No. 26-30203

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

STATE OF LOUISIANA, by & through its ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,

Plaintiffs-Appellants,

v.

FOOD & DRUG ADMINISTRATION; KYLE DIAMANTAS, ACTING COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION; MICHAEL DAVIS, in his official capacity as ACTING 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/Cross-Appellants.

On Appeal from the United States District Court
for the Western District of Louisiana

DEFENDANTS' OPPOSITION TO MOTION TO EXPEDITE

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CERTIFICATE OF INTERESTED PERSONS

Louisiana v. FDA

A certificate of interested persons is not required, under Fifth Circuit Rule 28.2.1, as appellees are all governmental parties.

/s/ Daniel Winik
Daniel Winik

INTRODUCTION

In September 2025, the Secretary of Health and Human Services and the Commissioner of Food and Drugs announced that the Food and Drug Administration (FDA) is reviewing the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, a drug approved for medical abortion. Dkt. 1-110. The announcement stated that this review is "informed by the lack of adequate consideration underlying the prior REMS approvals," including a 2023 approval of a modification that removed the in-person dispensing requirement. *Id.* at 1. It expressed FDA's commitment "to protecting the health and safety of pregnant women" and "ensur[ing] … decisions are grounded in Gold Standard Science and rigorous, transparent, and objective evidence." *Id.* at 2. And it is consistent with this Court's criticism of the reasoning FDA employed in calling for the removal of the in-person dispensing requirement in 2021. *See Alliance for Hippocratic Med. v. FDA*, 78 F.4th 210, 249-51 (5th Cir. 2023), *rev'd on other grounds*, 602 U.S. 367 (2024).

In undertaking this review, FDA recognized that the validity of its mifepristone restrictions is hotly contested. Five other States are challenging the approval of mifepristone or subsequent actions easing restrictions. *See Missouri v. FDA*, No. 25-cv-1580 (E.D. Mo.); *Florida v. FDA*, No. 25-cv-126 (N.D.

Tex.). Other plaintiffs have challenged FDA's restrictions as too burdensome. *Purcell v. Kennedy*, 2025 WL 3101785 (D. Haw. Oct. 30, 2025); *Washington v. FDA*, 2025 WL 1888794 (E.D. Wash. July 8, 2025); *Whole Woman's Health All. v. FDA*, No. 23-cv-19 (W.D. Va.). And numerous citizen petitions are pending before FDA, seeking relief in both directions.

Given this complexity, FDA concluded that the best path forward is to review the REMS based on all the evidence before it, including a new study it is undertaking. FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (No. 37).[1]

Plaintiffs waited nearly three years after the 2023 REMS modification to bring this challenge to the modification, and waited another two and a half months before asking the district court to pretermit FDA's review and impose an immediate stay of the modification. Instead of granting that request, the district court chose to exercise its broad discretion "to control the disposition of the causes on its docket with economy of time and effort," *Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936), by granting a "time-limited"

[1] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (visited June 15, 2026).

stay of the litigation to allow FDA "to complete its review and carry out the responsibilities assigned to it by Congress," *Louisiana v. FDA*, 2026 WL 936958, at *17 (W.D. La. Apr. 7, 2026). Louisiana appealed, and this Court stayed the 2023 REMS modification pending appeal. *Louisiana v. FDA*, 175 F.4th 310 (5th Cir. 2026). But the Supreme Court stayed this Court's action until the conclusion of this appeal and any subsequent proceedings in the Supreme Court. *Danco Labs., LLC v. Louisiana*, 146 S. Ct. 1192 (2026).

That was more than a month ago—yet Louisiana is now moving to expedite the appeal. The Court should deny its motion for the same reasons it was appropriate for the district court and the Supreme Court to deny Louisiana interim relief. While FDA completes its review, Louisiana is free to make and enforce pro-life policies under *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022). The motion to expedite should be denied.

STATEMENT

1. In 2000, FDA approved mifepristone for medical abortion, subject to restrictions to assure safe use. *See FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 376 (2024).[2] Since 2008, those restrictions—previously imposed

[2] FDA has separately approved another manufacturer's mifepristone product, Korlym, for Cushing's syndrome. It is not at issue here.

under another regulatory framework—have been part of a "risk evaluation and mitigation strategy," 21 U.S.C. § 355-1. *See* 73 Fed. Reg. 16313, 16314 (Mar. 27, 2008).

For most of the drug's history, mifepristone's restrictions included an "in-person dispensing requirement," ensuring that the drug could be dispensed only in "clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber." *See, e.g.*, Dkt. 20-16 (REMS document dated May 2021). In December 2021, FDA directed mifepristone's sponsors to submit supplemental applications proposing to remove the in-person dispensing requirement. *See* Dkt. 1 ¶ 56; 21 U.S.C. § 355-1(g)(4)(B). The sponsors submitted those applications, and FDA approved them in January 2023.

As noted above, FDA is now conducting a new review of the mifepristone REMS. In announcing the review, the Secretary and Commissioner explained that, "to determine whether modifications [to the REMS] are necessary," FDA will consider evidence relating to "real-world outcomes" and conduct "a study of the safety of the current REMS." Dkt. 1-110 at 1. FDA will also comply with the *Purcell* court's order to reassess the REMS, 2025 WL 3101785, at *28, and address numerous pending citizen petitions.

2. Shortly after the Secretary and Commissioner issued their September 2025 letter, plaintiffs here—Louisiana and Rosalie Markezich—brought this challenge to the 2023 REMS modification. Two and a half months later, and nearly three years after the challenged REMS modification, they moved for a stay of the REMS modification under 5 U.S.C. § 705 or a preliminary injunction. Two mifepristone manufacturers intervened and moved to dismiss. The government moved to stay the case pending FDA's review.

3. The district court granted the government's motion to stay the litigation and denied plaintiffs' motion (as well as intervenors' motions to dismiss) without prejudice to the refiling of those motions upon the lifting of the stay. *Louisiana v. FDA*, 2026 WL 936958 (W.D. La. Apr. 7, 2026). The court determined that Louisiana was likely to prevail on the merits but that the balance-of-harms and public-interest factors weighed against preliminary relief for three reasons.

First, the court explained that this case "implicate[s] scientific and medical judgments committed by Congress to an agency with specialized knowledge"—one that is "accountable to the President" and thus to the political process—and that "[t]he public interest in the proper function of FDA

and its scientifically grounded, congressionally authorized protocol is substantial." *Id.* at *14-15. The court noted that it was "ill-equipped" "to evaluate scientific evidence and make" the sorts of "public health judgments" that Congress vested in the agency. *Id.* at *16.

Second, the court noted that the requested relief "would, as a practical matter, have a nationwide effect," *id.* at *15, and thus implicated the concerns animating *Trump v. CASA, Inc.*, 606 U.S. 831 (2025). Those concerns are particularly acute, the court explained, given the need for a "nationally integrated regulatory scheme" and the "substantial risk of inconsistent judicial outcomes" created by the "multiple parallel lawsuits across the country addressing the same regulatory issues surrounding access to mifepristone." 2026 WL 936958, at *15, *17.

Finally, the court explained that even if the requested relief were granted, "mifepristone would likely continue to reach those" in Louisiana "who seek it," and that "Louisiana retains many meaningful, boots-on-the-ground law enforcement mechanisms to mitigate its sovereign and financial harms while FDA completes its ongoing review." *Id.* at *15.

The court accordingly stayed the case to "afford the agency a time-limited period of deference to complete its review and carry out the responsibilities assigned to it by Congress." *Id.* at *17.

This Court granted Louisiana's motion to stay the 2023 REMS modification pending appeal. *Louisiana v. FDA*, 175 F.4th 310 (5th Cir. 2026). The Supreme Court, however, stayed this Court's action pending the resolution of this appeal and any subsequent proceedings in the Supreme Court. *Danco Labs., LLC v. Louisiana*, 146 S. Ct. 1192 (2026).

ARGUMENT

Expedition of this appeal would be unwarranted for the same reasons that, as the district court and the Supreme Court concluded, interim equitable relief was unwarranted. This Court should not hasten to inject itself into FDA's ongoing review of mifepristone, and Louisiana has shown no need for urgent resolution of this appeal because it has not established a judicially cognizable injury.

1. As the district court and the Supreme Court recognized, prudence counsels against hasty judicial intervention in this case. The Court should allow FDA to conduct its ongoing review.

This case "implicate[s] scientific and medical judgments committed by Congress to an agency with specialized knowledge"—judgments that courts are "ill-equipped" to make. 2026 WL 936958, at *14, *16. Of course, courts sometimes must address scientific and medical issues in reviewing agency actions under the deferential standards of the Administrative Procedure Act (APA), *see* 5 U.S.C. § 706(2). But as the district court recognized, it would be imprudent to do so when FDA is conducting a review that could moot this case, obviating the need for judicial intervention, or bring FDA's expertise to bear in a way that would illuminate subsequent judicial review.

This Court appraised the equities differently in granting Louisiana's motion to stay the 2023 REMS modification pending appeal. *See* 175 F.4th at 321-23. But the Supreme Court necessarily reached a different conclusion when it stayed that relief, and that conclusion governs this Court going forward. *See Trump v. Boyle*, 145 S. Ct. 2653, 2654 (2025) ("Although our interim orders are not conclusive as to the merits, they inform how a court should exercise its equitable discretion in like cases.").

2. Louisiana ignores all this in its motion for expedition, arguing—in a single paragraph—that expedition is warranted because of "the irreparable harm the State faces every day that the challenged 2023 REMS remains

in place." But the question whether the challenged REMS should remain in place in the short term was resolved by the Supreme Court in its stay decision. That order provided that the REMS would stay in effect not only during the pendency of proceedings in this Court, but also during the resolution of any petition for certiorari to the Supreme Court after this Court renders a decision—unless, of course, FDA takes administrative action during that time. No expedition order could change that.

There is no dispute that while this appeal is pending, Louisiana retains authority to "regulate abortion for legitimate reasons," including "respect for and preservation of prenatal life at all stages of development," *Dobbs*, 597 U.S. at 300-01. *See GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 274 (4th Cir. 2025) (correctly holding that the REMS establishes "a regulatory floor, not a ceiling"). And Louisiana also retains full authority to enforce those laws. *See Harrison v. Jefferson Parish Sch. Bd.*, 78 F.4th 765, 772 (5th Cir. 2023) ("[W]hen speaking about the sovereign's interest in enforcing its laws, the Supreme Court has spoken about the state's interest in the *enforceability* of its laws.").

Louisiana's argument boils down, then, to the proposition that it is "more difficult to police" violations of its laws when mifepristone can be mailed into the State, *Washington v. FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024).

The parties have previously disputed whether this interest suffices to establish standing, much less irreparable harm. *See Louisiana v. Horseracing Integrity & Safety Auth. Inc.*, 617 F. Supp. 3d 478, 498-99 (W.D. La. 2022) (noting that demonstrating irreparable injury is "a higher burden than that of standing"). As noted above, the Supreme Court's granting of a stay suggests some agreement that this sort of "logistical burden on law enforcement" cannot "constitute[] a cognizable Article III injury," *Washington*, 108 F.4th at 1177. Otherwise, States could "challenge any federal action"—for example, any loosening of regulations relating to firearms, the environment, or banking—that they can allege would "increase[] crime or disorder, or impose[] indirect compliance costs for state law enforcement." *Id.* Louisiana also previously asserted standing based on "financial injury," *Louisiana*, 175 F.4th at 319, on the theory that some women who take mifepristone will require emergency care covered by its Medicaid program, but the Supreme Court found that unpersuasive as well, just as it has rejected similarly "attenuated" theories of state standing resting on claims that a federal policy "has produced only" "indirect effects on state revenues or state spending," *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023).

In addition, expedition would not materially affect the status quo as a practical matter, given that the Supreme Court has made clear that any stay of the 2023 REMS modification should not take effect until after the resolution of any Supreme Court proceedings in this case. There is no reason to grant expedition merely for the sake of expedition, a step that would be inappropriate in any case but is particularly unwarranted given the lack of urgency that Louisiana has shown throughout this case. This Court should follow the Supreme Court's lead and allow FDA's process to unfold, rather than hastening this litigation.

CONCLUSION

Plaintiffs' motion should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this response complies with Federal Rule of Appellate Procedure 27(d)(1)(E) because it has been prepared in 14-point Book Antiqua, a proportionally spaced font, and that it complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 2102 words, according to Microsoft Word.

/s/ Daniel Winik
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