No. 26-30203

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants/Cross-Appellees,

v.

U.S. FOOD AND 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 and Research, U.S. Food and Drug Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., Secretary, U.S. Department of Health and Human Services,
Defendants-Appellees,

v.

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
No. 6:25-cv-01491 (Hon. David C. Joseph)

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STATEMENT REGARDING ORAL ARGUMENT

The Court has scheduled this case for argument on September 9, 2026. GenBioPro respectfully requests that the Court allocate it argument time.

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INTRODUCTION

Louisiana asks this Court to issue a nationwide suspension of FDA's conditions governing access to mifepristone and reimpose an in-person dispensing requirement that FDA has not enforced since 2021. That extraordinary relief would upend a years-long status quo, disrupt settled reliance interests, affect patients and sovereign States far beyond Louisiana's borders, and interfere with FDA's ongoing review of the very REMS at issue. Louisiana grounds that request on attenuated standing theories and a demand that the court second-guess FDA's scientific judgment, and do so on a rushed, interim basis. The Supreme Court already intervened once after a motions panel of this Court granted that relief. The district court, too, declined Louisiana's invitation, instead preserving the status quo while FDA completes the expert review Congress assigned to it. That judgment was correct—not just for the sound equitable reasons the district court provided, but because Louisiana's challenge does not belong in court in the first place.

Louisiana lacks Article III standing. The 2023 Risk Evaluation and Mitigation Strategy ("REMS") that Louisiana challenges does not regulate the State. It does not require Louisiana to do anything, forbid Louisiana from doing anything, or bar Louisiana from enforcing its abortion restrictions against anyone who violates them. It regulates manufacturers, prescribers, and pharmacies. General statements by federal officials about reproductive rights do not transform FDA's drug-safety

determination into regulation of Louisiana, much less give Louisiana standing to sue the federal government.

Louisiana is thus left asserting injuries—a prospect of higher Medicaid payments and reduced efficacy and increased costs of state law-enforcement—that depend on a long chain of independent choices by actors not before the Court: out-of-state prescribers, pharmacies, mail carriers, patients, treating physicians, Medicaid billers, and other sovereign States that have enacted laws Louisiana opposes. But Article III does not permit a State to challenge a federal regulation governing others based on these sorts of speculative, "indirect effects"—a theory that cannot be squared with "our system of dual federal and state sovereignty." *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023). The Court shut the door on Louisiana's freewheeling conception of standing in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), where it rejected claims premised on downstream medical consequences of FDA's regulatory decisions for mifepristone. Louisiana's theory combines the defects of both rejected approaches. It would give States a roving license to sue the federal government for all manner of policy disagreements—from drugs to guns to immigration to environmental protection—simply by alleging some tenuous downstream effect on the State's fisc or enforcement priorities.

Even if Louisiana could establish standing, the district court correctly denied extraordinary preliminary relief. The State bypassed FDA's administrative processes, sought judicial intervention while FDA is actively reconsidering the REMS, and failed to demonstrate that FDA's scientific judgment was arbitrary or capricious. FDA's ongoing review does not change that conclusion. Ordinary administrative law principles as well as FDA's organic law provide that the existing REMS must remain in effect while FDA considers whether a REMS modification is warranted. The district court acted well within its discretion in concluding that the equities and public interest overwhelmingly favor preserving the longstanding status quo while FDA completes its reconsideration—rather than imposing a nationwide judicial override of an established system, which would immediately disrupt settled reliance interests, impose unrecoverable harms on manufacturers and healthcare providers, affect patients and sovereign States far beyond Louisiana's borders, and interfere with FDA's ongoing regulatory process.

Louisiana has many political, administrative, and law-enforcement avenues to press its objections to FDA policy and to enforce Louisiana law. Litigation seeking nationwide emergency relief from an FDA REMS is not one of them. Because the State has not established standing—or any of the prerequisites for extraordinary interim relief—the judgment should be affirmed. And because the same standing defects deprive the district court of jurisdiction, the district court's denial of the

motions to dismiss should be reversed, and the case remanded with instructions to dismiss.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1331. The district court entered its order on April 7, 2026, ROA.9084-9120, and GenBioPro filed a notice of appeal on May 1, 2026, Doc. 138. This Court has jurisdiction to review the denial of preliminary relief under 28 U.S.C. § 1292(a)(1). The Court also has jurisdiction to review the denial of GenBioPro's motion to dismiss under § 1292(a)(1) and the doctrine of pendent appellate jurisdiction, as the "underpinnings" of that motion are "inextricably intertwined" with the denial of the motion for preliminary relief. *Jiao v. Xu*, 28 F.4th 591, 596 (5th Cir. 2022).

STATEMENT OF THE ISSUES

1. Whether the district court correctly denied Plaintiffs' request for relief that would force immediate nationwide reimposition of the long-discontinued in-person dispensing requirement for the duration of this case.

2. Whether the district court erred in declining to dismiss Plaintiffs' complaint for lack of Article III standing.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

Congress entrusted FDA with the authority and responsibility to determine whether a "new drug" is safe and effective for its intended use. 21 U.S.C. §§ 321(p),

355; *see id.* § 393(b)(2)(B). The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., directs FDA to approve a new drug if, among other things, the sponsor's application contains evidence demonstrating that the drug is safe and effective under the proposed conditions of use, *id.* § 355(d); *see* 21 C.F.R. §§ 314.50, 314.105(c).

In 2007, Congress codified and expanded a prior FDA regulatory regime by authorizing the agency to require a "risk evaluation and mitigation strategy" when it determines that such a strategy is necessary to ensure that the benefits of a drug outweigh its risks. 21 U.S.C. § 355-1; *see* Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, tit. IX, § 901, 121 Stat. 922. Under the REMS framework, FDA's approval of a drug may include "elements to assure safe use," such as a requirement that a drug's prescribers have particular training or that a drug be dispensed only in certain settings. 21 U.S.C. § 355-1(f)(3). FDA's REMS authority is ongoing. FDA may require submission of a proposed modification to an approved REMS if it determines that the modification should be made to ensure the benefits of the drug outweigh the risks. *Id.* § 355-1(g)(4)(B). Modifications may include changes to requirements previously imposed to assure safe use of the drug. *Id.* § 355-1(g), (h). While FDA considers whether to require a REMS modification, the existing approved REMS remains in effect. *Id.* § 355-1(h)(2)(B). In addition, Congress has directed that REMS elements must be

"commensurate with" the drug's risks, must "not be unduly burdensome on patient access to the drug," and, "to the extent practicable," must "minimize the burden on the health care delivery system." *Id*. § 355-1(f)(2).

B. Factual Background

2000 Mifeprex Approval and 2008 REMS. In 2000, FDA approved Danco Laboratories, LLC's application for approval of mifepristone for medical abortion under the brand name Mifeprex. *See FDA v. All. for Hippocratic Med.* (*Alliance*), 602 U.S. 367, 375 (2024). Mifepristone is approved for use in a regimen with another drug, misoprostol, to terminate an early pregnancy. In approving mifepristone, FDA invoked then-applicable regulations known as "Subpart H" to impose requirements to assure the drug's safe use, including a requirement that mifepristone be dispensed in person. In 2008, pursuant to the FDAAA, FDA identified mifepristone as subject to a REMS. 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008). The REMS required, among other conditions, that the drug be dispensed exclusively in a healthcare setting, such as a hospital or medical center. ROA.349.

2016 Changes and 2019 Abbreviated New Drug Application. 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. *See* ROA.350. FDA's approval was based on a comprehensive review that considered the "well-characterized" safety profile of Mifeprex "over 15 years,"

published studies, review articles, and guidelines from professional organizations. ROA.392, ROA.413. FDA concluded that the use of mifepristone under the revised conditions would be "safe[]," emphasizing that "known risks occur[] rarely." ROA.413.

As part of the 2016 changes, FDA determined based on "15 years of reporting" that the REMS requirement for prescribers to report all serious adverse events was no longer necessary and that, as with the vast majority of other drugs, information on non-fatal adverse events could be "collected in the periodic safety update reports and annual reports" submitted by the drug's sponsor to FDA. ROA.415. FDA therefore changed prescribers' adverse event reporting obligations to require prescribers to report only fatalities—"a reporting requirement that was still more stringent than the requirements for most other drugs." *Alliance*, 602 U.S. at 376. Federal law also already requires all manufacturers to review and submit to FDA adverse-event reports 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. *Alliance*, 602 U.S. at 376; 21 U.S.C. § 355(j).

2020–2023 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. *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020). The injunction was in effect for six months, during which FDA observed no impact on patient safety. ROA.1023-1026.

Subsequently, in April 2021, FDA suspended enforcement of the in-person dispensing requirement. ROA.259-260. FDA relied on data from the period the injunction was in effect, as well as medical literature, postmarketing adverse-event reporting, and information about deviations or noncompliance events associated with the REMS. ROA.259-260. FDA found no indication that adverse events occurred with greater frequency when a patient received the drug by a method other than in-person dispensing. *Id.* FDA then began a full review of the mifepristone REMS.

In December 2021, FDA announced a modification to the REMS that would permit mailing to patients and dispensing by certified pharmacies, concluding that "mifepristone may be safely used without in-person dispensing," ROA.374, and that in-person dispensing was "no longer necessary to ensure" the drug's benefits outweigh the risks, ROA.372. 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. ROA.352, ROA.372-384. FDA also relied on safety data from the nonenforcement period, which showed "no indication" that suspending in-person dispensing "contributed to" adverse events. ROA.1092. FDA additionally reviewed 15 studies evaluating the safety and efficacy of mifepristone when dispensed outside the clinical setting, including by pharmacies and through the mail. ROA.1027. These studies, which collectively evaluated outcomes for more than 55,000 individuals, repeatedly showed the safety of the drug was consistent when dispensed across a wide variety of non-clinical settings. *See* ROA.1027-1039. FDA thus directed Danco and GenBioPro to initiate the process of modifying the REMS. ROA.967; *see* 21 U.S.C. § 355-1(g)(4)(B).

In January 2023, FDA approved the sponsors' applications to remove the in-person dispensing requirement from the REMS, which had not been enforced since April 2021. ROA.967-972. The 2023 REMS permitted mifepristone to be dispensed with a prescription from a certified prescriber who has ensured that the patient has reviewed and signed a patient agreement form providing information on the drug, including its risks, and instructions on when and how to seek follow-up care if necessary. The REMS also added a certification requirement for pharmacies dispensing mifepristone to "ensure[] that pharmacies are aware of and agree to follow applicable REMS requirements." ROA.1043.

FDA's Review of the REMS. FDA is required to engage in a periodic evaluation of the REMS. 21 U.S.C. § 355-1(f)(5)(B). FDA regulations also 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. ROA.6884, ROA.6897 & n.50.

In September 2025, in response to requests from state attorneys general and anti-abortion organizations, FDA announced it would conduct a study of the 2023 REMS "in order to determine whether modifications are necessary." ROA.2201. This review includes a new study FDA is undertaking; FDA has said it 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." FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, https://bit.ly/44NH2U1. Although such studies "often take approximately a year or more to conduct," FDA has stated that its "current … plan" is to complete the study "sooner." *Id.* FDA has explained that once it has 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." *Id.*

C. Procedural History

In 2022, physicians opposed to abortion sued in the Northern District of Texas, challenging various FDA decisions related to mifepristone, including FDA's 2021 decision not to enforce the in-person dispensing requirement. *See Alliance*, 602 U.S. at 376–77. That court issued a preliminary injunction granting all requested relief, which this Court stayed in part, and the Supreme Court subsequently stayed in its entirety. *Id.* at 377. This Court then affirmed the preliminary injunction as to the 2016 REMS and the 2021 non-enforcement decision. *Id.* at 377–78. The Supreme Court granted review and reversed, unanimously holding in June 2024 that the plaintiffs lacked standing. *Id.* at 374.

Over a year later, Louisiana and a Louisiana citizen, Rosalie Markezich, filed this action in October 2025 challenging the 2023 REMS modification. ROA.82. They did so more than two years after the REMS was modified, more than five years after FDA suspended enforcement of the in-person dispensing requirement, and without filing a citizen petition with FDA. ROA.82. After two more months, Plaintiffs moved to enjoin the 2023 REMS or "stay" its long-elapsed effective date under 5 U.S.C. § 705. ROA.2298. GenBioPro and Danco intervened and opposed the motion. ROA.2828, ROA.2856; ROA.2763, ROA.2789. FDA also opposed Plaintiffs' motion and further moved to stay the case while FDA reviews the REMS. ROA.2706; ROA.2737. The district court directed and received a supplemental brief

from FDA confirming its authority to take immediate action on mifepristone in the event of an exigent public health crisis. ROA.8999.

On April 7, 2026, the district court stayed the case during FDA's ongoing review and denied Plaintiffs' request for preliminary relief. ROA.9084. The court declined to dismiss for lack of standing, concluding that Louisiana's allegations of sovereign and pocketbook injuries sufficed at this early stage of the litigation, even though a stronger showing may be needed at "later stages." ROA.9100, ROA.9107. The court also concluded Plaintiffs were likely to succeed on the merits of their arbitrary-and-capricious claim and would suffer irreparable injury. ROA.9109-9111.

But the court concluded that the balance of the equities and the public interest warranted denying preliminary relief—and, on the same grounds, that a stay of proceedings was appropriate. ROA.9111-9119. The court declined to disturb the years-long status quo while FDA completes its review of the mifepristone 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." ROA.9112, ROA.9117. And 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. ROA.9118. 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." ROA.9118-9119. The court ordered FDA to file status reports within six months and within 14 days of FDA completing its review. ROA.9119-9120.

Louisiana appealed to this Court and moved for a stay of the 2023 REMS pending appeal under 5 U.S.C. § 705. Doc. 12. Danco and GenBioPro cross-appealed the district court's order insofar as it denied their motions to dismiss. Doc. 127; Doc. 138. On May 1, 2026, a panel of the Court granted a stay of the 2023 REMS' effective date under 5 U.S.C. § 705. Doc. 119. Agreeing with Louisiana that the district court misapplied the § 705 stay factors, the motions panel held that Louisiana had shown irreparable harm that outweighed FDA's interest in continuing its REMS review and the manufacturers' "financial interests in selling mifepristone." ROA.9146. The panel concluded that the manufacturers were "exaggerat[ing]" the disruption to mifepristone distribution that would result from a stay of the 2023 REMS. ROA.9147; *see id.* (further concluding that "in any event, [the manufacturers'] potential financial losses pale beside Louisiana's sovereign interest"). Finally, the panel rejected the district court's concerns about the equities and public interest. ROA.9147-9148.

The following day, GenBioPro and Danco each sought a stay of the order pending review by the U.S. Supreme Court. The Court granted administrative stays of the panel's decision on May 4 and extended them on May 11. On May 14, the Supreme Court granted the stay applications and ordered that this Court's May 1 order is stayed pending disposition of this appeal and disposition of a petition for certiorari, if one is timely sought. *Danco Lab'ys, LLC v. Louisiana*, 146 S. Ct. 1192 (2026).

SUMMARY OF ARGUMENT

I. The district court, in a sound exercise of discretion, declined to stay the REMS under 5 U.S.C. § 705 or to issue a preliminary injunction. There are numerous independent reasons to affirm denial of the extraordinary interim relief that Louisiana seeks.

A. Louisiana lacks Article III standing. The 2023 REMS does not regulate Louisiana, require Louisiana to do anything, or prevent Louisiana from doing anything. Louisiana is therefore not an object of the challenged agency action, and its asserted injuries must be traced through the independent choices of third parties. That is precisely the kind of attenuated theory of injury that the Supreme Court rejected in *Alliance* and *Texas*, which hold that plaintiffs cannot establish standing by pointing to downstream consequences of how an agency regulates someone else.

Louisiana's economic-injury theory fares no better. Its reliance on two Medicaid payments over several years does not show that the challenged feature of the 2023 REMS—mail or pharmacy dispensing rather than in-person dispensing—actually caused those costs, much less that future costs are certainly impending. The same is true of the expenses Louisiana claims to have incurred to investigate violations of its own laws, which are ordinary enforcement costs incurred in response to alleged violations by independent actors not injuries inflicted by FDA. Accepting Louisiana's theory would allow States to challenge virtually any federal health, safety, or enforcement policy by alleging indirect effects on state spending. Article III does not permit that result.

Louisiana's sovereign-injury theory is equally unmoored. The principle that a sovereign may prosecute violations of its own law does not mean a State may sue the federal government whenever it claims that federal regulation played some attenuated role in causing third parties downstream to violate state law. At most, Louisiana alleges that FDA's regulatory decisions directed to other parties make enforcement of its own laws more difficult. But any practical enforcement burdens caused by the independent conduct of private parties and other sovereign States are not injuries to Louisiana fairly traceable to FDA's 2023 REMS.

B. Plaintiffs' challenge fails for additional threshold reasons. Plaintiffs bypassed FDA's mandatory citizen-petition process and never gave the agency the

first opportunity to address their objections to the 2023 REMS, even though those objections turn on precisely the scientific and regulatory judgments Congress entrusted to FDA. And their claims are unripe while FDA is actively reviewing the REMS and considering whether any modification is warranted.

C. Even if Plaintiffs could surmount these threshold hurdles, their claims would fail on the merits. FDA reasonably concluded, based on periodic statutory reviews of the REMS' implementation, *see* 21 U.S.C. § 355-1(d), postmarketing safety information, adverse-event data, published literature, and decades of experience with mifepristone, that the in-person dispensing requirement was no longer necessary to ensure the drug's safe use. Louisiana's contrary arguments ask the Court to reject FDA's reasoned consideration of data sources with typical, acknowledged limitations, and apply a heightened evidentiary standard the APA does not require. And the Comstock Act does not make the 2023 REMS unlawful: FDA does not ship mifepristone, require anyone else to do so, or otherwise authorize unlawful shipments, and regardless, Louisiana's boundless reading of that prohibition defies settled precedent.

D. The remaining injunction factors independently foreclose preliminary relief, as the district court properly held. A stay of the 2023 REMS would upend a years-long status quo, disrupt FDA's ongoing review, override the interests of States that have made different lawful choices, and inflict unrecoverable operational,

compliance, and revenue harms on GenBioPro. Louisiana's asserted harms, by contrast, are speculative and belied by its years-long delay in seeking emergency relief. And the public interest does not favor a nationwide judicial rewrite of a REMS before FDA completes its review. The district court reasonably concluded that the equities and public interest favor preserving the operative regulatory regime while FDA does the work Congress assigned to it. And FDA's choice to conduct that review does not justify suspending the operative REMS; it confirms that judicial intervention would be premature before FDA completes that review.

II. Louisiana's failure to establish standing also requires dismissal of the complaint. This Court has jurisdiction over the denial of GenBioPro's motion to dismiss because that ruling depends on the same theory of standing that underlies Louisiana's request for preliminary relief. Those standing theories fail for all the same reasons that they fail in the context of Louisiana's request for emergency relief. Because Plaintiffs have not shown an injury fairly traceable to the 2023 REMS or redressable by the relief they seek, this Court should remand with instructions that the complaint be dismissed.

STANDARD OF REVIEW

To justify the extraordinary relief of a § 705 stay or preliminary injunction, 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. *See Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1135 (5th Cir. 2021). This Court reviews the denial of preliminary relief under this standard for abuse of discretion. *See Clarke v. Commodity Futures Trading Comm'n*, 74 F.4th 627, 640 (5th Cir. 2023). This Court reviews the denial of a motion to dismiss and issues of Article III standing *de novo*. *See Burnett Specialists v. Cowen*, 140 F.4th 686, 693 (5th Cir. 2025).

ARGUMENT

I. THE DISTRICT COURT CORRECTLY DENIED PRELIMINARY RELIEF

The district court soundly exercised its discretion by declining to disturb the operative REMS nationally while FDA completes its review. That ruling should be affirmed for multiple independent reasons. 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. *Alliance*, 602 U.S. at 397. Even if Plaintiffs had standing, their challenge would be unlikely to succeed because it is unexhausted, unripe, and fails on the merits—and the equities and public interest strongly favor preserving the multi-year status quo. The Supreme Court was right to stay the sweeping relief Louisiana seeks, and Louisiana provides no compelling reason to reinstate that relief in this appeal.

A. Plaintiffs Lack Article III 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." *Alliance*, 602 U.S. at 380. "At the preliminary injunction stage," a plaintiff "must make a 'clear showing' that [it] is 'likely' to establish each element of standing." *Murthy v. Missouri*, 603 U.S. 43, 58 (2024) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)).

The district court erred in holding that Louisiana made that showing here. To establish injury in fact, Louisiana must identify "an invasion of a legally protected interest" that is both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins,* 578 U.S. 330, 339 (2016) (quotation omitted). "'[A]llegations of *possible* future injury' are not sufficient." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (citation omitted). Rather, "the injury must have already occurred or be likely to occur soon." *Alliance*, 602 U.S. at 381. And because Louisiana seeks "prospective relief," it "must establish a sufficient likelihood of future injury." *Id.* It cannot.[1]

[1] Louisiana's brief does not address standing for the individual plaintiff, Ms. Markezich, so GenBioPro likewise focuses on Louisiana's arguments. But, to be clear, Ms. Markezich also lacks standing because she alleges only past harm and makes no plausible or concrete allegation that any future injury is "*certainly* impending." *Clapper*, 568 U.S. at 409 (citation omitted).

1. Louisiana Is Not an Object of the 2023 REMS

Louisiana asserts (and the district court and motions panel credited) two types of harm: "economic injuries" in the form of Medicaid expenditures and investigatory costs (Br. 35-41), and "sovereign injuries" in the supposed inability to "create and enforce [its] legal code." Br. 41-52.[2] But Louisiana faces a fundamental threshold problem asserting either type of injury: it is not an object of the federal regulation that it challenges, which "neither require[s] nor forbid[s] any action on the part of" the State. *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009).

Like the plaintiffs in *Alliance*, whom the Supreme Court held lacked standing, Louisiana "do[es] not prescribe or use mifepristone," and the 2023 REMS does not "require[] [Louisiana] to do anything or to refrain from doing anything." 602 U.S. at 385. Standing for such an "unregulated part[y]" is "substantially more difficult to establish" because causation requires "linking their asserted injuries to the government's regulation (or lack of regulation) of someone else." *Id.* at 382 (citation omitted). That requires showing 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," while avoiding both "speculative links" and

[2] The motions panel's determinations on these issues, necessarily made "in the haste of an emergency appeal" on Louisiana's "stay application," do not bind "a merits panel after full briefing." *X Corp. v. Media Matters for Am.*, 120 F.4th 190, 198 & n.6 (5th Cir. 2024).

"attenuated links … where the government action is" too "far removed from its distant (even if predictable) ripple effects." *Id.* at 383 (quotation marks omitted) (emphasis added).

The motions panel permitted Louisiana to avoid this problem by recasting itself as the *target* of the 2023 REMS—arguing that FDA adopted the REMS with the specific purpose of undermining post-*Dobbs* state abortion restrictions. ROA.9140-9143. Respectfully, that narrative is inconsistent with the facts, as the chronology of events shows. The process leading to the 2023 REMS modification started in connection with litigation filed in 2017, which the FDA has confirmed. ROA.1008. The in-person dispensing requirement was first lifted by court order in 2020 and then voluntarily suspended by FDA in April 2021—more than a year before *Dobbs*, when abortion remained protected nationwide, including in Louisiana. *See* ROA.970. Louisiana cannot plausibly convert a generally applicable regulatory decision about drug-dispensing protocols, initiated years before *Dobbs* and not directed at States, into a regulation targeting Louisiana's post-*Dobbs* laws.

Nor do Louisiana's quotations of statements by Biden Administration officials change that conclusion. *See* Br. 45-46. Louisiana does not contend that the officials who made the statements were the FDA decisionmakers responsible for the 2023 REMS. Judicial review of agency action must be based on the "record" generated by the agency decision-makers, *Biden v. Texas*, 597 U.S. 785, 812 (2022), not extra-

record statements by non-decisionmakers. While *Department of Commerce v. New York* permits courts to consider predictable third-party responses to government action for traceability, 588 U.S. 752, 768 (2019), it does not allow inferring an agency's purpose from "extrinsic" political statements and unsupported innuendo, *Trump v. Hawaii*, 585 U.S. 667, 702-05 (2018).

In any event, none of the statements Louisiana cites (at 45-46) show that FDA adopted the 2023 REMS to evade state law, nor do any of the quotations indicate an intent by non-FDA officials to dictate the specific elements FDA should include in the new REMS. The White House statement issued the day of the *Dobbs* decision mentioned distribution "by mail" of FDA-approved medication "in light of the FDA's determination that the drug is safe and effective," not as a pledge to circumvent state law. Br. 45 (citing ROA.956). The same statement recognized that nationwide abortion access would require "*Congress* to restore the protections of *Roe* as federal law." ROA.955 (emphases added). The August 24, 2022 HHS report that Louisiana cites (at 46) likewise recounted FDA's 2021 enforcement decision on in-person dispensing and reported that "FDA has [since] undertaken a full review of the Mifepristone REMS program and has determined that the in-person dispensing requirement is no longer necessary." ROA.1239.

So too with the January 19, 2023 HHS press release Louisiana quotes (at 46 (quoting ROA.1226)), which merely announced a short report that described

"modifications" to the mifepristone REMS that "the FDA approved" in January 2023 following "a comprehensive review." ROA.1223-1224. And the April 2023 White House fact sheet Louisiana emphasizes (at 45-46) post-dated the 2023 REMS and described FDA's actions on mifepristone distribution as "independent" and "evidence-based." ROA.1230-1231. In short, none of those statements transforms a drug-dispensing rule first implemented through enforcement discretion in 2021 and formalized in the 2023 REMS into federal regulation *of Louisiana*. Nor do they collapse the attenuated chain of third-party choices on which Louisiana's asserted injuries depend.

Diamond Alternative Energy, LLC v. EPA, 606 U.S. 100 (2025), does not rescue Louisiana's theory. There, fuel producers challenged rules that required manufacturers to make "more electric vehicles and fewer gasoline-powered vehicles." *Id.* at 116-17. The plaintiffs' asserted injury thus arose directly from the rules' "explicit[]" purpose: "to restrict the use of gasoline and other liquid fuels." *Id.* at 114-15. The 2023 REMS is not comparable. Louisiana alleges injuries revolving around downstream Medicaid expenditures and sovereign-enforcement burdens, but there is no record evidence that FDA adopted the 2023 REMS to impair Louisiana's sovereignty, frustrate Louisiana's law-enforcement authority, or impose Medicaid costs on the State. Post-*Dobbs* statements about expanding access to

medication abortion, even if considered, do not establish that Louisiana's alleged injuries were the purpose of the REMS.

Indeed, Louisiana's own allegations belie any notion that the State's injuries arise from the 2023 REMS—let alone that the State was its target. Louisiana says its injuries stem from "'out-of-state prescribers' sending FDA-approved mifepristone" to Louisiana. Br. 21. But Louisiana concedes that out-of-state medical providers' independent actions under out-of-state laws (so-called "shield laws") are what frustrate Louisiana's asserted interests in enforcing its abortion restrictions and impose the alleged costs, *e.g., id.* at 17, 46; ROA.83-84, ROA.106-114. FDA has not enforced in-person dispensing since April 2021. The Supreme Court decided *Dobbs* in June 2022. Under Louisiana's own account, neither of these events precipitated an increase in medication abortion in Louisiana; *that* changed, according to Louisiana, with the enactment of shield laws in 2023. ROA.106 (complaint allegation); *see* ROA.2331 (marking increase in telehealth abortions in Q3 2023). Louisiana's asserted injuries therefore derive from the "unfettered choices made by independent" actors—*i.e.*, medical providers in other states who ship mifepristone in reliance on shield laws that Louisiana's co-equal sovereign states have enacted. *Clapper*, 568 U.S. at 414 & n.5. They are not fairly traceable to the 2023 REMS.

2. Louisiana Lacks Cognizable Economic Injury Traceable to the 2023 REMS

Each of Louisiana's theories of harm suffers from additional defects that preclude Article III standing. As to economic injury, Louisiana claims it has an injury sufficient for standing because it allegedly paid $92,000 in Medicaid costs for two women who received emergency care after taking mifepristone. Br. 14, 36. On that basis, Louisiana speculates that similar costs may occur in the future so long as mifepristone can be dispensed by mail. Br. 35-36. The motions panel agreed that was sufficient—overlooking the absence of any authority holding that expenditure of money in this manner constitutes a cognizable injury. ROA.9142-9143. Louisiana offers no such authority at this stage either. Furthermore, Louisiana has never adequately explained how staying the 2023 REMS would reliably prevent the sorts of Medicaid costs it alleges from recurring. That failure forecloses Louisiana from showing either causation or redressability.

a. The 2023 REMS could play a role in Louisiana's Medicaid expenditures only through a long chain of independent decisions that the State does not meaningfully address. Under Louisiana's theory, an out-of-state provider must first choose to prescribe mifepristone to a patient in Louisiana. That patient must then choose to receive the medication by mail or from a certified pharmacy rather than in person; only then will the REMS—as opposed to FDA's actions *approving* mifepristone, which are unchallenged here—have enabled that patient's use of the

drug. That patient must then experience a complication from using the drug, which is itself exceedingly rare. That patient must seek care for that complication, be enrolled in Medicaid, and the provider must bill Louisiana for the care. Even then, establishing that the REMS caused a given expenditure would prove elusive: Similar complications could arise if a patient obtained mifepristone in person outside Louisiana, if medication were mailed unlawfully, or if a patient elected to use a different method for pregnancy termination. Article III does not permit standing to rest on that kind of multi-step causal chain, particularly when, at each step, a court must engage in "guesswork as to how independent decisionmakers will exercise their judgment." *Clapper*, 568 U.S. at 413.

The Supreme Court has made clear that these attenuation concerns are even greater in the context of suits by *States*. In *Texas*, state plaintiffs challenged federal immigration enforcement guidelines on a standing theory that the guidelines "impose[d] costs on the States," such as by requiring them to "continue to incarcerate or supply social services … to noncitizens." 599 U.S. at 674. The Supreme Court rejected such an "attenuated" theory of standing based on claimed "indirect effects" of a federal policy on "state revenues or state spending." *Id.* at 680 n.3. Although "[m]onetary costs are of course an injury," that was insufficient for standing: a State "incurr[ing] additional costs" because of a federal policy was not a "legally and judicially cognizable" injury. *Id.* at 676-78. That conclusion reflects a basic limit

on State suits against the federal government. "In our system of dual federal and state sovereignty, federal policies frequently generate indirect effects on state revenues or state spending," and a theory that countenanced standing anytime a State could point to monetary effects from a federal policy would dismantle "bedrock Article III constraints in cases brought by States" against the federal government. *Id.* at 680 n.3. The motions panel entirely disregarded *Texas*, and Louisiana barely mentions it. Br. 35-36.

Texas's limitation carries even greater force after the Supreme Court's decision in *Alliance*, which addressed the exact same regulatory context as this action. There, the Supreme Court rejected a "limitless approach" to standing that would allow plaintiffs to "challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries." 602 U.S. at 391-92. The Court held that the "chain of causation" between FDA's regulation of mifepristone and patients "show[ing] up at emergency rooms or in doctors' offices with follow-on injuries" is "simply too attenuated" to satisfy Article III. *Id.* That is because "virtually 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." *Id*. at 392. To allow plaintiffs "to challenge FDA's drug approvals simply on the

theory that use of the drugs by others may cause more visits to doctors" would represent an "unprecedented" expansion of Article III requirements and would have no "principled" endpoint. *Id.* at 391-92.

Taking *Texas* and *Alliance* together, Louisiana cannot rely on incidental "additional costs," 599 U.S. at 676-77, such as Medicaid expenses from "treat[ing] complications or side effects" of mifepristone, *Alliance*, 602 U.S. at 392, to establish standing. Such downstream fiscal effects are not "legally and judicially cognizable" injuries in a suit by a State against the federal government, nor do they satisfy Article III traceability. *Texas*, 599 U.S. at 676-77; *Alliance*, 602 U.S. at 383. As in *Alliance*, the 2023 REMS is "so far removed from its distant (*even if predictable*) ripple effects that [Louisiana] cannot establish Article III standing." 602 U.S. at 383 (emphasis added). Indeed, Louisiana's theory is even weaker than the theory the Supreme Court rejected in *Alliance*. If doctors lacked standing based on "downstream economic injuries" from treating patients with mifepristone complications, *id.* at 386, Louisiana cannot establish standing because the doctor later sends an invoice to the State. Louisiana's asserted expenditure is thus no more cognizable than the downstream costs the Supreme Court unanimously found to be insufficient in *Alliance*.

Indeed, the Ninth Circuit has applied *Alliance* and *Texas* to reject other states' materially identical theories of economic harm—namely, that elimination of the in-

person dispensing requirement would cause an "uptick in Medicaid costs." *Washington v. FDA*, 108 F.4th 1163, 1176 (9th Cir. 2024). In the Ninth Circuit's view, this was "exactly the kind of 'indirect effect[] on … state spending'" that, under the Supreme Court's decisions, could not support standing. *Id.* Louisiana does not mention the Ninth Circuit's decision, let alone distinguish it.

b. Louisiana's heavy reliance on emergency-room statistics further underscores the flaw in its argument. Louisiana makes a speculative leap from FDA labeling stating that a low percentage of women prescribed mifepristone in person will seek care in an emergency room to the conclusion that remote dispensing increases the number of women seeking care. Br. 14-16. But FDA concluded the opposite each time it reconsidered the in-person dispensing requirement, *see* ROA.1042. The fact that emergency room visits can occur even with in-person dispensing does not show that the 2023 REMS caused Louisiana's Medicaid costs. If anything, it shows merely that use of mifepristone (like use of countless other drugs) can result in rare complications. Article III requires traceability to the challenged agency action, not merely to use of the regulated drug, and Louisiana's speculation is insufficient to meet its burden.

And, importantly, mifepristone is associated with significantly fewer and less severe complications than full-term pregnancy. ROA.6897. Louisiana does not estimate what Medicaid costs would have been had those same patients obtained

mifepristone outside Louisiana or through another channel, elected to use a different method for pregnancy termination, or carried the pregnancy to term. Without evidence showing the net economic effect traceable to the challenged REMS change, Louisiana's claimed fiscal injury is "speculative." *See Alliance*, 602 U.S. at 383. What remains is not an economic injury but a "policy objection" to spending any Medicaid funding on anything related to abortion care. *Id.* at 381.

Article III similarly precludes Louisiana's attempt to establish standing by citing a few thousand dollars in investigatory costs. This claim boils down to an assertion that the State must expend resources to pursue its chosen policies. While the Supreme Court has sometimes found standing on behalf of private litigants who incurred preventive costs to avoid a "substantial risk" of harm, *Bost v. Ill. State Bd. of Elections*, 146 S. Ct. 513, 524 (2026) (Barrett, J., concurring in the judgment) (citing *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153–55 (2010)), it has never extended that principle to find that States have standing merely because they incurred costs in the ordinary course of enforcing State law. For good reason: if a State had standing anytime it spent money that it might not have had to spend if federal policy were different, any State could challenge virtually any federal policy with which it disagreed.

c. Notwithstanding the motions panel's conclusion otherwise, ROA.9141-9142, respectfully, Louisiana's reliance on "predictable effect[s]" (or

"commonsense inferences") about third-party behavior does not bridge the gap. Br. 35, 39 (quoting *Dep't of Comm.*, 588 U.S. at 768; *First Choice Women's Res. Centers, Inc. v. Davenport*, 146 S. Ct. 1114, 1125 (2026)). Those cases involved direct injuries with well-documented, immediate links to the challenged government action.

In *Department of Commerce*, the plaintiff States had proven that the challenged Census question would cause an "undercount" in the States' populations, producing a cognizable injury because the States "w[ould] lose out on federal funds that are distributed on the basis of state population." 588 U.S. at 767. *Davenport* likewise involved a subpoena demanding "a charity's private member or donor information," which—under settled precedent involving harms to "a plaintiff's constitutional rights"—*itself* created a cognizable injury in fact by "deter[ring] the exercise of First Amendment rights." 146 S. Ct. at 1125. Louisiana's theory depends on a much longer causal chain, with each link involving independent actors not before the Court. *See* p. 25-26, *supra*. And unlike the plaintiff States in *Department of Commerce*, which had proven that they would likely lose population-based funding as a direct result of the added Census question, Louisiana identifies no support for the notion that FDA's actions will predictably cause Medicaid expenses—let alone *net* expenses, given Louisiana's failure to establish that any

Medicaid costs associated with mifepristone exceed those of carrying those pregnancies to full term. *Supra* p. 30.

Louisiana's analogy to *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), is equally untenable. Br. 37-38. Louisiana says that because it participates in Medicaid, it is like an insurer and may therefore challenge any federal action that it predicts will increase healthcare costs. *Id.* But every State participates in Medicaid. If that were enough, then every State could challenge virtually any federal policy touching on health or safety—from drug approvals to food safety to vaccines to environmental rules to firearms policy—on the theory that the federal policy sets in motion a chain of events that might ultimately result in additional Medicaid expenditures. That boundless approach is irreconcilable with Article III and with the limits the Supreme Court has emphasized in cases involving our "system of dual federal and state sovereignty." *Texas*, 599 U.S. at 680 n.3.

d. Finally, independent of Louisiana's attenuation problem, its economic-injury theory fails because Louisiana has not established a sufficient likelihood of future harm. Allegations of "past wrongs" do not support standing to seek prospective relief. *City of Los Angeles v. Lyons*, 461 U.S. 95, 103 (1983). That remains true even when claims of past harm are coupled with "a statistical

probability that some [plaintiffs] are threatened with concrete injury." *Summers*, 555 U.S. at 497.

At most, Louisiana alleges that the REMS could lead to higher future Medicaid expenditures. ROA.121-123. But Louisiana does not quantify those future expenditures, predict when they will occur, or tie them to the 2023 REMS changes rather than to independent third-party conduct or FDA actions Louisiana does not challenge (*e.g.*, the underlying approval of mifepristone). That is a far cry from a "certainly impending" future injury from the 2023 REMS. *Clapper*, 568 U.S. at 410-12. Two alleged examples over three years cannot establish the "real and immediate threat" of recurrence required for prospective relief, *Coalition for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1280 (D.C. Cir. 2012) (Kavanaugh, J.) (quoting *Lyons*, 461 U.S. at 105), and are grossly insufficient to demonstrate that Louisiana is *likely* to expend Medicaid funds again in the future.

3. Louisiana Lacks Sovereign Injury Traceable to the 2023 REMS

a. Louisiana's two sovereign-harm theories fail, too. Relying on irrelevant False Claims Act law and a brief snippet from Blackstone, Louisiana first claims to be injured whenever a third party distributes an FDA-regulated drug in a way Louisiana believes violates state law. Br. 42-44. Article III standing must turn on what *FDA* did to Louisiana—not what *independent third parties* did after FDA regulated others. Again, the 2023 REMS does not regulate Louisiana. It is a safety-

and-access regulation that sets federal conditions for dispensing mifepristone. And Louisiana does not ban mifepristone outright; it prohibits administering or prescribing drugs with the specific intent to terminate certain pregnancies,[3] and mifepristone has lawful uses in the State. *See* La. Rev. Stat. Ann. § 14:87.1(1)(b), (2)(a).

FDA's policy therefore does not inflict a cognizable "public wrong[]" that could support standing. Br. 43-44. The principle that crimes were understood as injuries to the sovereign means that Louisiana has standing to prosecute those who violate Louisiana law. It does not mean Louisiana may sue the federal government whenever federal regulation of third parties allegedly facilitates some downstream violation of state law. False Claims Act decisions like *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), recognize that certain third parties can sometimes proceed as assignees of the sovereign's claims when it is injured. But Louisiana is not proceeding here as an assignee; it is alleging its *own* injury. And Louisiana identifies no authority extending those public-rights principles to say that states *categorically* have standing to challenge any federal policy that allegedly makes a downstream violation of a state law more likely.

[3] Louisiana law excludes from its definition of "abortion" procedures necessary to prevent a patient's death (or substantial risk of death), to prevent the serious, permanent impairment of a life-sustaining organ, or to terminate certain "medically futile" pregnancies. La. Rev. Stat. Ann. § 14:87.1(1)(b); *see id.* § 40:1061(F).

b. At most, then, Louisiana claims that FDA's decisions about how to regulate third parties make state enforcement more difficult—its second theory of sovereign harm. Br. 47-52. Article III does not recognize sovereign injury that allows a state into federal court every time a federal policy increases the practical burdens of enforcing state law. *See Texas*, 599 U.S. at 680 n.3. The motions panel reached a contrary preliminary conclusion. ROA.9140-9142. But respectfully, the Supreme Court's warnings against overly capacious views of state standing apply to both Louisiana's sovereign interest theories and to its economic ones. *See* section I.A.2, *supra*. Because "federal policies frequently generate indirect effects on state revenues or state spending," *Texas*, 599 U.S. at 680 n.3, under Louisiana's theory, "virtually every" state would have "standing to challenge virtually every government action that they do not like—an approach to standing that th[e] [Supreme] Court has consistently rejected as flatly inconsistent with Article III," *Alliance*, 602 U.S. at 392.

As with Louisiana's economic theory, any asserted burden on State enforcement efforts depends on a chain of independent third-party choices: out-of-state medical professionals decide to prescribe mifepristone; patients decide to seek it; and pharmacies or mail-order providers decide to dispense it. That is not federal interference with state law. It is, at most, the kind of attenuated downstream effect of federal regulation that the Supreme Court rejected in *Texas*. The Court there

rebuffed a theory that allegations of insufficient federal regulatory stringency—and incidental State burdens that follow—can support standing. *Texas*, 599 U.S. at 681. Reversing the district court's finding of State standing based on evidence that a federal immigration policy led to individuals "committing[] more crimes in Texas," *Texas v. United States*, 606 F. Supp. 3d 437, 467 (S.D. Tex. 2022), the Supreme Court explained that "none of the various theories of standing asserted by the States … overcomes the fundamental Article III problem with this lawsuit," 599 U.S. at 680 n.3. Otherwise, States could invoke Article III whenever a federal policy allegedly increases unlawful conduct or makes state enforcement more resource-intensive, inviting the federal courts down an "uncharted path" that the Supreme Court in *Texas* refused to take. *Id.* at 681. The Ninth Circuit applied *Texas* to reject the very same theory that FDA's safety-and-access conditions on mifepristone cause sovereign injury to states. *Washington*, 108 F.4th at 1177. Louisiana cannot distinguish its theory from what the Ninth Circuit rejected in an identical factual context.

c. The "lack of historical precedent" for Louisiana's standing theory, made plain by the absence of any on-point case law supporting its argument, is another "telling indication of the severe constitutional problem." *Texas*, 599 U.S. at 677 (citation omitted). As the Supreme Court explained in *Alliance*, "the standing requirement means that the federal courts decide some contested legal questions later

rather than sooner, thereby allowing issues to percolate and potentially be resolved by the political branches in the democratic process." 602 U.S. at 380. "And the standing requirement means that the federal courts may never need to decide some contested legal questions: 'Our system of government leaves many crucial decisions to the political processes,' where democratic debate can occur and a wide variety of interests and views can be weighed." *Id.* (citation omitted). The contrary approach Louisiana demands would unleash precisely the kind of the "government by lawsuit" that the district court rightly rejected. ROA.9116 (quoting *Texas*, 599 U.S. at 704 (Gorsuch, J., concurring)).

Louisiana remains free to attempt to enforce its laws against those who violate them. It also remains free to file a citizen petition arguing the existing REMS are insufficiently safe, or it could even join other states applying political pressure on HHS leadership to revisit the REMS. *See* ROA.2201 (HHS and FDA letter responding to request from state Attorneys General for reconsideration of the REMS). But Article III does not permit Louisiana to transform the practical difficulty of enforcing state law against independent actors—particularly actors outside its borders and protected by other States' laws—into a sovereign injury supporting an action against FDA. To hold otherwise would validate a "boundless theory of standing—in which all peripheral costs imposed on States by actions of the [executive branch] create a cognizable Article III injury"—that Chief Judge

Jeffrey Sutton has warned "'would make a mockery … of the constitutional requirement of case or controversy.'" *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) (quoting Alexander Bickel, *The Voting Rights Cases*, 1966 Sup. Ct. Rev. 79, 89-90 (1966)). In our federal system, the national and state governments each act directly on the people "within their respective spheres." *Printz v. United States*, 521 U.S. 898, 920 (1997) (citation omitted). That structure is incompatible with treating every downstream effect of federal regulation—repackaged as a violation of state law—as a judicially cognizable injury to state sovereignty.

4. The Relief Louisiana Seeks Would Not Redress Its Asserted Injuries

Lastly, Louisiana lacks standing because the relief it seeks would not redress its claimed injuries. Reimposing the requirement that mifepristone be dispensed only in person at a clinic or hospital would not make any third party comply with Louisiana law or resolve Louisiana's disputes with other States' shield laws. It would simply replace one dispensing condition applicable to regulated third parties with another. Louisiana's injury, by its own account, comes not from FDA, but from "the act of mailing mifepristone into Louisiana." Br. 44. If Louisiana's theory is that those third parties would predictably change their conduct if the federal REMS changed, that only underscores the attenuated nature of the claim: Louisiana's sovereign-injury theory depends on speculation about how independent actors not

before the Court will respond to interim relief, not on any legal constraint FDA has imposed on Louisiana. Article III requires more.

B. Plaintiffs Fail to Satisfy Other Threshold Requirements for Judicial Review

Standing is not Plaintiffs' only threshold problem. Louisiana also bypassed the administrative process FDA regulations require and now seeks judicial intervention while FDA is actively reviewing the very REMS Louisiana challenges. Plaintiffs offer no sound reason why they may skip the agency process that binds other stakeholders, or why this Court should intervene before FDA has completed the scientific and regulatory review Congress assigned to it.

1. Plaintiffs' Challenge Is Unexhausted

FDA regulations generally require parties to pursue the administrative remedy of a citizen petition to 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) (quoting 21 C.F.R. § 10.25(b)). Courts strictly enforce those requirements because exhaustion gives the agency an opportunity to bring its expertise to bear, creates a record for judicial review, and prevents litigants from circumventing agency procedures. *See Gulf Restoration Network v. Salazar*, 683 F.3d 158, 175 (5th Cir.

2012); *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 here. Plaintiffs challenge FDA's science-driven judgment about what conditions are necessary to ensure the safe use of mifepristone while avoiding undue burdens on patient access and minimizing burdens on the healthcare system. *See* 21 U.S.C. § 355-1(f)(2). That inquiry requires precisely the kind of technical, record-based assessment Congress entrusted to FDA—not an emergency judicial override in the first instance. "[C]ourts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'" *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring in grant of application for stay) (quoting *S. Bay United Pentecostal Church v. Newsom*, 590 U.S. 965, 967 (2020) (Roberts, C.J., concurring)).

Neither Louisiana nor Ms. Markezich 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. §§ 10.25(b), 10.45(b). Plaintiffs offer no reason they should be exempt from FDA rules binding every other stakeholder, and none exists. Meanwhile, other parties (including GenBioPro) have followed FDA's rules, submitting a host of petitions seeking a variety of actions from FDA related to

mifepristone. *See* ROA.2907 (GenBioPro citizen petition); *see also* ROA.2721 (listing citizen petitions).

Nor can Plaintiffs show futility. The motions panel reached a contrary preliminary conclusion, ROA.9139, but FDA is actively reviewing the REMS alongside the many citizen petitions raising identical issues. That was not the case during the *Alliance* litigation. As FDA has explained to this Court, that review "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." Doc. 160 at 8. That is the opposite of futility; it is the reason exhaustion matters. Alleged agency delay in resolving *others'* petitions cannot establish "administrative abuse," as Plaintiffs claimed below, ROA.5722. Nor is there any indication that a decision by FDA would "certain[ly]" be adverse, in light of FDA's ongoing review of the REMS. *Tesoro Refining & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009) (futility requires "certainty of an adverse decision" (citation omitted)). And Plaintiffs' years-long delay, combined with FDA's authority to address exigent public health concerns that might arise in the midst of its ongoing review, *see* ROA.8999, defeats any claim of irreparable harm. Plaintiffs' impatience does not grant them a license to bypass the agency's mandatory administrative review process.

2. Plaintiffs' Challenge Is Unripe

For similar reasons, Plaintiffs' challenge is not ripe for judicial review. Ripeness doctrine prevents courts from resolving disputes that would benefit from further factual development or that rest on contingent future events. "A claim is not ripe for adjudication if it rests upon '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) (citation omitted). Courts find claims unripe, for example, when "[f]urther factual development … would enhance th[e] case's fitness for judicial review." *Miss. State Democratic Party v. Barbour*, 529 F.3d 538, 547 (5th Cir. 2008).

That is this case. FDA is actively reviewing the mifepristone REMS and considering whether any modification is warranted. That review involves "scientific and medical judgments committed by Congress" to FDA, "an agency ultimately accountable to the President." ROA.9112-9113. 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).

FDA has made the same point. In opposing Plaintiffs' motion for a stay of the 2023 REMS in this Court, FDA explained that "the relief plaintiffs seek … would disrupt FDA's ongoing review." Doc. 74 at 3. FDA further explained that the

district court "reasonably determined that it would be imprudent" to adjudicate Plaintiffs' claims "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." *Id.* at 14.

Plaintiffs offer no grounds for short-circuiting the FDA's administrative process—indeed, they fail to address ripeness at all. FDA should be permitted to finish the work Congress assigned to it.

C. Plaintiffs' Claims Are Meritless

FDA reasonably determined that mifepristone—like the vast majority of prescription drugs—could be safely dispensed without requiring an in-person visit. That determination rested on substantial scientific evidence, real-world experience, and the agency's expert judgment. It also faithfully implemented Congress's directives that REMS elements must "not be unduly burdensome on patient access to the drug," and, "to the extent practicable," must "minimize the burden on the health care delivery system." 21 U.S.C. § 355-1(f)(2).

Louisiana does not show that FDA ignored the statutory REMS criteria or failed to provide a reasoned safety-and-access judgment. Instead, Louisiana faults FDA for not satisfying heightened evidentiary demands the APA does not require and treats FDA's ongoing review as a concession of error. The motions panel made the same preliminary conclusion. ROA.9148. But none of Louisiana's theories

establishes that the 2023 REMS is arbitrary and capricious. And even as FDA opted to reconsider the 2023 REMS, FDA assured the public at the outset of that process that mifepristone remains "safe when used as indicated and directed and consistent with the Mifepristone [REMS] Program." FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, https://bit.ly/44NH2U1 (last updated Apr. 8, 2026).

1. The 2023 REMS Reflects FDA's Lawful and Reasoned Scientific Judgment

Mifepristone is safe, effective, and exceptionally well studied. FDA has regulated the drug for more than twenty-five years, continually monitored its safety, and repeatedly concluded that its risks are exceedingly rare. Consistent with its statutory mandate not to "unduly burden[]" patient access while ensuring patient safety, 21 U.S.C. § 355-1(f)(2)(C), in 2021, FDA removed a single access burden: the requirement that the drug be *dispensed* in person.

FDA formalized its 2021 decision in the 2023 REMS, after reasonably concluding—based on decades of experience, more than five years of adverse-event data, REMS assessments, and published studies of mail and pharmacy dispensing—that the in-clinic dispensing requirement was no longer necessary to ensure safe use. ROA.1025; ROA.1044. But FDA did not eliminate the REMS framework or leave distribution unregulated. It replaced the in-clinic dispensing requirement with a pharmacy-certification requirement, while preserving the REMS's other core

safeguards, including prescriber certification and the Patient Agreement Form. *See, e.g.*, ROA.333. That measured approach reduced an unnecessary patient-access burden while maintaining controls designed to ensure safe use.

The APA requires only reasoned decisionmaking, not scientific certainty beyond a shadow of a doubt. *See FCC v. Prometheus Radio Project*, 592 U.S. 414, 423, 427 (2021). And neither the FDCA nor the FDAAA directs FDA to preserve REMS restrictions unless and until every conceivable uncertainty and risk has been studied and eliminated. Louisiana's contrary argument relies on general drug-approval provisions, Br. 58-59 (citing 21 U.S.C. § 355(d) and 21 C.F.R § 314.71), not the REMS-specific framework Congress enacted. That framework directs FDA to ensure that REMS elements are necessary, commensurate with the drug's risks, not "unduly burdensome on patient access," and minimally burdensome on the healthcare system. 21 U.S.C. § 355-1(f)(2)(C)–(D). FDA's application of those factors in adopting the 2023 REMS easily satisfies the APA's standards. *See Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 923 (D.C. Cir. 2013) (Kavanaugh, J.) ("[C]ourts must be careful not to unduly second-guess [FDA's] scientific judgments.").

a. Louisiana identifies no scientific evidence that FDA failed to consider—no clinical trials, adverse event reports, post-approval studies, peer-reviewed literature, or other relevant data. Louisiana instead challenges FDA's consideration

of FAERS data. That argument rests on both a false premise and an unduly demanding view of APA review.

Contrary to Louisiana's assertions and the motions panel's analysis, ROA.9144, FDA did not give "dispositive weight" to the number of adverse-event reports in FAERS. Br. 54. It considered FAERS for what FDA says it is: an adverse event monitoring system containing data drawn from adverse-event reports submitted to FDA and used to identify emergency safety concerns and trends. *See* FDA, *FDA Adverse Event Monitoring System (AEMS) Public Dashboard*, https://bit.ly/4youPTu (last visited July 15, 2026).[4] FDA compared FAERS data from periods when the in-clinic dispensing requirement was in effect with periods when it was not, and considered that evidence alongside REMS assessments, sponsor submissions, published literature, postmarketing experience, and other real-world evidence. ROA.1024-1027. That is not arbitrary decisionmaking. It is exactly how FDA is supposed to evaluate postmarketing safety information.

Louisiana's attempt to distinguish "adverse event reports" from "FAERS data," Br. 57, is a non sequitur: as the words that make up the acronym make clear, FAERS is a collection of adverse event reports. And contrary to Louisiana's suggestion, Br. 56-57, nothing in the REMS statute makes adverse-event data a one-

[4] FDA has now replaced FAERS with the FDA Adverse Event Monitoring System (AEMS). FDA, *FDA Launches New Adverse Event Look-Up Tool* (Mar. 11, 2026), https://bit.ly/4f51A0t.

way ratchet that FDA may consider only to impose restrictions, but not to modify or remove them. FDA must determine whether REMS elements remain necessary to ensure that a drug's benefits outweigh its risks, while minimizing burdens. 21 U.S.C. § 355-1(f)(2)(C)–(D), (g), (h). The absence of a safety signal in FAERS is directly relevant to that safety-and-access judgment—not because FAERS establishes the rates of adverse events caused by the drug, given that the reports do not incorporate any kind of causation analysis, *see* 21 C.F.R. § 314.80(a)—but because the data helps FDA assess whether known or potential risks warrant continued regulatory burdens.

The APA question is not whether FAERS alone could establish rates of adverse events. It cannot, and FDA understood that. The question is whether FDA could consider FAERS for its ordinary safety-signal function as part of a broader predictive scientific judgment. Agencies may make "reasonable predictive judgment[s]" from the evidence before them. *Prometheus Radio*, 592 U.S. at 427. The APA does not demand "perfect empirical or statistical data." *Id.* It is not enough to disagree with FDA's weighing of the evidence. A court may set aside agency action only if the agency failed to consider an important aspect of the problem, relied on impermissible factors, contradicted the evidence before it, or failed to draw a rational connection between the facts found and the choice made. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). And when

an agency makes a "scientific determination" based on a prediction "within its area of special expertise," "a reviewing court must generally be at its most deferential." *Baltimore Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983); *see also Cytori Therapeutics*, 715 F.3d at 923 (similar).

Louisiana is wrong that FDA "eliminate[d]" adverse-event reporting in 2016. Br. 31. Manufacturers remain subject to mandatory adverse-event reporting obligations, 21 C.F.R. § 314.80(b)-(c), and mifepristone retains a fatality-reporting requirement that is "more stringent than the requirements for most other drugs," *Alliance*, 602 U.S. at 376. FDA's 2016 change to the FAERS procedures for mifepristone simply brought the regime for mifepristone closer in line with the protocol applicable to *virtually all other prescription drugs*, including many drugs with a REMS and *hundreds* of drugs with boxed warnings, under which prescribers are permitted (but not required) to report non-fatal adverse events. *See* ROA.413, ROA.415. Louisiana's suggestion that mifepristone's treatment is extraordinary is simply wrong. *See* Br. 55-56.

Nor is FAERS data unreliable simply because prescribers are not required to report non-fatal adverse events. Most drugs have no such reporting requirement. *See Alliance*, 602 U.S. at 376. As FDA explained in 2016, "serious adverse events other than deaths" for mifepristone would continue to reach FAERS through manufacturers' "periodic safety update reports and annual reports," ROA.415,

because manufacturers of all drugs are required to report all adverse-event reports that they receive, which encompass a variety of different sources other than physician reports. *See* 21 C.F.R. § 314.80(b)-(c). If Louisiana's critique were accepted, FDA could not rely on FAERS as it usually does for most approved drugs. That would upend the postmarketing safety system Congress and FDA have developed over decades.

b. Louisiana's attack on FDA's review of the published literature fails for the same reason as its FAERS argument: it isolates acknowledged limitations in materials FDA reviewed and then demands a level of certainty the APA does not require. It treats FDA's recognition that the studies were one part of the agency's broader evidentiary assessment as a supposed concession. But that argument would impose a new *mifepristone-specific* evidentiary rule that applies to no other drugs: that FDA may only rely on literature that "affirmatively support[s] its position," Br. 57-58 (citing ROA.1093), and only if those studies independently and conclusively establish the safety of the precise dispensing model at issue.

The APA contains no such requirement; nor does the FDAAA. Agencies may rely on multiple imperfect sources of evidence, acknowledge limitations in each, and still make a reasoned predictive judgment based on the record as a whole. *See Prometheus*, 592 U.S. at 427. Indeed, even under substantial-evidence review, "the possibility of drawing two inconsistent conclusions from the evidence does not

prevent an administrative agency's finding from being supported by substantial evidence." *Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 620 (1966). That principle applies with particular force where FDA is weighing scientific literature because FDA "possesses the requisite know-how" to "weigh each conflicting study," *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996), and its "judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from [courts]," *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995).

Louisiana identifies no study showing that distributing mifepristone through means other than in-person dispensing at a hospital or clinic increases serious adverse events. FDA reviewed 15 studies addressing alternative dispensing models, including mail, courier, partner-entity, and pharmacy dispensing, involving over 55,000 patients. ROA.1027-1043. 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. ROA.1025. The largest study—involving patients in the United Kingdom—found "no significant differences in the rates of reported [serious adverse events]" between patients who received mifepristone by mail or picked it up at a clinic after a telemedicine visit, on the one hand, and those who received it in-person after a clinic visit, on the other. ROA.1035-1036. And four studies evaluating post-telemedicine dispensing by mail

in the United States showed "no increased frequency of [serious adverse events]," supporting the "conclusion that dispensing by mail is safe." ROA.1042. FDA thus explained that the studies it examined "generally support a conclusion that dispensing by mail is safe" and "there was no increased frequency of" serious adverse events. ROA.1042.

Louisiana does not show that those 15 studies, considered collectively with the rest of the record, failed to support FDA's judgment. Instead, Louisiana discusses claimed limitations in only a handful of studies, focusing principally on individual studies reflecting more frequent urgent-care or emergency-department visits among some patients using non-in-clinic dispensing. Br. 59-60. But those visits are not the same thing as a serious adverse event. Studies show that patients may seek emergency or urgent care to confirm pregnancy termination, obtain treatment for expected symptoms such as cramping or bleeding, ask questions, obtain reassurance, or because they lack convenient access to another provider—especially in rural or underserved areas. ROA.4597-4605; *see also* ROA.4565-4572; ROA.4554-4664. FDA explicitly acknowledged that these visits frequently do not involve any serious adverse event or even require any medical treatment. *See* ROA.379 ("half of the ED/urgent care visits did not entail any medical treatment.").

Louisiana's reliance (at 56) on mifepristone's labeling does not change that point. Although the "Black Box" label reflects that some patients may visit an

emergency room, that statistic does not correspond to serious adverse events, which the same label indicates occur at a far lower rate. ROA.335. FDA reasonably distinguished emergency room visits from safety outcomes and found that the evidence did not show that mail or pharmacy dispensing increased serious adverse events. ROA.1042.

Nor does FDA's acknowledgment of study limitations help Louisiana. *See* Br. 58. That acknowledgment exemplifies objective, reasoned scientific decisionmaking. FDA did not claim that any single study was perfect or dispositive. It evaluated the literature together with adverse-event data, REMS assessments, sponsor submissions, and decades of postmarketing experience. Louisiana isolates FDA's statement that the literature was "not inconsistent with" its conclusion and treats that cautious scientific formulation as a concession that the evidence did not support the 2023 REMS. Br. 58. But the surrounding analysis shows the opposite: FDA reviewed the studies, acknowledged their limits, weighed them collectively with the rest of the record, and reasonably concluded that mifepristone would remain safe and effective without the in-clinic dispensing requirement. *See* ROA.1078-1095.

That is reasoned decisionmaking supporting 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). Louisiana claims that FDA inadequately justified its change in approach to in-person dispensing, Br. 53-54, 61-62, but FDA explained the scientific and practical basis for its decision in voluminous detail. ROA.1064-1066, ROA.1073-1095. The APA requires nothing more. *See, e.g.*, *Shenzhen IVPS Tech. Co., Ltd. v. FDA*, 148 F.4th 306, 316 (5th Cir. 2025) (agencies need only "acknowledge the change in position and offer good reasons for the change").

2. The 2023 REMS Does Not Violate the Comstock Act

Plaintiffs are also wrong that the 2023 REMS is contrary to the Comstock Act, 18 U.S.C. §§ 1461, 1462. The threshold point is straightforward: FDA does not ship mifepristone at all, let alone risk implicating the Act by knowingly shipping it for the purpose of illegal abortions. There is no plausible theory that by adopting the 2023 REMS, FDA somehow engaged in illegal shipping. Nor does the REMS compel or authorize anyone else to violate the Act. FDA's remit under the FDAAA is narrow and technical: to determine whether various conditions, including the requirement of in-person dispensing, are appropriate in light of the dual criteria of "assur[ing] safe use" while "not be[ing] unduly burdensome on patient access." 21 U.S.C. § 355-1(f). In the 2023 REMS, FDA determined, based on overwhelming data, that maintaining the in-person dispensing requirement was unnecessary for safe

use and would impede patient access. FDA's scientific judgment based on its evaluation of those criteria neither required, nor purported to permit, anyone to knowingly ship mifepristone for the purpose of illegal abortions.

Moreover, while the Act restricts shipping of items "intended for producing abortion," 18 U.S.C. §§ 1461, 1462, it has long been construed as applicable only to knowingly shipping such items for the purpose of illegal abortions, *see United States v. One Package*, 86 F.2d 737, 739-40 (2d Cir. 1936); *Youngs Rubber Corp. v. C.I. Lee & Co.*, 45 F.2d 103, 108 (2d Cir. 1930); *Davis v. United States*, 62 F.2d 473, 475 (6th Cir. 1933); *Application of the Comstock Act to the Mailing of Prescription Drugs that Can Be Used for Abortions*, 46 Op. O.L.C. __ (Dec. 23, 2022), https://www.justice.gov/olc/opinion/file/1560596/dl ("OLC Opinion"). By repeatedly amending the statute against that judicial backdrop without changing it to reject that construction, Congress has ratified that interpretation. *See* OLC Opinion, *supra*, at 13-15; *Tex. Dep't of Hous. & Cmty. Affairs v. Inclusive Cmtys. Project*, 576 U.S. 519, 536 (2015).

D. FDA's Ongoing Review Does Not Justify Suspension of the Operative REMS

Louisiana erroneously claims, echoing the motions panel, ROA.9148, that FDA conceded the 2023 REMS is unlawful in a September 2025 letter from the HHS Secretary and FDA Commissioner. Br. 62. That letter stated that FDA's "prior REMS approvals" "lack[ed] adequate consideration" and indicated that FDA would

"conduct a study of the safety of the current REMS, in order to determine whether modifications are necessary." ROA.2201. But the letter did not withdraw FDA's prior determination, identify any specific defect in the 2023 REMS, explain how FDA's prior reasoning was inadequate, assert that mail or pharmacy dispensing is unsafe, or suggest that the ultimate predictive judgment reflected in the 2023 REMS—that mifepristone could be safely used when prescribed and distributed remotely—was incorrect. That is not a rescission, and it is not a concession that the current REMS is unlawful. It merely announced further data collection and review "in order to determine whether modifications are necessary." ROA.2201. That is the very process Congress prescribed for FDA to assess whether a REMS change may be warranted, *see* 21 U.S.C. § 355-1(g)(4), (h).

Louisiana counters that "it makes no sense to deny preliminary relief on the grounds that agency action is so unlawful that the agency openly concedes a review is necessary." Br. 70. To the contrary, that is the *very process Congress statutorily requires*: during the time in which the FDA is considering whether a REMS modification is necessary, the existing REMS "remain[s] in effect." 21 U.S.C. § 355-1(h)(2)(B). And it bears repeating that, as of today, FDA's public position continues to be that mifepristone "is safe when used as indicated and directed and consistent with the Mifepristone [REMS] Program." FDA, *Questions and Answers*

on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, https://bit.ly/44NH2U1.

Indeed, even if the September 2025 letter had confessed error—which it did not—that would not render the 2023 REMS unlawful and void. Of course agencies may change their positions, including on complex scientific matters like drug safety. But they must do so through reasoned decisionmaking. As Louisiana itself argues, Br. 61-62, an agency changing course must "display awareness that it *is* changing position," "provide [a] reasoned explanation," "show that there are good reasons for the new policy," and account for "reliance interests." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). To treat FDA's announcement of intent to reconsider the REMS as an effective invalidation would allow agencies to evade their core administrative law obligations whenever a new Administration takes office. Neither the APA nor any case law supports such an end-run around the processes Congress has prescribed.

The lawfulness of the 2023 REMS can be judged only on "the reasons [FDA] gave when it acted," *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 23-24 (2020), not later characterizations, litigation positions, or the mere announcement of further review. And even if the Court credited those post-decision statements, Louisiana still would not be entitled to the extraordinary relief it seeks. The ordinary remedy would be to remand for FDA to review and address any

deficiency—leaving the existing REMS "in effect," 21 U.S.C. § 355-1(h)(2)(B)—not a universal stay that immediately and summarily overturns a nationwide regulatory regime that has been in place for years. "Even when a court sets aside an unlawful agency action under the APA, it is ordinarily 'the prerogative of the agency to decide in the first instance how best to provide relief.'" *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 959 F.3d 1113, 1118 (D.C. Cir. 2020) (quoting *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013)).

"These principles apply with no less force when an agency voluntarily abandons its own action." *Id.* When that happens, courts routinely remand without vacatur to allow the agency to bring its expertise to bear. *See, e.g.*, *Clean Wis. v. EPA*, 964 F.3d 1145, 1175-76 (D.C. Cir. 2020); *Limnia, Inc. v. U.S. Dep't of Energy*, 857 F.3d 379, 386-87 (D.C. Cir. 2017). And remand without vacatur is virtually always best when "the disruptive consequences of vacating are substantial." *Apache Corp. v. FERC*, 627 F.3d 1220, 1223 (D.C. Cir. 2010) (Kavanaugh, J.) (quoting *Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993)).

Here, FDA is already doing what remand would require: determining whether a reasoned modification is warranted and supported under the statute. If FDA ultimately determines that changes to the mifepristone REMS are necessary, it must make that determination through reasoned and lawful decisionmaking grounded in

the required statutory criteria and the record before it. *See* ROA.9001-9002 (FDA's acknowledgment of the mandatory agency procedures and the process due to drug sponsors if the agency determines the REMS must be modified). Until then, the mere announcement of further review provides no basis for Louisiana's claims and no justification for judicially suspending the operative REMS nationwide.

E. The Equities and Public Interest Preclude Louisiana's Request

Staying the 2023 REMS would override coequal sovereigns' interests, disserve the public interest, and irreparably harm GenBioPro. And it would do so through interim relief that upends a settled status quo. FDA has not enforced the in-clinic dispensing requirement for more than five years, and the 2023 REMS has governed for more than three. Louisiana could have sued at any point during that period. Against that backdrop, there is no equitable reason to impose a sweeping nationwide disruption now—before final judgment—rather than wait for FDA to complete its ongoing review.

1. Interim Relief Would Immediately and Irreparably Harm GenBioPro

GenBioPro would be unavoidably and irreparably harmed by a stay of the 2023 REMS. Contrary to Louisiana's claims otherwise, Br. 63-64, and the motions panel's preliminary analysis, ROA.9147, GenBioPro's unrebutted evidence demonstrates that a stay would risk far more than lost sales. Mifepristone accounts for the majority of GenBioPro's revenue, and pharmacy distribution makes up a

substantial portion of that revenue—losses that cannot be recovered if the order is later vacated. ROA.2852. A stay would also force GenBioPro, on an emergency basis, to unwind the pharmacy-distribution framework that took months to build in reliance on the 2023 REMS, and disrupt existing supply and distribution channels—only to incur still more unrecoverable costs if a stay is later lifted, modified, vacated, or reversed. ROA.2852-2854. Louisiana nowhere grapples with these concrete and unrecoverable financial, operational, and compliance harms.

Suspending the 2023 REMS would also create immediate regulatory uncertainty: about whether GenBioPro, pharmacies, and providers may continue selling and dispensing existing product under their current REMS agreements; whether REMS documents and labeling must be changed; and whether already-manufactured inventory must be relabeled. ROA.2853-2854. In fact, as FDA previously represented, relief could potentially halt distribution of mifepristone entirely, *see* ROA.4920-4926. At minimum, an order that purports to disable the operative 2023 regulatory regime on an interim basis—without identifying what REMS, labeling, Patient Agreement, pharmacy certification, or dispensing infrastructure that governs in its place—would bring regulatory chaos for manufacturers, prescribers, and patients who lawfully receive this medication every day.

Louisiana makes no showing of harm to itself that could outweigh the chaos threatened by the relief it seeks. Louisiana argues that the public-interest factor is settled by the proposition that "neither the FDA nor the public has any interest in enforcing a regulation that violates federal law." Br. 69 (citation omitted). But whether the 2023 REMS "violates federal law" is precisely the merits question presented in this case. Louisiana's circular logic is not enough to justify the nationwide disruption—especially on an interim basis—to patients, providers, manufacturers, pharmacies, FDA's ongoing review, and the sovereign interests of States that have made different lawful choices. 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).

2. The Public Interest Precludes Interim Relief

Louisiana likewise discounts the broader policy harms of the relief it seeks, which are grave, immediate, and nationwide. A stay would eliminate access to mifepristone by mail and through certified pharmacies across the country—including in States that oppose Louisiana's requested relief and have made different policy choices about patient access to reproductive healthcare. *Dobbs v. Jackson Women's Health Organization* returned abortion policy to "the people and their elected representatives," 597 U.S. 215, 292 (2022); it did not empower one State to

impose its policy judgments on its coequal sovereigns nationwide. It is no answer, as Louisiana now claims, that mailed mifepristone accounts for a smaller percentage of abortion "in states like New York and California" than in Louisiana. Br. 64. That is simply a concession that millions of Americans outside Louisiana's borders would be harmed by the nationwide effect of the relief it seeks to impose on them.

The FDCA requires FDA to ensure that a REMS is not "unduly burdensome on patient access to the drug." 21 U.S.C. § 355-1(f)(2)(C). But Louisiana asks this Court to impose those burdens itself—without the administrative record, without the scientific expertise, and before FDA completes its ongoing review. That kind of judicial override impairs FDA's ability to use its expertise to carry out its statutory mandates and undermines the integrity of the drug-approval and distribution process as a whole.[5]

[5] That judicial override is especially improper because Louisiana seeks it under 5 U.S.C. § 705, which is a status-preserving tool, not a mechanism for undoing years-old agency action. That statute authorizes courts to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of [judicial] review." To "postpone" means to "defer," "put off," or "delay." *See Postpone*, *Black's Law Dictionary* 1389 (3d ed. 1933). The 2023 REMS has been in effect for years; it cannot sensibly be "postpone[d]." Nor would relief "preserve" the status quo; it would upend it. *Preserve*, Webster's New International Dictionary 1699 (1st ed. rev. 1927) ("[t]o keep or save from injury or destruction," "to guard or defend from evil," "to protect," "[t]o maintain" or "to retain"). As for Plaintiffs' alternative request for traditional injunctive relief, 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. *Louisiana v. Becerra*, 20 F.4th 260, 263-64 (5th Cir. 2021).

3. Louisiana Faces No Irreparable Harm

On the other side of the scale, Louisiana's delay in seeking relief belies any claim that it will be irreparably harmed if the 2023 REMS remains in place. Louisiana waited nearly three years after FDA adopted the 2023 REMS, more than five years after FDA first stopped enforcing the in-person dispensing requirement, more than a year and a half after the Supreme Court rejected the *Alliance* plaintiffs' suit, and 72 more days after filing this action before seeking preliminary relief. A party seeking such relief "must generally show reasonable diligence." *Benisek v. Lamone*, 585 U.S. 155, 159 (2018). Louisiana did not. That delay is powerful evidence that any asserted harm is not so immediate as to justify *emergency* relief—much less relief that suspends a nationwide FDA regime, disrupts settled reliance interests, and inflicts irreparable harm on GenBioPro, patients, providers, and the public.

Louisiana's extra-record press accounts and expert-report-style affidavits fail to substantiate its supposed harm or explain its delay. Br. 67-68 (citing record materials and allegations in the complaint). Louisiana's isolation in seeking immediate relief underscores that the equities favor preserving the status quo. Even among the six States currently challenging the mifepristone REMS based on identical assertions of injury, Louisiana alone seeks a nationwide stay on an

emergency basis.[6] Louisiana therefore gets the equities backwards, as did the motions panel, ROA.9146-9148: the only concrete and imminent harms presented here would flow from granting a stay. The balance of harms and the public interest overwhelmingly favor preserving the longstanding status quo.

4. The District Court Properly Evaluated the Equities and Public Interest

The district court acted well "within [its] sound discretion," *Benisek*, 585 U.S. at 161, in weighing each of 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. ROA.9113-9118. 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.

[6] In addition to Louisiana, Florida, Texas, Missouri, Idaho, and Kansas have all sued FDA challenging the mifepristone REMS. None of them have sought any form of interim relief. In fact, Florida and Texas consented to a seven-month stay of their case while the FDA reviews the REMS – similar to the district court's order in this case. *See* Pls.' Resp. to Mot. to Stay or Dismiss at 6, *Florida v. FDA*, No. 7:25-cv-00126-O (N.D. Tex. Apr. 24, 2026), ECF No. 56.

ROA.9113, ROA.9118. 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. ROA.9113. GenBioPro, however, has no similarly ready means to alleviate the damage that a stay of the REMS would cause.

Plaintiffs do not meaningfully engage with the district court's balancing of harms, let alone show it to be an abuse of discretion. Instead, Plaintiffs—like the motions panel—focus on three isolated pieces of the court's analysis. Respectfully, none undermines the district court's sound judgment about the balance of harms.

First, Plaintiffs fault the district court for declining to "adjudicate moral and scientific disputes." Br. 70; *see* ROA.9111-9112; ROA.9147. But the district court did not decline Plaintiffs' request because of some abstract fear of moral or scientific controversy. Rather, the court sensibly recognized that this case concerns issues "committed by Congress" to FDA in the first instance, ROA.9112, 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 challenge the district court's apprehension about interim judicial relief interfering with FDA's ongoing review of the mifepristone REMS, echoing the motions panel's assertion that a stay would not prevent FDA from completing its procedures. Br. 70 (quoting ROA.9148). But Plaintiffs do not substantiate that claim, and it goes without saying that FDA's data-collection activities would be disrupted by a sudden, externally imposed change in the regulatory regime governing mifepristone's distribution. At minimum, as FDA explained in opposing expedition of this appeal, it would be "imprudent" for the Court to examine FDA's past scientific and medical judgments "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." Doc. 160 at 8.

Third, Plaintiffs repeat the motions panel's rejection of concerns the district court voiced about "the possibility of conflicting judicial outcomes." Br. 70-71 (quoting ROA.9149). 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. *Louisiana v. Becerra*, 20 F.4th 260, 263 (5th Cir. 2021). That concern is especially acute here, where Louisiana seeks relief affecting nationwide access to a medication in States that oppose its requested remedy. 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.

II. THE DISTRICT COURT SHOULD HAVE DISMISSED THE COMPLAINT

The district court erred in denying GenBioPro's motion to dismiss Plaintiffs' complaint. ROA.9087. GenBioPro appealed that denial to ensure that, if this Court concludes that Louisiana lacks standing and rejects its appeal on that basis, the Court also can direct the remedy that necessarily follows from that conclusion: dismissal of the complaint. After all, "Article III standing is a jurisdictional requirement," *N.A.A.C.P. v. City of Kyle*, 626 F.3d 233, 237 (5th Cir. 2010), and "[w]ithout jurisdiction the court cannot proceed at all in any cause," *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) (citation omitted). Rather, when standing is lacking, "the only function remaining to the court is that of announcing the fact and dismissing the cause." *Id.* (citation omitted).

This Court has appellate jurisdiction to review the motion-to-dismiss denial because the issue of standing is "inextricably intertwined with" the ruling "challenged on appeal," giving this Court "jurisdiction to address those issues." *Jiao*, 28 F.4th at 596. Specifically, in both its opposition to Louisiana's request for preliminary relief and its motion to dismiss, GenBioPro asserted that Louisiana lacked standing—and that its challenge was unexhausted, unripe, and failed to allege

any violation of the Comstock Act. ROA.6833-6855, ROA.8957-8959. The substance of these issues is identical in both contexts; resolving one as it pertains to preliminary relief would resolve the issue as it pertains to dismissal. This Court therefore has pendent appellate jurisdiction to decide the standing question and, if it rules in GenBioPro's favor, to direct dismissal. *See Jiao*, 28 F.4th at 596.

As explained in section I.A, *supra*, Louisiana lacks standing. The 2023 REMS does not regulate Louisiana, compel it to act, or prevent it from enforcing its own laws; Louisiana therefore must establish standing through the downstream effects of FDA's regulation of third parties. *Supra* pp. 20-24. But those asserted effects depend on a highly attenuated chain of choices by out-of-state prescribers, pharmacies, patients, medical providers, and other sovereign States—the very kind of indirect and speculative causation the Supreme Court rejected in *Alliance* and *Texas*. Louisiana's reliance on two Medicaid expenditures over several years cannot establish that FDA's challenged dispensing conditions caused those costs. *Supra* pp. 25-33. Its sovereign-injury theory fares no better because practical difficulty enforcing state law against independent actors is not federal interference with Louisiana's sovereign authority. *Supra* pp. 33-38. Accepting Louisiana's theories would allow States to challenge virtually any federal policy that produces some downstream effect on state spending or enforcement priorities.

Because Louisiana "lacks standing to maintain this suit," this Court should remand "with instructions … that the complaint be dismissed." *Steel Co.*, 523 U.S. at 109-10.

CONCLUSION

The Court should affirm the district court's denial of interim relief and remand this case with instructions to dismiss.

Dated: July 15, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that the foregoing brief has been served via the Court's CM/ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure, on July 15, 2026, on all registered counsel of record, and has been transmitted to the Clerk of the Court.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this principal and response brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 28.1(e)(2)(B) and Fifth Circuit Rule 32.2 because it contains 15,292 words, according to the count of Microsoft Word. I further certify that this principal and response brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman, a proportionally spaced font.

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

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