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

REPLY IN SUPPORT OF MOTION FOR § 705 STAY OR INJUNCTION PENDING APPEAL

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

REPLY

As Danco dismissively acknowledged below, "some judges" (Dist.Ct.ECF.52-4 at 17) of this Court—namely, Chief Judge Elrod and Judges Ho, Wilson, Engelhardt, and Oldham—have already recognized that the Biden Administration's 2023 REMS is likely unlawful. The court below agreed: "Plaintiffs are likely to succeed on the merits of their 2023 REMS challenge." Dist.Ct.Op.28. The court below likewise agreed that Louisiana has "establish[ed] irreparable harm" absent a § 705 stay (or injunction against the enforcement) of the 2023 REMS. *Id.* So, a § 705 stay is warranted.

FDA's tortured opposition underscores the point. FDA professes a "profoundly important" interest in "[p]rotecting the health and safety of pregnant women." ECF.74 at 1. FDA also criticizes the 2023 REMS as "lack[ing] [] adequate consideration." *Id.* (citation omitted). But the remainder of FDA's brief is an array of half-hearted excuses for *keeping* the 2023 REMS in effect indefinitely. Never mind pregnant women like Plaintiff Rosalie Markezich who would not have been coerced to abort her baby via mailed mifepristone but for the 2023 REMS. Never mind the pregnant Louisiana women who, according to unrebutted declarations,

are arriving in emergency rooms because of mailed mifepristone authorized by the 2023 REMS. And never mind the approximately 1,000 unborn Louisiana children who are killed every month in violation of Louisiana law because of the 2023 REMS.

This was the Biden Administration's avowed goal—to nullify the each-state-can-decide-for-itself promise of *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), by removing the in-person dispensing requirement that would otherwise prevent activists and prescribers in pro-abortion states from remotely sending illegal abortion drugs into pro-life states. Understandably, this FDA's heart is not in the fight. That is why its brief never defends the 2023 REMS. The Court should read FDA's token opposition for what it is—and enter the same § 705 stay this Court has twice upheld. *See All. for Hippocratic Med. v. FDA* (*Alliance I*), 2023 WL 2913725 (5th Cir. Apr. 12, 2023); *All. for Hippocratic Med. v. FDA* (*Alliance II*), 78 F.4th 210 (5th Cir. 2023).

ARGUMENT

I. THERE IS NO RULE 8 ISSUE.

FDA argues that Plaintiffs should have first asked the district court for a stay and complains that Plaintiffs did not recite the word

"impracticable" in explaining why they declined to request a futile stay. ECF.74 at 11. But there is nothing talismanic about the word "impracticable." And in any event, FDA does not dispute that such a request would have been futile (and therefore impracticable) because, as Louisiana explained (Mot.1), "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." Nor does FDA acknowledge that declining to credit such futility would split with the Sixth and Ninth Circuits. *See id.* (citing cases). That is sufficient to reject FDA's complaint.

FDA's own cited precedent confirms the point. *See* ECF.74 at 12 (citing *Whole Woman's Health v. Paxton*, 972 F.3d 649, 654 (5th Cir. 2020)). Rule 8 requires presentation first to the district court "unless it clearly appears that further arguments ... would be pointless in the district court." *Paxton*, 972 F.3d at 653 (quoting *Ruiz v. Estelle*, 650 F.2d 555, 567 (5th Cir. 1981)). That is the case here for the reasons just explained. *Bayless v. Martine*, 430 F.2d 873 (5th Cir. 1970) (cited at ECF.74 at 12), is inapposite because the district court there did not couple its denial of preliminary relief with a stay of proceedings—which

prevents further litigation below. Indeed, FDA never acknowledges (*see* ECF.74 at 11–13) the irony in FDA's (a) having successfully moved to stay proceedings yet (b) simultaneously claiming that Plaintiffs should have filed a "pointless" motion, *Paxton*, 972 F.3d at 653 (citation omitted). Neither Rule 8 nor this Court's precedents require such futile measures.

II. THE PRELIMINARY-RELIEF FACTORS WARRANT A § 705 STAY.

FDA's "opposition" on the preliminary-relief factors is even more puzzling because FDA never disputes that "Plaintiffs are [] likely to 'succeed on the merits of their 2023 REMS challenge.'" Mot.12.[1] Worse, FDA never acknowledges this Court's square holdings that (a) "FDA and the public will not be injured by an order staying" the 2023 REMS, and (b) "the public interest is disserved by" keeping the 2023 REMS in effect. Mot.19–20 (quoting *Alliance II*, 78 F.4th at 251–53). FDA's refusal to engage these holdings is significant because, in the ordinary case, a grant of preliminary relief plainly would be in order.

[1] To the extent that the Intervenors wish to revisit the merits, the *Alliance I* and *Alliance II* panels rejected most of those tired arguments, which are all addressed in Plaintiffs' briefing below. *See* Mot.9 n.5 (providing relevant citations).

Recognizing as much, FDA resists relief on two theories: (A) the district court correctly invoked "the balance-of-equities and public-interest factors" to deny preliminary relief; and (B) contrary to the district court's holding, Louisiana lacks both standing and irreparable harm. FDA is wrong.

A. FDA's "Equities" Analysis Is Non-Existent.

Start with the equities. *First*, FDA concedes (at 14) that courts must review the *lawfulness* of agency actions—even those "implicat[ing] scientific and medical judgments"—under the APA. ECF.74 at 14.

FDA reframes the district court's concern as one about the possibility that "FDA's expertise" and "review" may "moot this case" or "illuminate subsequent judicial review." *Id.* That is not what the district court was saying in complaining about being "ill-equipped" to "determin[e] whether FDA's in-person dispensing requirement is scientifically necessary." Dist.Ct.Op.33–34. But to the extent FDA wants to lean on its alleged review,[2] FDA does not address Louisiana's direct

[2] The Court should be aware of FDA's unmoored use (at 2) of the terms "a year" and "sooner." It remains unclear when the supposed one-year clock will begin ticking. FDA announced last September that it would conduct a study, but at the February hearing, FDA's attorney balked at the idea that FDA's review would be complete by September

response on that score: "[I]t 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." Mot.26.

Second, FDA concedes that courts do "entertain challenges to agency action where the requested relief [has] nationwide implications" and that sometimes there is no "way to avoid the possibility of conflicting decisions that could occasion the need for Supreme Court review." ECF.74 at 15; *see also* Mot.23–25 (giving four reasons why the district court's concern with nationwide relief is misplaced).

FDA says merely that in considering the possibility of conflicting decisions the district court appropriately exercised "equitable reasoning." ECF.74 at 15. But to avoid review because another court might disagree is not equity; it is judicial abdication. As Justice Kavanaugh has said, "determining the nationally uniform *interim* legal status ... of, say, ... mifepristone rules is a role that the American people appropriately expect ... the courts of appeals or district courts ... to fulfill." *Trump v. CASA, Inc.*, 606 U.S. 831, 877–78 (2025) (Kavanaugh, J., concurring). If

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2026. Tr.33. And since FDA has again stated (at 2) that it is still collecting data, the need for preliminary relief remains stark.

conflicting lower court rulings happen to arise, the Supreme Court exists to resolve that conflict. But, as this Court has already held, the mere possibility of such a conflict offers no basis to refuse to carry out the judicial role. See Mot.22 (quoting *Alliance I*, 2023 WL 2913725, at *19).

That is the sum total of FDA's effort on the equities—and it is self-defeating. There is no plausible argument that FDA or the public would suffer any sort of harm from a § 705 stay. Given all this—and given the district court's own correct determination that Louisiana is suffering ongoing irreparable harm while the 2023 REMS remains in effect—there is no question that a § 705 stay is warranted.[3]

[3] FDA includes a throwaway sentence claiming that "'Louisiana retains many meaningful, boots-on-the-ground law enforcement mechanisms to mitigate its' asserted 'sovereign and financial harms while FDA completes its ongoing review.'" ECF.74 at 15 (quoting Dist.Ct.Op.30). That sentence does not make up for the absence of any cognizable harm on FDA's side of the ledger. That sentence also is citation-less because it is incorrect. As the district court separately acknowledged, Dist.Ct.Op.23, pro-abortion states have enacted so-called "shield laws" aimed at insulating activists and prescribers in those states from liability. Indeed, despite pro-life states' efforts, no activist or prescriber has been held to account for their conduct. That is why interim relief is so important.

B. Louisiana Has Standing and Is Suffering Irreparable Harm.

FDA next turns on the district court by disputing Louisiana's Article III standing—an issue that FDA then folds into a single paragraph on irreparable harm. ECF.74 at 25. FDA's argument is no more than a copy-and-paste of its cursory district court brief; it thus fails for all the reasons the district court and Plaintiffs explained below. Dist.Ct.Op.16–25; Mot.9 n.5 (collecting citations).

1. The injury-in-fact analysis is straightforward. FDA concedes that Louisiana's incurred "Medicaid costs constitute an Article III injury." ECF.74 at 22. FDA disputes only traceability (addressed below) and whether Louisiana's sovereign harm also qualifies as an Article III injury. *Id.* at 18. It is.

This Court has long recognized that "federal interference with the enforcement of state law" may constitute an Article III injury. *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015). And that is the problem here: In a world with the in-person dispensing requirement, Louisiana would be fully capable of enforcing its abortion laws—for any mine-run violator would need to be physically present in Louisiana and thus subject to apprehension within Louisiana's borders. The 2023 REMS's

removal of the in-person dispensing requirement, however, introduces a new (and now virtually exclusive) way of violating Louisiana law—namely, through out-of-state activists and prescribers who mail mifepristone into Louisiana while avoiding capture in Louisiana. Coupled with shield laws intended to protect those individuals, the 2023 REMS brings the enforcement of Louisiana's abortion laws to a halt.

As the district court correctly recognized, "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." Dist.Ct.Op.28. And that distinguishes FDA's passing citation (ECF.74 at 19) of *Harrison v. Jefferson Parish School Board*, 78 F.4th 765, 772 (5th Cir. 2023), which sought to distinguish between a violation of law and hindering the law's enforcement. The 2023 REMS effectively has nullified, not just hindered, the enforcement of Louisiana law by allowing activists and prescribers to launch their pro-abortion attacks outside of Louisiana's borders.

2. The only real question, then, is traceability and redressability—but FDA avoids the word "redressability." That is presumably because the redressability question ends the whole standing inquiry. Traceability

and redressability "are usually 'flip sides of the same coin'" in that, "'[i]f a defendant's action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury.'" *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 111 (2025).

Applied here, therefore, the question is whether vacating the 2023 REMS would, at least in part, redress Louisiana's sovereign and economic harms. Both below and here, FDA has never disputed that the answer is yes. Rightly so: As the ACLU has publicly complained, "If the court grants Louisiana's motion, [requesters] will no longer be able to fill their mifepristone prescription by mail[.]" Dist.Ct.ECF.111 at 13. Put otherwise, the 1,000 abortion drugs that are being mailed into Louisiana every month could no longer be lawfully (under federal law) mailed into Louisiana—thereby eliminating the ongoing violations of Louisiana law and the direct Medicaid costs arising out of related emergency room visits. That is textbook redressability.

FDA never acknowledges the undisputed record evidence that—as the district court recounted, Dist.Ct.Op.24–25—directly ties the Medicaid costs to mail-order mifepristone made possible by the 2023 REMS. Relatedly, FDA's invocation of *Washington v. FDA*, 108 F.4th

1163 (9th Cir. 2024), omits (among other things) the Ninth Circuit's emphasis that, unlike the court below, it was considering only "highly speculative allegations" in a complaint. *Id.* at 1175.

FDA also does not seriously dispute that the Biden Administration's targeting of pro-life states leaves no doubt that Louisiana has standing. In fact, FDA does not even acknowledge that record evidence. *See* Dist.Ct.Op.21. Instead, FDA tries (ECF.74 at 24) to limit *Diamond* to suspicious targeting of actors within the same "economic chain." But FDA is just highlighting the unremarkable fact that *Diamond* happened to arise in the business context. Nothing in *Diamond* says that where, as here, a President directs his administration to actively pursue regulations designed to undercut pro-life states' laws, the federal government can thereafter "evade the resulting lawsuits by claiming that the targets of its regulation should be locked out of court as unaffected bystanders." 606 U.S. at 125. That is preposterous. If anything, under our federalism, the *Diamond* principle applies *a fortiori* where a sovereign state is the target of federal regulation.

FDA, in addition, says next to nothing about the district court's holding that "there is evidence that the consequences of [the 2023 REMS]

were predictable—out-of-state providers and related entities would expand access to mifepristone in ways designed to reach into jurisdictions like Louisiana." Dist.Ct.Op.21. Because (a) the redressability element is clearly satisfied (and thus so is the traceability element), (b) the REMS is the product of direct targeting against pro-life states, and (c) the REMS has worked not just predictably but as intended, Louisiana, of course, has standing to challenge the REMS. Based on all the same evidence, the district court correctly concluded that Louisiana has "establish[ed] irreparable harm." Dist.Ct.Op.28.

One final point: There is extensive hyperbole in the drug manufacturers' briefs claiming that Louisiana somehow is in a *worse* position to claim standing as compared to the plaintiffs in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024). The exact opposite is true in at least two respects. *First*, unlike those plaintiffs, Louisiana and its sister pro-life states were the unfortunate targets of a Biden Administration that sought to undercut pro-life states' laws post-*Dobbs*. *Second*, unlike those plaintiffs, Louisiana has "offered evidence tending to suggest that FDA's deregulatory actions have both caused an increase in the number of pregnant women seeking" emergency care "*and* caused

a resulting" increase in costs to the State (not to mention the attendant sovereign harm). *Id.* at 390–91. Those key distinctions assure Louisiana's standing—and foreclose the manufacturers' hyperbolic claims about the supposed unlimited nature of Louisiana's standing theory.

CONCLUSION

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

Dated: April 24, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 24, 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 2462 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 24, 2026