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; MARTY MAKARY, COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION; TRACY BETH HØEG, in her 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.

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

RESPONSE TO PLAINTIFFS' MOTION FOR § 705 STAY OR INJUNCTION PENDING APPEAL

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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
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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. 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, 249-251 (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).[1] FDA is actively "work[ing] on the collection of the robust and timely data that is necessary for a well-controlled study with adequate statistical power." *Id.* Although such studies "often take approximately a year or more to conduct," FDA's "current … plan" is to complete the study "sooner." *Id.* And once FDA has analyzed the data from that study (as well as all other

[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 Apr. 22, 2026).

evidence before it), it will decide whether "substantive changes to the REMS" are "warranted." *Id.*

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" stay of the litigation to allow FDA "to complete its review and carry out the responsibilities assigned to it by Congress," Op. 35. The district court's ruling is reviewable only for abuse of discretion. Indeed, it would not have been reviewable, except by mandamus, had the district court simply held plaintiffs' motion in abeyance during the stay. That would have been functionally equivalent to the court's actual ruling, which denied plaintiffs' motion without prejudice to its renewal upon the lifting of the stay.

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 Org.*, 597 U.S. 215 (2022).

Having failed to persuade the district court, plaintiffs now ask this Court to grant immediate injunctive relief, or an equivalent stay of the 2023 REMS modification under 5 U.S.C. § 705, while they appeal. But they cannot satisfy the demanding standard for that extraordinary relief. To start, plaintiffs failed to comply with Federal Rule of Appellate Procedure 8(a)(1)'s requirement that they "move first in the district court for" the relief. Plaintiffs also cannot show "'a strong likelihood of success on the merits,'" *Vapor Tech. Ass'n v. Graham*, 167 F.4th 302, 305 (5th Cir. 2026), because there is no basis to conclude that the district court abused its equitable discretion and because plaintiffs lack standing. Plaintiffs' lack of standing means they cannot

establish "'irreparable injury in the absence of an injunction,'" *id.* And for the same reasons it was appropriate for the district court to stay the litigation, plaintiffs cannot establish "'that the balance of hardships weighs in their favor'" or "'that the public interest favors'" the relief they seek, *id.* Plaintiffs' motion should be denied.

STATEMENT

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

[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 REMS. *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." Dkt. 20-16 (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* Dkt. 1-10 at 5, 6 n.10.

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 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." 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. On the day the Secretary and Commissioner issued their letter, plaintiffs here—Louisiana and Rosalie Markezich—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. 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 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. Op. 21, 23-24. The court also concluded that Louisiana is likely to prevail in its challenge to the REMS modification, Op. 26-28, and that the "same facts" that establish its standing also "establish irreparable harm," Op. 28.

But the court determined that the balance-of-harms and public-interest factors weighed against preliminary relief. Op. 28-35. The court identified three factors bearing on its equitable discretion.

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." Op. 29-30. 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. Op. 34.

Second, the court noted that the requested relief "would, as a practical matter, have a nationwide effect," Op. 32, 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." Op. 31, 34.

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." Op. 30.

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." Op. 35. 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." Op. 36. 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." *Id.* It ordered a status report in six months. *Id.*

ARGUMENT

To obtain "an injunction pending appeal," "[t]he movant must show '(1) a strong likelihood of success on the merits; (2) irreparable injury in the absence of an injunction; (3) that the balance of hardships weighs in their favor if injunctive relief is granted; and (4) that the public interest favors such relief.'" *Vapor Tech. Ass'n v. Graham*, 167 F.4th 302, 305 (5th Cir. 2026). The same factors apply to § 705 stays pending review. *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1135 (5th Cir. 2021).

Plaintiffs invoke the "'sliding-scale' approach" (Mot. 8), under which "'a showing of some likelihood of success on the merits'" may "'justify

temporary injunctive relief'" in the district court if the movant's showing on "'the other factors'" of the preliminary-injunction standard is "'strong,'" *TitleMax of Tex., Inc v. City of Dallas*, 142 F.4th 322, 328 (5th Cir. 2025). But this Court has rejected the proposition that something less than a likelihood of success can justify an injunction pending appeal if "'the balance of equities weighs heavily in favor of'" the movant. *Vapor Tech.*, 167 F.4th at 305 n.10.

Plaintiffs therefore must satisfy all four elements of the standard, and they have not come close. Nor did they comply with the requirement to "move first in the district court," Fed. R. App. P. 8(a)(1).

I. Plaintiffs Failed To Comply With Rule 8

At the threshold, this Court can and should deny plaintiffs' motion because plaintiffs failed to "move first in the district court" for the relief they seek, as Federal Rule of Appellate Procedure 8(a)(1)(C) requires. That requirement does not apply when "moving first in the district court would be impracticable," Fed. R. App. P. 8(a)(2)(A)(i), but there is no basis for any assertion of impracticability here. Plaintiffs waited ten days to file their motion in this Court (on April 17) after the district court ruled (on April 7), and they rightly did not characterize their motion here as an emergency; they sought relief only by May 11. They could easily have used some of the time between

the district court's ruling and their filing of this motion to file a similar motion in the district court and allow that court to rule.

Plaintiffs make no effort to argue that "moving first in the district court would [have been] impracticable," Fed. R. App. P. 8(a)(2)(A)(i). They argue, citing out-of-Circuit cases, that it would have been "futile." Mot. 1. But the rule sets impracticability, not futility, as the standard, and in any event, *this* Court has explained that "[i]t does not follow from" a district court's "refusal to grant a preliminary injunction … that the district court would refuse injunctive relief pending an appeal." *Bayless v. Martine*, 430 F.2d 873, 879 n.4 (5th Cir. 1970); *see Whole Woman's Health v. Paxton*, 972 F.3d 649, 654 (5th Cir. 2020) (citing *Bayless* for the proposition that "it would not be" "'pointless' to move first" for a stay in a district court that previously rejected the movant's argument). If a movant's prediction that the district court would deny the motion required by Rule 8(a)(1)(C) were an excuse for bypassing that requirement, the rule would be a nullity.

A movant's "failure to show the impracticability of moving first in the district court is sufficient grounds to deny its motion" for a stay or injunction pending appeal in this Court. *Whole Woman's Health*, 972 F.3d at 654 (stay); *see Brantley v. University of Tex. at Austin*, 2026 U.S. App. LEXIS 2874 (5th Cir.

Jan. 30, 2026) (per curiam) (unpublished) (injunction); *Brown v. Cain*, 546 F. App'x 471, 477 (5th Cir. 2013) (per curiam) (unpublished) (injunction); *Jenoriki v. U.S. Postal Inspection Serv.*, 24 F.3d 240 (5th Cir. 1994) (per curiam) (unpublished) (injunction); *Cullum v. Attorney Gen.*, 5 F.3d 1495 (5th Cir. 1993) (unpublished) (injunction).

II. Plaintiffs' Appeal Is Likely To Fail

Plaintiffs' motion also fails because plaintiffs are unlikely to prevail in this appeal. They cannot show that the district court's assessment of the equities was an abuse of its discretion, and they lack standing.

A. The District Court's Assessment Of The Equities Was Well Within Its Discretion

"'The decision to grant or deny a preliminary injunction … 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). The same is true of a district court's exercise of its equitable power to stay proceedings. *See GATX Aircraft Corp. v. M/V Courtney Leigh*, 768 F.2d 711, 716 (5th Cir. 1985); *see also Landis*, 299 U.S. at 254 (discussing the power). And here, the district court acted well within its discretion by staying the litigation rather than granting plaintiffs' request for preliminary relief. As the district court explained,

there are at least three reasons the balance-of-equities and public-interest factors weighed in favor of that outcome.

First, 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. Op. 29, 34. 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 the district court reasonably determined that 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.

Second, the district court recognized that the requested relief—which "would, as a practical matter, have a nationwide effect," Op. 32—would create a "substantial risk of inconsistent judicial outcomes" given the "multiple parallel lawsuits across the country addressing the same regulatory issues surrounding access to mifepristone." Op. 31. As noted above, an injunction in plaintiffs' favor, from the district court or this Court, could well lead one of the courts presiding over related litigation to enter a dueling injunction forbidding any greater restrictions on mifepristone (or perhaps any REMS

restrictions at all). That is what happened immediately after the district court's § 705 stay in *Alliance*. *See supra* p. 4.

As plaintiffs note (Mot. 22), courts do entertain challenges to agency action where the requested relief would have nationwide implications, and there is sometimes no way to avoid the possibility of conflicting decisions that could occasion the need for Supreme Court review. But, like plaintiffs' point that courts must sometimes consider scientific issues in conducting APA review (Mot. 21), that is non-responsive to the district court's equitable reasoning. The court's point was not that it *could* not consider plaintiffs' request but that it *should* not do so precipitously, when allowing FDA's review to unfold could lead to a more orderly and efficient disposition.

Finally, the district court explained 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." Op. 30. That is consistent with plaintiffs' having waited three years after the 2023 REMS modification (and a year and a half after the Supreme Court's *Alliance* decision) to challenge the modification in this case—a delay that itself weighs against plaintiffs' request for interim relief, *see, e.g.*, *Benisek v. Lamone*, 585 U.S. 155, 159-160 (2018).

At bottom, plaintiffs' insistence that they are entitled to an injunction fails to acknowledge the "extraordinary" nature of interim equitable relief, *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). Such relief is "never awarded as of right," *id.*, even assuming the movant is likely to prevail on the merits. It requires courts to "'balance the competing claims of injury,'" to "'consider the effect on each party of the granting or withholding of the requested relief,'" and to "'pay particular regard for the public consequences in employing the extraordinary remedy.'" *Id.* In conducting that assessment, moreover, courts must consider that the purpose of preliminary relief is "to preserve" the parties' existing positions and thus "'prevent irreparable harm'" during the litigation, not to upend the status quo. *City of Dallas v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017).[3]

The district court was sensitive to plaintiffs' concerns. It emphasized the "time-limited" nature of the "deference" it was affording FDA and stated that its analysis would "change" if FDA does not "complete its review and

[3] Indeed, it is doubtful that § 705 *can* be employed to "postpone" the effective date of an agency action that has already taken effect. We raise this point only to preserve it, since the Court has employed § 705 in this fashion, *see Career Colleges & Schs. of Texas v. U.S. Dep't of Educ.*, 98 F.4th 220 (5th Cir. 2024), *cert. granted*, 145 S. Ct. 1039 (2025), *and dismissed*, 146 S. Ct. 59 (2025).

make any necessary revisions to the REMS within a reasonable timeframe." Op. 35-36. And it allowed plaintiffs to refile their motion, "as appropriate, following completion of FDA's review or upon a lifting of the stay upon a material change in circumstances." Op. 36. There is no basis to disturb its assessment of the equities.

B. Plaintiffs Lack Standing

Plaintiffs are also unlikely to succeed because they lack standing.

Standing "'is ordinarily substantially more difficult to establish'" where, as here, "a plaintiff challenges the government's 'unlawful regulation (or lack of regulation) of *someone else*'" than where the plaintiff is regulated. *Alliance*, 602 U.S. at 382. "That is often because unregulated parties may have more difficulty establishing causation—that is, linking their asserted injuries to the government's regulation (or lack of regulation) of someone else." *Id.* An unregulated party's showing of causation generally must rest on the proposition that "third parties" who are directly affected by the government's regulatory choices "will likely react in predictable ways that in turn will likely injure the plaintiffs." *Id.* at 383 (quotation marks omitted). But "[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.*

Plaintiffs' motion does not argue that Ms. Markezich has standing, and the district court made no such determination. The district court did conclude that Louisiana has standing. But that was error: Neither of Louisiana's two theories of standing can surmount the hurdles discussed above.

1. Start with Louisiana's assertion of harm to its "'sovereign interest in the power to create and enforce a legal code'" (Mot. 12).

Plaintiffs' motion does not suggest that the 2023 REMS modification affects Louisiana's power to "regulate abortion for legitimate reasons," including "respect for and preservation of prenatal life at all stages of development," *Dobbs*, 597 U.S. at 300-301. *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"). So there is no doubt that Louisiana can "'create'" (Mot. 12) a prohibition against abortion.

Louisiana argues (Mot. 12-13) that the removal of the in-person dispensing requirement undermines its ability to "'enforce'" that prohibition because it facilitates mailing mifepristone into the State. But Louisiana's

laws apply to abortions conducted using mifepristone delivered from out of state just as they do to abortions by other means. Louisiana appears to suggest (Mot. 13) that violations of its laws themselves constitute sovereign injuries. But this Court rejected Louisiana's assertion of that argument in another case, explaining that "[v]iolating the law is different from hindering its enforcement" and that, "when 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." *Harrison v. Jefferson Parish Sch. Bd.*, 78 F.4th 765, 772 (5th Cir. 2023).

Louisiana's argument must boil 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). But this sort of "logistical burden on law enforcement" cannot suffice to establish standing, or else 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.

Indeed, the Supreme Court rejected precisely such a theory of state standing in the Term before *Alliance*. In *United States v. Texas*, 599 U.S. 670 (2023), the district court had concluded that Texas established standing to challenge federal immigration-enforcement guidelines partly on the ground that 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). But the Supreme Court held that "none of the" plaintiffs' "various theories of standing" could establish an Article III controversy. 599 U.S. at 680 n.3.

2. Louisiana's remaining theory—that it suffers a "monetary injury" because some women who take mifepristone will require emergency care covered by its Medicaid program (Mot. 13-14)—is no more persuasive.

Again, that is clear from the Supreme Court's *Texas* decision. The state plaintiffs there asserted standing to challenge the guidelines on the theory that they "impose[d] costs on the States," such as by requiring them to "continue to incarcerate or supply social services … to noncitizens who should [have been] (but [were] not being) arrested by the Federal Government." 599 U.S. at 674. The district court accepted that theory, *id.* at 675, but the

Supreme Court reversed. In doing so, it 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. And "attenuated links" cannot establish the causation element of standing. *Alliance*, 602 U.S. at 383.

As the Ninth Circuit explained in applying these decisions to a claim like this, "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 accepting it would have radical consequences. "[V]irtually all drugs come with complications, risks, and side effects," 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. Allowing Louisiana to challenge the 2023 REMS modification based on downstream Medicaid costs would thus allow States—and even private entities "that provide[] health insurance or subsidized medical care"—"'to challenge any FDA decision approving a new drug'" or loosening restrictions on one. *Washington*, 108 F.4th

at 1176. And the theory would extend beyond FDA actions. 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. 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).

In accepting Louisiana's theory, the district court cited *Texas v. United States*, 126 F.4th 392, 411 n.22 (5th Cir. 2025), for the proposition that "[a] state's increased medical costs, such as increased Medicaid costs due to a federal agency action, can constitute a 'pocket-book injury' sufficient to satisfy the injury-in-fact requirement of standing." Op. 23-24. But no one disputes that Medicaid costs constitute an Article III injury. The relevant question is whether they are, with sufficient certainty and proximity, *caused* by the challenged federal action. And on that question, the *Texas* decision sheds little light. The question there was whether the plaintiff States had standing

to challenge the Deferred Action for Childhood Arrivals (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 498, 517-520 (5th Cir. 2022), 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," 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.

3. In defense of its standing theories, Louisiana invokes *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025), and *Bost v. Illinois State Board of Elections*, 146 S. Ct. 513 (2026), for the proposition that the government cannot "'target a [State] through stringent and allegedly unlawful regulation, and then evade the resulting lawsuit[] by claiming that the target[] of its regulation should be locked out of court as [an] unaffected bystander[].'" Mot. 15-16 (quoting *Diamond*, 606 U.S. at 125). But in both cases,

the challenged actions "'target[ed]'" the plaintiffs (*id.*) in a manner plainly absent here.

In *Diamond*, fuel producers challenged the federal approval of state regulations requiring automakers to "manufacture more electric vehicles and fewer gasoline-powered vehicles," and the Supreme Court held that they 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.'" *Diamond*, 606 U.S. at 116-117 (quoting *Alliance*, 602 U.S. at 384). Louisiana experiences no such "commonsense economic" consequence, *id.*, from the action challenged here.

Bost is just as far afield. It involved no claim of standing by an unregulated party. Rather, the Court held that a political candidate had standing to "challenge[] Illinois's procedure for counting mail-in ballots received after election day" because "an unlawful extension of vote counting deprives candidates of the opportunity to compete for election under the Constitution and laws of the United States." 146 S. Ct. at 518, 521. That is a direct harm, not a derivative one.

Finally, Louisiana argues (Mot. 16) that it "need not show that the 2023 REMS is *solely* responsible for [its] harms, or that vacating the REMS would *completely* eliminate [its] harms," to establish standing. We agree. But Louisiana must show, among other things, that the challenged action is *a* sufficiently non-speculative, non-attenuated cause of its harms. It has not.

III. The Equitable Factors Disfavor An Injunction Pending Appeal

Finally, for the same reasons plaintiffs are unlikely to prevail in this appeal, they cannot satisfy the equitable factors of the injunction-pending-appeal standard. They cannot show "'irreparable injury in the absence of an injunction,'" *Vapor Tech.*, 167 F.4th at 305, because they have not established any Article III injury bearing the requisite connection to the challenged action. And they cannot show "'that the balance of hardships weighs in their favor,'" or "'that the public interest favors'" relief, *id.*, for the same reasons they are unlikely to persuade this Court to disturb the district court's contrary assessment.

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 5,199 words, according to Microsoft Word.

/s/ Daniel Winik
Daniel Winik