No. 26-30203

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

THE STATE OF LOUISIANA, by and through its Attorney General LIZ MURRILL, and ROSALIE MARKEZICH,
Plaintiffs-Appellants,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants-Appellees,

and

GENBIOPRO, INC.; DANCO LABORATORIES, LLC,
Intervenor-Defendants-Appellees,

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

GENBIOPRO, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR STAY OR INJUNCTION PENDING APPEAL

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INTRODUCTION

Plaintiffs seek the drastic remedy of an injunction pending appeal upending an FDA framework that, for years, has governed how mifepristone may be dispensed nationwide. That request was extraordinary when Plaintiffs made it below. It is doubly so now that the district court has denied it. Asking this Court to superimpose equitable relief denied below "demands a significantly higher justification" than an ordinary stay request. *Respect Me. PAC v. McKee*, 562 U.S. 996, 996 (2010). Plaintiffs cannot meet that heavy burden for three reasons.

First, the court appropriately declined to disturb the years-long status quo while FDA completes a review of the mifepristone Risk Evaluation and Mitigation Strategy ("REMS"). The court recognized that this suit "implicate[s] scientific and medical judgments committed by Congress" to FDA, and that FDA should be permitted in the first instance to "evaluate scientific evidence and make public health judgments." Op.29, 34. The court stressed that sweeping relief would affect states "with differing abortion laws"—and that judicial intervention at this stage would risk a "patchwork" of conflicting remedies on a matter of nationwide importance. Op.34-36. That equitable judgment is reviewable only for abuse of discretion, and Plaintiffs provide no basis for upsetting it through the exceptional device of interim appellate relief.

Second, Plaintiffs are unlikely to succeed on the merits of their appeal for multiple reasons. Plaintiffs lack Article III standing, relying on attenuated theories of sovereign and indirect economic injury that are materially indistinguishable from those the Supreme Court already rejected—including in a precursor suit challenging "FDA's relaxed regulation of mifepristone." *FDA v. All. for Hippocratic Med.* ("*AHM*"), 602 U.S. 367, 390 (2024). If these interests sufficed, it would collapse Article III's limits and permit states to challenge virtually any federal action with indirect downstream effects on state policy or spending.

Plaintiffs' claims are also not exhausted, and FDA's ongoing review makes them unripe. Even if Plaintiffs could establish standing, exhaustion, and ripeness, they are unlikely to succeed in overturning FDA's expert scientific determination supported by its careful review of an extensive record—an administrative record that was not even before the district court and remains absent in this Court—demonstrating the safety of the current REMS. Plaintiffs cannot make the requisite strong showing on *any* of these necessary ingredients of their claim—let alone *all* of them.

Third, Plaintiffs cannot satisfy the remaining requirements for the extraordinary relief they seek. They waited years to sue and months more to seek an injunction, undermining any claim of urgency or irreparable harm that would unfold *during their appeal*—particularly given the availability of expedited briefing.

Granting Plaintiffs' requested order, meanwhile, would halt the nationwide distribution framework, inflict immediate and irreparable injury on GenBioPro, and impede access for patients everywhere—not just in Louisiana—to a medication FDA has long found safe and effective. Plaintiffs' request should be denied.

STATEMENT OF THE CASE

FDA's mifepristone REMS. The Food and Drug Administration Amendments Act (FDAAA) directs FDA to evaluate whether a REMS "is necessary to ensure that the benefits of [each new] drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). Each REMS must "assur[e] access and minimiz[e] burden" on "the health care delivery system," *id.* § 355-1(f)(2), (f)(2)(D). In 2008, FDA identified mifepristone, approved since 2000 as a safe and effective medication for terminating pregnancy, as subject to a REMS. 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008). At the time, the mifepristone REMS required the drug to be dispensed exclusively in a healthcare setting, such as a hospital or medical center. ECF 1-24 at 2-3.

In 2016, after reviewing over a decade of safety and efficacy data, peer-reviewed studies, and professional medical guidelines, FDA approved changes to the mifepristone REMS and label. The changes included rescinding an unusual condition requiring prescribers to report serious adverse events to mifepristone's manufacturer. ECF 1-11 at 26. Federal law already requires manufacturers to review

and report to FDA all adverse events received by prescribers and patients and in clinical investigations, studies, and scientific literature. 21 U.S.C. § 355(k)(1); 21 C.F.R. §§ 314.98, 314.80(b)-(c), 314.81. In 2019, FDA approved GenBioPro's application to market a generic version of mifepristone, subject to the existing REMS.

Rescission of the in-person dispensing requirement. In July 2020, during the COVID-19 pandemic, a district court enjoined mifepristone's in-person dispensing requirement. That injunction was in effect for six months, during which FDA observed no impact on patient safety. ECF 1-50 at 61-64. Based in part on data from that period, in April 2021, FDA suspended enforcement of the in-person dispensing requirement and began a full review of the mifepristone REMS. *Id.* at 46.

In December 2021, FDA announced that the in-person dispensing requirement was not necessary to assure mifepristone could be safely used. *Id.* at 45. The decision was based on "a thorough scientific review by [agency] experts," who evaluated data from FDA's periodic assessment reports for the mifepristone REMS, postmarketing safety information, and published studies evaluating different methods for dispensing mifepristone. ECF 1-10 at 5, 25-37.

In January 2023, FDA issued a new REMS formally removing the in-person dispensing requirement, which had not been enforced since April 2021. ECF 1-50 at 3, 8. The 2023 REMS added new requirements for prescribers, *id.*, and a pharmacy

certification requirement to "ensure[] that pharmacies are aware of and agree to follow applicable REMS requirements," *id.* at 15.

FDA's ongoing review. FDA regulations establish a process for any interested person to file a "citizen petition" requesting that FDA "take or refrain from taking any . . . form of administrative action," 21 C.F.R. § 10.25(a), including action related to a REMS. Eight mifepristone-related citizen petitions are currently pending before FDA, including one from GenBioPro compiling recent data reaffirming the drug's safety. ECF 54-7 at 13-14 n.50.

FDA is currently revisiting the mifepristone REMS that Plaintiffs challenge in this suit. In September 2025, facing pressure from abortion opponents, FDA announced it would conduct a study of the 2023 REMS "in order to determine whether modifications are necessary." ECF 1-110 at 2. FDA confirmed this review is ongoing. ECF 51 at 1-3; FDA, Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, https://tinyurl.com/38m6ea9f.

This litigation. Plaintiffs filed this action in October 2025, more than two years after the REMS was adopted, more than four years after FDA suspended enforcement of the in-person dispensing requirement, and a week after another district court denied Louisiana's "belated" request to intervene in the *AHM* litigation. *Missouri v. FDA*, 2025 WL 2825980, at *11-*12 (N.D. Tex. Sept. 30, 2025). Two

months after their initial filing, Plaintiffs moved to enjoin the 2023 REMS or "stay" its long-elapsed effective date under 5 U.S.C. § 705. ECF 20. GenBioPro, a manufacturer of generic mifepristone, intervened and opposed the motion on threshold and merits grounds, as did Danco Laboratories LLC. ECF 52, 54. FDA moved to stay the case while FDA reviews the REMS. ECF 51. The district court directed and received a supplemental brief from FDA confirming its authorities to take immediate action on mifepristone in the event of an exigent public health crisis. ECF 250.

On April 7, 2026, the court stayed the case during FDA's ongoing review and denied Plaintiffs' request for preliminary relief. ECF 258. The court declined to dismiss for lack of standing, concluding that Louisiana's allegations of sovereign and pocketbook injuries sufficed at this "earl[y] stage[ ]." Op.17-25. The court also concluded Plaintiffs were likely to succeed on the merits of their arbitrary-and-capricious claim and would suffer irreparable injury. Op.26-28.

But the court concluded that the balance of the equities and the public interest warranted denying relief—and, on the same grounds, that a stay of proceedings was appropriate. Op.35-36. The court underscored that its stay "will not remain open-ended," and that if FDA did not "complete its review and make any necessary revisions to the REMS within a reasonable timeframe, the Court's analysis … will inevitably change." Op.35-36. The court ordered FDA to file status reports within

six months and within 14 days of FDA completing its review, and to file the administrative record within 60 days. Op.36.

ARGUMENT

Plaintiffs are not entitled to an injunction or stay pending appeal of a years-long status quo. To justify that extraordinary relief, Plaintiffs "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." *Whole Woman's Health v. Jackson*, 13 F.4th 434, 441 (5th Cir. 2021) (injunctions pending appeal); *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1135 (5th Cir. 2021) (§ 705 stays).

Plaintiffs' requested relief also "demands a significantly higher justification" under these four factors than in the district court: Interim appellate relief "does not simply suspend judicial alteration of the status quo but grants judicial intervention that has been withheld by lower courts." *McKee*, 562 U.S. at 996. The court's assessment of the equities is subject to deferential review only "for an abuse of discretion." *Benisek v. Lamone*, 585 U.S. 155, 158 (2018).

I. THE DISTRICT COURT APPROPRIATELY BALANCED THE EQUITIES TO CONCLUDE THAT PRELIMINARY RELIEF WAS UNWARRANTED WHILE FDA COMPLETES ITS REVIEW

Equitable relief "does not follow from success on the merits as a matter of course," *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 32 (2008), but rather

turns on "what is necessary, what is fair, and what is workable," *North Carolina v. Covington*, 581 U.S. 486, 488 (2017). The district court acted well "within its sound discretion," *Benisek*, 585 U.S. at 161, in weighing these considerations and concluding that the balance of hardships and the public interest foreclose the extraordinary relief Plaintiffs seek.

On one side of the ledger, the court identified multiple ways in which the public's "substantial" interest is advanced by FDA completing its ongoing review of mifepristone's dispensing conditions "free from judicial interference," as courts are "ill-equipped" to make the requisite scientific decisions of when and under what conditions mifepristone should be dispensed. Op.33-35. It underscored that GenBioPro would suffer decreased revenue and increased "compliance costs"—harms compounded by the "length of time the 2023 REMS has been in effect" and the reasonable "reliance interests" that have developed during that period. Op.30, 35. And although the court concluded (wrongly) that Louisiana would suffer "sovereign and financial harms" from the 2023 REMS, it recognized that Louisiana "retains many meaningful" tools to "mitigate" those harms over the next few months, unlike GenBioPro and FDA. Op.30.

Plaintiffs do not engage with the court's balancing of harms, let alone show it to be an abuse of discretion. Instead, Plaintiffs isolate three narrow pieces of the

court's analysis and attack them in the abstract. None undermines the court's judgment about the balance of harms at this stage of the litigation.

First, Plaintiffs fault the district court for declining to "becom[e] 'a forum for resolving moral or policy disagreements' (or 'scientific or medical judgments')." Mot.21 (quoting Op.28-29). But this was a sensible recognition that this case concerns issues Congress requires to be first considered by FDA—and that courts should be reluctant to impose accelerated, interim nationwide relief based on "the court's own evaluation" of the scientific issues while the agency with the relevant "background, competence, and expertise to assess public health" is actively reconsidering the matter. *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring).

Second, Plaintiffs criticize the court's concerns about the possibility of "inconsistent judicial outcomes" or relief exceeding "settled limits on equitable relief." Mot.21-23. Yet this Court has admonished against allowing "one district court [to] make a binding judgment for the entire country," especially when "many states [] have not brought suit" and may have "accepted and even endorsed" the federal policy, which is particularly acute when considering nationwide access to a medication. *Louisiana v. Becerra*, 20 F.4th 260, 263 (5th Cir. 2021). And Plaintiffs' extended, in-the-abstract defense of universal APA relief (Mot.23-25) is irrelevant. The district court properly recognized that a nationwide stay of the 2023 REMS

would be exceptionally disruptive here—and thus exceptionally relevant to the overall balance of harms.

Third, Plaintiffs argue that allowing "FDA's review [to] be conducted and completed free from judicial interference" is "badly mistaken," including because it would "allow the government to avoid preliminary review in *every* APA case." Mot.25-26. But this is no ordinary case, and Plaintiffs' concerns are hyperbolic. Plaintiffs seek to upend a years-old status quo on an interim basis where the agency already announced, prior to this lawsuit, that it was reviewing the decision now challenged. And unlike in many APA cases, Plaintiffs here do not assert a pure issue of statutory interpretation; they challenge FDA's scientific judgment as unreasonable. Nor is the stay order an "open-ended" invitation to evade judicial review: FDA "has an obligation to act with all deliberate speed to review its past actions and complete a thorough analysis that addresses the deficiencies it has acknowledged." Op.35.

Finally, while Plaintiffs insist that the question here "is legal not scientific," Mot.26, their APA claims boil down to disagreements with FDA's assessment of the scientific record. FDA has not remotely "concede[d]" legal violations. Mot.11-12, 26. Although FDA referenced "concerns about removing the in-person dispensing requirement" raised by this Court's since-vacated decision in *AHM*, the agency confirmed that it is conducting a *scientific* review "based on all the evidence before

the agency," including "FDA's own study." ECF 51 at 1, 3. The court was right to recognize that FDA, rather than the judiciary, is better suited (and statutorily required) to conduct that scientific assessment *first*, followed by judicial review as necessary. All the more so because FDA has authority to take "interim actions to ensure drug safety" if concerns arise regarding mifepristone's safety during FDA's review. Op.31.

II. PLAINTIFFS' REQUEST FAILS FOR MULTIPLE INDEPENDENT REASONS

A. Plaintiffs Are Unlikely to Succeed on the Merits

Aside from the district court's well-grounded bases for denying relief while FDA reviews the REMS, there are several additional reasons to deny Plaintiffs' request. Most significantly, Plaintiffs do not have a strong likelihood of success in their appeal because they lack Article III standing—a jurisdictional issue this Court reviews *de novo*, and which mandates dismissal. *AHM*, 602 U.S. at 397. Even if Plaintiffs had standing, their challenge would unlikely succeed because it is unexhausted, unripe, and fails on the merits.

1. Plaintiffs Lack Article III Standing

Plaintiffs advance (and the district court credited) two standing theories, both of which are foreclosed by controlling precedent.

First, Louisiana asserts a sovereign injury, claiming the 2023 REMS prevents it from effectively "enforc[ing]" its prohibitions on abortion. Mot.12-13. The 2023 REMS, at most, imposes increased logistical burdens on Louisiana's efforts to

enforce its laws, but the Supreme Court has rejected that standing theory. *United States v. Texas*, 599 U.S. 670 (2023) held that allegations of insufficient regulatory stringency—and state burdens that follow—cannot alone support state standing, lest the federal judiciary start down "th[e] uncharted path" of adjudicating "alleged Executive Branch under-enforcement of any similarly worded laws[,] whether they be drug laws, gun laws, obstruction of justice laws, or the like." *Id.* at 681. Another court of appeals applied *Texas* to reject the very same theory that FDA's safety-and-access conditions on mifepristone cause sovereign injury to states. *Washington v. FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024).

Louisiana claims that the 2023 REMS was *designed* to interfere with state abortion laws after *Dobbs*. Mot.2, 15-16 (citing *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 125 (2025)). But that "targeting" narrative is demonstrably false. The in-person dispensing requirement was first lifted by injunction in 2020, and then voluntarily suspended by FDA in April 2021, more than a year before *Dobbs*, when abortion was still protected nationwide. FDA has stated that it initiated the process leading to the 2023 REMS change "[i]n connection with the *Chelius v. Becerra* litigation," a *2017* lawsuit. ECF 1-50 at 46.

Plaintiffs rely on statements from various non-FDA officials about abortion access, Mot.15, but they all postdate FDA's 2021 suspension of the in-person

dispensing requirement and none of them evinces a goal of overriding state law.[1] Agency action must be reviewed using the "record" generated by the agency decision-makers, *Biden v. Texas*, 597 U.S. 785, 812 (2022), not extra-record statements by non-decisionmakers.

Even if Louisiana had a cognizable sovereign injury, it would be traceable solely to independent actors, not the 2023 REMS, and would not be redressed by the relief they seek. Plaintiffs offer no evidence that the parties they claim are mailing mifepristone illegally into Louisiana (Mot.13, 15) would stop if FDA reimposed in-person dispensing. To the contrary, drawing on lessons from the war on drugs, the district court acknowledged that third parties would continue mailing mifepristone to "those who seek it" regardless of the 2023 REMS. Op.30 & n.17. Plaintiffs cannot "rely on speculation about the unfettered choices made by independent actors not before the courts" to show causation. *AHM*, 602 U.S. at 383.

Second, Louisiana claims, and the district court agreed, that FDA's rescission of the in-person dispensing requirement causes Louisiana "pocketbook injur[ies]" in

[1] The court cited an executive order on "reproductive healthcare services" as evidence that the REMS sought "to circumvent anti-abortion states' ability to regulate abortion." Op.20-21. The quoted portions of the order described overall policy goals, none of which suggested—let alone directed—the use of FDA policy to override state law. And the *operative* portions of the order, which Louisiana ignores, merely directed HHS to "submit a *report* to the President … identifying *potential* actions" that could "protect and expand access to abortion care, including medication abortion." Exec. Order No. 14,076, 87 Fed. Reg. 42,053 (July 8, 2022) (emphasis added).

the form of Medicaid-related expenses and increased payments to public hospitals for treating mifepristone side effects. Mot.13-14; Op.24. But the Supreme Court has considered and rejected that theory, too. *United States v. Texas* rebuffed arguments that a federal policy's "indirect effects" on "state spending" or "revenues" establish standing. 599 U.S. at 680 n.3. Any impact of the 2023 REMS on Louisiana's Medicaid costs is even "far[ther] removed from" the "distant … ripple effects" that the Court found too attenuated in *AHM*, 602 U.S. at 383. It depends on proving that the REMS will lead independent actors to dispense mifepristone using methods different from those they would otherwise use; that patients will experience complications due to those differences; that those patients will seek particular forms of treatment; and that the resulting costs will be borne by Louisiana. At bottom, neither Louisiana nor the district court could link these purported expenses *to the 2023 REMS*, as opposed to FDA's underlying approval of mifepristone, which Plaintiffs have not challenged.

Texas v. United States, 50 F.4th 498, 519 (5th Cir. 2022), on which Plaintiffs rely for the proposition that the 2023 REMS need only "exacerbate[]" their harms, does not fill the gap. That case involved a policy that increased the *number* of Medicaid beneficiaries Texas had to serve; the 2023 REMS (at most and allegedly) affects the amount spent—an effect that, if alone sufficient, would permit states to challenge virtually any federal policy.

2. Plaintiffs' Challenge Is Unexhausted and Unripe for Review

Plaintiffs also failed to exhaust mandatory administrative remedies and their claims are unripe. Plaintiffs make no attempt to justify their failure to exhaust, and the district court inexplicably "decline[d] to substantively address" it. Op.3 n.3.

FDA regulations require parties to pursue administrative remedies with the agency before filing suit. 21 C.F.R. §§ 10.45(b), 10.25(a). FDA also requires "issue-exhaustion," giving FDA "'primary jurisdiction to make the initial determination on issues within its statutory mandate.'" *Indep. Turtle Farmers of La., Inc. v. United States*, 703 F. Supp. 2d 604, 616 (W.D. La. 2010). Courts apply these requirements strictly. *See Ass'n of Am. Physicians v. FDA*, 358 F. App'x 179, 180-81 (D.C. Cir. 2009); *Cody Lab'ys., Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011).

Exhaustion is especially important for challenges involving FDA's science-driven REMS determinations regarding "public health." *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1614 (2020) (Roberts, C.J., concurring). Congress's determination that each REMS must "assur[e] access and minimiz[e] burden" on "the health care delivery system," 21 U.S.C. § 355-1(f)(2), underscores the intricate balancing inherent to FDA's REMS decisions.

Neither plaintiff ever filed a citizen petition challenging the 2023 REMS, and FDA therefore never issued a "final administrative decision" addressing the claims

they raise here—both of which are necessary preconditions to judicial review. 21 C.F.R. §§ 10.45(b), 10.25(b).

Plaintiffs offer no reason they should be exempt from FDA rules binding every other stakeholder, and none exists. ECF 257 at 11-12. Exhaustion would not be futile: FDA is actively reviewing the REMS alongside citizen petitions (including by GenBioPro) raising identical issues. Alleged agency delay in resolving *others'* petitions cannot establish "administrative abuse," as Plaintiffs claimed below. And Plaintiffs' years-long delay, combined with FDA's authority to address exigent public health concerns mid-review, defeats any claim of irreparable harm.

Separately, Plaintiffs' claims are unripe because they rest on "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998). There is no basis for "inappropriately interfer[ing]" with FDA's ongoing administrative action midstream, *Ondrusek v. U.S. Army Corps of Eng'rs*, 123 F.4th 720, 728 (5th Cir. 2024), especially because it entails complicated "scientific and medical judgments committed by Congress" to FDA in the first instance, Op.29.

3. Plaintiffs' Claims Will Likely Fail on the Merits

Because FDA's 2023 REMS modification is "reasonable and reasonably explained," *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021), Plaintiffs are unlikely to prevail on their arbitrary-and-capricious claim.[2]

The REMS statute charges FDA with making a "fact-dependent" determination, *Seven Cnty. Infrastructure Coal. v. Eagle Cnty.*, 605 U.S. 168, 183 (2025), about what REMS conditions most appropriately ensure that a drug's benefits outweigh its risks while minimizing burdens on access and the health care delivery system, 21 U.S.C. § 355-1(f)(2), (g)(4)(B). Although FDA has not produced the administrative record in this case, it has been produced in other litigation—and it shows that the 2023 REMS is supported by several independent evidentiary sources, including comparisons of adverse event data before and after the in-person dispensing requirement was lifted, and a cumulative review of 15 studies that covered more than 55,000 patients receiving mifepristone outside the clinic setting. ECF 1-50 at 63, 65-81. FDA found "no new safety concerns" from its review and reasonably concluded that mifepristone could be used safely without requiring that the medication be dispensed in person. *Id.* at 63.

[2] Plaintiffs are also unlikely to succeed on their Comstock Act claim, which they do not meaningfully press here and which the court did not address. Mot.12 n.6; Op.3 n.3.

The 2023 REMS easily satisfies the APA's reasonableness standard. Nothing before the agency in 2023 undermines that conclusion—nor does any of the extra-record and post-decision material that Plaintiffs inappropriately cite, ECF 1-13, ECF 1-14, which would not be part of the administrative record in any event, *Texas v. EPA*, 156 F.4th 523, 537-38 (5th Cir. 2025). Any limitations in the specific studies FDA examined were outweighed by the fact that *all* the studies supported that it was safe to remove the in-person dispensing requirement, and FDA's *additional* requirements on pharmacies and physicians to ensure patient safety. ECF 1-50 at 80-81.

The court nevertheless agreed with Plaintiffs that the 2023 REMS was likely arbitrary and capricious for two principal reasons—which echo remarks in this Court's expedited and since-vacated decisions in *AHM*. Mot.9-12; Op.26-28. None of these grounds provides reason to jettison FDA's determination.

First, Plaintiffs argue that FDA's 2016 change to prescriber adverse-event reporting for mifepristone rendered subsequent data in the FAERS database unreliable, and that FDA relied on the supposed "absence" of adverse-event data to justify removing the in-person dispensing requirement. Mot.10-11; Op.26-27. But the 2016 change simply aligned mifepristone with the *optional* physician reporting program in effect for virtually every other drug, including those subject to REMS programs. ECF 1-11 at 26-28; 21 C.F.R. § 314.80(c) (imposing reporting

requirements on manufacturers but not providers). FDA retained a mifepristone-specific reporting requirement for fatalities, while recognizing that, as with other drugs, "serious adverse events other than deaths" continue to reach FDA through manufacturers' "periodic safety update reports and annual reports." ECF 1-11 at 28.

Indeed, manufacturers are required to report *all* adverse events that they receive, including from a variety of different sources that are *not* limited to physician reports. 21 C.F.R. § 314.80(b)-(c). The FAERS database that FDA considered in its assessment incorporates all of this data. The 2023 REMS is thus fully consistent with FDA's duty to consider "adverse event report[s]." 21 U.S.C. § 355-1(a)(2)(A), (b)(3).

Second, Plaintiffs argue that FDA's analysis relied on literature that did not support the 2023 REMS. Mot.11; Op.27. But Plaintiffs ignore the surrounding context of FDA's analysis—which the administrative record would show once produced. Before removing the in-person dispensing requirement, FDA reviewed 15 studies that evaluated medication abortion outcomes for over 55,000 patients. ECF 54-4 at 16. Each study concluded that dispensing by mail, courier, or through pharmacies was safe and effective, and *none* of the studies identified any new or increased risks when mifepristone is dispensed outside a clinic or hospital. FDA explained that these findings (and more), supported the "conclusion that dispensing by mail is safe" and "there was no increased frequency of" serious adverse events.

Id. at 18. The studies on which FDA relied fully supported the agency's predictive judgment that "mifepristone will remain safe" without requiring in-person dispensing at a clinic or hospital. *Id.*

B. Additional Equities and the Public Interest Overwhelmingly Counsel Against a Stay or Injunction Pending Appeal

Plaintiffs fail to demonstrate irreparable harm, and yet their requested relief will cause serious and irreparable harm to the public and the other parties, as the court recognized, *see* Op.28-36.

1. Plaintiffs Will Not Be Substantially Injured if the 2023 REMS Remains In Effect During the Pendency of this Appeal

In this posture, it is not enough for Plaintiffs to show that they will be irreparably harmed in the "long-term" or even while the litigation continues; they must establish that they will be irreparably harmed in the short period "while the *appeal* proceeds." *Texas v. Biden*, 10 F.4th 538, 559 (5th Cir. 2021).

Plaintiffs' inexplicable delay in seeking relief belies any notion that they can make that showing. They waited to sue for *nearly three years* after FDA adopted the 2023 REMS, and *more than four years* after FDA first lifted the in-person dispensing requirement in 2021. Even after suing, Plaintiffs waited another 72 days to seek preliminary relief in the district court. Yet, despite supposedly suffering the injuries of which they now complain for years, Plaintiffs do not even attempt to explain their delay—or why they waited until September 2025 to seek intervention in *AHM*. Nor

do they explain how that delay is consistent with their demand for immediate appellate intervention—ignoring that "a party requesting a preliminary injunction must generally show reasonable diligence." *Benisek*, 585 U.S. at 159.

As Plaintiffs' delay illustrates, they will not suffer irreparable injury during this litigation, let alone this appeal. Plaintiffs argue, at most, that the REMS "could" cause Louisiana to incur expenses for Medicaid patients in the future. ECF 1 ¶¶134-43. They do not and cannot quantify those expenditures (that by their own telling have been occurring for three years), predict when they will occur again, or link them causally to the 2023 REMS itself, as opposed to the independent acts of third parties or other FDA actions that Plaintiffs do not challenge. *Supra* section II.A.

As for sovereign injury, the REMS neither overrides Louisiana's law nor prevents its enforcement. Louisiana continues to prohibit the use of mifepristone for many purposes and retains its existing enforcement tools. Moreover, any frustration Louisiana experiences stems from the independent actions of third parties not before this Court—and certainly not FDA. As the district court recognized, Louisiana is not powerless to prevent its purported injuries: it "retains many meaningful, boots-on-the-ground law enforcement mechanisms to mitigate its sovereign and financial harms" while this appeal proceeds. Op.30. In short, Plaintiffs "present[] no reason to think" they "will be irreparably harmed *during the pendency of the appeal*." *Biden*, 10 F.4th at 559.

The district court conducted no assessment of whether Louisiana would suffer irreparable harm during the pendency of this case, and entirely ignored Louisiana's delay in seeking relief. Op.28. The court instead concluded that because Louisiana had "demonstrated an injury-in-fact" for Article III standing, it *necessarily* "establish[ed] irreparable harm," given the unavailability of money damages. Op.28. But it is blackletter law that a "constitutionally cognizable injury" supporting "standing to seek injunctive relief" does *not* equate to "irreparable injury" supporting the "drastic and extraordinary remedy" of an injunction. *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153, 162-65 (2010). Under the district court's contrary approach, preliminary injunctive relief would be justified in virtually every APA challenge, given the government's sovereign immunity from damages suits. Irreparable harm requires more, and neither Plaintiffs nor the district court explained how FDA's action—as opposed to the actions of third parties or FDA actions they have *not* challenged—would cause irreparable harm during this litigation.

2. The Public and GenBioPro Will Be Irreparably Harmed by a Stay of the 2023 REMS

By contrast, suspending the 2023 REMS, even just during this appeal, would cause immediate and irreparable harm to the public and GenBioPro. Plaintiffs cannot show that the district court abused its discretion in so concluding.

The district court recognized that interim relief would disrupt established channels of access and distribution of mifepristone, reverberating far beyond

Louisiana into non-party states that have made different policy choices and whose citizens and health-care systems would be immediately impacted. *See* ECF 210. The court also recognized that GenBioPro would be irreparably harmed. Op.30. Mifepristone accounts for the majority of GenBioPro's revenue, and sales through pharmacy distribution that would be cut off by the requested stay are a substantial portion of that revenue. ECF 54-2 ¶¶5, 10. The order Plaintiffs seek would also create significant confusion and compliance burdens, on an interim basis, and potentially even compel reversion to an obsolete regulatory regime. *Id.* ¶¶9, 12-15. In turn, as FDA previously represented, relief could potentially halt distribution of mifepristone entirely, *see* Decl. of Janet Woodcock, M.D., *FDA v. All. for Hippocratic Med.*, No. 22A902 (U.S. Apr. 14, 2023), https://bit.ly/4rYmIZI.

At bottom, Plaintiffs ask this Court, on a threadbare record and breakneck timetable, to impose a new nationwide regime that unsettles a years-long status quo. The public interest lies not in rushed intervention, but in maintaining the status quo, respecting FDA's congressionally assigned role, and allowing the merits to be resolved on a full record once FDA completes its review.

CONCLUSION

The Court should deny Plaintiffs' motion. If the Court grants relief, GenBioPro requests a seven-day administrative stay to permit an emergency application in the Supreme Court.

Dated: April 23, 2026

Respectfully submitted,

/s/ *John P. Elwood*

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CERTIFICATE OF SERVICE

This is to certify that the foregoing response has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure, on April 23, 2026, on all registered counsel of record, and has been transmitted to the Clerk of the Court.

/s/ John P. Elwood
John P. Elwood

CERTIFICATE OF COMPLIANCE

I hereby certify that this response complies with the requirements of Federal Rule of Appellate Procedure 27(d) because it has been prepared in 14-point Times New Roman, a proportionally spaced font. I further certify that this response complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 5,198 words, according to the count of Microsoft Word.

/s/ John P. Elwood
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