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/Cross-Appellees

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

GENBIOPRO, INCORPORATED,

Intervenor-Appellee/Cross-Appellant

v.

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellee/Cross-Appellant

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

BRIEF FOR FEDERAL APPELLEES

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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

STATEMENT REGARDING ORAL ARGUMENT

The Court has set oral argument for September 9.

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INTRODUCTION

Protecting the health and safety of pregnant women is profoundly important. To that end, 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. ROA.2201-2202. 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. ROA.2201. 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." ROA.2202. 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, 249-251 (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 mifepristone 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) ("*Questions and Answers*").[1] FDA has explained that it is "press[ing] forward to complete its science-based safety review of the mifepristone REMS and, in an effort to provide greater transparency, will provide updates as key milestones are reached." FDA (@US_FDA), X (May 14, 2026, at 9:52 pm), https://x.com/US_FDA/status/2055043549062991971. And once FDA has

[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 July 14, 2026).

analyzed the data from that study (as well as all other evidence before it), it will decide whether "substantive changes to the REMS" are "warranted." FDA, *Questions and Answers*, *supra* (No. 37).

Plaintiffs—Louisiana and an individual, Rosalie Markezich—waited nearly three years after the 2023 REMS modification to bring this challenge to the modification, asking the district court to pretermit FDA's review and impose an immediate stay of the modification under 5 U.S.C. § 705. 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" stay of the litigation to allow FDA "to complete its review and carry out the responsibilities assigned to it by Congress," ROA.9118.

That ruling, as an exercise of the district court's inherent case-management discretion, is reviewable only for abuse of discretion. Indeed, it would not have been reviewable at all, other than by mandamus, had the district court simply held plaintiffs' motion in abeyance during the stay rather than doing the functional equivalent of denying plaintiffs' motion without prejudice to its renewal upon the lifting of the stay.

And the district court's ruling, far from an abuse of its discretion, was a sound exercise of it. As the court observed, the relief plaintiffs seek not only would disrupt FDA's ongoing review, and usurp FDA's scientific role, but also would threaten chaos if (as is likely) it prompted plaintiffs elsewhere to seek a conflicting injunction. This is not a theoretical risk: In 2023, minutes after the district court in *Alliance* stayed FDA's approval of mifepristone, another district court in another Circuit issued a contrary edict. *Washington v. FDA*, 668 F. Supp. 3d 1125, 1144 (E.D. Wash. 2023), *vacated*, 2025 WL 1888794 (E.D. Wash. July 8, 2025). There is no need to intervene in this precipitous way, particularly given plaintiffs' long delay in bringing this suit and given Louisiana's freedom in the interim to make and enforce pro-life policies under *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022). The Supreme Court recently confirmed as much by deciding to leave the 2023 REMS modification in place pending the conclusion of this appeal and any subsequent Supreme Court proceedings. *Danco Labs., LLC v. Louisiana*, 146 S. Ct. 1192 (2026). The district court's action here was not unlike the practice of remand without vacatur, or with a time-limited stay of vacatur, which courts can employ when the inadequacy of an agency's consideration of a decision could be rectified on remand.

Because plaintiffs cannot overcome the deference owed to the district court's exercise of its case-management discretion, they do not even try. Instead of asking the Court to reverse the district court's decision to stay the case rather than granting a preliminary injunction or 5 U.S.C. § 705 stay of the 2023 REMS modification, plaintiffs ask the Court to "enter[] a § 705 stay of the 2023 REMS" modification in the first instance. Br. 5; *see* Br. 32-34 (similar); Br. 63-71 (discussing equitable factors for a stay). But plaintiffs have already lost that fight: Although this Court initially issued a § 705 stay of the 2023 REMS modification, *Louisiana ex rel. Murrill v. FDA*, 175 F.4th 310 (5th Cir. 2026), the Supreme Court stayed that action, as discussed above. It would defy the Supreme Court's ruling for this Court to issue a § 705 stay once again. *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.").

In any event, even if plaintiffs could show that the district court abused its discretion in staying the litigation, or if the Supreme Court's order did not preclude a new § 705 stay, plaintiffs still cannot prevail because they lack standing to pursue the litigation. Plaintiffs do not even try to argue that Ms. Markezich has standing, and their arguments for Louisiana's standing lack

merit. Louisiana's asserted economic harms—even if fully predictable—are too far removed from the 2023 REMS modification to establish standing to challenge it, and Louisiana identifies no cognizable sovereign injury caused by the REMS modification.

This Court should therefore affirm the district court's denial of a preliminary injunction. In the alternative, this Court, like the district court, could simply hold this appeal in abeyance pending FDA's review.

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. § 1331. ROA.86. The district court lacked jurisdiction, however, because plaintiffs lack standing. The district court denied plaintiffs' motion for a preliminary injunction, or an equivalent stay of agency action under 5 U.S.C. § 705, on April 7, 2026. ROA.9119-9120. Plaintiffs timely appealed the following day. ROA.9121-9122; *see* Fed. R. App. P. 4(a)(1)(B). This Court has appellate jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF ISSUES

1. Whether the district court abused its discretion by staying the litigation pending the completion of FDA's review.

2. Whether the Supreme Court's ruling in this case bars this Court from staying the challenged REMS modification under 5 U.S.C. § 705.

3. Whether plaintiffs lack standing.

STATEMENT OF THE CASE

1. The Federal Food, Drug, and Cosmetic Act generally prohibits introducing a "new drug" into interstate commerce without FDA approval. 21 U.S.C. § 355(a). In 2007, Congress codified and expanded FDA's regulatory regime by authorizing FDA to require a "risk evaluation and mitigation strategy," or REMS, when necessary to ensure that a drug's benefits outweigh its risks. *Id.* § 355-1. Under the REMS framework, FDA's approval of a drug may include "elements to assure safe use," like a requirement that a drug be dispensed only in certain settings. *Id.* § 355-1(f)(3).

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 under another regulatory framework—have been part of a REMS. *See* 73 Fed. Reg. 16313, 16314 (Mar. 27, 2008).

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

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." ROA.2498 (2021 REMS). In July 2020, a district court enjoined enforcement of that requirement during the COVID-19 pandemic. *American Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020). The Supreme Court stayed that injunction pending appeal in January 2021. *FDA v. American Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021). But in April 2021, FDA announced that it would not enforce the in-person dispensing requirement during the COVID-19 public health emergency, and the following month it announced it would review the REMS. *See* ROA.352-353; ROA.353 n.10.

In December 2021, FDA directed mifepristone's sponsors to submit supplemental applications proposing to remove the in-person dispensing requirement. *See* 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 in a letter, 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." ROA.2201. FDA will also comply with the *Purcell* court's order to reassess the REMS, *Purcell v. Kennedy*, 2025 WL 3101785, at *28 (D. Haw. Oct. 30, 2025), and address numerous pending citizen petitions.

2. On the day the Secretary and Commissioner issued their letter, plaintiffs here sought to intervene in *Missouri v. FDA*, No. 22-cv-223 (N.D. Tex.), after the Supreme Court had held that the original plaintiffs in that case (then styled *Alliance for Hippocratic Medicine v. FDA*) lacked standing. The district court denied plaintiffs' motion to intervene and transferred that case to Missouri. *Missouri v. FDA*, 2025 WL 2825980, at *13 (N.D. Tex. Sept. 30, 2025).

A week later, plaintiffs brought this challenge to the 2023 REMS modification. They then moved for a stay of the REMS modification under 5 U.S.C. § 705, or a preliminary injunction, nearly three years after the REMS modification had been approved. Two mifepristone manufacturers intervened and moved to dismiss. The government moved to stay the case pending FDA's review of the mifepristone REMS.

3. The district court granted the government's motion 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.

The court determined that Louisiana has standing on the theory that the 2023 REMS modification has the "predictable" effect of leading third parties to "expand access to mifepristone in ways designed to reach into jurisdictions like Louisiana," causing "sovereign harm[]" to Louisiana's interest in enforcing its laws and "pocketbook injury" to its Medicaid program. ROA.9104; ROA.9106-9107. The court also concluded that Louisiana is likely to prevail in its challenge to the REMS modification, ROA.9109-9111, and that the "same facts" that establish its standing also "establish irreparable harm," ROA.9111.

But the court exercised its case-management discretion to stay the litigation, rather than granting immediate relief, for three reasons. ROA.9111-9118. *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." ROA.9112-9113. 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. ROA.9117.

Second, the court noted that the requested relief "would, as a practical matter, have a nationwide effect," ROA.9115, 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." ROA.9114; ROA.9117.

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." ROA.9113.

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." ROA.9118. The court stated that its

analysis would "change" if FDA did not "complete its review and make any necessary revisions to the REMS within a reasonable timeframe." ROA.9119. The court therefore denied plaintiffs' motion "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." ROA.9119. It ordered a status report in six months. ROA.9119.

4. Plaintiffs appealed, and a motions panel of this Court entered a § 705 stay of the challenged REMS modification pending appeal. *Louisiana ex rel. Murrill v. FDA*, 175 F.4th 310 (5th Cir. 2026). The panel concluded that Louisiana had established standing on the basis of sovereign harm because the REMS modification "opened the door for mifepristone to be remotely prescribed to Louisiana women," "facilitat[ing] nearly 1,000 illegal abortions in Louisiana per month," and on the basis of "financial injury" because women who use mifepristone in Louisiana may require emergency care covered by Louisiana's Medicaid program. *Id.* at 318-320. The panel further concluded that Louisiana was likely to succeed on the merits, *id.* at 320-321, and that the equitable factors for relief under § 705 weighed in its favor, *id.* at 321-323.

The Supreme Court, however, stayed the § 705 stay—in other words, provided that the challenged REMS modification would remain in effect—on applications by the manufacturer intervenors. *Danco Labs., LLC v. Louisiana*, 146 S. Ct. 1192, 1192 (2026). The Supreme Court's stay operates through the disposition of this appeal and any subsequent Supreme Court review. *Id.* Two Justices dissented. *Id.* at 1193 (Thomas, J., dissenting); *id.* at 1193-1196 (Alito, J., dissenting).

SUMMARY OF ARGUMENT

The district court acted well within its discretion in entering a time-limited stay of the litigation rather than granting the immediate equitable relief that plaintiffs sought. The court reasonably determined that, given the significance of this litigation, a stay would benefit the public—by giving precedence to FDA's orderly review process, while avoiding the potential for dueling injunctions to create nationwide chaos—much more than it would harm plaintiffs. Louisiana is free to make pro-life laws under *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), and free to enforce those laws against abortions conducted using mifepristone just as it enforces them against abortions by other means. The district court's stay was not unlike the practice of remand without vacatur, or with a time-

limited stay of vacatur, which courts can employ when the inadequacy of an agency's consideration of a decision could be rectified on remand.

Plaintiffs do not even try to show that the district court abused its discretion in staying the litigation. They instead try to persuade this Court to grant a § 705 stay in the first instance. But this Court has already done that—and the Supreme Court intervened to stay the relief this Court entered. Plaintiffs are asking the Court to defy the Supreme Court by granting, once again, the same relief the Supreme Court has already rejected.

Even if plaintiffs could show that the district court abused its discretion in staying the litigation, or if the Supreme Court's ruling did not foreclose a new § 705 stay, plaintiffs still cannot prevail because they lack standing. Plaintiffs make no effort to show that Ms. Markezich has standing. They assert that Louisiana has standing based on economic and sovereign harms from the challenged REMS modification. But Louisiana's asserted economic harms (even if concrete and certain) are too far removed from the REMS modification to establish standing, and its theories of sovereign injury are not legally cognizable.

STANDARD OF REVIEW

Decisions to stay a case are reviewed for abuse of discretion. *Kelly Inv., Inc. v. Continental Common Corp.*, 315 F.3d 494, 497 (5th Cir. 2002); *see In re Beebe*, 1995 WL 337666, at *2 (5th Cir. May 15, 1995) (per curiam) (unpublished). "'The decision to grant or deny a preliminary injunction'" likewise "'may be reversed on appeal only by a showing of abuse of discretion.'" *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 642 (5th Cir. 2025) (per curiam). "'A district court abuses its discretion'" only "'if it bases its decision on an erroneous view of the law or on a clearly erroneous assessment of the evidence.'" *Langiano v. City of Fort Worth*, 131 F.4th 285, 290 (5th Cir. 2025).

ARGUMENT

I. The District Court's Decision To Stay This Litigation Was Well Within Its Discretion

The question properly presented by this appeal is not, as plaintiffs suggest, whether this Court should grant a § 705 stay of the 2023 REMS modification. That question has already been decided—first by this Court, *Louisiana ex rel. Murrill v. FDA*, 175 F.4th 310 (5th Cir. 2026), and then the opposite way by the Supreme Court, *Danco Labs., LLC v. Louisiana*, 146 S. Ct. 1192 (2026). The question now is whether this Court should affirm or reverse the

district court's decision to stay this litigation rather than granting a preliminary injunction or § 705 stay. And there is plainly no abuse of discretion that would warrant reversal. Plaintiffs do not even try to argue otherwise.

1. A district court's discretion "to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. North American Co.*, 299 U.S. 248, 254 (1936). In *Landis*, the canonical case, the Supreme Court described the broad and flexible nature of that discretion in evaluating a district court's decision to stay one case pending the resolution of another. The Court explained that a district court's "exercise of judgment" as to a stay "must weigh competing interests and maintain an even balance." *Id.* at 254-255. The power to stay proceedings is not unlimited: A stay movant "must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to some one else." *Id.* at 255. But "[e]specially in cases of extraordinary public moment," the Court recognized, a plaintiff who would prefer immediate adjudication of a particular proceeding "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." *Id.* at 256; *see Clinton v. Jones*, 520 U.S. 681, 707 (1997) (same).

The district court's action here fits precisely within those parameters. This is certainly a "case[] of extraordinary public moment," *Landis*, 299 U.S. at 256. And the district court reasonably exercised its discretion by imposing a stay "not immoderate in extent and not oppressive in its consequences," on the view that "the public welfare or convenience [would] thereby be promoted," *id.* Consider each of those requirements in turn.

First, the stay is "not immoderate in extent," *Landis*, 299 U.S. at 256, because it is "time-limited" and subject to reconsideration if FDA does not "complete its review and make any necessary revisions to the REMS within a reasonable timeframe," ROA.9118-9119. The district court ordered FDA to file a status report in six months, ROA.9119, making clear that it intends to monitor FDA's progress to ensure that the stay remains in effect only as long as necessary to allow FDA to finish its review in an efficient manner.

Second, the stay is "not oppressive in its consequences," *Landis*, 299 U.S. at 256. The district court determined—erroneously, for the reasons discussed later in this brief—that the challenged REMS modification is causing financial and sovereign harms to Louisiana. But the court concluded that

even the requested relief would not eliminate those harms, because "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." ROA.9113. Those are classically the sorts of fact-intensive, case-specific determinations that fall within the discretion of district courts. They are certainly not "'clearly erroneous,'" as would be necessary for a decision based on them to constitute an abuse of discretion, *Langiano v. City of Fort Worth*, 131 F.4th 285, 290 (5th Cir. 2025). Indeed, their reasonableness is underscored by the fact that, as noted above, plaintiffs waited nearly three years after the 2023 REMS modification to bring this challenge to the modification—conduct that suggests a modest additional delay would not be "oppressive," *Landis*, 299 U.S. at 256.

Finally, the district court determined that a stay would "promote[]" "the public welfare or convenience," *Landis*, 299 U.S. at 256, in multiple ways. It would serve the "substantial" "public interest in the proper function of FDA and its scientifically grounded, congressionally authorized protocol," by allowing FDA to make the sorts of "public health judgments" in which it holds expertise. ROA.9112-9113; ROA.9117. And it would avoid

creating a "substantial risk of inconsistent judicial outcomes," threatening nationwide chaos, given the "multiple parallel lawsuits across the country addressing the same regulatory issues surrounding access to mifepristone." ROA.9114; ROA.9117-9118. Again, these sorts of determinations are well within the district court's discretion, and there is no basis for this Court to disturb them under an abuse-of-discretion standard.

2. The propriety of the district court's action is underscored by its close resemblance to remedies that are routinely recognized in administrative law: remand without vacatur or with a time-limited stay of vacatur.

The practice of remand without vacatur—that is, allowing an agency action to remain in place, notwithstanding the deficiencies of the agency's consideration of the action, while the agency reconsiders it—reflects the potential for vacatur during remand to have "'disruptive consequences.'" *Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 150-151 (D.C. Cir. 1993). To be sure, "remand without vacatur is available only rarely," when vacatur would in fact have such "'disruptive consequences'" and "there is 'at least a serious possibility' that the deficiency" identified by the court "can be corrected on remand." *Texas Med. Ass'n v. HHS*, 110 F.4th 762, 779 (5th Cir. 2024). But the Court has repeatedly found it appropriate. *See Texas Ass'n*

of Mfrs. v. CPSC, 989 F.3d 368, 389 (5th Cir. 2021) (declining to vacate consumer-product safety rule during agency's reconsideration of it); *Central & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (same, as to environmental rule).

What the district court did here is functionally equivalent to remand without vacatur in the sense that it leaves an agency action in effect pending the agency's reconsideration of that action. But it is more modest than remand without vacatur in two respects. First, the litigation had only reached the preliminary-injunction stage; the district court had not reached a final conclusion, at summary judgment, that the agency acted arbitrarily in approving the challenged REMS modification. And second, the stay the district court granted was not indefinite.

In its limited duration, the district court's action closely resembles the Eleventh Circuit's recent decision to stay its decision to vacate an amendment to a Securities and Exchange Commission (SEC) rule while the SEC reconsidered the rule on remand. *American Sec. Ass'n v. SEC*, 147 F.4th 1264, 1278-1280 (11th Cir. 2025). The Eleventh Circuit decided in that case that vacatur (rather than remand without vacatur) was warranted, including because the court did not believe that vacatur was likely to "trigger serious

'disruptive consequences.'" *Id.* at 1279. But the court nonetheless stayed the vacatur for a finite period of time to avoid "uncertainty in the short term" and "afford the Commission an opportunity to conduct the appropriate economic analysis that was lacking in the" challenged rule amendment. *Id.* at 1279-1280. Citing *Landis*'s "extraordinary public moment" language, the court explained that a stay of this nature "is 'typically afforded' where the 'public interest is served by providing an opportunity' for the government to address the 'appropriate remedy in the first instance.'" *Id.* at 1280. As discussed above, that was exactly the district court's rationale for a stay here.

This Court has likewise recognized that a stay of vacatur can be appropriate even when remand without vacatur is not. In *Texas v. United States*, 50 F.4th 498 (5th Cir. 2022), the Court affirmed the vacatur of President Obama's Deferred Action for Childhood Arrivals (DACA) memorandum, but it favorably described the district court's temporary and partial stay of the vacatur, "pending the outcome of a rulemaking proceeding," as "exhibit[ing] restraint." *Id.* at 530.

Presumably for these reasons, plaintiffs' brief never tries to persuade the Court that the district court abused its discretion by staying the litigation.

II. This Court Lacks Authority To Grant A New § 705 Stay

Plaintiffs instead urge this Court to grant a § 705 stay in the first instance, bypassing the question whether the district court erred in staying the litigation rather than granting a § 705 stay or a preliminary injunction. *See* 5 U.S.C. § 705 (stay of agency action may be granted by a "reviewing court, including the court to which a case may be taken on appeal"). Plaintiffs presumably take this approach because they know they cannot show that the district court abused its case-management discretion.

The problem for plaintiffs is that the Supreme Court has already ruled against them on exactly the question they now seek to raise: whether a § 705 stay is warranted. This Court's motions panel granted a § 705 stay. *Louisiana*, 175 F.4th 310. But the Supreme Court stayed it. *Danco*, 146 S. Ct. 1192.

There is simply no way to argue that this Court could grant the relief plaintiffs now seek in a manner consistent with the Supreme Court's ruling. Plaintiffs argue that they have standing, that they are likely to prevail on the merits of their challenge to the 2023 REMS modification, and that the equities and public interest favor a § 705 stay. But the Supreme Court necessarily reached the opposite conclusion, on at least one of those requirements for a § 705 stay, when it stayed this Court's action in *Danco*. *See Hollingsworth v.*

Perry, 558 U.S. 183, 190 (2010) (per curiam) (stay pending certiorari requires, among other things, "a fair prospect that a majority of the Court will vote to reverse the judgment below" and "a likelihood that irreparable harm will result from the denial of a stay"). This Court's consideration of a § 705 stay "is squarely controlled by" that decision of the Supreme Court. *Trump v. Boyle*, 145 S. Ct. 2653, 2654 (2025); *see also, e.g.*, *Gateway City Church v. Newsom,* 141 S. Ct. 1460 (2021) (failure to grant interlocutory relief pending appeal was "erroneous" where "outcome [was] clearly dictated" by earlier interim order); *Tandon v. Newsom*, 593 U.S. 61 (2021) (per curiam) (similar); *Garland v. Blackhawk Mfg. Grp., Inc.*, 144 S. Ct. 338 (2023) (vacating, without noted dissent, injunction entered after Supreme Court had previously stayed prior relief in same case); *NIH v. American Pub. Health Ass'n*, 145 S. Ct. 2658, 2664 (2025) (Gorsuch, J., concurring in part and dissenting in part) ("[E]ven probabilistic holdings … must 'inform how a [lower] court' proceeds 'in like cases[.]'").

The closest that plaintiffs come to acknowledging the dispositive effect of the Supreme Court's ruling is their statement that, "[i]n light of the Supreme Court's stay order, [they] understand that this Court's entry of a [§ 705] stay … would be stayed pending appeal to the Supreme Court." Br.

5. But that concession only underscores the futility of plaintiffs' argument. A new § 705 stay from this Court would not *automatically* be stayed by operation of the Supreme Court's prior stay order: That order solely stayed "[t]he May 1, 2026 order of" this Court. *Danco*, 146 S. Ct. at 1192. So what plaintiffs must mean is that this Court should grant a § 705 stay, then stay its own stay pending Supreme Court review. But there is no practical difference between that outcome and the denial of a stay in this Court, since either way, plaintiffs concede (as they must) that the 2023 REMS modification will remain in force until either the Supreme Court reviews it or FDA alters it. Given the practical futility of the relief they are seeking, this Court cannot award the relief plaintiffs seek in the face of the Supreme Court's prior rejection of the same relief.

III. Plaintiffs Lack Standing

Finally, even if plaintiffs could show that the district court abused its case-management discretion, or if the Supreme Court's ruling in this case did not definitively foreclose a new § 705 stay, plaintiffs cannot prevail because they lack standing.

"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." *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 380 (2024). "[T]he two key questions in most standing disputes are injury in fact and causation," because the "redressability" inquiry is generally the "'flip side[]'" of the "causation" inquiry: "If a defendant's action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury." *Id.* at 381. "Government regulations that require or forbid some action by the *plaintiff* almost invariably satisfy both the injury in fact and causation requirements." *Id.* at 382 (emphasis added). But "when (as here) a plaintiff challenges the government's 'unlawful regulation (or lack of regulation) of *someone else*,' 'standing'"—while "'not precluded'"—"'is ordinarily substantially more difficult to establish.'" *Id.*

Plaintiffs cannot surmount that "difficult" hurdle. They do not argue that Ms. Markezich has standing, and the district court made no such determination. The district court did conclude that Louisiana has standing, as did this Court in its stay opinion. But that was error: Neither of Louisiana's theories of standing can surmount the hurdles discussed above.

A. This Court's Stay Opinion Is Not Binding

As an initial matter, the stay panel's ruling that Louisiana had standing, 175 F.4th at 318-320, is not dispositive. A merits panel of this Court is "not bound by the ruling of [a] motions panel in the same case," *Voting for America, Inc. v. Steen*, 732 F.3d 382, 386 (5th Cir. 2013), and merits panels of this Court have disagreed with motions panels in multiple recent cases, even where (as here) the motions panels had issued precedential opinions. *Compare Airlines for Am. v. Department of Transp.*, 127 F.4th 563 (5th Cir.) (merits panel), *reh'g en banc granted, opinion vacated*, 154 F.4th 323 (5th Cir. 2025), *and on reh'g en banc*, 166 F.4th 487 (5th Cir. 2026), *with Airlines for Am. v. Department of Transp.*, 110 F.4th 672 (5th Cir. 2024) (motions panel); *compare Wages & White Lion Invs., LLC v. FDA*, 41 F.4th 427 (5th Cir. 2022) (merits panel), *reh'g en banc granted, opinion vacated*, 58 F.4th 233 (5th Cir. 2023), *and on reh'g en banc*, 90 F.4th 357 (5th Cir. 2024), *vacated and remanded*, 604 U.S. 542 (2025), *with Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130 (5th Cir. 2021) (motions panel).

This Court's merits panel therefore must independently analyze standing, rather than relying on the stay opinion, given its "'obligation to assess the basis for subject matter jurisdiction before wielding the judicial power of

the United States,'" *Gonzalez v. El Centro Del Barrio*, 167 F.4th 271, 276 (5th Cir. 2026). For the reasons discussed below, the Court should conclude that Louisiana failed to establish jurisdiction and should affirm the district court's denial of preliminary relief on that ground.

B. Louisiana's Asserted Economic Harms Do Not Establish Standing

Start with plaintiffs' lead argument: that the 2023 REMS modification "is causing Louisiana to suffer economic injuries," which "a favorable ruling would redress" (Br. 35). Plaintiffs cite two types of economic harms to Louisiana: Medicaid costs from "two hospitalizations caused by FDA-approved mifepristone unlawfully mailed into the State" (Br. 36) and the costs of "[i]nvestigations into … three instances of unlawfully mailed abortion drugs" (Br. 37). These sorts of harms satisfy the "injury" component of the Article III standard. But they fail the "causation" standard.

As the Supreme Court explained in *Alliance*, "unregulated parties" like Louisiana "often … have more difficulty establishing causation—that is, linking their asserted injuries to the government's regulation (or lack of regulation) of someone else." 602 U.S. at 382. That is because "[t]he causation requirement precludes" both "*speculative* links … , where it is not sufficiently

predictable how third parties would react to government action or cause downstream injury to plaintiffs," and "*attenuated* links … , where the government action is" too "far removed from its distant (even if predictable) ripple effects." *Id.* at 383 (emphases added).

Plaintiffs focus (Br. 38-40) on arguing that Louisiana's costs were "predictable" rather than "speculative" consequences of the challenged FDA action. That was likewise the thrust of the single paragraph that this Court devoted to the causation requirement in its stay opinion. 175 F.4th at 319 (explaining that the expanded use of mifepristone in Louisiana was an "'entirely predictable'" consequence of the 2023 REMS modification). But the causation requirement precludes reliance not just on "speculative links" but also on "attenuated" ones, *Alliance*, 602 U.S. at 383, and the problem here is not speculativeness; it is attenuation. Even assuming Louisiana's costs were completely predictable, these sorts of "ripple effects" of government action are simply too "far removed" from the action to establish standing to challenge it, *id.*

That is clear from the Supreme Court's decision in *United States v. Texas*, 599 U.S. 670 (2023). There, Texas challenged federal immigration-enforcement guidelines, asserting standing on multiple theories that closely

resemble Louisiana's here. The district court determined, for example, that the guidelines "shifted the cost of incarcerating or paroling certain criminal aliens from [the federal government] to Texas"; that Texas "incur[red] substantial costs associated with criminal recidivism" within "the criminal alien population"; and that it had "absorbed, or at least [would] imminently absorb, the costs of providing public education and state-sponsored healthcare to aliens who would otherwise have been removed pursuant to federal statutory law." *Texas v. United States*, 40 F.4th 205, 216-217 (5th Cir. 2022) (per curiam) (describing the district court's ruling in denying a stay). But the Supreme Court found those costs, however concrete and certain, insufficient for standing. 599 U.S. at 675-686. In doing so, the Court described as "attenuated" theories of state standing resting on claims that a federal policy "has produced only" "indirect effects on state revenues or state spending." *Id.* at 680 n.3. Such "attenuated links" cannot establish causation. *Alliance*, 602 U.S. at 383.

Applying *Alliance* and *United States v. Texas*, the Ninth Circuit held that other States lacked standing to raise exactly the same sort of challenge to the 2023 REMS modification that Louisiana now asserts. *Washington v. FDA*, 108 F.4th 1163 (9th Cir. 2024). The would-be-plaintiff States in *Washington*

argued, just as Louisiana does, that the "elimination of the in-person dispensing requirement" would cause them "economic injury in the form of increased costs to [their] Medicaid system[s]," *id.* at 1174, as well as costs associated with "making illegal mifepristone use harder to detect," *id.* at 1176. But the Ninth Circuit rejected both theories.

First, the Ninth Circuit explained that "an alleged uptick in Medicaid costs" from the elimination of the in-person dispensing requirement, leading to greater mifepristone use within a State's borders, "is exactly the kind of 'indirect effect[] on … state spending'" that the Supreme Court has made clear is insufficient for standing. *Washington*, 108 F.4th at 1176. And the court noted that accepting the theory would have radical consequences. "[V]irtually all drugs come with complications, risks, and side effects," the court explained, and "[a]pproval of a new drug may therefore yield more visits to doctors"—some of which will be reimbursable by Medicaid—"to treat complications or side effects." *Alliance*, 602 U.S. at 392. So if downstream Medicaid costs could establish standing, then States—and even private entities "that provide[] health insurance or subsidized medical care"—could "'challenge any FDA decision approving a new drug'" or loosening restrictions on one. *Washington*, 108 F.4th at 1176.

And not just FDA actions, either: All sorts of other federal actions—"roll[ing] back emissions standards for power plants," "increas[ing] a speed limit from 65 to 80 miles per hour," or rescinding "certain restrictions on guns," *Alliance*, 602 U.S. at 391—could likewise be challenged by a State, or a private healthcare payor, on the theory that they would increase the need for reimbursable medical care. The Fourth and Sixth Circuits have recognized that this sort of "boundless theory of standing," "in which all peripheral costs imposed on States" by federal actions can allow the States to challenge the actions in federal court, "'would make a mockery … of the constitutional requirement of case or controversy.'" *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022); *see Maryland v. U.S. Dep't of Agric.*, 151 F.4th 197, 210 (4th Cir. 2025) (similar).

The Ninth Circuit likewise concluded that "a logistical burden on law enforcement" could not establish standing, even if the elimination of the in-person dispensing requirement "make[s] mifepristone more difficult to police." *Washington*, 108 F.4th at 1177. Otherwise, the court explained, States would have "standing to 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.* That sort of "attenuated link[]" cannot establish the requisite nexus between a challenged action and a harm allegedly flowing from it. *Alliance*, 602 U.S. at 383.

The district court here relied on *Texas v. United States*, 126 F.4th 392, 411 n.22 (5th Cir. 2025), for the proposition that a State can establish standing based on "increased Medicaid costs due to a federal agency action." ROA.9106-9107. But that case sheds little light on the causation issue here. The question there was whether the plaintiff States had standing to challenge the DACA program, which led directly to the continued presence of noncitizens for whom the States bore monetary support obligations. The Court had previously held that those costs allowed States to challenge DACA, *see Texas v. United States*, 50 F.4th at 517-520, so the relevant question was whether the Supreme Court's intervening decision in the immigration-priorities case (*United States v. Texas*) had abrogated that decision with the clarity required to overcome the "rule of orderliness," *Texas v. United States*, 126 F.4th at 409. The Court's determination that the immigration-priorities decision did not abrogate its prior DACA holding, *id.* at 409-411, has little bearing here given the far more attenuated connection between the challenged federal action and the costs that Louisiana asserts.

Plaintiffs' brief offers no more compelling argument that Louisiana satisfies the causation requirement. Plaintiffs cite *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), for the proposition that "[f]inancial costs borne by an unregulated party as a downstream consequence of an unlawful agency action have long been recognized as sufficient for standing" (Br. 37). But *State Farm* says not a word about standing. Nor does Justice Kavanaugh's discussion of *State Farm* in his concurring opinion in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, 603 U.S. 799 (2024). What Justice Kavanaugh said was "obvious to all involved" in *State Farm* was not, as plaintiffs suggest (Br. 38), that the insurer plaintiffs had standing; it was that vacatur of the challenged agency action was available as a remedy. *Corner Post*, 603 U.S. at 834-835 (Kavanaugh, J., concurring). It is well established that the Supreme Court's resolution of a case in which no jurisdictional question was raised does not establish that jurisdiction was proper. *See, e.g.*, *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 91 (1998); *FEC v. NRA Pol. Victory Fund*, 513 U.S. 88, 97 (1994). In any event, the action challenged in *State Farm*—the revocation of an auto safety requirement—had a far more direct (*i.e.*, less attenuated) effect

on the insurer plaintiffs in that case than the action challenged here does on Louisiana.

Plaintiffs also cite *Department of Commerce v. New York*, 588 U.S. 752 (2019), where the Supreme Court held that States had standing to challenge the addition of a citizenship question to the Census. But the opinion in *Department of Commerce* described the contested standing issue as whether the States' theory of harm rested on "mere speculation." *Id.* at 768. Here, as discussed above, the problem with Louisiana's theories of injury is not speculativeness but attenuation. The analysis in *Department of Commerce* is therefore inapposite. And in any event, the downstream economic injuries that Louisiana asserts here are far more "removed" from the challenged action, *Alliance*, 602 U.S. at 383, than was the injury to state revenue asserted in *Department of Commerce*. A Census undercount has a direct effect on State revenues—not an "indirect effect," *United States v. Texas*, 599 U.S. at 699 n.3, or a "distant … ripple effect[]," *Alliance*, 602 U.S. at 383—because federal funding of States is often population-based. *See Arizona*, 40 F.4th at 386 (distinguishing *Department of Commerce*). The asserted nexus between Louisiana's injuries and the action challenged here is much more like those that the

Supreme Court found insufficient, several Terms after *Department of Commerce*, in *United States v. Texas*.

That leaves *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025), which plaintiffs briefly cite (Br. 40) for the proposition that the government cannot "target a business or industry through stringent and allegedly unlawful regulation, and then evade the resulting lawsuits by claiming that the targets of its regulation should be locked out of court as unaffected bystanders," *Diamond*, 606 U.S. at 125. But the action challenged in *Diamond*—federal approval of state regulations requiring automakers to "manufacture more electric vehicles and fewer gasoline-powered vehicles," *id.* at 104,—"target[ed]" the fuel-producer plaintiffs, *id.* at 125, in a manner plainly absent here. The Supreme Court held that the plaintiffs had standing based on one of the established doctrines discussed in *Alliance*: the proposition that regulating one participant in an economic chain "'may cause downstream or upstream economic injuries to others in the chain.'" *Id.* at 116-117 (quoting *Alliance*, 602 U.S. at 384). Louisiana experiences no such direct consequence from the action challenged here.

In short, Louisiana offers no defense for the "boundless[ness]" of its "theory of standing," "in which all peripheral costs imposed on States" by

federal actions can allow the States to challenge the actions in federal court, *Arizona*, 40 F.4th at 386. It is not difficult to see how this sort of theory "would allow [States] to challenge a 'disagreeable war,'" among any number of other federal actions that might subject them to some cost. *Id.* "That is a bridge much too far." *Id.*

C. Louisiana's Asserted Sovereign Harms Do Not Establish Standing

Louisiana's other theory of harm—sovereign injury, arising from "violations of state law and the inability to enforce those laws" (Br. 42)—is no more persuasive.

1. Start with the theory that Louisiana has standing because the challenged REMS modification will lead to violations of its abortion laws.

Louisiana, like the federal government, certainly has standing to bring actions seeking enforcement of its laws. That is the point the Supreme Court made in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), when it stated that a False Claims Act complaint "asserts an injury to" the "sovereignty" of the United States "arising from violation of its laws"—the same sort of injury that "suffices to support a criminal lawsuit by the Government." *Id.* at 771.

But as this Court recognized in *Harrison v. Jefferson Parish School Board*, 78 F.4th 765 (5th Cir. 2023), the proposition that the sovereign is harmed when its laws are violated is not properly understood to allow the sovereign to challenge any action that might increase the number of violations. In that case, Louisiana intervened in a challenge brought by two families to disciplinary actions imposed by a school board, then tried to continue the action (after the board settled with the families) on the theory—essentially the same one it asserts here—that it was harmed by the illegality of the board's disciplinary policies. *See id.* at 767-768. This Court disagreed, explaining that "what has traditionally counted as an injury to a sovereign interest does not include every act of disobedience to a state's edicts." *Id.* at 770. Rather, the Court held, "a sovereign interest" cannot "serve as a cognizable injury for federal standing" unless the challenged actions have "'result[ed] in some tangible interference with [a State's] authority to regulate or to enforce its laws.'" *Id.* Because no one doubted that Louisiana could "use its full arsenal of enforcement mechanisms to force [the school board] to comply with state law," the Court concluded that the board's "alleged failure to follow" state law did not "injur[e] Louisiana's sovereign interest." *Id.* at 770, 772. A violation of Louisiana's laws would "become an injury" to its sovereignty, the

Court explained, only if "Louisiana br[ought] an enforcement action" to bring the violator "into compliance with the law," and the violator "or another entity hinder[ed] the state from doing so." *Id.* at 771.

Plaintiffs fail even to cite *Harrison*, despite our discussion of it in opposing a stay. But *Harrison* is fatal to their theory that Louisiana can challenge the 2023 REMS modification because it will lead to violations of Louisiana's laws. Here, as in *Harrison*, there is no doubt that Louisiana has the power to "regulate abortion for legitimate reasons," including "respect for and preservation of prenatal life at all stages of development." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 300-301 (2022); *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"). Nor is there any doubt that Louisiana has the power to enforce its abortion laws against conduct that violates those laws. And as *Harrison* explains, a violation of Louisiana's abortion laws—through the use of mifepristone or otherwise—would "become an injury" to its sovereignty only if "Louisiana br[ought] an enforcement action" to bring the violator "into compliance with the law," and the violator "or another entity hinder[ed] the state from doing so." 78 F.4th at 771.

Plaintiffs identify no contrary authority. They cite *Stevens* (Br. 42), but as the *Harrison* panel explained in distinguishing it, *Stevens* is inapposite because it was an "enforcement action[]," 78 F.4th at 771 & n.27.[3] *Harrison*'s distinction of *Stevens* is binding here. And the Sixth Circuit has likewise explained, consistently with *Harrison*, that a "violat[ion]" of law "does not by itself injure the government in an Article III way"; "[o]nly 'actual or threatened interference with [its] authority' does." *Saginaw County v. STAT Emergency Med. Servs., Inc.*, 946 F.3d 951, 956 (6th Cir. 2020) (quoting *United States v. West Virginia*, 295 U.S. 463, 473 (1935)).

Moreover, even if *Stevens* stood for the proposition that any violation of Louisiana's laws constitutes an injury-in-fact for Article III purposes, *Harrison*'s holding can also be understood as an application of the broader principle that Article III authorizes federal courts to hear only those types of disputes that they have "traditionally entertained," *United States v. Texas*, 599 U.S. at 678; *see id.* at 676-677. In *United States v. Texas*, among the other

[3] Justice Thomas's concurring opinion in *Ellingburg v. United States*, 607 U.S. 163 (2026), which plaintiffs cite (Br. 42-43) alongside *Stevens*, is similarly inapposite. The question Justice Thomas addressed there was which types of enforcement actions (civil or only criminal) are subject to the Ex Post Facto Clauses, *see* 607 U.S. at 178-179 (Thomas, J., concurring).

theories of standing that the Supreme Court rejected (as discussed above) was the theory that Texas could challenge the immigration-enforcement guidelines because they led to the "commi[ssion]" of "more crimes" within the State, *Texas v. United States*, 606 F. Supp. 3d 437, 467 (S.D. Tex. 2022). *See* 599 U.S. at 680 n.3 (concluding that "none of the" plaintiffs' "various theories of standing" could establish an Article III controversy). That ruling makes clear that suits of this sort, where a State challenges a federal action on the theory that it causes violations of state law, fall outside the jurisdiction of the federal courts.

Neither this Court's stay opinion nor the district court's opinion cited *Harrison*, and neither opinion provides meaningful support for Louisiana's position. Both opinions rest their analysis on the proposition that "Louisiana has a 'sovereign interest in the power to create and enforce a legal code.'" 175 F.4th at 318 (quoting *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015)); *see* ROA.9105 (citing the same language). But the challenged REMS modification does not affect Louisiana's power to "create" laws against abortion, including medical abortion using mifepristone. And as discussed above, *Harrison* explains what type of threat to a State's ability to "enforce" its laws can confer standing—namely, one that "hinders" the State's pursuit

of "an enforcement action" it has brought, *Harrison*, 78 F.4th at 771—and nothing like that has occurred here. Nor does Louisiana's argument find any support in the actual holding of the decision on which this Court and the district court relied. The cited holding there was that States had standing to challenge the Deferred Action for Parents of Americans and Lawful Permanent Residents program because it "impos[ed] substantial pressure on them to change their laws." *Texas v. United States*, 809 F.3d at 153. But the action challenged here has no such effect.

2. Louisiana's assertion that it suffers sovereign injury by virtue of its "inability to enforce [its] pro-life laws" (Br. 47) is no more persuasive. States, like the federal government, obviously have interest in "the *enforceability* of [their] laws." *Harrison*, 78 F.4th at 772. That is the principle undergirding the cases Louisiana cites—cases about a State's "opportunity to defend its laws in federal court," *Cameron v. EMW Women's Surgical Ctr., P.S.C.*, 595 U.S. 267, 277 (2022), including against federal interference, *see, e.g.*, *Bowen v. Public Agencies Opposed to Soc. Sec. Entrapment*, 477 U.S. 41, 50 n.17 (1986); about the federal government's authority to challenge state and local interference with federal law, *see, e.g.*, *Arizona v. United States*, 567 U.S. 387 (2012);

and about the irreparable injuries that occur when the enforcement of laws is enjoined, *see, e.g.*, *Trump v. CASA, Inc.*, 606 U.S. 831, 861 (2025).

But there is no issue of enforceability here. Louisiana's argument (Br. 50) is that the challenged REMS modification renders its abortion laws unenforceable because it "permits out-of-state prescribers to mail mifepristone into Louisiana with impunity." But conduct by out-of-state prescribers is not an unpunishable violation of Louisiana's laws; rather, it is not a violation of Louisiana's laws at all. That is because "[a] State cannot punish a defendant for conduct that may have been lawful where it occurred." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 421 (2003) (collecting cases); *see also, e.g.*, *Huntington v. Attrill*, 146 U.S. 657, 669 (1892) ("Laws have no force of themselves beyond the jurisdiction of the State which enacts them, and can have extra-territorial effect only by the comity of other States."). Indeed, the 21 States that filed an amicus brief on Louisiana's behalf make exactly this point: "In our constitutional system, no State can 'have any right beyond its territorial boundary.'" State Amicus Br. 11 (quoting *Rhode Island v. Massachusetts*, 37 U.S. (12 Pet.) 657, 733 (1838)). For the same reason that California cannot punish a Louisiana firearms dealer for selling a California resident a type of firearm that is allowed in Louisiana but prohibited by

California law, Louisiana lacks the power to punish out-of-state conduct here. That limitation, which flows from "horizontal federalism" (*id.* at 9), has nothing to do with the challenged REMS modification.

As to in-state conduct—the only conduct on which they can operate—Louisiana's abortion laws have full force. They forbid the in-state distribution of mifepristone for use in abortions, regardless of whether the mifepristone is dispensed in-person. La. Stat. Ann. § 40:1061(C); *id.* § 14:87.9(A). Louisiana therefore cannot establish standing on the theory that the challenged REMS modification inhibits the enforceability of its laws.

CONCLUSION

The district court's ruling should be affirmed, and this Court should not issue a § 705 stay.

Respectfully submitted,

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This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 8,925 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in 14-point Book Antiqua, a proportionally spaced typeface.

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No. 26-30203 State of Louisiana v. FDA
USDC No. 6:25-CV-1491

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