9–14 (APA), 17–25 (standing); Dist.Ct.ECF.111 at 2–13 (standing), 15–18 (APA).

considered the relevant issues and reasonably explained the decision." *Wages & White Lion*, 16 F.4th at 1136 (citation omitted). The fatal defect in the 2023 REMS is that the Biden 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. The district court well summarized the two bases for this Court's conclusions in *Alliance I* and *Alliance II*. Dist.Ct.Op.7–11.

First, FDA based its removal of the in-person dispensing requirement "on the absence of data that [FDA] had only five years previously intentionally eliminated," using that absence to justify deeming mifepristone safe without an in-person dispensing requirement. Dist.Ct.Op.26–27 (citing *Alliance II*, 78 F.4th at 249). This Court was astounded by FDA's "declar[ation] [that] 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," the Court said. *Id.* "It'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.

Second, FDA also "relied on various literature relating to remote prescription of mifepristone—despite FDA's admission that the literature did not affirmatively support its position." Dist.Ct.Op.27 (quoting *Alliance II*, 78 F.4th at 250). That makes this an 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." *Alliance II*, 78 F.4th at 250. Because FDA "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," Plaintiffs "are likely to succeed in showing that [the 2023 REMS] violated the APA." *Id.* at 251.

This Court's own prior merits determinations are correct—and that is even truer today because "HHS Secretary Kennedy and FDA Commissioner Makary [have] essentially acknowledged APA procedural deficits," "stating that FDA's intention to review the mifepristone regulatory framework was precipitated by 'the lack of adequate consideration underlying the prior REMS approvals' and recent safety

concerns." Dist.Ct.Op.27–28. Plaintiffs are thus likely to "succeed on the merits of their 2023 REMS challenge." Dist.Ct.Op.28.[6]

B. Louisiana Has Standing.

The district court likewise rightly held that Louisiana has Article III standing to challenge the 2023 REMS. "To establish 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." Dist.Ct.Op.16 (citing *Texas v. United States*, 126 F.4th 392, 407 (5th Cir. 2025)). Each element is satisfied. Dist.Ct.Op.16–25.

1. The district court correctly determined that Louisiana suffers at least two distinct injuries in fact.

First is the harm to Louisiana's "sovereign interest in the power to create and enforce a legal code." Dist.Ct.Op.22 (quoting *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015)). Louisiana expressly prohibits

[6] Omitted here for efficiency, Louisiana also has an APA claim based on the Comstock Act, which is an independent basis for likelihood of success on the merits. *See* Dist.Ct.ECF.20-26 at 13–14; *Alliance II*, 78 F.4th at 267–70 (Ho, J., concurring in part and dissenting in part).

abortion (with narrow exceptions), including the dispensing of mifepristone to induce an abortion. Dist.Ct.Op.18 n.10 (collecting statutes). Louisiana law also expressly "reaffirm[s] the longstanding public policy of this state that every unborn child is a human being from the moment of conception." *Id.* (quoting La. R.S. 40:1061.1(A)(1)). Yet Louisiana law is violated some 1,000 times a month when mifepristone is mailed into Louisiana to effectuate illegal abortions. "Louisiana suffers sovereign harm each time those laws are circumvented." Dist.Ct.Op.28. That is a textbook injury-in-fact.[7]

Second is monetary injury. As the district court recounted from this Court's precedents, "[a] state's increased medical costs, such as increased Medicaid costs due to a federal agency action, can constitute a 'pocket-book injury' sufficient to satisfy the injury-in-fact requirement of standing." Dist.Ct.Op.23–24; *see Texas*, 126 F.4th at 408, 411, 413 n.26. And that is the case here: Louisiana's unrebutted record evidence shows that many of the 1,000 mifepristone abortions per month in Louisiana

[7] Louisiana also independently established monetary harm in the form of its reasonable "costs to mitigate or avoid" these legal violations. *See* Dist.Ct.ECF.111 at 3–4 & n.4 (citing *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013)).

are for women on Medicaid. Dist.Ct.Op.24. That record evidence also shows that, by FDA's own telling, roughly 1 in 25 women who take mifepristone will end up in the emergency room. *Id.*; *accord Alliance I*, 2023 WL 2913725, at *10 ("emergency room care is statistically certain"). The same evidence shows that Louisiana has incurred "more than $92,000 in [such] Medicaid costs" due to only two mifepristone-induced abortions requiring emergency care in 2025—a number that is "likely" severely underinclusive. Dist.Ct.Op.25. "[B]ecause 'even one dollar's worth of harm' is sufficient, Louisiana has put forth sufficient evidence to demonstrate a substantial likelihood of success in proving it has suffered financial injury for standing purposes." *Id.* (citation omitted).

2. The only real question below was traceability and redressability, which "are often flip sides of the same coin" since "if a defendant's action causes an injury, enjoining the action ... will typically redress that injury." Dist.Ct.Op.17 (citation modified). On this question, the district court made two key points.

First, the district court rejected FDA's claim that the above harms are not traceable to the 2023 REMS since "Louisiana is not a regulated party." Dist.Ct.Op.18. That is because "standing may exist where

[independent] actors predictably respond to the challenged action" in a manner that generates those harms. Dist.Ct.Op.19 (collecting cases). That is the case here because "the evidence in the record shows that the 'independent actors'—that is, the out-of-state medical providers prescribing mifepristone via telemedicine or mail—responded to the 2023 REMS by expanding mifepristone access to pro-life states like Louisiana in ways that were entirely predictable." Dist.Ct.Op.19–20.

In fact, this was not just the *predictable* consequence of the REMS, but its *intended* consequence. The Biden Administration openly advertised that it was seeking to preserve abortion in pro-life states after *Dobbs*. Dist.Ct.Op.20–21; *accord* Dist.Ct.ECF.20-26 at 4; Dist.Ct.ECF.111 at 9. The district court thus correctly held that "there is evidence that the 2023 REMS was approved without adequate consideration, at least in part, to circumvent anti-abortion states' ability to regulate abortion." Dist.Ct.Op.21.

That is the end of the traceability analysis: "The government generally may not target a [state] through stringent and allegedly unlawful regulation, and then evade the resulting lawsuit[] by claiming that the target[] of its regulation should be locked out of court as [an]

unaffected bystander[]." *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 125 (2025); *Bost v. Ill. State Bd. of Elections*, 146 S. Ct. 513, 520–21 (2026). It is also the end of the redressability analysis since "the fact that a regulation was designed to produce a particular effect on the market ordinarily means that the likely result of vacating that regulation would be to reduce that effect on the market." *Diamond*, 606 U.S. at 117.

Second, the district court correctly recognized that Louisiana need not show that the 2023 REMS is *solely* responsible for Louisiana's harms, or that vacating the REMS would *completely* eliminate Louisiana's harms. *See Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982). There are, of course, other actors "influenc[ing] the arrival of mifepristone in Louisiana," including pro-abortion states and out-of-state prescribers. Dist.Ct.Op.23. "But there can be little doubt that the 2023 REMS is a factor, which is all that is required for Louisiana to show injury-in-fact and traceability." *Id.* After all, *but for the 2023 REMS*, no out-of-state prescriber could legally (under federal law) mail mifepristone into Louisiana. In that way, the 2023 REMS is the indispensable ingredient in the nearly 1,000 mifepristone abortions occurring in Louisiana every month. "Thus, even if the 2023 REMS is not the 'sole cause' of Louisiana's

[] harms, it has surely 'exacerbated' them; 'that is sufficient' for standing to assert its claims." Dist.Ct.Op.23 (citing *Texas v. United States*, 50 F.4th 498, 519 (5th Cir. 2022)).

II. AS THE DISTRICT COURT CONCLUDED, LOUISIANA IS SUFFERING IRREPARABLE HARM.

The district court also correctly concluded that Louisiana "establish[ed] irreparable harm." Dist.Ct.Op.28.

First, the 2023 REMS operates "in derogation of Louisiana law and interferes with Louisiana's ability to enforce its laws and implement the policy choices of its citizens." *Id.* In particular, "[b]y permitting medical providers to prescribe mifepristone remotely, the 2023 REMS facilitates the distribution of mifepristone into Louisiana notwithstanding contrary law." *Id.* "Louisiana suffers sovereign harm each time those laws are circumvented," the court explained. *Id.* And because "[n]o remedy at law can redress that sovereign harm," *id.*, it is irreparable, *see Alliance II*, 78 F.4th at 251.

Second, the district court recognized that Louisiana is suffering irreparable economic harm. Specifically, as discussed above, the 2023 REMS is causing direct and predictable economic injuries to Louisiana—and those injuries "cannot be 'remedied where, as here, the defendant is

entitled to sovereign immunity.'" Dist.Ct.Op.28 (citing *Alliance II*, 78 F.4th at 251).

III. THE BALANCE OF EQUITIES AND PUBLIC INTEREST FAVOR A STAY OR INJUNCTION.

So far, Louisiana has satisfied the two "most important" factors. *Abbott*, 110 F.4th at 706; *Moore*, 507 F. App'x at 399. In fact, Louisiana is so strong on those two core factors that, under this Court's "sliding-scale" approach, *TitleMax of Tex., Inc.*, 142 F.4th at 329, even a negligible showing on the "less significant" equities and public-interest inquiries, *Moore*, 507 F. App'x at 399, would warrant a § 705 stay. *See, e.g.*, *Speech First, Inc. v. Killeen*, 968 F.3d 628, 637 (7th Cir. 2020) ("If the plaintiff is likely to win on the merits, the balance of harms need not weigh as heavily in his favor.").

In all events, those remaining inquiries are easily resolved for Louisiana—and the district court's reasoning otherwise is misplaced.

A. The Remaining Factors Are Straightforward.

Begin with the equities and recall the district court's emphatic determination that Louisiana is suffering irreparable harm. The district court did not identify any cognizable irreparable harm to any other party that would be caused by the § 705 stay requested by Plaintiffs. *See*

Alliance II, 78 F.4th at 251 ("This risk of irreparable harm must be weighed against any injury FDA and [the drug manufacturers] would sustain as a result of the [§ 705] stay order, as well as against the public interest."). Common sense and the law of gravity suggest, therefore, that Louisiana must win any balancing analysis.[8]

That point is reinforced by this Court's own determination that it would be *against the public interest* to allow the 2023 REMS to remain in effect. *First*, although "anytime the Government is enjoined from enforcing its statutes, or regulations, 'it suffers a form of irreparable injury,'" "neither the FDA nor the public has any interest in enforcing a regulation that violates federal law." *Alliance II*, 78 F.4th at 251 (citation omitted). "In this regard, the government/public-interest analysis collapses with the merits"—and "[i]t follows that FDA and the public will not be injured by an order staying" the 2023 REMS. *Id.* at 251–52.[9]

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[8] The district court asserted in passing that the drug manufacturers "have a substantial financial interest" because "[a]ny change in the current regulatory regime ... would affect their profit margins and compliance costs." Dist.Ct.Op.30. But the district court did not elaborate, deem that interest an irreparable harm, or even weigh it against Louisiana's irreparable harm.

[9] The court "note[d]" that the Supreme Court stayed the *Alliance* district court's § 705 stay, thereby "allow[ing] the challenged FDA actions with respect to mifepristone to continue throughout the course of the

Second, the Court recognized that, "of course, the public interest is disserved by a drug that does not afford adequate protections to its users." *Id.* at 253. And this preliminary-relief record shows that the 2023 REMS lacks "sufficient consideration of the effects [its] changes would have on patients." *Id.*[10]

These basic facts confirm that preliminary relief is warranted: (a) Louisiana is suffering irreparable harm absent a § 705 stay, (b) no other party will suffer irreparable harm with a § 705 stay, and (c) the public interest is decidedly against keeping the 2023 REMS in effect.

B. The District Court's Considerations Are Misplaced.

Rather than take this straightforward path, the district court offered several thoughts under the heading "Balance of Harms/Public

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appeal." Dist.Ct.Op.31. This statement implies that perhaps the public *does* have an interest in the enforcement of illegal regulations. That is incorrect. As the ultimate *Alliance* decision illustrates, the Supreme Court believed there was no Article III standing. Thus, the "no public interest in enforcing a regulation that violates federal law" principle was not triggered. Not so here, where the district court agreed that Louisiana has standing and is likely to succeed on the merits.

[10] These points address the district court's puzzling assertion that there are cognizable "reliance interests on [the 2023 REMS]" that should be preserved. Dist.Ct.Op.35. *Alliance II* said exactly the opposite in emphasizing that the public has no interest in the perpetuation of this unlawful and unreasoned regulation.

Interest" that led the court to deny preliminary relief. Each consideration is misplaced.

1. The district court principally resisted becoming "a forum for resolving moral or policy disagreements" (or "scientific or medical judgments"). Dist.Ct.Op.28–29. But as this Court's (and the district court's) merits analyses reflect, this lawsuit asks no court to resolve moral, policy, scientific, or medical disagreements; it asks only for a plain APA analysis, which courts run every day. *See Alliance II*, 78 F.4th at 249–50 (explaining why the 2023 REMS "was [likely] arbitrary and capricious"); *accord* Dist.Ct.Op.26–28. To the extent the district court was invoking the Supreme Court's discussion of moral and policy objections in *Alliance*, that discussion was in the context of explaining why such objections do not establish Article III standing. *See* 602 U.S. at 396. That is not an issue here.

2. The district court also worried "that this case arises amid multiple parallel lawsuits across the country addressing the same regulatory issues surrounding access to mifepristone, creating a substantial risk of inconsistent judicial outcomes on a question of

nationwide importance." Dist.Ct.Op.31, 35. That worry appears to come in two parts, each unavailing.

First is a concern that a court elsewhere considering similar issues might reach a different conclusion. But that is an unremarkable feature of high-profile litigation, which often occurs on multiple fronts and leads to diverse results. Taken to its logical conclusion, this concern would paralyze every judge, preventing them from independently deciding important issues in their best judgment. *Cf. Buenrosto-Mendez v. Bondi*, 166 F.4th 494 (5th Cir. 2026) (resolving immigration issue over which district courts have split nationwide). That is not the proper judicial role.

More fundamentally, the *Alliance I* Court already rejected a similar concern. There, the Court expressed "every respect for fellow federal courts," but refused to "embrace an argument that would, in effect, allow the decision of an out-of-circuit district court to impel us towards [a stay] that would be otherwise inappropriate." 2023 WL 2913725, at *19. So here: The Court should reject the notion that the mere possibility of contrary decisions elsewhere in the Nation can be a basis for denying preliminary relief Louisiana needs.

Second is a concern that the universal scope of a § 705 stay would run into "settled limits on equitable relief." Dist.Ct.Op.31–33. Four important points in response.

One, that chafes against this Court's precedents. This Court has held that "the scope of preliminary relief under Section 705 aligns with the scope of ultimate relief under Section 706, which is not party-restricted and allows a court to 'set aside' an unlawful agency action." *Career Colls. & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024). That is why *Alliance I* and *Alliance II* upheld a universal § 705 stay.

Two, the district court's conflation (Dist.Ct.Op.32) of the *equitable* relief considered in *Trump v. CASA, Inc.*, 606 U.S. 831 (2025), with the *legal* relief provided by § 705 runs into the same problem. By its own terms, *CASA* expressly avoided the "distinct" question of vacatur under the APA. *CASA*, 606 U.S. at 847 n.10; Dist.Ct.ECF.20-26 at 17. Accordingly, *CASA* does not excuse the district court from applying this Court's own vacatur precedents.

Three, it is not Louisiana's fault that only a universal § 705 stay could remedy Louisiana's harm. Louisiana would be open to a Louisiana-

specific remedy—except that no one can figure out how to build one considering the indiscriminate, nationwide attacks from doctors and activists in pro-abortion states that FDA has facilitated. The court below directly addressed that issue, and the federal government threw up its hands. *See* Tr.53 (Q: "I asked plaintiffs' counsel if she could conceive of any remedy limited to the parties of this case, Rule 65 remedy. Can you think of any?" A: "We aren't proposing any narrowing of relief...." Q: "All right. I'm asking you: Can you think of any way, as a technical matter, to do that in this case?" A: "I can't, Your Honor.").

Because only a universal § 705 stay appears workable, the right answer is not to level down and deny Louisiana the relief it needs just because the relief would sweep more broadly. For all the district court's reliance on *CASA*, *CASA* squarely holds in the equity context that "courts generally 'may administer complete relief *between the parties*'" even if doing so happens to benefit others. 606 U.S. at 851–52 (using the example of ordering a neighbor to turn loud music down or off; that order "will necessarily benefit the defendant's surrounding neighbors too; there is no way 'to peel off just the portion of the nuisance that harmed the plaintiff'"). All the same here.

Four, it bears noting that none of this is relevant to the remaining preliminary-relief factors—the equities and public interest. This discussion at most goes to *scope* of relief, not whether Louisiana is *entitled* to relief. The district court thus erred multiple times over in citing this discussion to deny Louisiana preliminary relief.

3. Last and "most important[]" in the district court's view is that FDA is entitled to a stay because it says it is "review[ing]" the 2023 REMS. Dist.Ct.Op.35. The lower court held "the APA deficiencies [as] found by the Fifth Circuit"—that the 2023 REMS was based on inadequate data—somehow "prevent[ed]" it from issuing preliminary relief because "ultimately it is FDA, not this Court, that possesses the expertise to evaluate scientific evidence and make public health judgments." Dist.Ct.Op.33–34. The lower court was willing to overlook clear "evidence of ongoing harm owing to the 2023 REMS," because "FDA has acknowledged its own deficits and has initiated an ongoing review of mifepristone." *Id.* At bottom, the court concluded that "FDA's review should be conducted and completed free from judicial interference." Dist.Ct.Op.35.

This reasoning is badly mistaken. To start, it would allow the government to avoid preliminary review in *every* APA case. More, the question before the Court is legal not scientific: Is the 2023 REMS lawful? No amount of further study or agency action will change that answer (which this Court has twice answered in the negative). More fundamentally, it makes no sense to *deny* preliminary relief on the grounds that agency action is *so* unlawful that the agency openly concedes a review is necessary. That is the strongest point in favor of *granting* preliminary relief, not giving FDA a free pass to maintain a concededly unlawful regulation. In short, FDA's review cannot magically render the 2023 REMS lawful, nor does it provide grounds to refuse to set aside unlawful action as ensured by § 705.

CONCLUSION

The Court should stay the 2023 REMS under § 705 pending appeal or, alternatively, enjoin its enforcement pending appeal.

Respectfully submitted,

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Dated: April 17, 2026

CERTIFICATE OF SERVICE

I certify that on April 17, 2026, I filed the foregoing brief with the Court's CM/ECF system, which will automatically send an electronic notice of filing to all counsel of record.

/s/ J. Benjamin Aguiñaga
J. BENJAMIN AGUIÑAGA

CERTIFICATE OF COMPLIANCE

Pursuant to Fifth Circuit Rule 32.3, the undersigned certifies that this motion complies with:

(1) the type-volume limitations of Federal Rule of Appellate Procedure 27(d)(2) because it contains 5,199 words; and

(2) the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface (14-point Century Schoolbook) using Microsoft Word 2016 (the same program used to calculate the word count).

/s/ J. Benjamin Aguiñaga
J. BENJAMIN AGUIÑAGA

Dated: April 17, 2026

EXHIBIT A

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	**CIVIL DOCKET NO. 6:25-cv-01491**
VERSUS	**JUDGE DAVID C. JOSEPH**
U.S. FOOD AND DRUG ADMINISTRATION, ET AL	**MAGISTRATE JUDGE DAVID J. AYO**

MEMORANDUM RULING

This case was brought by the State of Louisiana and Louisiana resident Rosalie Markezich ("Plaintiffs") against the U.S. Food and Drug Administration ("FDA") and several related agency heads[1] (collectively, the "Government"), challenging the legality of FDA's 2023 agency action removing the in-person dispensing requirement for the abortion drug, mifepristone. Shortly after filing the lawsuit, Plaintiffs moved for preliminary injunctive relief, which was quickly followed by a flurry of motions by the Government and other parties in interest, including the drug's manufacturers, Danco Laboratories, LLC ("Danco") and GenBioPro, Inc. ("GenBioPro"). Also filed with the Court were twenty-two (22) amicus briefs authored by persons and organizations with a variety of viewpoints.[2]

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[1] The defendants in this matter are the U.S. Food and Drug Administration ("FDA"); Martin Makary, in his official capacity as Commissioner of Food and Drugs at FDA; George Francis Tidmarsh, in his official capacity as the Director of FDA's Center for Drug Evaluation and Research; the U.S. Department of Health and Human Services ("HHS"); and Robert F. Kennedy, Jr., in his official capacity as the Secretary of HHS.

[2] Amicus briefs were filed in support of the Plaintiffs' motion by the following entities: (i) Family Research Council and Martha Shuping, M.D. [Doc. 66]; (ii) Women Injured by

The Court heard oral argument on the pending motions on February 24, 2026, and at that time granted motions to intervene by the two drug manufacturers. [Docs. 52, 54, 229, 246]. Now before the Court for consideration are: (i) a MOTION FOR PRELIMINARY RELIEF UNDER 5 U.S.C. § 705 [Doc. 20] filed by Plaintiffs; (ii) a MOTION TO STAY THE CASE [Doc. 50] filed by the Government; (iii) a MOTION TO DISMISS [Doc. 230] filed by Intervenor-Defendant Danco; and (iv) a MOTION TO DISMISS [Doc. 232] filed by Intervenor-Defendant GenBioPro.[3]

Abortion, The Justice Foundation and its Center Against Forced Abortions, and the National Association of Christian Lawmakers [Doc. 92]; (iii) American Association of Pro-Life Obstetricians and Gynecologists and Samaritan's Purse [Doc. 96]; (iv) The American Center for Law and Justice [Doc. 99]; (v) Ethics and Public Policy Center [Doc. 101]; (vi) Women and Families Harmed by Mifepristone and Former Abortion Providers [Doc. 118]; (vii) Advancing American Freedom, Inc., et al [Doc. 123]; (viii) Concerned Women for America [Doc. 128]; (ix) Dr. Calum Miller [Doc. 130]; (x) Heartbeat International [Doc. 132]; (xi) Students for Life of America [Doc. 136]; (xii) Senator Bill Cassidy, M.D., Representative Christopher H. Smith, and 58 Members of Congress [Doc. 141]; and (xiii) the States of Nebraska, Alabama, Alaska, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Mississippi, Missouri, Montana, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wyoming [Doc. 121].

Amicus briefs were filed in opposition to the Plaintiffs' Motion by the following entities: (i) IGH PLLC d/b/a Abortion on Demand, Hey Jane, and The Reproductive Health Initiative for Telehealth Equity & Solutions (RHITES) [Doc. 204]; (ii) National Domestic Violence Hotline and Legal Voice [Doc. 206]; (iii) Former Commissioners and Acting Commissioners of the U.S. Food and Drug Administration [Doc. 208]; (iv) the States of New York, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, Washington, and the District of Columbia filed an amicus brief in opposition to the Defendants' Motion to Stay [Doc. 210]; (v) Over 100 Reproductive Health, Rights, and Justice Organizations [Doc. 218]; (vi) Former U.S. Department of Justice Officials [Doc. 220]; (vii) Disability Rights Education and Defense Fund and Others [Doc. 222]; (viii) American College of Obstetricians & Gynecologists, et al [Doc. 224]; and (ix) Medical Students for Choice [Doc. 226].

[3] Plaintiffs' Motion for Preliminary Injunction is opposed by the Defendants [Doc. 51] and by the Intervenors [Docs. 230, 231], and Plaintiffs filed a single brief both in reply to the Defendants' opposition brief and in opposition to the Defendants' Motion to Stay [Doc. 111]. Plaintiffs oppose the Motions to Dismiss filed by Danco and GenBioPro [Doc. 253], and Danco and GenBioPro filed reply briefs [Docs. 256, 257, respectively].

After a review of the record and the complex regulatory and judicial history of this subject matter, the Court declines to grant the Plaintiffs § 705 relief at this time. The record shows that FDA is currently in the process of "conducting its own review of the evidence" with respect to the current Risk Evaluation and Mitigation Strategies ("REMS"), "to determine whether modifications are necessary." [Doc. 1-110]. And "courts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'" *FDA v. Am. Coll. of Obstetricians & Gynecologists,* 141 S. Ct. 578, 578-79 (2021) (Roberts, C.J., concurring in grant of application for stay).

Indeed, given the information available – and, importantly, the dearth of information upon which FDA previously acted to significantly loosen safety restrictions for prescribing mifepristone – the equities and the public interest weigh heavily in favor of FDA completing the job that the law requires it to do. Put differently, at this juncture, it is the completion of FDA's promised good faith, evidence-based, and expeditious review of the mifepristone REMS, not "government by lawsuit," that this Court finds to be in the public interest. *See United States v. Texas*, 599 U.S. 670, 704 (2023) (Gorsuch, J., concurring).

The Motions to Dismiss filed by the drug manufacturers Danco and GenBioPro [Docs. 230, 232, respectively] move to dismiss on the bases that Plaintiffs: (i) lack Article III standing; (ii) are outside "zone of interests" of the APA and Comstock Act; (iii) have failed to exhaust their claims administratively pursuant to 21 C.F.R. § 10.45(b); (iv) have asserted claims not yet ripe for adjudication; and (v) that on the merits their claims fail to state a claim upon which relief can be granted. This ruling addresses the Intervenors' primary contention – the threshold jurisdictional issue of the Plaintiffs' standing to bring this action. But because the Court grants the Governments motion to stay this case pending completion of FDA's mifepristone REMS review, the Court declines to substantively address the remaining issues raised by Intervenors at this time. Intervenors may renew their Motions to Dismiss upon the Court's lifting of the stay.

For these reasons and as further detailed below, the Court finds that the Government's Motion to Stay the Case [Doc. 50] should be GRANTED. Plaintiffs' Motion for Preliminary Relief Under 5 U.S.C. § 705 [Doc. 20] is DENIED without prejudice to refiling upon the Court lifting the stay. Likewise, the two Motions to Dismiss filed by Intervenors [Docs. 230, 232] are DENIED without prejudice to refiling upon the Court lifting the stay. This action will remain STAYED until further order of the Court.

FACTUAL BACKGROUND AND PROCEDURAL HISTORY

I. Regulatory History of Mifepristone[4]

This case arises under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. ch. 9., the principal federal statute governing the regulation of food, drugs, medical devices, and cosmetics in the United States. The U.S. Department of Health and Human Services ("HHS") is charged with the responsibility for implementing that law and has delegated the obligation to FDA, its subagency. Under federal law, FDA is responsible for ensuring that drugs marketed in the United States are safe and effective.

To that end, a drug sponsor seeking approval – typically the manufacturer or prospective marketer – must submit an application to FDA demonstrating that the drug is safe and effective for its intended use. *Alliance IV*, 602 U.S. at 375, *citing* 21 U.S.C. § 355(d). The application must generally include proposed labeling that

[4] Although the Court provides herein a summary of the complex regulatory history pertinent to its ruling, a more exhaustive regulatory history is provided in *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 233 (5th Cir. 2023) ("*Alliance III*"), *rev'd and remanded sub nom., FDA v. All. for Hippocratic Med.,* 602 U.S. 367, 375 (2024) ("*Alliance IV*").

specifies, among other things, the drug's dosage, directions for use, and the specific conditions the drug is approved to treat. *Id.* at 375, *citing* 21 C.F.R. §§ 201.5, 314.50 (2022). FDA may also impose additional conditions on a drug's prescription and use when it finds that enhanced safety measures are necessary. *Id.*, *citing* 21 U.S.C. § 355-1(f)(3). Such conditions may include prescriber training, dispensing limitations, or patient-monitoring requirements. *Id.*

In 2000, FDA approved a new drug application for mifepristone tablets under its Subpart H regulations, 21 C.F.R. § 314.500. *Id.* This newly approved drug was marketed under the brand name Mifeprex and was used to terminate pregnancies through seven weeks of gestation (the "2000 Approval").[5] *Alliance IV*, 602 U.S. at 375. To help ensure that Mifeprex would be used safely and effectively, FDA placed further restrictions on the drug's use and distribution. *Id.* Among other requirements, only physicians were permitted to prescribe or supervise the prescription of Mifeprex, and patients were required to follow a regimen involving three in-person visits with a physician. *Id.* FDA also required prescribing physicians to report hospitalizations, blood transfusions, and other serious adverse events to the drug sponsor, which in turn was obligated to report those events to FDA. *Id.*

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[5] In 1992, FDA promulgated the "Subpart H" regulations, which permit the accelerated approval of drugs intended to treat serious or life-threatening illnesses based on evidence of meaningful therapeutic benefit. *See* 21 C.F.R. § 314.500. Recognizing that such approvals rest on an expedited evidentiary basis, Subpart H also authorized post-approval restrictions "to assure safe use." *Id.* § 314.520. Mifepristone was approved under this framework. In 2007, Congress codified and expanded these post-approval safety authorities by establishing Risk Evaluation and Mitigation Strategies (REMS), which are designed to ensure that a drug's benefits outweigh its risks. *See All. for Hippocratic Med. v. FDA,* 2023 WL 2913725, at *21 (5th Cir. Apr. 12, 2023) ("*Alliance II*"), *citing* 21 U.S.C. § 355-1 (a)(1)-(2).

In 2015, Mifeprex's distributor, Danco, submitted a supplemental new drug application seeking to amend Mifeprex's labeling and to relax some of the restrictions that FDA had imposed. *Id.* In 2016, FDA approved the proposed changes, which: (i) deemed Mifeprex safe to terminate pregnancies up to ten weeks rather than seven weeks; (ii) allowed healthcare providers such as nurse practitioners to prescribe Mifeprex; and (iii) approved a dosing regimen that reduced the number of required in-person visits from three to one. *Id.* at 375-76. In addition, FDA approved a change in the prescribers' adverse event reporting obligations to require prescribers to report only fatalities (collectively, the "2016 Amendments"). *Id.* at 376.

In April 2019, FDA approved an application for generic mifepristone, manufactured by GenBioPro (the "2019 Generic Application"). *Id.* FDA established the same conditions of use for generic mifepristone as for Mifeprex. *Id.* Then, in April 2021, at the height of the COVID-19 pandemic, FDA again relaxed the requirements for Mifeprex and generic mifepristone, announcing that it would temporarily "exercise enforcement discretion" to allow "dispensing mifepristone through the mail ... or through mail-order pharmacy" (the "2021 Nonenforcement Decision"). *Id.*

In January 2023, FDA issued its most recent REMS for mifepristone (the "2023 REMS"), which codified and refined prior changes, including, among other things: (i) the removal of an in-person dispensing requirement; (ii) permitting certified pharmacies to dispense mifepristone (including by mail); and (iii) otherwise continuing the post-2016 framework, including limited adverse-event reporting (primarily deaths). *Alliance III*, 78 F.4th at 247.

II. History of Mifepristone Litigation in the Fifth Circuit

In 2022, physicians providing pregnancy-related health care, including emergency care after unsuccessful medication abortions using mifepristone, and national organizations of such physicians, brought an action in a Texas district court under the Administrative Procedure Act ("APA") against FDA, HHS, and agency officials. *See All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 560 (N.D. Tex. Apr. 7, 2023) ("*Alliance I*"). These plaintiffs challenged both the lawfulness of FDA's initial approval of mifepristone (which had occurred more than 20 years earlier), and each post-approval action (at that time, the 2016 Amendments, 2019 Generic Approval, and 2021 Nonenforcement Decision). *Id.* After concluding that the plaintiffs had standing, the *Alliance I* district court entered a preliminary injunction staying the 2000 Approval of mifepristone and each of the subsequent agency actions – effectively removing the drug from the market pending a full trial on the merits. *Id.*

FDA and Danco appealed the injunction to the Fifth Circuit and asked for an emergency stay of the district court's order pending appeal. The Fifth Circuit granted a partial stay, temporarily reinstating FDA's original 2000 Approval of Mifeprex. *Alliance II*, 2023 WL 2913725, at *21. This partial stay permitted the drug to remain available only under the earlier, more restrictive conditions but left in place the district court's injunction as to later regulatory changes. *Id.* Specifically, the *Alliance II* court found that the plaintiffs were likely to succeed on the merits of their claims under 5 U.S.C. § 706(2)(A) in at least two respects. *Id.* at *17.

First, the *Alliance II* court determined that FDA had failed to examine the relevant data when adopting the 2016 Amendments – relying instead on data that included the very safeguards the 2016 REMS had therein dispensed with. *Id.* And second, in a similar vein, FDA thereafter relied on the absence of non-fatal adverse-event reports in FDA's Adverse Event Reporting System ("FAERS") after eliminating the requirement that such events even be reported. *Id.* As to the latter error, the Fifth Circuit pointedly explained 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." *Id.*

Thus, the Fifth Circuit concluded that the *Alliance* plaintiffs were likely to succeed on the merits of their APA challenges with respect to FDA's decisions beginning with the 2016 Amendments and "all subsequent actions." *Id.* at *17-21. Following the Fifth Circuit's partial stay, FDA and Danco sought a full stay from the United States Supreme Court, which they obtained, thereby preserving the current regulatory regime during the pendency of the appeal. *Danco Lab'ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023).

Then, in August 2023, a different panel of the Fifth Circuit addressed the merits appeal of the *Alliance I* administrative stay and preliminary injunction. *See generally Alliance III*, 78 F.4th at 233. The merits panel agreed with the *Alliance II* court's determination that both the individual doctors and the plaintiff medical associations had Article III standing. And in assessing FDA's 2016 Amendments and the 2021 Nonenforcement Decision, the *Alliance III* court agreed that FDA had acted arbitrarily and capriciously and otherwise abused its discretion under 5 U.S.C.

§ 706(2)(A) when it, among other things: (i) failed to consider the cumulative effect of the 2016 Amendments; (ii) failed to consider whether it needed to continue to collect data of non-fatal adverse events in light of the "major" 2016 changes to the mifepristone REMS; (iii) gave dispositive weight in making the 2021 Non-Enforcement Decision to FAERS data that had been compromised by FDA's 2016 removal of non-fatal reporting requirements; and (iv) relied on literature that did not support its position in making the 2021 Nonenforcement Decision.[6] *Id.*

Specifically, the *Alliance III* court found that the studies underpinning FDA's approval of the 2016 Amendments failed to consider any data that cumulatively evaluated the effect of implementing each of its proposed "major" changes, which included:

> … increasing the maximum gestational age from forty-nine days to seventy days; allowing non-physicians to prescribe mifepristone; removing the requirement that the administration of misoprostol and the subsequent follow-up appointment be conducted in person; eliminating prescribers' obligation to report non-fatal adverse events; switching the method of administration for misoprostol from oral to buccal; and changing the dose of mifepristone (600 mg to 200 mg) and misoprostol (400 mcg to 800 mcg).

Id. at 246.

Instead, the *Alliance III* court found that the "FDA neither considered the effects as a whole, nor explained why it declined to do so[,]" even though FDA had acknowledged that "[t]he cumulative effect of the 2016 Amendments is

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[6] The merits panel disagreed with the district court's determination that plaintiffs were likely to succeed on their challenge to FDA's 2000 Approval of Mifeprex and 2019 Approval of generic mifepristone. *Id.* at 256. Accordingly, the Fifth Circuit vacated the district court's order as to those agency actions. *Id.*

unquestionably an important aspect of the problem[.]" *Id.* The court also determined that FDA's failure to consider whether it needed to continue to collect data of non-fatal adverse events in light of the "major" changes to the mifepristone REMS was likely arbitrary and capricious. *Id.* at 246-47.

As to the 2021 Nonenforcement decision (that was later formalized in the 2023 REMS at issue here), the *Alliance III* court found, in essence, that FDA had based its decision on the absence of data that it had only five years previously intentionally eliminated – finding that "considerable evidence shows that FAERS data is insufficient to draw general conclusions about adverse events." *Id.* at 249. The Court also found that FDA had "relied on various literature relating to remote prescription of mifepristone" in spite of "FDA's admission that the literature did not affirmatively support its position." *Id.* at 250.

In 2024, the Supreme Court reversed, finding that the *Alliance* plaintiffs lacked Article III standing to challenge FDA's regulatory actions. *Alliance IV*, 602 U.S. at 396-97. The Court explained that Article III's case-or-controversy requirement confines federal judicial power to actual "personal stake" injuries. And because the plaintiff doctors and physician associations did not prescribe, use, manufacture, sell, or otherwise face regulation stemming from FDA's actions, their asserted injuries were speculative and not fairly traceable to the challenged FDA actions. *Id.* at 385-86.

In so finding, the Court emphasized that sincere legal, moral, ideological, and policy objections to another's conduct – here, the prescription and use of mifepristone – standing alone, do not satisfy Article III's standing requirements. *Id.* at 396.

Accordingly, the Supreme Court reversed the Fifth Circuit and remanded for further proceedings consistent with its opinion. *Id.* at 397.

III. Recent Actions of FDA

Important to the Court's determination here, on September 19, 2025, undoubtedly aware of the mifepristone regulatory deficiencies identified by the Fifth Circuit in the *Alliance* cases, FDA agreed to undergo a thorough review of the mifepristone REMS. Specifically, in direct response to a letter sent to HHS by the Attorneys General of 22 states,[7] HHS Secretary Kennedy and FDA Commissioner Makary responded with a letter agreeing to conduct a comprehensive safety review of the mifepristone REMS, including the 2023 REMS at issue here. [Doc. 1-110].

In their letter, Secretary Kennedy and Commissioner Makary stated that, "[s]ince its original approval, the FDA has received reports of serious adverse events in patients who took mifepristone," and consequently, FDA's review would "study[] the adverse consequences reported in relation to mifepristone to ensure the REMS are sufficient to protect women from unstated risks." [*Id.*]. FDA premised this review on a frank acknowledgement of the "lack of adequate consideration underlying the prior REMS approvals" as well as "recent studies raising concerns about the safety of mifepristone as currently administered," including those that "indicate potential dangers that may attend offering mifepristone without sufficient medical support or supervision." [*Id.*]. The letter promised to ensure that FDA's analysis and any

[7] The letter, sent by Kansas Attorney General Kris Kobach and 21 other AGs on July 31, 2025, asked for a comprehensive review of mifepristone or, alternatively, a removal of the drug from the market pending additional safety testing.

resulting revisions to the mifepristone REMS would be "grounded in Gold Standard Science." [*Id.*]. Commissioner Makary publicly acknowledged that the review of mifepristone safety was underway as of January 2026.[8]

IV. The Instant Lawsuit

On October 6, 2025, the State of Louisiana and Rosalie Markezich filed the instant lawsuit, challenging FDA's January 2023 REMS, and particularly, the removal of the in-person dispensing requirement and authorization of dispensation of the drug by mail and telehealth.[9] Plaintiffs claimed injuries include: (i) harm to state sovereignty; (ii) increased Medicaid expenditures, including over $92,000 in 2025 emergency room and hospitalization costs from two mifepristone-induced abortions and projections of hundreds of thousands of dollars in similar costs; and (iii) public-health harms, including statistically-certain emergency room visits and risks of serious and sometimes fatal infections and bleeding. Plaintiffs seek preliminary relief to stay or set aside the 2023 REMS under 5 U.S.C. § 705, or an injunction mandating that FDA enforce mifepristone's previous in-person dispensing requirement. In response, the Government asks this Court to stay the litigation while FDA conducts its review of the mifepristone REMS.

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[8] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation,* FDA, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (last updated Feb. 2, 2026).

[9] Plaintiff Markezich alleges that in October 2023, her then-boyfriend used her email address to obtain mifepristone (and a second drug, misoprostol) from a physician in California via mail order. [Doc. 1, ¶ 10]. She alleges that she did not want to take the drug, was pressured by him, and that the result of taking the medication caused the termination of her pregnancy and ongoing distress and trauma. [*Id.*].

On February 24, 2026, the Court granted the Motions to Intervene filed by mifepristone manufacturers Danco and GenBioPro [Docs. 52 and 54, respectively], and thereafter, the Intervenors' Motions to Dismiss were filed into the record. [Docs. 230 and 232, respectively].

LAW AND ANALYSIS

I. Legal Standards

A. APA Standard of Review

The APA was designed by Congress to act as "a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices." *United States v. Morton Salt Co.*, 338 U.S. 632, 644 (1950). It requires federal courts to "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). The standard set forth by the Fifth Circuit is clear:

> … [A]n agency must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" An agency violates these rules where it "entirely fail[s] to consider an important aspect of the problem," or offers "an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."

Alliance III, 78 F.4th at 245 (internal citations omitted).

To be sure, the arbitrary and capricious standard is narrow, and courts must be careful not to "substitute" their own "policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). But ultimately, Congress has vested federal courts with the responsibility to "ensure that the agency 'examined the

relevant data and articulated a satisfactory explanation for its action.'" *Sierra Club v. EPA*, 939 F.3d 649, 664 (5th Cir. 2019). And applying this standard, courts may vacate agency decisions containing "unexplained inconsistencies in the rulemaking record." *Id.*

If an agency's deliberative process falls short of the APA's requirements, Section 705 authorizes courts to stay an agency action while the action undergoes judicial review. 5 U.S.C. § 705. "In the same way that a preliminary injunction is the temporary form of a permanent injunction, a stay is the temporary form of vacatur." *Alliance III*, 78 F.4th at 254*, quoting Monsanto Co. v. Geerston Seed Farms*, 561 U.S. 139, 165 (2010).

B. Injunctive Relief Pursuant to 5 U.S.C. § 705

Here, Plaintiffs urge the Court in their Motion for Preliminary Relief to issue an order under § 705 of the APA, "staying or postponing the effective date of the [2023 REMS]." [Doc. 20]. Because "a stay [under the APA] has the practical effects of an injunction," the preliminary injunction factors applicable to Federal Rule of Civil Procedure 65 motions apply. *Alliance III*, 78 F.4th at 242*, citing* 28 U.S.C. § 1292(a) *and Alliance II*, 2023 WL 291375, at *3 n.3; *see also Colorado v. EPA*, 989 F.3d 874, 883 (10th Cir. 2021). "Injunctive relief is an extraordinary and drastic remedy, not to be granted routinely, but only when the movant, by a clear showing, carries the burden of persuasion." *Louisiana v. Biden*, 575 F. Supp. 3d 680, 691 (W.D. La. Dec. 16, 2021), *aff'd*, 55 F.4th 1017 (5th Cir. 2022), *citing Holland Am. Ins. Co. v. Succession of Roy*, 777 F.2d 992, 997 (5th Cir. 1985). "To be entitled to a preliminary injunction, a movant must establish: (1) a likelihood of success on the merits; (2) a

substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest." *Id.* at 691, *quoting Ladd v. Livingston*, 777 F.3d 286, 288 (5th Cir. 2015); *Alliance III*, 78 F.4th at 241.

C. Motion to Stay

The above notwithstanding, a district court always retains the inherent authority to stay a proceeding "to control the disposition of the causes on its docket …." *Crimson Bldg. Co. v. Plutus Grp., LLC*, 2020 WL 13616911, at *1 (N.D. Tex. Feb. 24, 2020), *quoting United States v. Rainey*, 757 F.3d 234, 241 (5th Cir. 2014) (internal quotation marks omitted). In staying a case pursuant to this authority, the Court should "balance between the harm of moving forward [with the litigation] and the harm of holding back." *Ali v. Quarterman*, 607 F.3d 1046, 1049 (5th Cir. 2010). Additionally, the Court should consider whether a stay is warranted in light of activity in a related action and other "present day realities." *In re Beebe*, 1995 WL 337666, at *3-4 (5th Cir. May 15, 1995); *see also Landis v. N. Am. Co.*, 299 U.S. 248, 258 (1936).

As the Supreme Court has explained, "[e]specially in cases of extraordinary public moment, [a plaintiff] may be required to submit to delay not immoderate in extent and not oppressive in its consequences if the public welfare or convenience will thereby be promoted." *Clinton v. Jones*, 520 U.S. 681, 706-07 (1997), *citing Landis*, 299 U.S. at 256. And district courts regularly stay proceedings to allow an agency to pursue further action on the rulemaking at issue. *See, e.g., Town & Cnty. of*

Nantucket v. Burgum, 2025 WL 3120419, at *2 (D.D.C. 2025), *citing Code v. McHugh*, 139 F. Supp. 3d 465, 466 (D.D.C. 2015); *FBME Bank Ltd. v. Lew*, 142 F. Supp. 3d 70, 76 (D.D.C. 2015); *Sierra Club v. Van Antwerp*, 560 F. Supp. 2d 21, 26 (D.D.C. 2008).

II. Standing

As a threshold matter, the Court is first charged with the important jurisdictional task of determining whether the Plaintiffs have standing to challenge the 2023 REMS. As previously discussed, the *Alliance* litigation was ultimately dismissed by the Supreme Court for those plaintiffs' lack of standing to challenge the mifepristone REMS. *Alliance IV*, 602 U.S. at 396-97. And here, both the Government and Intervenors argue in their briefing that the Plaintiffs lack standing for their requested relief. [Docs. 51, 230, 231]. Intervenors Danco and GenBioPro also specifically seek dismissal of this action on that basis. [Docs. 230, 232].

The Court will therefore first carefully evaluate Plaintiffs' Article III standing. Standing is "built on a single basic idea – the idea of the separation of power." *Alliance IV*, 602 U.S. at 378. "Article III requires a plaintiff to show that she has suffered an injury-in-fact that is fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Haaland v. Brackeen*, 599 U.S. 255, 291-92 (2023), *citing California v. Texas*, 593 U.S. 659, 668-69 (2021); *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

To establish 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." *Texas v. United States*, 126 F.4th 392, 407 (5th Cir. 2025),

quoting Alliance IV, 602 U.S. at 380. "The second and third standing requirements – causation and redressability – are often 'flip sides of the same coin,'" meaning if "a defendant's action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury. So the two key questions in most standing disputes are injury-in-fact and causation." *Texas*, 126 F.4th at 407, *quoting Alliance IV*, 602 U.S. at 380-81.

The Court is also cognizant that at earlier stages of litigation, such as in adjudicating a motion for injunctive relief, the manner and degree of evidence required to show standing may be less than at later stages. *Speech First, Inc. v. Fenves*, 979 F.3d 319, 329-30 (5th Cir. 2020), *as revised* (Oct. 30, 2020), *citing Lujan*, 504 U.S. at 561 ("each element [of standing] must be supported ... with the manner and degree of evidence required at the successive stages of the litigation"); s*ee also Barber v. Bryant*, 860 F.3d 345, 352 (5th Cir. 2017), *citing Lujan*, 504 U.S. at 561 ("Since they are not mere pleading requirements but rather an indispensable part of the plaintiff's case, each element must be supported ... with the manner and degree of evidence required at the successive stages of litigation."). Thus, at this stage, it is the Plaintiffs' burden to put forth facts establishing that they have standing to seek the requested § 705 relief.

Louisiana argues that it has standing both because: (i) the 2023 REMS causes sovereign harm by facilitating abortions that violate numerous Louisiana state

laws,[10] [Doc. 20-26, p. 24]; and (ii) it continues to suffer ongoing financial injury resulting from the 2023 REMS and has already paid hundreds of thousands of dollars through Louisiana Medicaid for emergency room medical care stemming from mifepristone use by residents. [*Id.*, p. 26]. In response, Defendants argue primarily that Louisiana lacks standing because it "do[es] not prescribe or use mifepristone" and the 2023 REMS Modification does not "require[] [Louisiana] to do anything or to refrain from doing anything" and the indirect causal chain between the REMS and Louisiana's alleged injury is too speculative or attenuated to establish standing. [Docs. 51, 230, 231]. Put another way, because Louisiana is not a regulated party, the Defendants allege that Louisiana is unable to establish traceability between

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[10] Louisiana prohibits all abortions except those that are determined to be medically necessary to prevent the death or substantial risk of death of the mother. *See* La. R.S. § 40:1061, La. R.S. § 14:87.7, and La. R.S. § 14:87.8.1.

Important here, Louisiana has also enacted a criminal prohibition on the prescribing and dispensing of mifepristone for purposes of inducing an abortion and classifies mifepristone as a Schedule IV controlled and dangerous substance under its drug laws. *See* La. R.S. § 14:87.1(2)(a) ("'Abortion-inducing drug' means any drug or chemical, or any combination of drugs or chemicals, or any other substance when used with the intent to cause an abortion."); La. R.S. § 40:964.

And if those criminal prohibitions were not clear, Louisiana's longstanding policy, enacted into statute, states, in part:

> It is the intention of the Legislature of Louisiana to regulate, prohibit, or restrict abortion to the fullest extent permitted by the decisions of the Supreme Court of the United States. The legislature does solemnly declare, find, and reaffirm the longstanding public policy of this state that every unborn child is a human being from the moment of conception and is, therefore, a legal person for purposes under the laws of this state and Constitution of Louisiana.

La. R.S. § 40:1061.1 (A)(1).

Louisiana's claimed sovereign and financial injuries and FDA's promulgation of the 2023 REMS. [*Id*].

Although the Supreme Court has observed that establishing standing is "ordinarily substantially more difficult" for unregulated parties – particularly where causation rests on "the unfettered choices of independent actors" – it has also made clear that standing may exist where such actors predictably respond to the challenged action. *Lujan*, 504 U.S. at 560-61; *see also California*, 593 U.S. at 675*, citing Dep't of Com v. New York*, 588 U.S. 752, 768 (2019). The Fifth Circuit treats this inquiry as part of the traceability analysis, not injury-in-fact. *See Reule v. Jackson*, 114 F.4th 360, 367 (5th Cir. 2024), *cert. denied*, 145 S. Ct. 1431 (2025). Thus, even where injury is undisputed, standing fails if the causal chain is too speculative. *Alliance IV*, 602 U.S. at 383.

As previously discussed, in *Alliance IV*, the Supreme Court dismissed for lack of standing where the plaintiff doctors and medical associations had no direct involvement with mifepristone, no cognizable economic injury, and no obligation to participate in abortion care, rendering any causal chain to FDA's actions too speculative. 602 U.S. at 385-86, 393-94. In the same vein, the Government attempts to distinguish this Court's standing analysis in *Louisiana v. EEOC*, 784 F. Supp. 3d 886 (W.D. La. 2025), arguing that, unlike the regulatory mandate there, the 2023 REMS imposes no obligations on the State. The Government further argues that any Medicaid-based economic harm is too attenuated.

After careful consideration, the Court finds that Defendants' arguments fall short at this stage. Here, the evidence in the record shows that the "independent

actors" – that is, the out-of-state medical providers prescribing mifepristone via telemedicine or mail – responded to the 2023 REMS by expanding mifepristone access to pro-life states like Louisiana in ways that were entirely predictable. On July 8, 2022, then-President Biden issued Executive Order 14076,[11] which expressly sought to protect and expand access to "*healthcare service delivery* and promote access to critical reproductive healthcare services, including abortion" in the wake of *Dobbs*. [Doc. 1-45, pp. 2-3] (emphasis added). And in a "Factsheet" issued by the White House

[11] Section 1 of EO 14076, enacted just one week after the *Dobbs* decision was issued, is entitled "Policy" and states:

> Nearly 50 years ago, *Roe* v. *Wade,* 410 U.S. 113 (1973), articulated the United States Constitution's protection of women's fundamental right to make reproductive healthcare decisions. These deeply private decisions should not be subject to government interference. Yet today, fundamental rights — to privacy, autonomy, freedom, and equality — have been denied to millions of women across the country.
>
> Eliminating the right recognized in *Roe* has already had and will continue to have devastating implications for women's health and public health more broadly. Access to reproductive healthcare services is now threatened for millions of Americans, and especially for those who live in States that are banning or severely restricting abortion care. Women's health clinics are being forced to close — including clinics that offer other preventive healthcare services such as contraception — leaving many communities without access to critical reproductive healthcare services. Women seeking abortion care — especially those in low-income, rural, and other underserved communities — now have to travel to jurisdictions where services remain legal notwithstanding the cost or risks.
>
> *In the face of this health crisis, the Federal Government is taking action to protect healthcare service delivery and promote access to critical reproductive healthcare services, including abortion.* It remains the policy of my Administration to support women's right to choose and to protect and defend reproductive rights. Doing so is essential to justice, equality, and our health, safety, and progress as a Nation.

Exec. Order No. 14,076, 88 Fed. Reg. 42,831 (July 7, 2023) (emphasis added).

on April 12, 2023, the administration touted, among other things, actions taken by FDA to "protect[] access to [abortion] care nationwide." [Doc. 1-60].

Thus, in that post-*Dobbs* regulatory environment, there is evidence that the 2023 REMS was approved without adequate consideration, at least in part, as part of an effort to circumvent anti-abortion states' ability to regulate abortion. Likewise, there is evidence that the consequences of this action were predictable – out-of-state providers and related entities would expand access to mifepristone in ways designed to reach into jurisdictions like Louisiana. These actions cause concrete and ongoing injury to Louisiana, as further discussed below.

But first, Louisiana's claimed injury must be put within the appropriate framework. The Constitution's Supremacy Clause declares that federal laws "shall be the supreme law of the land" when conflicting with state laws. U.S. CONST. art. VI, cl. 2. This includes the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and the resulting authority vested in FDA to approve and regulate drugs. Nevertheless, respect for the federal nature of our government is also paramount – "a system in which … the National Government, anxious though it may be to vindicate and protect federal rights and federal interests, always endeavors to do so in ways that will not unduly interfere with the legitimate activities of the [states]." *Younger v. Harris*, 401 U.S. 37, 44 (1971). The Supreme Court has consistently considered federalism concerns when, for example, determining the reach of federal law. *See, e.g., Sackett v. EPA*, 598 U.S. 651, 683 (2023); *U.S. Forest Serv. v. Cowpasture River Pres. Ass'n*, 590 U.S. 604, 621 (2020).

Here, Louisiana alleges that an unlawful use of federal regulatory power by an administrative agency directly undermines the enforcement of its own laws and forces it to incur additional costs.[12] *See Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015) ("States have a sovereign interest in the power to create and enforce a legal code."). Of course, if this Court or others ultimately determine that FDA acted lawfully in its removal of the in-person dispensing requirement for mifepristone, then Louisiana would have no judicial recourse under the APA.[13] After all, this would directly implicate the Constitution's Supremacy Clause and the power vested by Congress in FDA to regulate drugs. U.S. CONST. art. VI, cl. 2; *see also GenBioPro, Inc.*, 144 F.4th at 273 (4th Cir. 2025) (finding that although state law determines whether "abortion may be performed at all," federal law "permits the FDA to regulate how mifepristone must be prescribed and dispensed *if and when* a medication abortion is performed.").

On the other hand, if FDA did not act lawfully under the APA but rather exceeded or abused the power vested in it by Congress as Plaintiffs contend, then Louisiana clearly has an interest in vindicating its sovereign prerogative under basic principles of federalism. And the Fifth Circuit has twice indicated in *Alliance II* and *Alliance III* that FDA was likely arbitrary and capricious under the APA in removing

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[12] *See supra* note 10.

[13] For the avoidance of doubt, this does not mean that medical providers would then be free to ignore the laws of the states in which they prescribe mifepristone without fear of criminal prosecution. As recently put by the Fourth Circuit Court of Appeals, "the text of the [Food, Drug and Cosmetic Act] suggests that Congress intended to create a regulatory floor, not a ceiling" on drug regulation by the states. *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 274 (4th Cir. 2025). But that issue is not before the Court here.

mifepristone's in-person dispensing requirement. *Alliance II*, 2023 WL 2913725, at *17; *Alliance III*, 78 F.4th at 241-48.

To be sure, there are factors other than the 2023 REMS that influence the arrival of mifepristone in Louisiana. For example, some states have enacted "shield laws" to protect medical practitioners in their states from extradition for prescribing and illegally shipping mifepristone into jurisdictions where it has been prohibited. *See generally What Are Shield Laws?*, CTR. FOR REPROD. RTS., (Oct. 9, 2025), https://reproductiverights.org/resources/what-are-shield-laws/; *see also, e.g.,* CAL. PENAL CODE § 847.5(b)-(c). There are also the usual practical and investigatory impediments faced by state law enforcement when engaging in drug interdiction efforts. And these may be even more significant than the 2023 REMS in influencing the accessibility of mifepristone to Louisiana residents. But there can be little doubt that the 2023 REMS is a factor, which is all that is required for Louisiana to show injury-in-fact and traceability. *See Texas v. United States*, 50 F.4th 498, 519 (5th Cir. 2022) ("DACA is not the sole cause of the State's injury, but DACA has exacerbated it. That is sufficient."). Thus, even if the 2023 REMS is not the "sole cause" of Louisiana's sovereign harms, it has surely "exacerbated" them; "that is sufficient" for standing to assert its claims. *Id.*

Furthermore, "[m]onetary costs are of course an injury" for standing purposes. *Texas*, 599 U.S. at 676. And "even one dollar's worth of harm is traditionally enough to" confer standing. *Id.* at 688 (Gorsuch, J., concurring). A state's increased medical costs, such as increased Medicaid costs due to a federal agency action, can constitute

a "pocket-book injury" sufficient to satisfy the injury-in-fact requirement of standing. *Texas v. United States*, 126 F.4th 392, 411 n.22 (5th Cir. 2025) (collecting cases).

Here, Louisiana has put forth sufficient evidence to demonstrate that it has suffered and continues to suffer pocketbook injury. Under the federal Medicaid statute, Louisiana is required to cover medical assistance for eligible pregnant women, which includes inpatient and outpatient medical services. 42 U.S.C. §§ 1396(a)(viii), (a)(1)-(2). Louisiana is required to pay a portion of the total Medicaid costs, *id.* § 1396a(a)(2), and the federal government will pay between 50 percent and 83 percent, *id.* § 1396d(b). Crucially, FDA's "own documents" show that "emergency room care is statistically certain" in mifepristone cases. *Alliance II*, 2023 WL 2913725, at *10. And according to FDA's own 2023 label, 2.9-4.6 percent of women who receive an in-person visit with a doctor, are prescribed mifepristone, and take it as directed will require an emergency room visit. [Doc. 1-9, p. 9]. Empirical evidence indicates that the emergency room visitation and hospitalization rate may be closer to ten percent for patients with an estimated gestational duration of 78-84 days. [Doc. 1-13, p. 2]; [Doc. 20-4, p. 2].[14] And rates may also be higher when mifepristone is dispensed by mail. [Doc. 1-10, pp. 34-35].

Plaintiffs further estimate that, on average, about 1,000 mifepristone-induced abortions are occurring per month in Louisiana. [Doc. 20-2, p. 36]; [Doc. 20-22, pp. 1-2]. And, according to Plaintiffs' expert, many of these women obtaining abortions are likely to be on Medicaid. [Doc. 20-22, pp. 2-3]. In support of this

[14] *See* https://www.contraceptionjournal.org/article/S0010-7824(25)00308-7/abstract for the complete study.

contention, Plaintiffs have supplied evidence from the Louisiana Department of Health identifying more than $92,000 in Medicaid costs incurred for emergency room care and hospitalizations required because of two mifepristone-induced abortions in 2025 in which the drugs were received from out-of-state prescribers. [Doc. 20-20, pp. 4-5, ¶¶ 11-12]. These two incidents alone are sufficient to establish Louisiana's standing, but it is likely that many more Medicaid patients have required similar care due to complications from mifepristone. [*Id.*, pp. 4-5, ¶¶ 10, 13-15]; [Doc. 20-19, pp. 3-4, ¶¶ 7-8]; [Doc. 20-23, p. 4, ¶¶ 14-16].

And regardless of whether Louisiana's financial harm is the $92,000 previously discussed or far more than that, Louisiana's harm is more than zero. *See 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."). Accordingly, because "even one dollar's worth of harm" is sufficient, Louisiana has put forth sufficient evidence to demonstrate a substantial likelihood of success in proving it has suffered financial injury for standing purposes. *Texas*, 599 U.S. at 688 (Gorsuch, J., concurring).

For all of these reasons, Louisiana has established injury that is traceable to FDA's actions and redressable, at least in part, by the relief requested herein. Louisiana therefore has standing to challenge the 2023 REMS on the record before the Court.[15]

[15] Because the Court determines that the State of Louisiana has standing, it need not consider standing for Markezich. *Biden v. Nebraska*, 600 U.S. 477, 489 (2023) ("If at least one plaintiff has standing, the suit may proceed."), *citing Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 52 n.2 (2006).

III. Analysis Under Rule 65

With standing established for these purposes, the Court next considers whether Plaintiffs have carried their burden under the Rule 65 framework applicable to the Plaintiffs' requested § 705 relief.[16]

A. Likelihood of Success on the Merits

"The exact quantum of evidence that a plaintiff must present to satisfy the likelihood-of-success factor varies from case to case." *League of United Latin Am. Citizens v. Abbott*, 809 F. Supp. 3d 502, 546 (W.D. Tex. 2025), *citing Jefferson Cmty. Health Care Ctrs., Inc. v. Jefferson Par. Gov't*, 849 F.3d 615, 626 (5th Cir. 2017) ("[T]here is no particular degree of likelihood of success that is required in every case. …"). "The Fifth Circuit applies a 'sliding scale' approach, whereby a plaintiff who makes a strong showing on the other three preliminary injunction factors bears a lesser burden on the likelihood-of-success requirement (and vice versa)." *Id.*, *citing TitleMax of Texas, Inc v. City of Dallas*, 142 F.4th 322, 328 (5th Cir. 2025). Thus, "[w]here the other factors are strong," the movant need only show "some likelihood of success on the merits" to obtain a preliminary injunction. *Id.*

As discussed above, in *Alliance III*, the Fifth Circuit found that FDA, in promulgating the 2021 Nonenforcement Decision, had based its decision on the absence of data that it had only five years previously intentionally eliminated – finding that "considerable evidence shows that FAERS data is insufficient to draw

[16] The Plaintiffs do not squarely address in their briefing the application of the Rule 65 factors as they apply to Plaintiff Markezich. The Court therefore limits its analysis to Plaintiff Louisiana.

general conclusions about adverse events." *Alliance III*, 78 F.4th at 249. The Court also found that FDA had "relied on various literature relating to remote prescription of mifepristone – despite FDA's admission that the literature did not affirmatively support its position." *Id.* at 250.

To be sure, the 2023 REMS had not yet been put into effect when suit was filed in *Alliance I*. Therefore, those plaintiffs did not specifically challenge the 2023 REMS, as the Plaintiffs do here. But the Fifth Circuit's analysis in *Alliance III* found fault with both the 2016 Amendments and the 2021 Nonenforcement Decision – and included in its discussion that "in January 2023, FDA amended mifepristone's REMS … formalizing the change" rendered in the 2021 Nonenforcement Decision. *Id.* at 247. Likewise, in rejecting a mootness challenge by FDA, the *Alliance III* court described the 2023 REMS as merely a "final form of a previous, identical policy," removing mifepristone's in-person dispensing requirement. *Id.* at 248-49.

Accordingly, Plaintiffs' challenge to the 2023 REMS focuses on the very same failure to engage in reasoned decision-making under the APA when FDA modified the mifepristone regulatory regime. *Id.* at 245, 255. And the Supreme Court, in vacating the Fifth Circuit's opinion in *Alliance III*, addressed only those plaintiffs' lack of Article III standing to bring an APA challenge. *Alliance IV*, 602 U.S. at 396-97. The *Alliance III* court's reasoning is therefore due strong consideration in weighing Plaintiffs' likelihood of success on the merits.

Further, HHS Secretary Kennedy and FDA Commissioner Makary essentially acknowledged APA procedural deficits with respect to mifepristone in their September 19, 2025, letter, stating that FDA's intention to review the mifepristone

regulatory framework was precipitated by "the lack of adequate consideration underlying the prior REMS approvals" and recent safety concerns. [Doc. 1-110]. Thus, the Court concludes that Plaintiffs are likely to succeed on the merits of their 2023 REMS challenge.

B. Irreparable Injury

The Court has already found that Louisiana demonstrated an injury-in-fact, and those same facts establish irreparable harm. An irreparable harm is one that has "no adequate remedy at law." *Louisiana v. Biden*, 55 F.4th 1017, 1033-34 (5th Cir. 2022). Here, the 2023 REMS operates, arguably, in derogation of Louisiana law and interferes with Louisiana's ability to enforce its laws and implement the policy choices of its citizens. *Louisiana v. EEOC*, 705 F. Supp. 3d 643, 653 (W.D. La. 2024).

No remedy at law can redress that sovereign harm. By permitting medical providers to prescribe mifepristone remotely, the 2023 REMS facilitates the distribution of mifepristone into Louisiana notwithstanding contrary law. Louisiana suffers sovereign harm each time those laws are circumvented. And Louisiana has also demonstrated financial injury that cannot be "remedied where, as here, the defendant is entitled to sovereign immunity." *Alliance III*, 78 F.4th at 251.

C. Balance of Harms/Public Interest

No one disputes that "[a]bortion presents a profound moral issue." *Dobbs*, 597 U.S. at 223; s*ee also Alliance IV*, 602 U.S. at 376, 396 (noting both the longstanding controversy surrounding mifepristone and plaintiffs' "sincere legal, moral, ideological, and policy objections"). But this Court is not a forum for resolving moral or policy disagreements. Its task is to apply established legal standards to the record

before it. That inquiry turns on legally cognizable harms to the parties and the public interest, not on the weight of competing moral views. And where, as here, the issues implicate scientific and medical judgments committed by Congress to an agency with specialized knowledge, that limitation carries particular force.

Having previously discussed the ongoing harm suffered by Plaintiff Louisiana, the Court starts its analysis by looking at the interests of the Government. First, the Court notes that "anytime the Government is enjoined … 'it suffers a form of irreparable injury.'" *Alliance III*, 78 F.4th at 251, *quoting Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers). Specific to this matter, FDA is charged with implementing federal statutes governing the safety and efficacy of drugs through an evidence-based administrative rule-making process. *Alliance IV*, 602 U.S. at 374-75.

In carrying out that mandate, the agency evaluates scientific and clinical data, makes factual findings based on the administrative record, and, where appropriate, considers public comments. *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 617 (1973) (explaining that FDA approval requires adequate, well-controlled clinical investigations by qualified experts, not anecdotal or uncontrolled data). The agency must also "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). This science-based regime derives from and is limited to the confines of its Congressional mandate.

And FDA, being a component of the Executive Branch, operates as an agency ultimately accountable to the President. The public interest in the proper function of FDA and its scientifically grounded, congressionally authorized protocol is substantial. The Intervenors also have a substantial financial interest in this matter. Any change in the current regulatory regime governing the prescription of mifepristone, which has now been in place for five years, would affect their profit margins and compliance costs.

No doubt Louisiana has a great interest in this issue as well. *Dobbs* returned the issue of abortion to the people of the States and their elected representatives, including regulation of abortion methods, procedures, and the use of related drugs. 597 U.S. at 302. The 2023 REMS clearly facilitates easier access to mifepristone for Louisiana residents. But the Court must also take into consideration that any interim relief ordered by this Court would not relieve Louisiana of its duty to enforce its own laws. In practice, even with the remedy requested herein, mifepristone would likely continue to reach those who seek it, as our country's decades of experience with the war on illegal drugs clearly and painfully demonstrates.[17] Meanwhile, Louisiana retains many meaningful, boots-on-the-ground law enforcement mechanisms to mitigate its sovereign and financial harms while FDA completes its ongoing review.

The Court next turns to the public interest and begins with the premise, as recognized by the *Alliance III* court, that "[t]here is generally no public interest in the

[17] In 2025, for instance, cocaine production reached record levels despite fifty-five years of counter-narcotics enforcement efforts by the United States and other nations. *World Drug Report 2025*, UNITED NATIONS OFF. ON DRUGS & CRIME (June 13, 2025).

perpetuation of unlawful agency action." *Louisiana,* 55 F.4th at 1035. But the Court also notes that the Supreme Court fully stayed the preliminary injunction issued by the *Alliance I* district court, as affirmed in part by the Fifth Circuit in *Alliance II*, (including its injunction of the 2021 Nonenforcement Decision). *Danco Lab'ys, LLC*, 143 S. Ct. 1075. This effectively allowed the challenged FDA actions with respect to mifepristone to continue throughout the course of the appeal. And, of course, that injunction was ultimately vacated for lack of standing. *Alliance IV*, 602 U.S. at 396-97.

Here, unlike in the *Alliance* cases, FDA does not defend its decision-making on the merits but instead acknowledges deficits and requests a stay to complete a fulsome review of the merits of Plaintiffs' claims – a review that was announced before this lawsuit was filed and has already been initiated. [Doc. 1-110]. FDA also has the authority to take interim actions to ensure drug safety if new information is discovered during the pendency of its review. *See generally* [Doc. 250].

Also weighing on its analysis is the Court's understanding that this case arises amid multiple parallel lawsuits across the country addressing the same regulatory issues surrounding access to mifepristone, creating a substantial risk of inconsistent judicial outcomes on a question of nationwide importance.[18] Although not styled as

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[18] *See Mifepristone Litigation and Federal Action Tracker*, UCLA LAW CTR. ON REPROD. HEALTH, LAW, & POLICY (last updated Apr. 2026), https://law.ucla.edu/academics/centers/center-reproductive-health-law-and-policy/mifepristone-litigation-and-federal-action-tracker.

At the time of the parties' briefing, 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

a universal injunction, the relief sought by Plaintiffs would, as a practical matter, have a nationwide effect. As the Supreme Court recently observed, such sweeping relief creates asymmetry because a plaintiff "must win just one suit to secure sweeping relief," whereas the Government "must win everywhere" to avoid it. *Trump v. CASA, Inc.*, 606 U.S. 831, 855 (2025). It also risks "rushed, high-stakes, [and] low-information" decision-making in consequential cases. *Id.* at 855-56, *quoting Labrador v. Poe ex rel. Poe*, 144 S. Ct. 921, 927 (2024) (Gorsuch, J., concurring).

These concerns are reinforced by settled limits on equitable relief, which require that remedies be tailored to the plaintiff's injury and may not be "more burdensome … than necessary." *Texas*, 599 U.S. at 702 (Gorsuch, J., concurring), *quoting Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (internal quotation marks omitted). "Faithful application of those principles suggests that an extraordinary remedy like vacatur would demand truly extraordinary circumstances to justify it." *Id.* at 702 (Gorsuch, J., concurring).

This is because, like "universal injunctions, vacatur can stymie the orderly review of important questions, lead to forum shopping … and facilitate efforts to evade the APA's normal rulemaking processes." *Id.* at 703 (Gorsuch, J., concurring). "Vacatur can also sweep up nonparties who may not wish to receive the benefit of the

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approval of mifepristone and actions easing REMS restrictions). Other plaintiffs have challenged FDA's restrictions as too burdensome. *See Purcell v. Kennedy*, 2025 WL 3101785 (D. Haw. Oct. 30, 2025) (finding that FDA violated the APA by failing to provide a reasoned explanation for its burdensome conditions on the prescription of mifepristone, which that court determined appeared to be unwarranted relative to the drug's safety); *Washington v. FDA*, No. 1:23-cv-3026-TOR, 2025 WL 1888794 (E.D. Wash. 2025) (plaintiffs challenge REMS as too restrictive); *Whole Woman's Health All. v. FDA*, No. 3:23-cv-19 (W.D. Va.) (same). This list does not include a multitude of citizen petitions.

court's decision," which, here, would include the 18 states and other amici that filed briefs urging denial of Plaintiffs' Motion. *Id.* (Gorsuch, J., concurring); *see also, e.g., supra* note 2. As a result, vacatur improperly applied, "strains our separation of powers" because "it exaggerates the role of the Judiciary in our constitutional order, allowing individual judges to act more like a legislature by decreeing the rights and duties of people nationwide." *Id.* (Gorsuch, J., concurring). All told, although federal courts are vested with much authority, the Constitution does not establish, nor does this Court condone, "government by lawsuit." *Id.* at 704, *quoting* ROBERT H. JACKSON, THE STRUGGLE FOR JUDICIAL SUPREMACY 286-87 (1941).

Next, the Court finds it appropriate to look at the substance of the alleged deficiencies pointed to by Plaintiffs in weighing the equities of issuing interim relief. No doubt, the State has shown evidence of ongoing harm owing to the 2023 REMS. But the APA deficiencies pointed to by the Plaintiffs and found by the Fifth Circuit in *Alliance III* show only that the 2023 REMS was "taken without sufficient consideration of the effects those changes would have on patients" due to a lack of underlying data. *Alliance III*, 78 F.4th at 253. Those same deficiencies likewise prevent this Court from determining whether FDA's in-person dispensing requirement is scientifically necessary to ensure mifepristone is "safe" and "effective." *Id.* at 245; *see also* 21 U.S.C. § 355(b)(1)(i).

On the one hand, a proper science-driven evaluation may lead FDA to conclude that the in-person dispensing requirement is necessary to comply with FDA's mandate to ensure that mifepristone is "safe and effective" for use, 21 U.S.C. § 355(b)(1)(i), and Plaintiffs offer substantial evidence supporting that possibility. On

the other hand, FDA may determine, after a thorough and scientifically-driven process, that such a requirement is not required. This Court is ill-equipped to make this determination, particularly where FDA has thus far failed to even collect the data necessary to comply with the APA's requirement that it "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Alliance III*, 78 F.4th at 245, *quoting Motor Vehicle Mfrs.*, 463 U.S. at 43. And ultimately it is FDA, not this Court, that possesses the expertise to evaluate scientific evidence and make public health judgments.[19]

At bottom, the APA does not charge the judiciary with the task of supplanting the role of federal agencies in promulgating regulations. *See Prometheus Radio Project*, 592 U.S. at 423. Rather, it is quite simply meant to be "a check" upon administrators to ensure that they are doing their job as directed by Congress. *Morton Salt Co.*, 338 U.S. at 644 (1950). Here, FDA has acknowledged its own deficits and has initiated an ongoing review of mifepristone.

Finally, this Court finds that prudence in issuing injunctive relief is warranted here because the 2023 REMS has governed a nationally integrated regulatory scheme

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[19] *See, e.g.*, *FDA,* 141 S. Ct. at 578-79 (Roberts, C.J., concurring in grant of application for stay) ("[C]ourts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'"); *Cytori Therapeutics, Inc.* v. *Food & Drug Admin.*, 715 F.3d 922, 927 (D.C. Cir. 2013) (Kavanaugh, J.) ("A court is ill-equipped to second-guess that kind of agency scientific judgment under the guise of the APA's arbitrary and capricious standard."); *Otsuka Pharm. Co.* v. *Burwell*, 302 F. Supp. 3d 375, 403 (D.D.C. 2016) (Jackson, J.) ("To begin with, the FDA is an expert agency charged with making precisely these sorts of highly technical determinations, and its interpretation … is premised on 'the agency's evaluations of scientific data within its area of expertise.'"), *aff'd sub nom. Otsuka Pharm. Co.* v. *Price*, 869 F.3d 987 (D.C. Cir. 2017).

for five years (since the promulgation of the 2021 Nonenforcement Decision), and imposing sweeping relief now risks the "patchwork" of judicial remedy the Court has warned against. *CASA*, 606 U.S. at 872 (Kavanaugh, J., concurring). There are now at least five other lawsuits in federal courts around the nation addressing issues similar to those before the Court. *See supra* note 18. And again, FDA's ongoing review of the mifepristone REMS indicates both responsiveness to Congress's directive that drugs be "safe and effective," 21 U.S.C. § 355, as well as accountability to the public. *See DHS v. Regents of the Univ. of California*, 591 U.S. 1, 16 (2020), *quoting Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992) ("The APA 'sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts.'"). FDA's review should be conducted and completed free from judicial interference.

Therefore, for the reasons discussed, the Court declines to grant the Plaintiffs § 705 relief at this time. Given the length of time the 2023 REMS has been in effect, reliance interests on that scheme throughout the nation, the sweeping effect any remedy would have across states with differing abortion laws, and most importantly, FDA's recognition of its own shortcomings in regulating mifepristone and ongoing fulsome review of the mifepristone REMS, the Court will afford the agency a time-limited period of deference to complete its review and carry out the responsibilities assigned to it by Congress. This case will therefore be stayed.

But the stay granted to FDA will not remain open-ended. FDA has an obligation to act with all deliberate speed to review its past actions and complete a thorough analysis that addresses the deficiencies it has acknowledged. The parties

and the American public deserve nothing less. Should the agency fail to complete its review and make any necessary revisions to the REMS within a reasonable timeframe, the Court's analysis – and the weight accorded to these factors – will inevitably change.

CONCLUSION

Considering the foregoing,

IT IS HEREBY ORDERED that Defendants' MOTION TO STAY THE CASE [Doc. 50] is GRANTED, and this matter is STAYED pending completion of FDA's ongoing review of the mifepristone REMS and issuance of any resulting agency decision.

IT IS FURTHER ORDERED that Plaintiffs' MOTION FOR PRELIMINARY RELIEF UNDER 5 U.S.C. § 705 [Doc. 20] is DENIED WITHOUT PREJUDICE and with permission to refile, as appropriate, following completion of FDA's review or upon a lifting of the stay upon a material change in circumstances.

IT IS FURTHER ORDERED, pursuant to Plaintiffs' request at the motions hearing on February 24, 2026, that FDA produce the entirety of the administrative record to Plaintiffs' counsel within sixty (60) days.

IT IS FURTHER ORDERED that Danco's MOTION TO DISMISS [Doc. 230] and GenBioPro's MOTION TO DISMISS [Doc. 232] are hereby DENIED WITHOUT PREJUDICE and with permission to refile, as appropriate, following completion of FDA's review or upon a lifting of the stay upon a material change in circumstances.

IT IS FURTHER ORDERED that FDA shall file a report on or before six (6) months from the date of this Order providing the Court with the status of its review in terms of process and any updated timeframe for completion of review. Within

fourteen (14) days after FDA completes its REMS review, FDA shall file a brief advising the Court of any agency action and proposing a schedule for further proceedings, if necessary.

THUS, DONE AND SIGNED in Chambers on this 7th day of April 2026.

DAVID C. JOSEPH
UNITED STATES DISTRICT JUDGE

EXHIBIT B

09:29:03

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

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STATE OF LOUISIANA ET AL	CASE NO. 6:25-cv-01491
VERSUS	JUDGE DAVID C. JOSEPH
U.S. FOOD & DRUG ADMINISTRATION ET AL	MAGISTRATE JUDGE DAVID J. AYO

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TRANSCRIPT OF MOTION HEARING PROCEEDINGS
HEARD BEFORE THE HONORABLE DAVID C. JOSEPH
UNITED STATES DISTRICT JUDGE
FEBRUARY 24, 2026

APPEARANCES:

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PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY. TRANSCRIPT PRODUCED BY COMPUTER.

COURT PROCEEDINGS

(Court is called to order.)

THE COURT: Thank you. Please be seated.

Okay. Good morning, everybody. We're on the record now in 25-cv-1491, *State of Louisiana versus The Food & Drug Administration.*

Counsel, please make your appearances.

MR. AGUINAGA: Good morning, Your Honor. Benjamin Aguinaga on behalf of the State.

THE COURT: Good morning.

MS. HAWLEY: Good morning, Your Honor. Erin Morrow Hawley on behalf of the State and Ms. Markezich.

MS. MURRILL: Good morning, Your Honor. Liz Murrill, Attorney General for the State of Louisiana.

THE COURT: Good morning to each of you.

MR. BAPTIST: Good morning, Your Honor. Erik Baptist on behalf of the State of Louisiana and Ms. Markezich.

MS. MCINTYRE: Good morning, Your Honor. Gabriella McIntyre on behalf of the State and Ms. Markezich.

MS. HUETTEMANN: Good morning, Your Honor. Caitlin Huettemann on behalf of the State of Louisiana.

MR. FAIRCLOTH: Good morning, Your Honor. Zach Faircloth on behalf of the State.

MR. BASGALL: Good morning, Your Honor. Frank Basgall on behalf of the State and Ms. Markezich.

10:00:54 **MR. KATZEN:** Good morning, Your Honor. Noah Katzen on
10:00:56 behalf of federal defendants.
10:00:58 **THE COURT:** You're all by yourself, Mr. Katzen?
10:01:00 **MR. KATZEN:** All by myself.
10:01:06 **THE COURT:** Okay.
10:01:06 **MS. ELLSWORTH:** Good morning, Your Honor. Jessica
10:01:06 Ellsworth on behalf of Danco Laboratories.
10:01:11 **MS. SVERDLOV:** Good morning, Your Honor. Alexander
10:01:11 Sverdlov on behalf of Danco Laboratories.
10:01:15 **MR. MOST:** William Most for the same plaintiff -- for the
10:01:17 same party. Thank you.
10:01:21 **MR. KATERBURG:** Good morning, Your Honor. Robert
10:01:22 Katerberg for intervener defendant GenBioPro.
10:01:22 **MS. O'CONNOR:** Good morning, Your Honor. Daphne O'Connor
10:01:22 on behalf of GenBioPro.
10:01:26 **MR. ADCOCK:** Good morning. John Adcock on behalf of the
10:01:29 intervener GenBioPro.
10:01:29 **THE COURT:** Good morning to each of you, as well. I
10:01:32 think the way we should proceed today -- we're here on plaintiffs'
10:01:36 motion for a preliminary injunction of the 2023 REMS. We have two
10:01:42 proposed interveners who have filed motions to intervene. My
10:01:47 understanding is that those motions are not opposed; is that
10:01:51 correct?
10:01:51 **MR. AGUINAGA:** That's correct, Your Honor.
10:01:52 **MR. KATZEN:** That's correct.

10:01:54 **THE COURT:** And that's as of right? That's a motion to
10:01:58 intervene as a right because they have a financial interest in the
10:02:02 litigation?
10:02:02 **MR. AGUINAGA:** That's correct, Your Honor.
10:02:03 **MR. KATZEN:** We have taken no position on that.
10:02:06 **THE COURT:** I think so. Because I think that they have a
10:02:10 right to intervene, I will allow them time today to address the
10:02:15 preliminary injunction. So I think the way we're going to proceed
10:02:20 is I will allow the plaintiffs 30 minutes to present their case. I
10:02:24 understand you're going to split your time. Is that right, Mr.
10:02:28 Aguinaga?
10:02:28 **MR. AGUINAGA:** That's correct, Your Honor.
10:02:31 **THE COURT:** And then the defendants will have -- well, is
10:02:33 20 minutes enough for you?
10:02:36 **MR. KATZEN:** I believe it should be, Your Honor.
10:02:37 **THE COURT:** Okay. And then 20 minutes for the --
10:02:39 collectively among the interveners, split however you would like to
10:02:42 do so, and then ten minutes for rebuttal by the plaintiffs because
10:02:47 the plaintiffs have the burden of proof. Does that sound
10:02:49 reasonable to everybody?
10:02:49 **MR. AGUINAGA:** Sounds good.
10:02:50 **THE COURT:** No one has to use all of their time. With
10:02:55 that, I think we should proceed. Please proceed, Mr. Aguinaga.
10:03:03 **MR. AGUINAGA:** Well, thank you, Judge Joseph, and may it
10:03:06 please the Court. Benjamin Aguinaga on behalf of the State.

10:03:10 As we explained and as we've just discussed, I'm going to
10:03:10 try to open the first half of the 30 minutes on Article III
10:03:14 standing, and then my colleague Ms. Hawley will address the
10:03:19 remaining preliminary relief and stay factors.
10:03:21 I begin with Article III standing because we do think
10:03:25 that in light of the Fifth Circuit's *Alliance* decisions that
10:03:29 Article III standing is really the ultimate question in this case.
10:03:31 That question is whether we, as plaintiffs, have standing to sue.
10:03:35 We do, and I think the best way to approach that issue is to start
10:03:39 with three points of common ground that I understand to be common
10:03:43 ground among the parties:
10:03:44 One is there is no dispute that approximately a thousand
10:03:48 abortions are occurring every month in Louisiana by mail-order
10:03:52 drugs;
10:03:52 Two, there is no dispute that each of those abortions is
10:03:56 an independent violation of Louisiana law, which is sort of the
10:03:59 classic sovereign harm;
10:04:02 And three, there's no dispute that flowing from each of
10:04:04 those abortions are classic pocketbook injuries that the State is
10:04:07 suffering.
10:04:08 I think those are facts that we can start with just in
10:04:10 terms of the Article III standing analysis, and that's why I think
10:04:14 the analysis itself becomes so easy, because the next question is:
10:04:18 Well, is there an injury in fact? And as I take the other side to
10:04:21 dispute, really the dispute comes down to causation and

redressability, not really whether these pocketbook injuries and the violations of our laws are classic pocketbook injuries in fact and classic sovereign harms. So I think the injury in fact question in this case is actually quite straightforward because nobody really raises a strong argument otherwise. And so I think ultimately, at the end of the day, what you've got is a question about whether the 2023 REMS is the cause of those harms. And that's where you get to Step 2 of the standing analysis.

As we lay out in the reply brief, Your Honor --

THE COURT: Traceability.

MR. AGUINAGA: Traceability, Your Honor.

As we lay out in the reply brief, I do think the way to frame that question is the way the Court, the Supreme Court in the *Alliance* case framed it, which is to say traceability and redressability are flip sides of the same coin. At the end of the day, what you're asking is: Would granting the plaintiffs the relief they seek -- here, ultimately vacatur of the 2023 REMS -- redress the harm that they are asserting as the injury in fact at Step 1 of the standing analysis? And that I think is where page 117 of the Supreme Court's *Diamond Alternative Energy* opinion comes into play because that's the page where the Court says: If by design a regulation is intended to produce an effect, then ordinarily that means that vacating that regulation will have the effect of reducing the intended effect.

And that's squarely on point here because if the

10:05:50 historical record is clear about anything, it is that when
10:05:52 President Biden saw the *Dobbs* decision come down, the same day he
10:05:56 issued a directive to all of his agency heads to say: Find me a
10:05:59 way to send mail order mifepristone into states that are now
10:06:04 attempting to restrict and ban abortion. That, I think, is what
10:06:08 makes this case an easy one for standing.
10:06:10 You know, the *Diamond* case is helpful in a lot of ways.
10:06:13 One of the ways it's helpful is it repeats the common line in the
10:06:15 Supreme Court's cases that say that courts and parties often make
10:06:18 the standing analysis more difficult than it has to be. This is
10:06:21 one of those cases because we've got a clear historical record that
10:06:26 the valid purpose of the 2023 REMS and removing the in-person
10:06:30 dispensing requirement is to produce exactly the injuries that we
10:06:34 are suffering today. That, I think, sets aside all of the parade
10:06:38 of horribles that you see from the other side on if you find
10:06:41 standing for us in this case, then every state has standing to
10:06:44 challenge every agency action in the future. Most, if not all, of
10:06:48 those cases are going to fail at the standing stage because they
10:06:51 don't have the historical record.
10:06:54 And I will slow down -- I'm so sorry -- for the court
10:06:54 reporter.
10:06:55 They don't have the historical record that we have in
10:06:59 this case. And that's, I think, something that is undisputed
10:07:03 because, of course, those words came from the President himself and
10:07:06 from his Secretary of Health and Human Services. And that's, I

10:07:10 think, why you see parties like GenBioPro coming in and trying to
10:07:15 rewrite that historical record. Because once you accept what those
10:07:18 statements say on their face, once you accept as fact the intended
10:07:22 consequences that we're suffering today of the 2023 REMS, then this
10:07:26 is basically *Diamond* itself. This is *Monsanto*. We're the alfalfa
10:07:32 farmers in *Monsanto* who say: We don't want genetically modified
10:07:37 alfalfa from the farm next door intruding into our farms where
10:07:38 we're trying to grow alfalfa that is pure.
10:07:43 That's exactly what we've done here. We closed our
10:07:44 market to abortion altogether. That includes mail-order abortion
10:07:48 drugs. And yet, because of the 2023 REMS, you see a thousand
10:07:53 abortions a month occurring in the state.
10:07:56 That's why we think this case is straightforward on
10:07:59 standing, Your Honor. And I think at the end of the day, at this
10:08:01 preliminary stage, what we're asking you to do is enter relief that
10:08:05 would redress that injury, which is exactly the same relief that
10:08:10 the *Alliance* two Fifth Circuit panel recognized was appropriate,
10:08:12 which is a stay of the REMS. And what the Fifth Circuit said in
10:08:18 *Alliance* two is that a stay of the REMS means that the in-person
10:08:19 dispensing requirement would remain in effect. And there is no
10:08:22 argument on the other side that that would not redress our
10:08:25 injuries.
10:08:26 In a way, Your Honor, I think the best amici in this case
10:08:29 are actually FDA's amici because what they tell you with one voice
10:08:34 is that if you grant us the relief we request, then mifepristone

10:08:38 cannot be mailed. And lo and behold, that's exactly what redress
10:08:43 our harm, which is the mailing of mifepristone into the state.
10:08:46 Let me start -- let me end, actually, with just one thing
10:08:49 about chain of causation, because there's a line in the
10:08:52 Government's brief that says that the State is not in the chain.
10:08:56 And I think that's a reference to the *Diamond* case which referred
10:09:00 to basically a manufacturing chain, a product that would go through
10:09:04 a manufacturing chain. The chain that the Supreme Court was
10:09:07 referring to in *Diamond* and that it referred to in *Alliance* -- if
10:09:12 you look at page -- or, like, around page 385 of *Alliance*, what the
10:09:15 Supreme Court was referring to is a chain of predictable events.
10:09:20 What *Alliance* says -- the Supreme Court says, is a
10:09:22 plaintiff has to show a chain of predictable events starting with
10:09:26 the Government action and ending with the asserted injury. And if
10:09:31 there's anything clear about what's happened here is that not just
10:09:34 the predictable effects, but the intended effects of the 2023 REMS
10:09:39 have played out exactly how they were intended to play out. Like,
10:09:42 this is just a textbook -- like, a textbook example of predictable
10:09:46 chain of events because we know, in fact, that they have occurred.
10:09:50 Your Honor, that's standing. We don't think there is a
10:09:54 difficult question there. And I think, you know, once you resolve
10:09:56 that question, then the Fifth Circuit has decided all the other
10:09:59 questions.
10:10:00 And at this point, unless the Court has questions about
10:10:02 standing, I'm happy to invite my colleague Ms. Hawley up to talk

about the remaining factors.

THE COURT: On standing -- in this case, because of the regulatory history, we don't know how many medication abortions would occur in Louisiana if not for the 2023 REMS because before that, you had the 2021 COVID relief, allowing for mailing of this drug; 2022 *Dobbs* happened; 2023 this regulation came out, as you say, in response to the *Dobbs* decision. So we don't know how many would occur if not for this 2023 REMS; correct?

MR. AGUINAGA: Not with scientific certainty, Your Honor. What we do know -- and if you haven't had a chance to look at the #WeCount PowerPoint slides --

THE COURT: Seen it.

MR. AGUINAGA: Yeah. The chart spikes, right, after *Dobbs.* Now, of course, I think the compilation of those numbers began in earnest after *Dobbs* because then everybody realized we need to assess how effective the 2023 REMS is in actually injecting mail-order drugs into those states that ban abortion. So I think that's part of the reason why you see the spike in those charts.

And at least at this point, as I say, I don't think there is any dispute among the parties that that data, the best available data we've got says at least a thousand abortions a month in the state. And to be clear, Your Honor, I think this is a difficult case insofar as what you see from states like New York and California are overt attempts to conceal what's happening so that when we get a drug within our state -- and I don't know if you have

seen the pill bottles. We have seen the pill bottles that don't have a doctor's name, don't have a pharmacy name, don't have a practice name. The only thing we know is, like, a FedEx shipping label from California. That's what shows up in our state.

And so it's going to be very, very difficult to come up with firmer evidence about the rate of abortions in states like Louisiana. So that's why I think we lean so heavily on that #WeCount data because that is abortion providers' own data that they're submitting to that organization, and that's really the best we've got to go on. And I think the good thing for us, at least at this preliminary stage, is nobody disputes that that number is a fact.

THE COURT: Would you agree that if the Court were to grant a preliminary injunction, as you request, that it would not solve the problem with this drug being sent into Louisiana? Do you agree there would still be that drug being sent into Louisiana?

MR. AGUINAGA: Well, Your Honor, I think there is certainly a possibility that a bad actor in California could say, "Notwithstanding the reinstatement of the federal in-person dispensing requirement, I'm going to violate my certifications to the manufacturers or whomever and still send the drug into the state." That's certainly a possibility.

What the Supreme Court said in *Department of Commerce versus New York* is that traditionally you don't base the Article III standing analysis on speculation about future unlawful

10:12:55 behavior. And so I think that's always going it to be a
10:12:58 possibility, but at the end of the day, the burden we have is to
10:13:01 show that it would at least partially alleviate our injury. And I
10:13:03 think that's why it referenced FDA's amici. Everybody's saying,
10:13:06 like, the world is going to fall if we can't mail mifepristone.
10:13:11 Well, if that's what everybody understands to be the natural
10:13:14 consequence of the relief we're seeking, then that, for sure, is at
10:13:16 least partial relief, if not total relief, Your Honor.
10:13:18 **THE COURT:** Yeah. There would still be demand in the
10:13:21 state; right? There would still be the same demand? These drugs
10:13:24 are being mailed at the request of Louisiana citizens; right?
10:13:28 **MR. AGUINAGA:** Allegedly, Your Honor. And, again, a lot
10:13:29 of this is anonymous. Yes, anybody in Louisiana can go on that
10:13:34 website, like aidaccess.org, fill out a five-minute form, and
10:13:38 request drugs to be mailed to a Louisiana address. So no doubt
10:13:40 that can continue to happen. The question is: Is there at least a
10:13:45 plausible argument that removing the in-person dispensing
10:13:49 requirement will at least stop some of that activity, if not all of
10:13:51 it? And I think what you see from everybody in this case is, like,
10:13:53 yes, that is the natural consequence of the relief we're seeking.
10:13:56 **THE COURT:** I mean, the war on drugs has been going on 50
10:13:59 years now, and just this past year there's more cocaine produced
10:14:02 than any year before. Okay?
10:14:04 **MR. AGUINAGA:** Yeah. No doubt, Your Honor. No doubt.
10:14:06 **THE COURT:** If there's a demand, there's going to be

supply. That's the point. So I mean, I'm not directly contesting what you're saying here, that it might ameliorate some of the, at least, obvious violation of Louisiana law; but I don't know that ultimately it would make any difference.

MR. AGUINAGA: Well, I think it will make a difference, Your Honor, and that's why you should take groups like the ACLU at their word. We've given you that quote in the reply brief, where everybody knows on the other side of the aisle in this case that if the in-person dispensing requirement is back in place, then if not eliminating the problem entirely, it will at least eliminate the bulk of the problem, which is the actors in states like California and New York who are attempting to send mifepristone into the state.

And just think about it, Judge Joseph. I mean, I think -- you know, I cited to you the *Department of Commerce versus New York* case that says you don't speculate about future unlawful activity. I mean, think about the rationale that --

THE COURT: It's already unlawful activity. It's already unlawful activity. The doctors that are shipping it already know that they're violating Louisiana law when they do it.

MR. AGUINAGA: That's correct. Under state law, it's unlawful, Your Honor. The reason they think they can do it with impunity is because they're doing it from states that have, themselves, enacted these so-called shield laws that try to immunize them from state law liability. They don't have immunity

10:15:29 from federal liability. And what we're talking about here when
10:15:31 we're talking about the in-person dispensing requirement is the
10:15:34 requirement that they have to certify to their manufacturers, to
10:15:38 the drug manufacturers and others, that they are complying with
10:15:41 that requirement. If they can't certify that or if they certify
10:15:45 that and break their oath, then what they're doing is basically
10:15:49 placing their own practice in jeopardy. And that's what I think is
10:15:52 more than sufficient for standing purposes here.
10:15:55 **THE COURT:** And I don't know who wants to address this
10:15:57 issue, because I do have questions about remedy, and then also, I
10:16:00 guess, one question that deals primarily with standing. What
10:16:04 efforts, other than this lawsuit, is Louisiana taking to try to
10:16:08 interdict these drugs? What other efforts are going on? Because,
10:16:11 I mean, we have a direct comparison. You know, this country has
10:16:16 banned certain substances, both by state and at the federal level,
10:16:21 for many, many years; and there are techniques that have been
10:16:25 developed by the DEA, the FBI, all other manner of law enforcement
10:16:29 agencies to try to interdict these drugs and prohibit them from
10:16:35 coming into the state. What else is Louisiana doing besides this
10:16:38 lawsuit? Because, again, I think there's -- you know, it may
10:16:40 change the method; but ultimately, if the demand is there, it's not
10:16:43 going to change the result.
10:16:45 **MR. AGUINAGA:** Your Honor, respectfully, if it were not
10:16:46 going to change the result, then nobody would care about this case.
10:16:49 You wouldn't see like millions of amicus briefs being filed in the

docket. I think that's a tell that this case matters, and it matters to the State, and it matters to the parties, and it matters to the people outside who are participating as amicus.

THE COURT: I certainly think there's lots of vested interest in this issue and there has been ever since *Roe v. Wade*.

MR. AGUINAGA: For sure. And to answer your question directly, so all those drug interdiction efforts where you've got federal and state collaboration, it must be nice to be able to work with the federal government hand in hand to combat a drug problem within your state. We don't have that luxury. What we do have, and what we've tried so far -- and you can see this in the Toner Declaration as well as our complaint, is we have identified a couple of names of doctors who are repeat offenders in the state. We have issued arrest warrants for them, indicted them, have extradition requests out for them, and we're going to pursue those avenues, as well. At the end of the day, because there are so many bad actors, that sort of technique is not going to solve our problem across the board. And that's why I think this case is so important, because when you talk about chain of causation and traceability, doesn't it make sense to start with the very first logical step in the analysis, which is: What is the first cause of this harm? It's the 2023 REMS taking away that requirement. If it had never done that, then prescribers in California and New York could have never been able to lawfully under federal law send mifepristone into the state.

10:18:13 **THE COURT:** As far as remedy, who wants to address
10:18:16 remedy?
10:18:16 **MR. AGUINAGA:** I'm happy to talk about it. I know Ms.
10:18:20 Hawley is primed for it, too. Why don't I defer to her.
10:18:25 **THE COURT:** All right.
10:18:26 **MR. AGUINAGA:** Thank you, Your Honor.
10:18:28 **MS. HAWLEY:** Thank you, Your Honor. May it please the
10:18:36 Court.
10:18:38 FDA does not defend the 2023 REMS on the merits. It
10:18:44 instead concedes that the 2023 REMS were, quote, informed by a lack
10:18:49 of adequate consideration that necessitates a new review. That
10:18:55 lack of adequate consideration is what caused two separate Fifth
10:18:59 Circuit panels to conclude that the 2023 REMS were inadequate,
10:19:04 defective, and deeply troubling. Those REMS remain so today.
10:19:10 Louisiana is entitled to preliminary relief because there
10:19:13 is no question it has a likelihood of success on the merits. As my
10:19:18 colleague explained, it's also suffering irreparable harm. Each
10:19:21 and every day, Louisiana gets flooded with mifepristone crossing
10:19:25 state lines, endangering women who are forced to take a black box
10:19:31 drug all alone without ever seeing a doctor who might advise them
10:19:35 if they have an ectopic pregnancy or are further along in their
10:19:39 gestational age than they thought. It takes the lives of tens of
10:19:41 thousands of unborn Louisiana children. It injures the State's
10:19:46 sovereign interest. Louisiana's pro-life law, it's democratically
10:19:49 pro-life law is basically unenforceable after the 2023 REMS, and it

causes unquestionable economic harm every time a woman harmed by mifepristone enters a Louisiana emergency room.

As the Fifth Circuit held in *Alliance*, there simply is no public interest. Neither the public nor the FDA have an interest in an unlawful regulation by an agency, nor is there a public interest in an especially risky drug being on the market without adequate protections.

With respect to the FDA's -- what it looked at in 2023, it looked at primarily two sources of information. One is the FAERS data. It called that data unreliable on its own website. I would point Your Honor to ECF 1-52, pages 3 and 5. On those pages, it says that the FAERS data cannot be used to assess the safety profile of a drug. It goes on to say that the FAERS data cannot be used to calculate the incidents of an adverse event. That's precisely what FDA used that data for in 2023. That's at ECF 1-50, 64. It looked at the time period before, with enforcement and without. It compared those data. That's precisely the prohibited purpose.

Now, GenBioPro and Danco attempt to wave away the problem with the FAERS data by pointing to their own requirement as sponsors to report adverse events. The problem with that analysis, Your Honor, is that the abortion providers have the exact same responsibility to report that data to sponsors as they do to FDA. That's precisely zero. That's why Commissioner Makary recently called self-reporting data in mifepristone, quote, not very good.

10:21:33 The reason is, when you have self-reported data a lot of the data
10:21:36 is not going to be recovered.
10:21:38 In fact, in the *Alliance* decision, the Fifth Circuit
10:21:41 quotes a doctor's testimony, saying that it takes at least 30
10:21:45 minutes to file every FAERS report. She tries to do it routinely.
10:21:50 There's a 48-page document that explains how to file a FAERS
10:21:54 report. It takes these doctors inordinate amounts of time. No one
10:21:59 does them.
10:22:00 And to be honest, Professor -- or, excuse me,
10:22:00 Commissioner Makary's statement saying the data is not really very
10:22:04 good is probably a vast understatement. In the time period the FDA
10:22:08 looked at from January 2020 to September 2021, there were only 8
10:22:13 cases identified by the FAERS data. That was the same data that
10:22:16 the sponsors identified. And if you look at Table 2 of the current
10:22:21 FDA label, you will see that there should have been at least 20,000
10:22:25 women who went to the emergency room after taking mifepristone.
10:22:29 This would be nationwide. These would be adverse events. But we
10:22:33 get 8 cases. The idea that that's a reliable indicator of adverse
10:22:40 events is simply laughable.
10:22:42 The second thing, and I'll hurry along here, Your Honor,
10:22:45 that the FDA looked at was the literature review. At 180 of ECF
10:22:52 1-50 it called that data, quote, not adequate on its own to justify
10:22:56 removing the safety protections. Instead it said that it was
10:22:58 merely not inconsistent with the FDA's apparently predetermined
10:23:03 conclusion that taking away mifepristone -- or the in-person visit

10:23:06 for mifepristone was safe. That's why the Fifth Circuit in two
10:23:12 different panels called reliance on that literature unreasonable.
10:23:15 The last thing I'll note with respect to the literature,
10:23:18 Your Honor, is that the problems with the FAERS data were of the
10:23:22 FDA's own making. As the stay panel noted, in 2016 FDA took away
10:23:28 the requirement that abortion providers report adverse events. In
10:23:32 2021 and 2023, it then relied on that absence of data to find the
10:23:37 drug safe.
10:23:38 **THE COURT:** The stay panel, you're talking about the
10:23:40 second procuring opinion by the Fifth Circuit?
10:23:40 **MS. HAWLEY:** The first --
10:23:45 **THE COURT:** *Alliance* one? Or *Alliance* two?
10:23:45 **MS. HAWLEY:** *Alliance* one, Your Honor, yes. And that
10:23:50 said, it was basically an ostrich's head in the sand approach to
10:23:53 first say: You don't need to report data, and then since there's
10:23:54 no data, we're going to find it safe.
10:23:54 **THE COURT:** Right.
10:23:56 **MS. HAWLEY:** Your Honor, I believe, had some questions
10:23:58 about remedy.
10:23:59 **THE COURT:** Right. Well, thank you. And first -- I do
10:24:06 have a question about remedy, but first, a couple of points.
10:24:09 So what percentage, on average, of Medicaid does the
10:24:16 State pay?
10:24:17 **MS. HAWLEY:** So I'm not sure. My colleague might know
10:24:20 that, but the reality is that under cases like *Uzuegbunam* and

10:24:24 others, a single dollar of expense is enough for standing purposes.
10:24:28 There are many women on Medicaid in Louisiana, and there are
10:24:34 specific examples in the record. The State has paid out tens of
10:24:38 thousands of dollars in only two documented cases.
10:24:42 **THE COURT:** Right. And a lot of that is federal money,
10:24:44 is my point.
10:24:45 **MS. HAWLEY:** Certainly, some of it is. I'm not specific
10:24:47 of the proportion. I'm sure my colleague will know that, but a
10:24:51 substantial portion is paid by Louisiana. And, again, Your Honor,
10:24:54 as you know, a dollar is enough for standing purposes.
10:24:59 **THE COURT:** So here, let's talk about the remedy that the
10:25:02 State is asking for. There are seven other cases, by my count,
10:25:07 pending in federal court dealing with this drug and the authorized
10:25:13 use of this drug. Is there a way that you could see to limit any
10:25:16 relief just to the parties of this case?
10:25:19 **MS. HAWLEY:** So I don't think so, Your Honor, for two
10:25:21 reasons. One, we think Section 705 of the Administrative Procedure
10:25:27 Act is directing relief against the agency action. Of course, the
10:25:32 text of that statute says to postpone the effective date.
10:25:36 **THE COURT:** Right. I think the statute is written in the
10:25:39 anticipation that it's filed before the regulation comes in effect.
10:25:43 I mean, that's clearly what the drafters intended.
10:25:46 **MS. HAWLEY:** I don't think that's true, Your Honor,
10:25:49 because if you look at Section 705, it's addressed in two parts.
10:25:52 One part is addressed to the agency, and the agency can stay its

10:25:55 1 own process before it comes into play; but the Court is instead
10:26:00 2 empowered to provide any appropriate and necessary relief to stay
10:26:03 3 the effective date.
10:26:05 4 As the Fifth Circuit said in *White Lions*, as well as
10:26:09 5 *Alliance*, it doesn't matter whether the effective date has passed
10:26:13 6 because there's the power in Section 05 [SIC] to stay in order to
10:26:19 7 preserve status or rights.
10:26:20 8 The Government and intervener suggest that the status quo
10:26:24 9 is the situation on the ground now. That's simply untrue. Again,
10:26:28 10 under cases like *White Lions*, *Alliance*, *Texas versus EPA*, even
10:26:35 11 going all the way back to the Supreme Court's decision in *Ken*, what
10:26:38 12 has been clear is the status quo -- even Wright & Miller says that
10:26:42 13 the status quo was the last uncontested state of affairs. So the
10:26:46 14 status quo is what was in place before the contested agency action.
10:26:50 15 So it's clear under the text of Section 705 that this
10:26:53 16 Court is empowered to put in place a stay, as happened in *Texas*
10:26:58 17 *versus EPA*, it's happened in *White Lion*, it's happened in *Alliance*
10:27:02 18 to stay that effective date.
10:27:04 19 **THE COURT:** Let's not talk about what the Court is
10:27:07 20 empowered to do. Let's talk about what the Court should do in
10:27:11 21 light of the seven other cases around the country that are pending
10:27:14 22 that may result in conflicting injunctions.
10:27:19 23 **MS. HAWLEY:** Certainly, Your Honor. So two responses to
10:27:19 24 that. So one, to get back to your question about, you know, the
10:27:21 25 practicalities, whether it would be possible to do relief only to

10:27:25 Louisiana, I guess theoretically the Court could do something, like
10:27:29 fashion a REMS to say you can mail the drugs everywhere except
10:27:34 Louisiana; but I think, to be honest, that would look more like an
10:27:37 injunction. It would require FDA to do something, and it seems a
10:27:41 lot more intrusive. Other than stopping short of doing something
10:27:46 like that, it is hard -- the issue is out-of-state providers
10:27:51 mailing into Louisiana, so it is difficult to foresee how a
10:27:56 Louisiana-specific remedy could take care of those out-of-state
10:27:59 providers.

10:28:00 With respect to the other pending cases, Your Honor, I
10:28:04 think only one of them is in any -- that's the West -- excuse me,
10:28:08 the Virginia case -- has any imminent chance of coming to the
10:28:12 contrary conclusion. But even if it did -- so we think that the
10:28:17 merits are so strong here, the Court should not come to that
10:28:20 conclusion; but even if it does, as the Court explained in the
10:28:26 *Alliance* decision, itself, that's really the job of the Supreme
10:28:30 Court to iron out those sorts of differences. And the fact that a
10:28:34 district judge might disagree in another case is not reason for
10:28:38 this Court to stay its hand.

10:28:41 **THE COURT:** Setting aside the possible application of the
10:28:47 Comstock Act to this, to this REMS -- and I think we need to
10:28:55 clearly separate these issues. Number one is standing, and that's,
10:28:58 you know, what the harm is and what the sovereign interest of
10:29:01 Louisiana is. But the only substantive claim Louisiana has is that
10:29:04 the procedure that the FDA took to implement this regulation,

again, setting aside the Comstock Act and possible conflict with the law, but that that's not valid. And then if the procedure was valid and they still came to the same conclusion, what would Louisiana do?

MS. HAWLEY: So I think that's partially correct, Your Honor. The Fifth Circuit held, and we believe, that the 2023 REMS is not only unreasonably explained but unreasonable. So Your Honor is correct that in some situation it might be possible. If the study showed something vastly different than they show, maybe the FDA could come to the conclusion it did in 2023. But even if that were to happen with this pending review, that would have nothing to do with the unlawfulness of the 2023 action. Under *State Farm* and more recent cases, the Supreme Court has been clear that an agency action is evaluated at the time that action was taken based on the rationale before the Court. So we think FDA is simply incorrect to suggest that its review might preclude this Court's. Again, nothing FDA can do will make the 2023 REMS lawful.

And in the meantime, Your Honor, what FDA and interveners are asking for is to leave in place a concededly unlawful REMS that is risking, even taking the lives of thousands of Louisiana children so the FDA can spend an indefinite amount of time to study and possibly come to the same or different results. Louisiana is suffering irreparable harm. It meets the factors for preliminary relief.

THE COURT: It seems that the decision to file the

10:30:45 preliminary injunction motion that we're here on today was due, at
10:30:49 least in part, to an anonymous report in the media that the FDA was
10:30:55 waiting until after the election to do anything on this REMS; is
10:31:01 that right?
10:31:01 **MS. HAWLEY:** So I think --
10:31:03 **THE COURT:** The case had been pending for a while before
10:31:05 this motion was filed.
10:31:07 **MS. HAWLEY:** So I think what can be said, Your Honor, is
10:31:11 that the MPI motion was filed as soon as we could. So we got the
10:31:15 complaint on file and I think the MPI was filed two months later,
10:31:20 which is not as quick as we would have liked, but it's certainly
10:31:23 not an inordinate delay.
10:31:24 The standard for delay, of course, is reasonable
10:31:27 diligence. The Court has found even up to a year is fine for an
10:31:31 MPI to be filed, especially where, as in this case, there is
10:31:34 irreparable harm. In fact, neither FDA nor the interveners have
10:31:38 cited a single case finding that delay should matter where there is
10:31:43 ongoing irreparable harm and a likelihood of success on the merits.
10:31:46 **THE COURT:** Right. I think the commissioner denies that
10:31:48 this is the case on the record; is that right?
10:31:51 **MS. HAWLEY:** I'm sorry. I'm not sure what you're saying,
10:31:53 sir.
10:31:53 **THE COURT:** The reason I know this is because it's
10:31:55 included in your brief.
10:31:56 **MS. HAWLEY:** So the commissioner denies what, Your Honor?

10:31:58 **THE COURT:** Denies that they are waiting until after the
10:32:00 midterms to conduct the review.
10:32:02 **MS. HAWLEY:** So I think that was --
10:32:06 **THE COURT:** I'm saying, the reason I know that it was
10:32:08 based on an anonymous report in the media about waiting until after
10:32:10 the midterms is because you put it in your brief.
10:32:12 **MS. HAWLEY:** Oh, sure, Your Honor.
10:32:12 **THE COURT:** That's how I know that.
10:32:14 **MS. HAWLEY:** Sure, Your Honor. But to be clear, we know
10:32:16 this won't take place before the midterms because of the timeline
10:32:20 that FDA has, itself, laid out. So if you look at what they
10:32:24 represent in their brief, as far as we're aware, there is no
10:32:28 evidence that they have even requested the data yet. Maybe our
10:32:32 friends can enlighten us on that. But even if they've requested
10:32:36 the data, even if they've received the data, they say it will take
10:32:38 a year or more but they hope to be sooner than that. In addition
10:32:42 to that, Your Honor, it will take at least six months for the
10:32:47 administrative process to run through its course after that study
10:32:50 is analyzed. So that puts us out to 2027, very best case scenario.
10:32:55 Again, I'm not even sure FDA has the data.
10:32:58 **THE COURT:** All right. Thank you very much.
10:33:00 **MS. HAWLEY:** Thank you, sir.
10:33:17 **MR. KATZEN:** Good morning, again, Your Honor.
10:33:20 FDA is conducting a review of the mifepristone REMS that
10:33:24 could, depending upon the outcome, result in plaintiffs' challenge

10:33:28 to the 2023 REMS modification becoming moot. Women's safety is an
10:33:34 important public health objective, and Congress entrusted the
10:33:38 agency with the responsibility, in particular, to ensure drug
10:33:41 safety. The best way for the agency to pursue that objective is
10:33:46 through an orderly review process that enables the agency to meet
10:33:50 its statutory responsibilities and apply gold-standard science.
10:33:55 Science, rather than political considerations, are what drives
10:33:59 FDA's review.

10:34:00 This Court should not reach the merits, let alone award
10:34:04 preliminary relief, without the full benefit of FDA's input
10:34:08 following its review. Instead, the Court should do what the
10:34:12 *Purcell* court did during the 2021 to 2023 period in which FDA last
10:34:17 reviewed the REMS: Stay its hand until the review is complete.
10:34:21 Put simply, the parties should not litigate, and this Court should
10:34:26 not decide, the complex issues of drug safety raised here at the
10:34:32 very moment that the agency charged with drug safety is considering
10:34:36 those issues.

10:34:37 Plaintiffs' request for judicial intervention at this
10:34:42 point also raises the specter of FDA having to potentially defend
10:34:45 against and maybe navigate conflicting injunctions and review
10:34:49 supplemental applications while its review is ongoing. Judicial
10:34:55 tug-of-war and regulatory whiplash are not conducive to orderly
10:35:00 agency proceeding. If Louisiana could wait nearly three years to
10:35:04 bring this suit, it does not need preliminary relief while the
10:35:09 agency is undertaking its review. Indeed, in its reply brief

10:35:15 Louisiana admits that it has long believed that its interests were
10:35:18 adequately represented by other state litigants in, for example,
10:35:24 the *Alliance for Hippocratic Medicine* case despite the fact that
10:35:26 those state plaintiffs never sought preliminary relief.
10:35:30 Our point about Section 705, since Your Honor raised
10:35:34 that, is that it underscores that the longer a plaintiff waits, the
10:35:40 less appropriate it is to award preliminary relief. Section 705
10:35:45 uses two verbs, postpone and preserve. It's talking about
10:35:50 postponing the effective date of agency action and preserving the
10:35:53 relative status of the parties while the Court adjudicates the
10:35:58 merits. And the preliminary relief in general is aimed at
10:36:02 preserving the relative position of the parties. I think the
10:36:04 Supreme Court in *Starbucks versus McKinney* recently said that is
10:36:07 the sole purpose of preliminary relief.
10:36:10 Three years after the agency action took effect is too
10:36:15 long for plaintiffs to claim, come to court, claiming that they
10:36:18 need instantaneous relief, especially given the pendency of the
10:36:25 ongoing agency review. But even if the Court does not stay
10:36:27 proceedings, it should at least deny preliminary relief for the
10:36:31 fundamental reason that plaintiffs lack standing. Both of the
10:36:34 theories of standing that Louisiana presses at this stage were
10:36:39 rejected squarely by the Ninth Circuit in *Washington versus FDA*,
10:36:46 and this Court should do the same here.
10:36:46 I'll start with sovereign harm. Courts have held that
10:36:50 states have standing to vindicate their authority to create and

enforce a legal code. There has been no injury to Louisiana in that interest. Louisiana's authority to create and enforce laws regulating abortion remains precisely the same now as it did before the 2023 REMS modification. The State identifies no case, and we're aware of none, in which a state was found to suffer an injury to this sovereign interest absent a conflict between state and federal law.

Now, that conflict can take several forms. It can be where the federal law preempts the state law or supersedes the state law. It can be, as in Your Honor's case in *Louisiana versus EOC*, where the federal agency action directs the state to do something that the state otherwise wouldn't do or that's contrary to the state's laws or policies. Or it can be where the federal action applies some kind of pressure to the state to change its laws, as was held to be the case in the *DAPA* case. Or as in the *Texas versus Becerra* EMTALA case, it could be where the federal government effectively -- is held to have effectively decreed that it is unlawful as a matter of federal law for third parties to follow a state law. The 2023 REMS modification poses no conflict of that time with Louisiana state law.

Louisiana today --

THE COURT: What about -- I think the main point -- I mean, there's two main points of Louisiana. Number one, that this agency action was actually directed by the FDA, undermining Louisiana and other states' laws. So it was not directed for any

10:38:37 health purposes. It was directed to undermine, you know, states
10:38:41 that have restrictions on abortion.
10:38:44 **MR. KATZEN:** I don't think Your Honor needs to reach that
10:38:46 issue because they failed to demonstrate an injury in fact, right.
10:38:50 They present that issue as relevant to the causation prong, but
10:38:54 they haven't demonstrated the sovereign injury in fact that could
10:38:58 even give rise to this theory of standing.
10:39:00 Now, they point to their allegation that actual
10:39:03 violations of Louisiana law are occurring when those drugs are
10:39:08 mailed into the state. The *Harrison versus Jefferson Parish School*
10:39:12 *Board* case, cited I think in the interveners' briefs, makes clear
10:39:16 that there is a distinction between the states' interest in
10:39:21 compliance with its laws that is ordinarily good enough to get the
10:39:25 state to be able to, you know, bring a suit, criminal or civil, in
10:39:27 its own courts, and the sovereign interest that's needed for
10:39:31 Article III in the authority to make and enforce the legal code.
10:39:39 And there has been no injury to the State's authority to make and
10:39:41 enforce its laws relating to abortion, so I don't think we need to
10:39:44 get to that causation analysis.
10:39:46 But the point about this *Diamond* theory of causation,
10:39:50 too, is if you look at the cases that talk about what it means to
10:39:53 be the object of regulation, they're using object to refer to the
10:39:59 party who is, in essence, the regulated party. And we don't need
10:40:02 to speculate about who the regulated party is in the case of
10:40:06 mifepristone regulation because the Supreme Court told us in

Alliance for Hippocratic Medicine. The Supreme Court said that the regulated party when it comes to the REMS are those who are required to do or prohibited to do something by the REMS, in other words, the sponsors, doctors who prescribe mifepristone, and women who use mifepristone. Louisiana is none of those.

And if Louisiana's theory were valid, it's hard to imagine any easing of federal restrictions or federal regulations that wouldn't result in a sovereign injury to the State. And we don't have to get very far from this case. Let's just take an ordinary FDA drug approval decision.

The legal effect when FDA approves a drug is that it lifts the FDCA's bar on introducing that drug into interstate commerce. When, as is typical, FDA approves a drug without imposing an in-person dispensing requirement, that will mean that prescribers, as far as the FDCA is concerned, can mail that drug into the state. And it could be that some of those prescribers -- those doctors' prescriptions will not comport with that state's laws regulating the practice of medicine. Under Louisiana's theory, it's difficult to see why the State wouldn't suffer an injury every time that happens and so in connection with every single FDA drug-approval decision.

Perhaps sensing that its sovereign harm theory might stretch the concept too far, Louisiana tries to recharacterize that injury as a pocketbook injury by pointing to the expenses that the State incurs to enforce its laws. That doesn't work, either.

10:42:03 Under *Clapper*, a plaintiff's expenses are a -- satisfy
10:42:09 Article III only if they're necessary to avoid another injury that
10:42:13 would, itself, satisfy Article III. Since their sovereign harm
10:42:17 theory fails to satisfy Article III, the expenses Louisiana incurs
10:42:23 to avoid that alleged harm or mitigate that alleged harm also
10:42:28 necessarily fail Article III under *Clapper*.
10:42:33 That leaves only Louisiana's Medicaid payor theory. Not
10:42:36 only did the Ninth Circuit reject that theory, so in effect did the
10:42:41 Supreme Court. Contrary to what Louisiana says in their reply
10:42:44 brief, the opinion in *Alliance for Hippocratic Medicine* did not
10:42:50 begin and end with the conscience injury that's discussed in Part
10:42:53 2(B)(1) of that opinion. In Part 2(B)(2), the Court goes on to
10:42:58 hold that doctors do not have standing to challenge the loosening
10:43:02 of public health regulations on the theory that they might be
10:43:05 burdened with more patients. That chain of causation, the Court
10:43:10 said, was just too attenuated and it necessarily follows from that;
10:43:15 that those same -- that when those same doctors with their
10:43:16 attenuated injury pass that attenuated injury on to the State by
10:43:23 billing Medicaid, that chain remains too attenuated.
10:43:28 In short, given FDA's ongoing review, the benefits of
10:43:31 waiting for the completion of that review, the disruptive effects
10:43:34 of judicial intervention, and Louisiana's delay, the Court should
10:43:36 stay this case and deny the motion for preliminary relief. But
10:43:39 even if the Court does not agree that it should stay the case, it
10:43:43 should at least deny preliminary relief because plaintiffs lack

standing. Thank you.

THE COURT: How long will the review of the 2023 REMS last?

MR. KATZEN: I don't have a timeline I can give Your Honor. I think the current plan is for FDA to try to complete the study it's undertaking in less than -- in sooner than a year, but I can't put a timeframe on the review as a whole.

THE COURT: So that was announced last September, is that right, by the secretary?

MR. KATZEN: It was confirmed last September. It may have been mentioned publicly before that, as well, but it was certainly stated in the September --

THE COURT: So by this September, you think the review would be complete?

MR. KATZEN: By this September?

THE COURT: Right.

MR. KATZEN: I can't make any representations about the time --

THE COURT: You said within a year and it was announced last September.

MR. KATZEN: I'm sorry. I'm sorry. In January of this year, FDA said on its website that it expects to have the study that it's doing, which is part of the review -- it's not the whole review itself -- have the study complete in sooner than a year. That's the current plan of the agency. But the review itself, I

don't have a timeframe to put on that.

THE COURT: So the review has begun? It began last month?

MR. KATZEN: The study is part of the review, and they're in the data collection phase of the study. FDA, yes. FDA is beginning its review -- begun its review.

THE COURT: What are they currently doing as part of their review?

MR. KATZEN: I can't talk specifically about what they are doing. I can say there's three different kind of work streams. One is the study. Well, maybe four different work streams. The study, there's just the review of all evidence before --

THE COURT: Why can't you talk specifically about it? Because you don't know? Or because you're not supposed to talk about it?

MR. KATZEN: No, no. This is my understanding of what, in general, the agency is doing. I can't review all their deliberative processes. I can't, you know, get ahead of the agency on anything; but I can tell you --

THE COURT: Well, you can say generally what they're doing. You're telling me to defer to the agency process. I'm asking you: What are they doing?

MR. KATZEN: Yeah, I think I am going to answer this question. They are conducting a study. They are reviewing all evidence before the agency. They are reviewing citizen petitions

10:46:05 that have requested various forms of action on the REMS and all the
10:46:11 material appended to those citizen petitions. And they are
10:46:15 reviewing, also, the issues identified in the *Purcell* remand that
10:46:22 was issued last October.
10:46:25 **THE COURT:** What's DOJ's position on the application of
10:46:31 the Comstock Act to the 2023 REMS? That wasn't addressed, I don't
10:46:35 think, in your brief.
10:46:35 **MR. KATZEN:** We're not taking a position on any merits
10:46:37 issue with respect to this motion.
10:46:40 **THE COURT:** Has the FDA produced the full administrative
10:46:44 record from the 2023 REMS to the plaintiffs in this case?
10:46:48 **MR. KATZEN:** We have not, Your Honor.
10:46:50 **THE COURT:** Have they asked for it?
10:46:52 **MR. KATZEN:** They have not asked for it.
10:46:55 **THE COURT:** Do the plaintiffs want the administrative
10:46:57 record?
10:46:58 **MR. AGUINAGA:** Absolutely, Your Honor.
10:47:01 **THE COURT:** All right. Thank you, sir. I appreciate
10:47:03 your argument. And we'll hear from the interveners now.
10:47:09 **MR. KATZEN:** Thank you, Your Honor.
10:47:09 **MS. ELLSWORTH:** Good morning, Your Honor. Jessica
10:47:17 Ellsworth on behalf of Danco Laboratories. And the two interveners
10:47:22 have conferred to try and split up the argument, similar to the way
10:47:25 the plaintiffs did. So I'm going to address standing and if you
10:47:29 have questions about any other procedural issues, and then Mr.

10:47:36 Katerberg is going to address the merits, the remedies, the other
10:47:37 PI factors.
10:47:37 **THE COURT:** Okay.
10:47:39 **MS. ELLSWORTH:** And I will try to also streamline based
10:47:42 on the Government's argument which also addressed standing.
10:47:45 Louisiana comes to this Court lacking a cognizable injury
10:47:50 in fact that is caused by Louisiana's 2023 REMS. The Supreme Court
10:47:55 addressed standing to challenge the mifepristone REMS just two
10:47:59 years ago, and it unanimously held that plaintiff doctors in that
10:48:04 case lacked standing for three, I think, primary reasons that are
10:48:07 relevant here:
10:48:08 The first is that FDA's regulation of mifepristone did
10:48:12 not require the plaintiffs to do or refrain from doing anything.
10:48:15 That's true here, as well;
10:48:17 The second is that Article III standing does not flow
10:48:20 from a plaintiff's desire, however genuine it is, that FDA make a
10:48:25 drug less available to individuals who want to take it. That's
10:48:29 also true here;
10:48:30 And the third is that because the plaintiff's claims of
10:48:34 injury were attenuated and not a predictable result of the
10:48:39 mifepristone REMS, they flowed from discretionary decisions of
10:48:42 third parties. That same shortcoming is here -- is true here, as
10:48:46 well.
10:48:46 The 2023 REMS does not require or forbid Louisiana to do
10:48:50 anything. In fact, it doesn't regulate Louisiana's conduct at all.

10:48:55 Louisiana can and does have its own additional state law
10:48:59 restrictions on mifepristone, and the 2023 REMS doesn't override,
10:49:03 preclude, or otherwise invalidate those state law restrictions.
10:49:08 Louisiana's claim is an equally attenuated chain of
10:49:15 healthcare decisions made by independent actors and not a
10:49:17 predictable result of the REMS. It is fairly traceable to
10:49:21 discretionary decisions by several layers of independent actors,
10:49:25 including other states who have taken a different policy approach
10:49:29 and providers in those states. The net result of this is Louisiana
10:49:33 lacks what the Supreme Court has called a personal stake in whether
10:49:42 federal law imposes an in-person dispensing requirement through the
10:49:44 mifepristone REMS.
10:49:45 As the Supreme Court recognized in the *Alliance* case,
10:49:48 when a plaintiff is challenging the Government's decision not -- to
10:49:52 regulate or not regulate someone other than the plaintiff, it is,
10:49:56 to quote the Supreme Court, ordinarily substantially more difficult
10:50:00 to establish standing. To be sure, Louisiana has strong views on
10:50:05 the availability of mifepristone, so did the *Alliance* doctors; but
10:50:10 the Supreme Court emphasized, with all nine justices speaking
10:50:14 together on this point, that legal, moral, ideological, and policy
10:50:18 objections to a particular government action are insufficient to
10:50:21 create standing.
10:50:22 Louisiana asserts two injuries in fact here. And the
10:50:27 first is their sovereign harms. And I want to note that I believe
10:50:31 I heard Louisiana's counsel say that there was not a challenge to

10:50:35 whether this was a cognizable injury in fact. They also say that
10:50:40 in their reply brief. We certainly challenge that is a cognizable
10:50:45 injury in fact. You can see it in our PI response at pages 5 and
10:50:50 6. It's right in the headers.
10:50:52 Louisiana asserts that it has a sovereign interest in
10:50:55 being able to enforce Louisiana law and that the 2023 REMS makes
10:51:01 mifepristone use harder to detect. This is exactly what the Ninth
10:51:07 Circuit rejected when Idaho made this same argument in a REMS
10:51:11 challenge just last year. Like Idaho, Louisiana does not argue
10:51:14 that the 2023 REMS preempts or otherwise interferes with the
10:51:18 State's ability to enact or enforce restrictions on its own laws
10:51:23 within its own boundaries. The reality is that Louisiana can have
10:51:28 whatever laws it wants to have, just like other states can have
10:51:32 whatever laws they want to have. Nothing in the 2023 REMS speaks
10:51:35 to any of that.
10:51:36 Louisiana's argument appears to be that it suffered a
10:51:41 sovereign injury because enforcing its laws has required them to
10:51:46 expend state resources. But expending state resources to enforce
10:51:51 state law is the norm in our system of government, where there is a
10:51:55 layer of federal law and there are layers of state law. No court,
10:52:00 and Louisiana can't point to any, has ever held that a state has a
10:52:04 sovereign interest in federal regulation aligning with the state's
10:52:10 legal priorities so that the state can save money on its own
10:52:13 enforcement actions, nor would that make any sense because there
10:52:17 are 50 states who can have 50 different sets of enforcement

priorities and enforcement actions, and there is simply no possible way that federal law could be required to advance all of those individual state interests.

Let's talk about the financial harms. Louisiana asserts two financial harms. One is what we have been talking about related to enforcement. The other are the Medicaid expenditures. Louisiana's Medicaid expenditure theory is the same attenuated downstream economic injury that the doctors offered in the *Alliance* case, except they've added an additional layer because now they say it's about who pays the doctors, who, themselves, don't have an Article III injury in fact because those doctors are at the end of an already too attenuated chain of healthcare decisions.

Louisiana doesn't grapple in its papers, and I didn't hear it talk today about the fact *Alliance* addressed this issue. What Louisiana does do is rely on the same basic assertion about complication rates that the doctors in the *Alliance* case pointed to, as well. But the Supreme Court forcefully rejected the argument that there could be this novel view that doctors got some special Article III standing authority because they might someday encounter someone who had been injured by some product that was out there. As the Court said, that would open floodgates; it was unprincipled; it was virtually limitless. And the same is true here. If a state or presumably any health insurance provider could sue, had Article III standing to sue, anytime that it thought a product should be regulated differently, that would -- what the

10:54:03 Ninth Circuit said, that would make a mockery of Article III. It
10:54:08 would open the floodgates to the same sort of novel standing
10:54:12 argument that the Supreme Court unanimously rejected for doctors.
10:54:15 And you can see this in part because the Supreme Court's
10:54:18 decision walks through a series of hypotheticals to show how novel
10:54:22 and unprincipled this theory would be, talking about what happens
10:54:27 when the government rolls back EPA emissions. What if a Louisiana
10:54:33 Medicaid enrollee then develops asthma? Does that give Louisiana
10:54:38 standing to challenge the EPA's rollback? What about when there is
10:54:42 a gun restriction that's appealed? The Supreme Court went through
10:54:46 hypothetical after hypothetical and then said, quite simply, the
10:54:49 answer is no. The chain of causation is simply too attenuated. It
10:54:55 would be unprecedented and a limitless approach that would allow
10:54:58 standing to exist to challenge almost any policy affecting public
10:55:03 health. That's at page 391.
10:55:04 In addition to this *Alliance*-based problem, the Supreme
10:55:07 Court has also cautioned against allowing state standing based on
10:55:11 federal policy that has some indirect effect on state revenue.
10:55:16 This is the *United States versus Texas* case. And the Court in that
10:55:20 case -- you can see it in Footnote 3 -- talked about indirect
10:55:23 effects being a common occurrence from federal government policies
10:55:29 and that it is too attenuated to constitute injury in fact.
10:55:34 That leaves us with the enforcement spending that I was
10:55:37 talking a little bit about earlier. The enforcement difficulty
10:55:40 here is not caused by FDA's action. It flows from independent

discretionary actions first of other states who have enacted a different set of policies, as *Dobbs* told them that they were entitled to do. It flows from actors, providers in those other states who have chosen not to comply with Louisiana law, whether because of the state laws where they practice or for other reasons. And that also is layered on top of the enforcement challenges coming at the end of this already attenuated chain of independent third-party decisions, starting with someone in Louisiana reaching out and requesting these drugs be mailed to them.

I think that I heard counsel on the other side say that it was very clear that the 2023 REMS were directed at states like Louisiana and that the harms in Louisiana, the mailing of drugs into Louisiana, was queued to this 2023 REMS decision. And that is flat wrong and inconsistent with the record that the plaintiffs themselves have put before the Court. You can see this most principally in the chart that's on page 1 of their principle -- their PI brief. That chart shows that the rise of medication abortions in Louisiana in 2023 coincided with shield laws being enacted by other states, not with *Dobbs* and not with the 2023 REMS. You can see it's a little, light-blue dotted line between June and July of 2023. And the #WeCount data, the #WeCount report that they rely on says the same thing. You can see that at ECF 20-2 at page 9 and in their complaint at paragraph 85.

So in other words, the spike did not begin after *Dobbs*, as Louisiana told you.

10:57:40 **THE COURT:** Is the shield law subject to any litigation
10:57:42 that you're aware of?
10:57:44 **MS. ELLSWORTH:** I believe that there is some litigation
10:57:46 or at least some -- I think there is some litigation between some
10:57:50 of the states about questions like extradition. I'm not involved
10:57:54 in any of that, but I have read about some of it.
10:57:54 **THE COURT:** All right.
10:57:59 **MS. ELLSWORTH:** This, I think, dovetails with Louisiana's
10:58:01 argument that somehow it was the object of the 2023 REMS. And,
10:58:08 Your Honor, the simplest way I think to know that's not true is to
10:58:10 just look at the timeline. The 2023 REMS formalized a policy that
10:58:14 FDA put in place in early 2021 and directed be formalized as a
10:58:20 permanent REMS change also in 2021. So that was before *Dobbs* came
10:58:25 down. It was before any of the statements that they're pointing to
10:58:29 from non-FDA officials. And their complaint in paragraph 64
10:58:35 specifically says that the 2023 REMS -- this is a quote -- imported
10:58:40 FDA's 2021 rationale when it implemented the 2023 changes.
10:58:45 **THE COURT:** You're saying the process to implement the
10:58:48 2023 REMS started in 2021?
10:58:51 **MS. ELLSWORTH:** Yes, Your Honor. In 2021, FDA first --
10:58:54 **THE COURT:** You're saying, basically, that after *Dobbs*
10:58:57 maybe some politicians tried to capitalize on that?
10:59:00 **MS. ELLSWORTH:** That's exactly right, Your Honor. But
10:59:03 that had already been put in place. It had been put in motion back
10:59:06 in 2021. The SNDA -- it's the Supplemental New Drug Application

that was approved, that is what the challenge is to here, was submitted to the agency also before *Dobbs* was decided so that the argument here that the 2023 REMS was directed at Louisiana state law just doesn't work on the reality of the timeline.

I have just two other points I want to make, Your Honor, cognizant of time.

I think I heard Louisiana talk about the first cause of the harm being an indication that this Court should find causation and redressability and that the first cause of the harm is this 2023 REMS approval. With all due respect, this first cause theory, or what they call in their brief the indispensable ingredient theory, is not how courts approach Article III standing. It's not how courts approach causation. And you know that because when courts are looking at causation, they're looking at two things. They're looking at whether something is fairly traceable to the government action, and they're looking at whether and how independent actors and their discretionary decisions play a role in it. And all of that would be cut out if you just said, "Well, the first step is that FDA had to approve this drug." So anything else, no matter how speculative, no matter how attenuated, no matter how predictable, you just don't pay any attention to that. That is not how the law has worked.

The last point on standing I want to make, Your Honor, is to address Louisiana's lack of standing on Count 2, which is the one that addresses the Comstock Act. In this count, Louisiana

seeks to force FDA to incorporate the Comstock Act restrictions into the 2023 REMS and thus to compel FDA to enforce Louisiana's reading of that criminal statute.

The Supreme Court has rejected that a state can use the APA to force the federal government to exercise enforcement of a criminal statute in a particular way. That is the *United States versus Texas* case where Texas claimed a Custom and Border Patrol policy violated the APA because it was contrary to a different federal statute that had an arrest mandate.

Louisiana, likewise, is claiming that the REMS violates the APA because it is contrary to a criminal prohibition. That conflicts with the principle holding of *U.S. v. Texas*, which is that a state does not have a judicially cognizable Article III injury -- interest in whether or how the federal government enforces a federal criminal statute.

THE COURT: Well, I don't think that's the position, though. Their position is: We have standing, A; and, B, because we have standing, we can challenge under the APA whether this conflicts with the law. And I tried to make that point earlier. What do you have to say? Do you have a response to that?

MS. ELLSWORTH: So, Your Honor, in order to show -- they have to show standing for each claim, as I think Your Honor knows.

THE COURT: They have to show standing that they can contest the lawfulness of the regulation under the APA, period. And then they have to show that the regulation violates the APA.

11:02:25 **MS. ELLSWORTH:** Yes, I do agree. It's a two-step inquiry
11:02:28 just like that. But in order to have standing to challenge the
11:02:32 fact that they say the REMS doesn't incorporate the Comstock Act
11:02:38 prohibitions, you know, first of all, the REMS statute specifically
11:02:40 tells FDA what it can and cannot consider. But I think even more
11:02:45 problematic for Louisiana is the statement in *United States versus*
11:02:48 *Texas* which is that a state does not have a judicially cognizable
11:02:54 injury in fact in how the federal government enforces federal
11:02:57 criminal law.
11:02:58 **THE COURT:** I have read that case.
11:02:59 **MS. ELLSWORTH:** So if Your Honor has further questions
11:03:01 about standing, I'm happy to address them; otherwise, I will turn
11:03:04 the mic over.
11:03:06 **THE COURT:** Thank you.
11:03:08 **MS. ELLSWORTH:** Thank you very much, Your Honor.
11:03:08 **MR. KATERBURG:** Thank you, Your Honor. Rob Katerberg for
11:03:21 GenBioPro.
11:03:21 So the threshold issues you've heard about already from
11:03:25 Ms. Ellsworth, Mr. Katzen. Those are one reason why plaintiffs
11:03:28 can't show a likelihood of success which is necessary for any
11:03:31 interim relief to issue. But it's important to note, even if
11:03:33 plaintiffs could overcome those threshold issues, that would just
11:03:37 get them in the door. They'd still obviously have to show that
11:03:40 they are likely to be able to prove their case ultimately,
11:03:42 factually, and legally to the point of being entitled to a final

judgment. And that's either on their arbitrary and capricious claim or on their unlawfulness claim.

Now, two points on that that are very important to keep in mind: The first is that the relevant FDA action here is a very narrow, technical one that calls for essentially an empirical exercise, scientific findings and judgments under a highly specialized statute. So we're looking at 21, U.S.C., 355-1, Risk Evaluation and Mitigation Strategies for Drugs. And the issue is: What set of special conditions, if any, is necessary to address particular risk situations with a drug without going overboard and impeding access to the drug?

And so that's the balancing that FDA had to do in finding that in-person dispensation is not necessary for safety, while adding here, as they did in the 2023 REMS, a new requirement for pharmacy certification as an additional guardrail. So that's an important thing to keep in mind, is FDA's very niche function to conduct a balancing under this very technical statute. It's not a political act. It's a judgment about what conditions are necessary to assure safe use of a drug.

The second, which was alluded to earlier, is that FDA conducted that balancing and found in-person dispensation unnecessary on an administrative record. And you heard it just a few moments ago. The plaintiffs haven't even asked for the administrative record, which is quite surprising to me, given that APA review by definition is on an administrative record. The

Court's not supposed to consider anything outside the administrative record, just like an appellate court hearing an appeal of a district court judgment focuses its review on the record before the district court.

The administrative record, which is massive, by the way -- I understand it's been produced in a Washington -- a litigation in Washington for the 2023 REMS. It's not before the Court. And that alone, we would submit, is enough reason for the Court to deny relief. I don't know how the Court could conclude that plaintiffs are likely to succeed on a claim that FDA's action is not supported by the administrative record without having the administrative record to consult.

But, Your Honor, just from the bits and pieces of the administrative record that have come into the Court, record through the parties' filings, because there are parts of it here and there -- for example, you do have the FDA's explanation of its decision at ECF 10 -- excuse me, 1-50. It's clear, Your Honor, the evidence is overwhelming to support the FDA's finding that in-person dispensation is not necessary to ensure safety.

FDA didn't just rely on one thing. They relied on multiple types of evidence to reach that conclusion. First, their own REMS assessment data. So when they put into place a REMS for a drug, what that involves is they're automatically engaged in monitoring to see how the REMS is working. They considered that as part of their analysis. And that's at ECF 1-50 at pages 60 to 62.

That's the -- I'm referring to the pagination in the ECF strip at the top of the page.

Secondly, Your Honor, FDA's own vast body of data on adverse events compared periods when the in-person dispensation requirement was being enforced and periods when it was not being enforced. So there was a natural experiment there from the period during COVID-19, when FDA was under a court injunction not to require in-person dispensal. And that is at pages 62 to 64 of ECF 1-50. And FDA concluded there does not appear to be a difference in adverse events between periods when the in-person dispensing requirement was being enforced and periods when it was not being enforced.

Now, Ms. Hawley has a criticism of that.

THE COURT: Didn't the Fifth Circuit point out that that's because that data wasn't requested by the FDA?

MR. KATERBURG: Your Honor, that's a misunderstanding. So there was a limited 2016 change in mandatory reporting by prescribers of adverse events. But let me be very clear about something. GenBioPro and Danco have always had extremely rigorous requirements to report all adverse events that come into their knowledge or possession about their drugs to FDA. There's an elaborate set of regulations governing this. It's 21 CFR 314.80. And I commend to you the amicus brief of the former FDA commissioners that provides a lot of informed background on that.

But as a general matter, drug adverse event reporting is

11:08:24 mandatory for drug companies but permitted, not mandatory,
11:08:28 permitted, encouraged for prescribers.
11:08:32 Mifepristone is subject to heightened requirements and
11:08:35 continues to be under the current REMS because prescribers are
11:08:39 required to report fatal adverse events. What the 2016 change that
11:08:44 plaintiffs put so much weight on and the Fifth Circuit referred to,
11:08:48 all it did was to change from prescribers having to report all
11:08:52 mandatory adverse events to just having to report fatal adverse
11:08:55 events.
11:08:57 And Your Honor, Justice Kavanaugh in his opinion in *AHM*
11:09:00 actually went out of his way to mention this. He said even post
11:09:04 the 2016 changes, mifepristone continued to have a prescriber
11:09:07 reporting requirement that was still more stringent than the
11:09:13 requirements for most other drugs. That's 602 U.S. at 376.
11:09:18 So there's really zero evidence that that change actually
11:09:24 affected at all the quality --
11:09:24 **THE COURT:** That's in the background factual section of
11:09:27 the opinion you're talking about?
11:09:28 **MR. KATERBURG:** That's right, Your Honor. That issue
11:09:32 wasn't really necessary. It didn't feed into the standing
11:09:35 analysis, but that makes it all the more significant that he really
11:09:38 went out of his way to make that observation.
11:09:41 And the former FDA commissioner's brief explains that FDA
11:09:44 uses that database, the FAERS database as a key analytical tool for
11:09:50 drugs across the board when the vast majority of drugs that FDA

11:09:55 regulates don't have any mandatory prescriber reporting requirement
11:09:57 at all.
11:09:58 Your Honor, just one other point on this. The periods,
11:10:02 the two periods being compared, so the period when in-person
11:10:07 dispensal was being enforced versus when it was not, they were both
11:10:10 well after this 2016 tweak. So they were in 2020 and 2021. The
11:10:16 specific periods compared are laid out in the FDA's analysis down
11:10:21 to the day. So you can look at that at page 62 of ECF 1-50. So my
11:10:26 point here is the comparison was apples to apples. So it's not as
11:10:30 if one of the periods being compared was subject to the earlier
11:10:33 reporting regime and the other was subject to a later reporting
11:10:37 regime, where, like, the conclusion might be skewed because they
11:10:39 were looking at two different data sources. The data source was
11:10:42 exactly the same, and what FDA concluded was that there was simply
11:10:46 no difference in the adverse events that were reported.
11:10:50 In addition to that, Your Honor, there was a literature
11:10:52 review. FDA analyzed numerous studies and came to the conclusion
11:10:57 that those studies essentially corroborated the conclusion based on
11:11:02 the adverse event reporting. Now, we've heard from my friends on
11:11:07 the other side that the FDA acknowledged limitations in those
11:11:11 studies. And we would respectfully submit that's good science. It
11:11:15 shows that they're taking a nuanced, thoughtful approach and
11:11:19 acknowledging, you know, that no one study is perfect. They all
11:11:22 have limitations. But when you look at them all together,
11:11:25 essentially a metaanalysis, they do support the underlying

11:11:28 conclusion.

11:11:31 So for example, the 2021 Chong study, the conclusion that
11:11:36 was reached is that the direct-to-patient telemedicine service was
11:11:42 safe, effective, and acceptable and supports the claim that there
11:11:45 is no medical reason for mifepristone to be dispensed in clinics as
11:11:49 required by the FDA at the time prior to the change that was first
11:11:53 made in 2021. And then the Aiken study, also -- all these studies,
11:11:57 by the way, are in the record as exhibits to our, GenBioPro's,
11:12:02 opposition to the motion for preliminary injunction. The Aiken
11:12:07 study, which was a study in the UK that involved some 50,000
11:12:11 patients, 50,000 observations, concluded that a telemedicine hybrid
11:12:15 model for medical abortion without an ultrasound is effective,
11:12:19 safe, and acceptable and improves access to care.

11:12:22 Your Honor, I would like to say a few words about the
11:12:25 balancing of the harms and the public interest considerations that
11:12:29 are also a part of the preliminary injunction analysis. The relief
11:12:34 that the plaintiffs are seeking here would have dramatic impact,
11:12:39 reaching far beyond Louisiana. Now, obviously, for my client,
11:12:43 GenBioPro, and for Danco, there are huge operational impacts on
11:12:47 both of the companies. And those impacts are detailed in
11:12:49 declarations that both companies submitted. Revamping a
11:12:52 distribution system is essentially like relaunching a product. But
11:12:56 that goes -- that's just the beginning of it. The impacts go far
11:12:58 beyond the upheaval operation of these companies.

11:13:02 And one thing that weighs particularly heavily in the

11:13:05 balancing here is the huge impact that granting the relief would
11:13:09 have on millions of Americans outside of Louisiana, states where
11:13:14 abortion is legal and that in some cases have policies to maintain
11:13:17 and expand access. And we'd urge Your Honor to take a close look
11:13:22 at the amicus briefs submitted by New York and 19 other states who
11:13:27 go into those profound nationwide effects. Those are effects that
11:13:31 sweep far and wide across the many states that allow abortion, and
11:13:34 they would be vastly disproportionate to the interests that
11:13:38 Louisiana invokes to support its standing here.

11:13:41 One thing, Judge, that I think bears noting about the
11:13:46 interest that Louisiana is asserting here. Your Honor noted
11:13:48 earlier that there is a number of different pending litigations
11:13:51 involving these REMS. Louisiana is actually just one of six states
11:13:55 asserting all the exact same interests and harms across three
11:13:59 different lawsuits against FDA over the same issues as here; and
11:14:03 yet, Louisiana, in addition to sitting on its hands for years
11:14:07 before filing, stands alone among its similarly motivated sister
11:14:12 states as an outlier in seeking this extraordinary preliminary
11:14:17 injunctive relief. None of the other states have done that. And
11:14:21 the relief that they are seeking, as I noted, would cause turmoil
11:14:23 and disruption in numerous other states that have different
11:14:27 policies.

11:14:27 There is collateral damage to those other states.
11:14:30 There's collateral damage to millions of Americans, including
11:14:35 people in rural communities, low-income communities, disabled,

11:14:38 domestic violence victims, who often don't have in-person dispensal
11:14:45 options. All those are detailed in the amicus briefs, and we
11:14:50 believe that they also would need to weigh heavily in this Court's
11:14:52 exercise of equitable powers. Even at the permanent injunction
11:14:54 stage, but doubly so in the current issue, is interim provisional
11:14:59 relief -- relief that, by definition, may be rescinded when the
11:15:02 case further progresses.
11:15:03 So for all these reasons, we ask that the Court deny the
11:15:07 motion for preliminary injunction. And since plaintiffs lack
11:15:10 Article III standing, we believe the Court should dismiss the case
11:15:14 for lack of jurisdiction, as well.
11:15:16 **THE COURT:** Okay. Thank you, Counsel.
11:15:20 Before any rebuttal, I do have a couple more questions
11:15:25 for the FDA. I asked plaintiffs' counsel if she could conceive of
11:15:31 any remedy limited to the parties of this case, Rule 65 remedy.
11:15:37 Can you think of any?
11:15:39 **MR. KATZEN:** We aren't proposing any narrowing of relief.
11:15:42 We've made an argument there's no relief should be granted, but
11:15:44 we're not proposing any way of narrowing the relief that they've
11:15:47 sought.
11:15:47 **THE COURT:** All right. I'm asking you: Can you think of
11:15:50 any way, as a technical matter, to do that in this case?
11:15:52 **MR. KATZEN:** I can't, Your Honor.
11:15:53 **THE COURT:** Secondly, is there a mechanism within the FDA
11:15:56 if during its review process, if it sees a public health issue with

11:16:06 the 2023 REMS -- particularly the dispensing of the in-person
11:16:12 dispensing requirement -- is there a way for the FDA to take
11:16:17 immediate action to change it, to restore it, or to alter the 2023
11:16:28 REMS to meet the public health concern?
11:16:31 **MR. KATZEN:** So the way the REMS modification works is
11:16:35 that FDA doesn't, itself, change the REMS. It has to direct the
11:16:38 sponsors to submit supplemental applications that if approved would
11:16:43 modify the REMS. And there are statutory timeframes that govern
11:16:49 that period.
11:16:50 **THE COURT:** Is there a way to act on an emergent basis to
11:16:55 do that? is my question. Is there a way that they can do that
11:16:57 based on what they're seeing in an emergent basis during the period
11:17:01 of review?
11:17:02 **MR. KATZEN:** I don't want to make representation about
11:17:05 what they can do practically. Under the regulation -- under the
11:17:13 statute, the sponsors have 120 days, or such reasonable time as FDA
11:17:19 directs, to submit the supplemental application; and then FDA has
11:17:23 180 days, by statute, to review that application once it's
11:17:28 received. There is also an administrative review process that the
11:17:31 sponsors could take advantage of if they're directed to submit --
11:17:32 **THE COURT:** Why don't you file a brief on that within
11:17:35 seven days of the hearing. I don't think that's the answer. There
11:17:38 has been many cases where a drug is being used in a particular way
11:17:41 based on approval from the FDA that later comes to the attention of
11:17:45 the FDA that this drug is causing outside harm to the proposed

benefit, and they do something quickly. So I need to know that.

MR. KATZEN: So the question that you want me to brief is whether there's anything FDA could do on an emergent basis --

THE COURT: If during the course of their review, they see a public health concern with a portion of 2023 REMS. Yes, that's my question.

MR. KATZEN: Okay.

THE COURT: All right. Thank you. All right.

MR. AGUINAGA: Your Honor, I'll be quick. Would it be possible for Ms. Hawley to offer a couple of thoughts right after me?

THE COURT: Okay.

MR. AGUINAGA: Thank you, Your Honor. I think just five brief points.

First, my friends on the other side love the *Washington versus FDA* case from the Ninth Circuit, which, of course, is not binding here. I think the most important thing to take away from that decision, if you look, I think it's around page 1174, the premise and the preface of the whole decision by that Court is they're dealing with a complaint, they have no evidence, and, in fact, that decision came out before we have all of the #WeCount data that we have in our case. And of course, in that case the Ninth Circuit didn't have receipts like the Medicaid receipts that we have in this case. So all of that is to say that when you read that opinion, it's -- I think virtually every paragraph has the

11:19:00 word of speculation because that was the way the Ninth Circuit got
11:19:04 rid of Idaho's arguments in that case, was to say this is all
11:19:08 speculative, which is not the case here.
11:19:09 The second thing I'd say is just turning to the harms
11:19:10 that we have asserted. If you haven't had a chance to look at
11:19:14 *Texas versus Becerra*, which we cite at pages 6 and 7 of our reply
11:19:19 brief -- that's Judge Hendrick's decision. And I think it's a
11:19:21 helpful decision because he does two things there. One thing he
11:19:24 says is that, of course, encouraging a violation of state law is a
11:19:28 sovereign harm, but separate and apart from that, the increased
11:19:33 regulatory burden that a state incurs to enforce basically criminal
11:19:38 law against those violations is, itself, a cognizable harm. Those
11:19:42 two things squarely apply here, and I think that's a helpful
11:19:46 decision for sort of assessing the sovereign harm in conjunction
11:19:50 with the economic harms associated with enforcement.
11:19:52 The other thing I'd say regarding Medicaid costs: You
11:19:55 didn't hear anything from my friends on the other side about the
11:19:58 *Texas versus United States* decisions from the Fifth Circuit that we
11:20:01 cite at pages 20 to 22 of our opening brief. Those are decisions
11:20:06 before and after the *United States versus Texas* Supreme Court case,
11:20:10 *Alliance for Hippocratic Medicine*, those decisions. And if you
11:20:14 look at the 2025 case from the Fifth Circuit which goes into detail
11:20:21 about Footnote 3 that my friends love so much from *United States*
11:20:24 *versus Texas*, a resounding rejection by the Fifth Circuit with --
11:20:27 **THE COURT:** *United States versus Texas*, what was the

11:20:30 subject matter of that? There's a lot of those cases, so which one
11:20:33 are you referring to?
11:20:33 **MR. AGUINAGA:** Right. This is one of the docket cases.
11:20:35 And I'll give you a pincite, Your Honor. 126 F.4th at 410. That's
11:20:39 the Fifth Circuit's express address and rejection of this sort of
11:20:44 argument.
11:20:44 **THE COURT:** What was the subject matter of that case? I
11:20:47 guess is my question.
11:20:47 **MR. AGUINAGA:** Right. The question was whether the
11:20:49 docket issue imposed harms on the State of Texas. And what the
11:20:53 Court reiterated after the *United States versus Texas* from the
11:20:57 Supreme Court, after *Alliance for Hippocratic Medicine*, is that the
11:21:01 exact sort of Medicaid costs that we're raising here were
11:21:04 cognizable injuries for the State of Texas in that litigation. And
11:21:07 so I think everything you hear from my friends on the other side
11:21:10 you have to filter through. The Fifth Circuit's already talked
11:21:13 about those express arguments.
11:21:13 **THE COURT:** About the traceability issues; correct? That
11:21:16 would be where it would leave us; right? With traceability?
11:21:19 **MR. AGUINAGA:** Right, right. And for all the reasons we
11:21:21 discussed earlier, we think we win that analysis. But just in
11:21:25 terms of whether at the injury in fact part of the first part of
11:21:27 the standing analysis, whether Medicaid costs are, like, cognizable
11:21:32 Article III injuries, the Fifth Circuit has said time and again,
11:21:35 even after all the decisions they lacked from the Supreme Court,

11:21:38 the answer is yes.

11:21:39 My friend from -- representing Danco said that this is
11:21:43 not the fault of the 2023 REMS; this is all the shield laws' fault.
11:21:49 And, like, respectfully, that's not true. That's not how causation
11:21:53 works in the Article III standing context. Look at pages -- and
11:21:56 these are really great pages on our opening brief -- pages 20 to
11:22:00 22. What we say there, one of the citations we give you is the
11:22:03 Fifth Circuit saying there is no sole cause standard under Article
11:22:08 III, which is we don't have a burden to say that the 2023 REMS was
11:22:11 the only cause of our harms. What we're saying, and what the Fifth
11:22:16 Circuit allows us to say, is it was one of two indispensable
11:22:20 ingredients. Yes, on the one hand, you've got prescribers who are
11:22:22 chomping at the bit to send mifepristone into Louisiana; but on the
11:22:26 other hand, the only reason that they are able to do that in the
11:22:29 first place is because HHS specifically lifted the in-person
11:22:33 dispensing requirement to allow that to happen. That's why we meet
11:22:37 our burden on causation under Article III.

11:22:41 The last thing I'll leave the Court with is just if
11:22:44 you're looking at a way to frame up your Article III standing
11:22:47 analysis and conclude it, I highly commend to you page 125 of the
11:22:51 Supreme Court's decision in *Diamond Alternative Energy* because
11:22:54 that's where the Supreme Court says, like, look, if the Government
11:22:56 sets out to target a person through regulation, they can't then
11:23:01 turn around and try to avoid lawsuits on the ground that the
11:23:06 targets are unaffected bystanders.

11:23:09 **THE COURT:** All right. What do you have? What do you say in response to the interveners' argument that actually this process of making the 2021 changes permanent started in 2021?

11:23:17 **MR. AGUINAGA:** Well, Your Honor, that's only half of the story. Look at around paragraph 56 of our complaint where we give you the background on how the 2023 REMS came to be. The date that FDA decided to make it permanent in 2021, just after the oral argument in *Dobbs* when it was clear to everybody where the Supreme Court was going to go in *Dobbs*. And then over the next course of the year, we give you the timeline on how the Biden Administration carried out that plan.

So, yes, they can say, as a technical matter, it began before 2023; but the driving force all along was a recognition by the Biden Administration that they needed a way to inject medication abortion drugs into states that were going to ban or heavily restrict abortion. That's common sense. And I want to zoom out to say when the Supreme Court says, at the end of the day, that this is all about common sense, let's use common sense here. All of this is the intended and predictable consequence of the 2023 REMS because that's how it was designed.

With that, Your Honor, I'm happy to submit and let Ms. Hawley take over.

THE COURT: Thank you.

MS. HAWLEY: Thank you, Your Honor. Just a few quick points.

11:24:28 First, in response to your question regarding Medicaid, the State of Louisiana is on the hook for approximately 25 percent of those costs. That's at Exhibit 20 to our MPI, paragraph 7.

11:24:41 Second, Your Honor, with respect to the stay, I think with your dialogue with FDA what that revealed is that we have an indefinite timeframe. Under decisions like *Wedgeworth*, stays are inappropriate when there is no sort of definitive time when relief might occur. Here, we don't know if the data has been acquired. We don't know if the study has started. In our best guess, it will take at least six months after the study is completed. I think the best that can be said is maybe that was started in January, but I'm not sure even that is true. So it would be January plus a year, plus at least six months.

11:25:15 **THE COURT:** Well, Counsel's represented to me that they have started it in January.

11:25:20 **MS. HAWLEY:** I'm not sure he said that they started the study, Your Honor. I think they have to have the data before they start the study. I don't know if they have the data.

11:25:25 **THE COURT:** They started the process, is what he told me.

11:25:27 **MS. HAWLEY:** Yes. Yes, sir.

11:25:29 With respect to Section 706 and the administrative record, Section 706 says that a Court can issue relief based on parts of the administrative record cited by the parties. That part of the administration is at ECF Section 1-50. That is the decisional document from 2023. That's all this Court needs to

11:25:50 decide on the merits, which, again, the Fifth Circuit has already
11:25:54 found a likelihood of success.
11:25:57 And really briefly, Your Honor, with respect to the FAERS
11:25:58 data, my friend on the other side representing GenBioPro said that
11:26:03 they report all of the information that, quote, comes into their
11:26:06 possession. With respect, they are not anywhere near the emergency
11:26:12 rooms that are treating women harmed by mifepristone. Again, in
11:26:15 the time period, a $1^{1}/_{2}$-year time period assessed by the FDA, there
11:26:20 were only 8 reported FAERS incidents. GenBioPro, in its brief,
11:26:26 touts a study -- actually one that FDA discounted and did not rely
11:26:29 on, but it touts a study with adverse event incidents of 0.9. If
11:26:36 you take the 1.5 million -- that's a conservative number from
11:26:40 Guttmacher's -- that occurred -- 1.5 million abortions during that
11:26:41 $1^{3}/_{4}$ of the year, we come away with tens of thousands of adverse
11:26:46 events, not 8. Again, Commissioner Makary's estimate of that data
11:26:50 is, quote, not very good, is, if anything, an understatement.
11:26:53 They also rely on the Aiken study. Not even the FDA
11:26:57 relied on the Aiken study because they found that study to be
11:27:00 wholly unreliable and ungeneralizable to the United States'
11:27:05 population, precisely because it didn't include serious adverse
11:27:10 events, things like infections without sepsis, hemorrhaging without
11:27:14 transfusions, hospitalizations without subsequent procedures. So
11:27:18 that study, even the FDA did not rely on. FDA, in fact, relied on
11:27:23 only four studies, not the 15 suggested by GenBioPro. And as the
11:27:28 Fifth Circuit found, even the reliance on those studies was

11:27:31 unreliable.

11:27:32 One thing on sort of the harms to GenBioPro and Danco. I
11:27:38 would point Your Honor to paragraph 15 of the Long Declaration
11:27:41 attached to Danco's MPI -- motion in response to the MPI. And that
11:27:47 clarifies that all of the steps that might have been necessary in
11:27:52 the Woodcock Declaration for the *AHM* case would not, in fact, be
11:27:55 necessary in this case. If there was a stay issued of the 2023
11:27:59 REMS, the last remaining REMS would automatically come into effect.
11:28:03 There would be no need for an SDNA. In addition, all GenBioPro and
11:28:09 Danco would need to do would be to notify their prescribers to
11:28:17 recertify. That's a short process. It's at ECF 1-50, page 30,
11:28:22 about a page-and-a-half long. The FDA, again, called it minimally
11:28:27 burdensome. And that can certainly happen in a very short time
11:28:31 period.

11:28:31 In conclusion, Your Honor, Louisiana does not believe
11:28:34 there is any public interest in leaving a risky and unsafe drug on
11:28:38 the market, one that the FDA in 2020 called the in-person visit
11:28:41 necessary to mitigate those risk profiles. Thank you.

11:28:45 **THE COURT:** One more question. So after the 2023 REMS --
11:28:52 I know there was litigation that's actually still pending now in
11:28:56 Missouri. But a stay was issued of the REMS by a colleague of mine
11:29:03 in Texas, and then the Fifth Circuit, I think, affirmed that, and I
11:29:06 have read the rulings on those. So how long was the stay in
11:29:14 effect?

11:29:14 **MS. HAWLEY:** So not very long, Your Honor.

11:29:16 **THE COURT:** Supreme Court vacated those? Is that what happened?

11:29:20 **MS. HAWLEY:** Yes, sir.

11:29:20 **THE COURT:** So basically the data is, since 2023 this has fairly consistently been the law of the land, so to speak?

11:29:21 **MS. HAWLEY:** Yes, Your Honor.

11:29:27 **THE COURT:** All right. I appreciate it, Counsel. The case is submitted. Court's adjourned.

11:29:28 (Whereupon the proceedings concluded at 11:29 a.m.)

11:29:32 * * *

11:29:39 **REPORTER'S CERTIFICATE**

I, Beth Delatte, Registered Professional Reporter, Certified Court Reporter in and for the State of Louisiana, Official Court Reporter for the United States District Court, Western District of Louisiana, do hereby certify that the foregoing is a true and correct transcript, to the best of my ability and understanding, from the record of the proceedings in the above-entitled and numbered matter.

/s/Beth Delatte

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