No. 25A___

In the Supreme Court of the United States

GENBIOPRO, INC., APPLICANT,

v.

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL, ET AL.

EMERGENCY APPLICATION TO VACATE STAY PENDING APPEAL AND FOR AN ADMINISTRATIVE STAY

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MAY 2, 2026

PARTIES TO THE PROCEEDING

Applicant GenBioPro, Inc. was Intervenor-Appellee below.

Respondents State of Louisiana, *by & through its Attorney General, Liz Murrill*; Rosalie Markezich were Plaintiffs-Appellants below.

Respondents Food & Drug Administration; Marty Makary, *Commissioner, U.S. Food and Drug Administration*; Richard Pazdur, *in his official capacity as Director, Center for Drug Evaluation & Research, U.S. Food & Drug Administration*; United States Department of Health and Human Services; Robert F. Kennedy, Jr., *Secretary, U.S. Department of Health and Human Services* were Defendants-Appellees below.

Danco Laboratories, L.L.C. was an Intervenor-Appellee below.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, Applicant GenBioPro, Inc. states that its parent company is Xenia Holdco LLC, and that there is no publicly held corporation that owns 10% or more of its stock.

RELATED PROCEEDINGS

U.S. District Court for the Western District of Louisiana (W.D. La.):

Louisiana, et al. v. *U S Food & Drug Administration, et al.*, No. 6:25-cv-01491 (Apr. 7, 2026)

U.S. Court of Appeals for the Fifth Circuit (5th Cir.):

Alliance for Hippocratic Medicine v. *FDA*, No. 23-10362 (Apr. 12, 2023)

Alliance for Hippocratic Medicine v. *FDA*, No. 23-10362 (Aug. 16, 2023)

Alliance for Hippocratic Medicine v. *FDA*, No. 23-10362 (Sept. 16, 2024)

State of Louisiana v. *FDA*, No. 26-30203 (May 1, 2026)

Supreme Court of the United States (U.S.):

Danco Laboratories, LLC v. *Alliance for Hippocratic Medicine*, No. 22A901 (Apr. 21, 2023)

FDA v. *Alliance for Hippocratic Medicine*, No. 22A902 (Apr. 21, 2023)

Danco Laboratories, LLC v. *Alliance for Hippocratic Medicine*, No. 23-236 (June 13, 2024)

FDA v. *Alliance for Hippocratic Medicine*, No. 23-235 (June 13, 2024)

United States Court of Appeals for the Ninth Circuit (9th Cir.):

Washington v. *FDA*, No. 23-35294 (May 1, 2023)

United States District Court for the District of Hawaii (D. Haw.):

Purcell v. *Kennedy*, No. 1:17-cv-00493 (Oct. 30, 2026)

United States District Court for the Eastern District of Missouri (E.D. Mo.):

State of Missouri v. *FDA*, No. 4:25-cv-01580-CMS (Oct. 23, 2025)

United States District Court for the Northern District of Texas (N.D. Tex.):

Alliance for Hippocratic Medicine v. *FDA*, No. 2:22-cv-00223 (Apr. 7, 2023)

Alliance for Hippocratic Medicine v. *FDA*, No. 2:22-cv-00223 (Jan. 16, 2025)

State of Missouri v. *FDA*, No. 2:22-cv-00223 (Sept. 30, 2025) (transferring case to Eastern District of Missouri)

State of Florida v. *FDA*, No. 7:25-cv-00126 (Dec. 9, 2025) (pending challenge to mifepristone's approval, conditions of use, and REMS)

United States District Court for the Western District of Virginia (W.D. Va.):

Whole Woman's Health Alliance v. *FDA*, No. 3:23-cv-00019 (May 8, 2023)

United States District Court for the Eastern District of Washington (E.D. Wash.):

Washington v. *FDA*, No. 1:23-cv-03026 (July 8, 2025)

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TO THE HONORABLE SAMUEL A. ALITO, JR., ASSOCIATE JUSTICE OF THE SUPREME COURT AND CIRCUIT JUSTICE FOR THE FIFTH CIRCUIT

INTRODUCTION

Pursuant to Rule 23 of the Rules of this Court and the All Writs Act, 28 U.S.C. § 1651, GenBioPro, Inc. respectfully requests that this Court vacate the stay pending appeal of the 2023 mifepristone Risk Evaluation and Mitigation Strategy ("REMS") entered by the United States Court of Appeals for the Fifth Circuit (App.1a–18a) under 5 U.S.C. § 705. Vacatur of that order will allow the years-long status quo to remain in force while the Food and Drug Administration ("FDA") completes its ongoing review of the mifepristone REMS. In the alternative, GenBioPro asks the Court to construe this application as a petition for a writ of certiorari before judgment, grant review, and set this case for full briefing and argument. GenBioPro also respectfully requests an immediate administrative stay of the order below to preserve the status quo while the Court considers this application.

This application concerns yet another unprecedented Fifth Circuit order suspending existing, years-old FDA-approved conditions of use for mifepristone—less than two years after this Court unanimously rejected a similar challenge for lack of standing. The order eliminates nationwide access to mifepristone from certified pharmacies and by mail, thereby disrupting a status quo that has been in place for more than five years and upending the reasonable reliance of patients, providers, pharmacies, and drug sponsors across the country. Even among States challenging the REMS, Louisiana is alone in seeking such sweeping preliminary relief. It does so despite twenty States' express support for the current REMS and request that it remain in effect. See Amicus Brief on Behalf of 20 States

Opposing Plaintiffs' Motion for a Stay, D. Ct. Doc. 210. And it seeks that extraordinary relief after years of delay—more than two years after FDA adopted the 2023 REMS and more than five years after FDA first stopped enforcing the in-person dispensing requirement.

The district court, in a sound exercise of discretion, granted a time-limited stay of proceedings to allow FDA to complete its ongoing review of the mifepristone REMS and declined to stay the REMS under 5 U.S.C. § 705 or to issue a preliminary injunction (App.19a–55a). In doing so, the district court declined Louisiana's invitation to engage in "rushed, high-stakes, [and] low-information decision-making" about "whether FDA's in-person dispensing requirement is scientifically necessary to ensure mifepristone is 'safe' and 'effective.'" App.50a–51a (quoting *Trump* v. *CASA*, *Inc.*, 606 U.S. 831, 855–56 (2025) (Gorsuch, J., concurring)). The district court rightly concluded that the equities and public interest "weigh heavily in favor of FDA completing the job that the law requires it to do," App.21a, and declined to engage in "government by lawsuit," *ibid.* (quoting *United States* v. *Texas*, 599 U.S. 670, 704 (2023) (Gorsuch, J., concurring)); see also App.46a–54a.

The Fifth Circuit did not exercise the same restraint. It elected to enter a § 705 stay pending appeal, thereby short-circuiting FDA's active review of the mifepristone REMS, disrupting a years-long status quo, and elevating its own judgment over that of the expert agency charged with—and currently considering—whether "substantive changes to the REMS" are "warranted." C.A. Doc. 74 at 3; FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, tinyurl.com/38m6ea9f. The Fifth Circuit reached that unprecedented result through a

series of fundamental errors that violate black-letter Article III law, administrative law, and equitable principles.

First, the balance of equities alone should have precluded the abrupt and disruptive interim relief granted below. "[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*, 140 S. Ct. 1613, 1614 (2020)). That is especially true where, as here, the Fifth Circuit's order "compel[s] the FDA to alter the regimen for medical abortion" based on the "court's own evaluation" of whether the FDA got the science right. *Ibid.*

The Fifth Circuit's order has unleashed regulatory chaos. If allowed to remain in effect, it would eliminate access to mifepristone through certified pharmacies and by mail, abruptly cutting off access for patients nationwide—including in the States that do not ban abortion and affirmatively support the current REMS—despite Louisiana's failure to establish that such access affects the frequency, severity, or nature of adverse events. That result is contrary to Congress's command that REMS elements not be "unduly burdensome on patient access," particularly for patients who have difficulty accessing health care, and that they minimize burdens on the health care delivery system. 21 U.S.C. § 355-1(f)(2)(C)–(D). The order is deeply unsettling to drug sponsors, healthcare providers, patients, and the public—all of whom rely on FDA's exercise of scientific judgment and orderly administration of the Nation's complex system of drug regulation. Today, patients who

planned to pick up a mifepristone prescription at their local pharmacy may no longer be able to do so, regardless of which State they live in.

The order will also immediately impact GenBioPro by eliminating the pharmacy and mail distribution that constitutes a substantial portion of its revenue and by creating immediate compliance burdens and regulatory confusion. That the Fifth Circuit inflicted those harms on an interim basis, without the administrative record, and without even granting GenBioPro's request for a seven-day administrative stay to seek this Court's review, makes the order all the more extraordinary. By contrast, Louisiana has not shown that it will likely be injured—much less irreparably harmed—by maintaining the status quo it left unchallenged for years.

Second, Louisiana lacks Article III standing, and the Fifth Circuit could hold otherwise only by ignoring this Court's precedent. The Fifth Circuit's "unusually broad and novel view of standing," *Valley Forge Christian Coll.* v. *Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 470 (1982), runs directly against this Court's recent cases, see *FDA* v. *Alliance for Hippocratic Medicine*, 602 U.S. 367, 376 (2024) ("*Alliance*"); *Texas*, 599 U.S. at 680, and would validate precisely the "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 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)). That theory is not limited to mifepristone, or even to FDA: it would allow States to challenge virtually any agency action whenever they allege

downstream costs or interference with state policy, inviting courts to displace the political branches' judgments under the guise of Article III.

The "pocketbook" Medicaid harm Louisiana asserts from Medicaid enrollees seeking follow-up care after a medication abortion is a more attenuated version of the doctor-standing theories this Court unanimously rejected in *Alliance*. And Louisiana's alleged sovereign injury from the 2023 REMS is not a "legally and judicially cognizable" injury at all. *Texas*, 599 U.S. at 676 (quotation omitted). The Fifth Circuit's contrary holding creates a direct conflict with the Ninth Circuit, which rejected materially indistinguishable state-standing theories in litigation over FDA's mifepristone REMS. See *Washington* v. *FDA*, 108 F.4th 1163, 1174–77 (9th Cir. 2024). Nor are Louisiana's asserted injuries fairly traceable to the 2023 REMS or likely to recur.

Third, Louisiana's challenge to the 2023 REMS fails on the merits. FDA determined that mifepristone—like the vast majority of drugs—could be safely dispensed without requiring that the drug be dispensed in a clinic or doctor's office based on substantial scientific evidence and real-world experience. That determination was not arbitrary or capricious. FDA reviewed 15 studies evaluating medication abortion outcomes for more than 55,000 patients, all of which supported the safety and effectiveness of dispensing mifepristone by mail, courier, or through pharmacies. The Fifth Circuit disregarded FDA's scientific judgment, rushed forward without even seeing the administrative record, and instead rested on demonstrably erroneous characterizations of that record, including a material misrepresentation of FDA's position that served as the linchpin of its conclusion that the 2023 REMS is arbitrary and capricious. This Court should vacate the Fifth

Circuit's order.

Statement

I. Statutory Background

Congress entrusted FDA with the authority and responsibility to determine whether a "new drug" is safe and effective before it is distributed. 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 for its intended 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 the 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 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).

II. Factual Background

2000 Mifeprex Approval and 2008 REMS. In 2000, FDA approved mifepristone for medical abortion under the brand name Mifeprex. See *Alliance*, 602 U.S. at 375. 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, FDA identified mifepristone, approved since 2000 as a safe and effective medication for terminating pregnancy, as subject to a REMS. 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008). Accordingly, at the time, the mifepristone REMS required, among other conditions, that the drug be dispensed exclusively in a healthcare setting, such as a hospital or medical center. D. Ct. Doc. 1-11 at 3.

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. 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. *Id.* at 3, 24. FDA concluded that the use of mifepristone under the revised conditions would be "safe," emphasizing that "known risks occur[ ] rarely." *Id.* at 24.

As part of the 2016 changes, FDA determined based on "15 years of reporting" that the REMS requirement to report non-fatal 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. D. Ct. Doc. 1-11 at 26. FDA thus, consistent with its statutory mandate to "minimize the burden on the health care delivery system," 21 U.S.C. § 355-1(f)(2)(D), 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 report 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. Notably, that requirement governed where mifepristone could be dispensed, not where the patient was required to take it. Even under the prior REMS, patients generally completed the regimen outside the clinic after receiving the drug and instructions for use and follow-up care. The injunction was in effect for six months, during which FDA observed no impact on patient safety. D. Ct. Doc. 1-50 at 61–64. In April 2021, FDA suspended enforcement of the in-person dispensing requirement. 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. D. Ct. Doc. 1-3. 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. *Ibid.* 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," D. Ct. Doc. 1-10 at 27, and that in-person dispensing was "no longer necessary to ensure" the drug's benefits outweigh the risks, *id.* at 25. 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. *Id.* at 5, 25–37. FDA also relied on safety data from the nonenforcement period, which showed "no indication" that suspending in-person dispensing "contributed to" adverse events. D. Ct. Doc. 1-51 at 38. FDA also reviewed 15 studies evaluating the safety and efficacy of mifepristone when dispensed outside the clinical setting, including by pharmacies and through the mail. D. Ct. Doc. 1-50 at 65. 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 *id.* at 65–77. FDA thus directed Danco and GenBioPro to initiate the process of modifying the REMS. D. Ct. Doc. 1-50 at 3; 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. D. Ct. Doc. 1-50 at 3, 8. 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," *id.* at 15.

FDA's ongoing 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. D. Ct. Doc. 231-3 at 13–14 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." D. Ct. Doc. 1-110 at 1. 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*, tinyurl.com/38m6ea9f. Although such studies "often take approximately a year or more to conduct," FDA's "current … plan" is to complete the study "sooner." *Ibid.* Once FDA 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." *Ibid.* FDA confirmed below that this review is ongoing. *Ibid.*; D. Ct. Doc. 51 at 1–3.

III. 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. The district court issued a preliminary injunction granting all requested relief, which the Fifth Circuit stayed only in part, and this Court subsequently stayed in its entirety. *Id.* at 377. The Fifth Circuit then affirmed the preliminary injunction as to the 2016 REMS and the 2021 non-enforcement decision. *Id.* at 377–78. This Court granted review and reversed, unanimously holding in June 2024 that the plaintiffs lacked standing. *Id.* at 374.

Louisiana and a Louisiana citizen, Rosalie Markezich, filed this action in October 2025 challenging the 2023 REMS modification. App.30a. 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 the FDA. See *ibid.* Another two months passed before Plaintiffs moved to enjoin the 2023 REMS or "stay" its long-elapsed effective date under 5 U.S.C. § 705. D. Ct. Doc. 20. GenBioPro, a manufacturer of generic mifepristone, intervened and opposed the motion. D. Ct. Doc. 52, 54. FDA opposed Plaintiffs' motion, and also moved to stay the case while FDA reviews the REMS. D. Ct. Doc. 51. 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. D. Ct. Doc. 250.

On April 7, 2026, the district court stayed the case during FDA's ongoing review and

denied Plaintiffs' request for preliminary relief. App.19a–55a. The court declined to dismiss for lack of standing, concluding that Louisiana's allegations of sovereign and pocketbook injuries sufficed at this "earl[y] stage[ ]." App.35a. The court also concluded Plaintiffs were likely to succeed on the merits of their arbitrary-and-capricious claim and would suffer irreparable injury. App.44a–46a.

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. App.46a–54a. 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." App.47a, 52a. 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. App.53a. 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." App.53a–54a. The court ordered FDA to file status reports within six months and within 14 days of FDA completing its review. App.54a–55a.

Louisiana appealed to the Fifth Circuit and moved for a stay of the 2023 REMS pending appeal under 5 U.S.C. § 705. On Friday, May 1, 2026—after *sua sponte* ordering expedited oppositions in just four business days—the Fifth Circuit granted that

extraordinary relief to "stay" the 2023 REMS' long-elapsed effective date under 5 U.S.C. § 705, ten days before Louisiana's request for a ruling by May 11. The court accepted Louisiana's sovereign-enforcement and downstream Medicaid-expenditure theories of injury without addressing this Court's rejection of a similarly attenuated State-standing theory in *Texas* or the Ninth Circuit's rejection of materially indistinguishable theories involving the mifepristone REMS, *Washington*, 108 F.4th at 1174–78. And without any administrative record before it, the Fifth Circuit concluded that the evidence before FDA in adopting the 2023 REMS was insufficient, relying on its vacated decisions in *Alliance for Hippocratic Medicine* v. *FDA*, 2023 WL 2913725, at *21 (5th Cir. Apr. 12, 2023) and *Alliance for Hippocratic Medicine* v. *FDA,* 78 F.4th 210 (5th Cir. 2023) ("*Alliance II*").

On the balance of equities and public interest, the Fifth Circuit gave short shrift to the district court's analysis, disposing of the public interest in a single sentence, while failing to address the impact on GenBioPro, the 20 States opposing relief, the patients who depend on pharmacy and mail access to receive their medication, or the years of healthcare infrastructure built in reliance on the current REMS framework. And the court denied GenBioPro's request for a seven-day administrative stay to permit it to seek relief from this Court.

ARGUMENT

In deciding whether to stay preliminary relief, the Court considers whether (1) there is "a reasonable probability that this Court would eventually grant review," (2) there is "a fair prospect that the Court would reverse," and (3) "the applicant would likely suffer irreparable harm absent the stay" and "the equities" support relief. *Merrill* v. *Milligan*,

142 S. Ct. 879, 880 (2022) (Kavanaugh, J., concurring); *Hollingsworth* v. *Perry*, 558 U.S. 183, 190 (2010) (per curiam); *Coleman* v. *PACCAR Inc.*, 424 U.S. 1301, 1304 (1976) (Rehnquist, J., in Chambers) (similar standard for vacating stay entered by lower court). Each of those factors weighs decisively in favor of staying the Fifth Circuit's destabilizing § 705 stay and preserving a status quo that has been in place for years.

I. This Court Would Likely Grant Review if the Fifth Circuit's Nationwide Stay of the 2023 REMS Remains in Effect After Louisiana's Appeal

This case readily satisfies the reasonable-probability-of-review standard. The Fifth Circuit has once again entered extraordinary interim relief disrupting FDA's longstanding mifepristone regime—this time by staying the 2023 REMS under 5 U.S.C. § 705 and suspending nationwide conditions of use that have governed access to this medication for years. Three years ago, this Court stepped in to stay the Fifth Circuit's last emergency interim order displacing FDA's mifepristone REMS, and later granted certiorari and unanimously reversed because the plaintiffs lacked Article III standing. See *Alliance*, 602 U.S. at 377–78, 396–97. Undeterred, the Fifth Circuit has again adopted sweeping standing theories that would dramatically expand States' ability to challenge federal regulations. Those holdings conflict with this Court's recent decisions in *Alliance* and *Texas*, and they directly conflict with the Ninth Circuit, which rejected a materially indistinguishable theory of state standing, see *Washington*, 108 F.4th at 1175–77.

In granting a § 705 stay pending appeal, the Fifth Circuit also rushed to countermand a scientific judgment that FDA has kept in effect across two administrations; nullified conditions of dispensing the drug that have been in place for more than five years; and upset reliance interests in a healthcare system that depends on the availability of

mifepristone by mail and through certified pharmacies. And the Fifth Circuit did so despite the fact that FDA is actively reviewing the mifepristone REMS based on all the evidence before it, including a new study it is undertaking, in order to determine whether substantive changes to the REMS are warranted.

In addition to the destabilizing practical consequences, a final decision of the Fifth Circuit that Louisiana is entitled to § 705 relief would warrant this Court's review because of its foundational legal errors. The Fifth Circuit accepted a novel and expansive theory of state standing at odds with this Court's holding in *Texas* and *Alliance*; applied an arbitrary-and-capricious analysis without the administrative record; and displaced FDA's expert judgment on drug safety in a manner inconsistent with Chief Justice Roberts's admonition that courts owe significant deference to agencies with "background, competence, and expertise to assess public health," *Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. at 579 (Roberts, C.J., concurring). Review is therefore reasonably probable because the order presents recurring and exceptionally important questions about Article III limits on State suits against federal agencies, the scope of § 705 relief, and the judiciary's authority to displace, through emergency litigation, the congressionally assigned expert judgments of FDA and other specialized agencies.

Review is especially likely because the Fifth Circuit's standing ruling creates a direct conflict with the Ninth Circuit on an outcome-determinative question of exceptional national importance: whether States have standing, and thereby can seek nationwide relief—based on attenuated sovereign-enforcement and downstream Medicaid-expenditure injuries. The Ninth Circuit considered and rejected materially

indistinguishable theories of state standing. It rejected the States' theory that "elimination of the in-person dispensing requirement will cause the state economic injury in the form of increased costs to the state's Medicaid system" because it "depends on an attenuated chain of healthcare decisions by independent actors that will have only indirect effects on state revenue." *Washington*, 108 F.4th at 1174. Citing Chief Judge Sutton's opinion in *Arizona* v. *Biden*, the court recognized that "a theory of state standing 'in which all peripheral costs imposed on the States by actions of the [executive branch]' constitute cognizable injuries would 'make a mockery' of Article III." *Id.* at 1175 (quoting *Arizona*, 40 F.4th at 386). The Ninth Circuit likewise rejected the theory that mail-order dispensing "will harm its sovereign interest in law enforcement," recognizing that "[h]olding otherwise would greatly expand state standing to challenge any federal action that allegedly increases crime or disorder, or imposes indirect compliance costs for state law enforcement." *Id.* at 1176–77.

If this Court grants review, it would likely reverse. The Fifth Circuit's § 705 stay pending appeal is premised on a plainly erroneous theory of Article III standing, and a straightforward application of this Court's precedents requires dismissal. Louisiana is not regulated by the 2023 REMS, and its asserted injuries depend on an attenuated chain of independent choices by third parties. Its APA claim fares no better: FDA's 2023 REMS is amply supported by evidence and fully consistent with applicable law.

A. Louisiana Lacks Article III Standing

The Fifth Circuit's "unusually broad and novel view of standing," *Valley Forge Christian Coll.*, 454 U.S. at 470, cannot be reconciled with this Court's precedent. Indeed, the Fifth Circuit's order made no mention of *Texas* and relegated *Alliance* to a sparse paragraph. A straightforward application of those precedents dictates dismissal.

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," Louisiana "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. Defense Council, Inc.*, 555 U.S. 7, 22 (2008)).

Louisiana cannot make that showing. 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." *Ibid.*

1. Louisiana Is Not an Object of the 2023 REMS

Louisiana faces a fundamental threshold problem: it is not an object of the federal regulation that it challenges. Like the plaintiffs in *Alliance* who 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." *Id.* at 385. Standing for such an "unregulated party" 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. 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 "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 Fifth Circuit credited Louisiana's attempt to escape 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. That narrative is demonstrably false, and the chronology alone defeats it. The in-person dispensing requirement was first lifted by court order in 2020 and then suspended by FDA in April 2021—more than a year before *Dobbs*, when abortion remained protected nationwide, including in Louisiana. FDA confirmed that the process leading to the 2023 REMS modification started in connection with litigation filed in 2017. D. Ct. Doc. 1-50 at 46. Louisiana cannot plausibly convert a generally applicable drug-dispensing condition, initiated years before *Dobbs* and never directed at any State, into a regulation targeting Louisiana's post-*Dobbs* laws. That is pleading by unsupported assertion, not evidence. And contrary to the Fifth Circuit's conclusion, App.9a, post hoc statements about expanding access to medication abortion do not transform the identical condition first imposed in 2021 and formalized in the 2023 REMS into federal regulation of Louisiana or eliminate the attenuated chain of third-party choices on which Louisiana's asserted injuries entirely depend.

Diamond Alternative Energy, LLC v. *EPA*, 606 U.S. 100 (2025), does not rescue

Louisiana's theory. There, the challenged rules sought to reduce gasoline consumption, and the plaintiffs' asserted injury was reduced fuel sales, *id.* at 116–17, making the alleged injury the very object of the regulation. The 2023 REMS is not comparable. Louisiana's alleged injuries are sovereign-enforcement burdens and downstream Medicaid expenditures, 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.

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

The Fifth Circuit's financial-injury analysis converts downstream consequences of independent third-party conduct into an Article III injury caused by FDA. The court reasoned that Louisiana had standing because it allegedly paid $92,000 in Medicaid costs for two women who received emergency care after taking mifepristone, and speculated that similar costs may occur as long as mifepristone can be dispensed by mail. App.11a–12a. But the court never explained why staying the 2023 REMS would prevent those alleged costs. 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. The Court's reasoning skips the critical Article III question. Medicaid expenditures may be monetary costs, but *Texas* makes clear that not every state expenditure allegedly associated with a federal policy is a legally and judicially cognizable injury traceable to that policy. 599 U.S. at 676–77, 680 n.3. The question is not

whether Louisiana can identify a Medicaid payment somewhere downstream. It is whether that payment is sufficiently direct and non-attenuated to the challenged federal action to support a State's suit against the federal government. It is not.

The Fifth Circuit's contrary conclusion cannot be squared with—and makes no mention of—*Texas*. There, the 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. This Court rejected the States' "attenuated" theory of standing that a federal policy "produced only" "indirect effects on state revenues or state spending." *Id.* at 680 n.3. Although the Court recognized that "monetary costs are of course an injury," that was insufficient for Article III: a State "incur[ing] additional costs" because of a federal policy was not a "legally and judicially cognizable" injury. *Id.* at 676–77. 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.

Alliance reinforces that point in this exact regulatory context. This 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." *Alliance*, 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. *Ibid.* 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 "treating complications or side effects" of mifepristone, *Alliance*, 602 U.S. at 383, both because such attenuated claims of injury are not "legally and judicially cognizable," and do not establish causation, *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 this 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. The alleged Medicaid payment is one step *further removed* from FDA's action, not one step closer. Louisiana's asserted expenditure is thus no more cognizable than the downstream costs this Court unanimously held insufficient in *Alliance*.

The Fifth Circuit's "hard evidence" rationale, App.12a, does not cure the attenuation problem. Louisiana identified only two Medicaid reimbursements for emergency room visits—out of the thousands of women Louisiana claims have received mifepristone in the State by mail since 2023. D. Ct. Doc. 20-20 at 3–4. Those two alleged reimbursements do not establish that the 2023 REMS caused increased Medicaid expenditures or that such expenditures are likely to recur. To reach that conclusion, one must assume that the 2023 REMS caused an out-of-state prescriber to dispense mifepristone by mail; that the patient would not otherwise have obtained mifepristone; that the patient experienced a rare complication; that the complication was the result of *the absence of an in-person dispensing requirement* rather than ordinary drug risks, contraindications, or other circumstances; that the patient sought emergency care; and that Medicaid, rather than another payor, bore the cost. That is precisely the kind of "distant … ripple effect[]" that *Alliance* held too attenuated. 602 U.S. at 383.

The Fifth Circuit's reliance on emergency-room statistics further underscores the flaw. The court made a leap from FDA labeling stating that a low percentage of women prescribed mifepristone in person will require emergency care to the conclusion that remote dispensing would "exacerbate" those risks, App.11a—a conclusion that is contrary to that reached by FDA each time it considered the in-person dispensing requirement, see D. Ct. Doc. 1-50 at 80. But evidence that emergency care can occur even with in-person dispensing does not show that the 2023 REMS caused Louisiana's Medicaid costs. It shows the opposite: complications may result from mifepristone use generally, not from the challenged removal of the in-person dispensing requirement. Article III requires

traceability to the challenged agency action, not merely to use of the regulated drug.

3. The 2023 REMS Does Not Cause Sovereign Harm to Louisiana

The Fifth Circuit's sovereign-harm analysis is even farther afield than its downstream Medicaid-expenditure theory. The Fifth Circuit reasoned that the 2023 REMS "sanctions and facilitates conduct with the express purpose of undermining Louisiana's legal restrictions on abortion," and therefore causes "federal interference with the enforcement of [Louisiana] law." App.10a. But the 2023 REMS does no such thing. It does not require anyone to prescribe mifepristone, require anyone to dispense mifepristone, or prevent Louisiana from creating or enforcing its abortion prohibitions. It simply removes a federal in-person dispensing requirement.

Louisiana's claim that "the 2023 REMS has functionally overridden Louisiana's pro-life laws" boils down to a claim that the state must expend state resources to pursue its chosen policies. D. Ct. Doc. 20-26 at 20 (asserting pursuit of violations "result[s] in monetary harm and depletion of resources"). But any asserted burden on Louisiana's enforcement efforts depends on a chain of independent third-party choices: out-of-state prescribers decide to provide 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 of States that this Court rejected in *Texas*.

This Court in *Texas* rebuffed a theory that allegations of insufficient federal regulatory stringency—and incidental State burdens that follow—can support standing. 599 U.S. at 681. There, the district court found 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). This Court reversed, explaining 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 the "uncharted path" *Texas* refused to take. *Id.* at 681.

The Ninth Circuit correctly applied that principle to reject materially similar standing theories asserted by a group of States, holding that the REMS does not "interfere[] with [a State's] authority to enact or enforce restrictions on medical abortion within its boundaries." *Washington*, 108 F.4th at 1177. That conclusion is equally true here. Louisiana remains free to prohibit abortion and to enforce its laws against those who violate them. 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 caused by FDA.

4. Louisiana's Asserted Injuries Are Not Traceable to the 2023 REMS or Likely to Recur

Louisiana's standing theory fails for an additional reason: neither Louisiana nor the Fifth Circuit has shown that the State's asserted injuries are fairly traceable to the 2023 REMS or likely to recur.

Taking the most obvious error first. Louisiana has not established that it will likely be injured again in the future. Allegations of past harm are not enough. *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 103 (1983) ("past wrongs do not in themselves amount to that real and immediate threat of injury necessary to make out a case or controversy"). That remains

true even when claims of past harm are coupled with "a statistical probability that some [plaintiffs] are threatened with concrete injury." *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 497 (2009).

At most, Louisiana alleged that the REMS could cause future Medicaid expenditures. D. Ct. Doc. 1 ¶¶ 134–43. 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. That is a far cry from a "certainly impending" future injury. In *Clapper*, this Court rejected an "objectively reasonable likelihood" standard and held that where a statute "at most authorizes—but does not mandate or direct" third-party conduct, alleged injury from an independent actor's discretionary choice is "necessarily conjectural." 568 U.S. at 410–12.

Pointing to past incidents of harm is no substitute for concrete, impending future injury. *Summers*, 555 U.S. at 497; *Lyons*, 461 U.S. at 103. As then-Judge Kavanaugh explained, "[e]ven if a plaintiff has suffered past harm from the kind of conduct the suit seeks to enjoin, the plaintiff must 'establish a real and immediate threat' that the harm-producing conduct will recur." *Coalition for Mercury-Free Drugs*, 671 F.3d 1275, 1278–80 (D.C. Cir. 2012) (quoting *Lyons*, 461 U.S. at 105). Two examples over the course of three years, see App.11a, is grossly insufficient to demonstrate that Louisiana is *likely* to expend Medicaid funds again in the future.

Traceability fails for similar reasons. The 2023 REMS do not regulate Louisiana. As in *Summers*, the agency "neither require[s] nor forbid[s] any action on the part of respondents." 555 U.S. at 493. The 2023 REMS becomes relevant to Louisiana only after

a long chain of independent decisions that the Fifth Circuit never meaningfully addressed: an out-of-state provider must choose to prescribe mifepristone; a patient must choose medication abortion; the patient must choose to receive the medication by mail or from a certified pharmacy rather than in person; the patient must experience a rare complication; the patient must seek care for that complication; the patient must be enrolled in Medicaid; and the provider must bill Louisiana Medicaid. Article III does not permit standing to rest on that kind of multi-step causal chain. "[T]heories that require guesswork as to how independent decisionmakers will exercise their judgment" are insufficient. *Clapper*, 568 U.S. at 413.

Louisiana's own allegations confirm that its asserted injuries are not caused by the 2023 REMS. Louisiana says its injuries stem from "doctors in states like New York and California" who "prescribe and mail FDA-approved mifepristone into pro-life states" like Louisiana. D. Ct. Doc. 20–26 at 1. But Louisiana itself 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 1, 5, 7; D. Ct. Doc. 1 ¶¶ 4–10, 81–107, and the Fifth Circuit's opinion acknowledges the same, see App.10a (describing "out-of-state prescriber[s]" acting in "defiance of Louisiana law"). 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 with the enactment of shield laws in 2023. See D. Ct. Doc. 20-2 at 9 (marking increase in telehealth abortions in Q3 2023, when "[p]rovision under US shield laws

begins"); D. Ct. Doc. 1 ¶ 85 (same). As a result, Louisiana's asserted injuries 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.

5. The Fifth Circuit's Theory of Standing Represents an Unprecedented Expansion of Article III

"[F]ederal courts must remain mindful of bedrock Article III constraints in cases brought by States" against the federal government. *Texas*, 599 U.S. at 680 n.3. The Fifth Circuit's standing theory disregards those constraints. App.8a–12a. If two downstream Medicaid reimbursements are enough to give Louisiana standing to challenge FDA's mifepristone REMS, then States may challenge virtually any federal policy that might predictably cause an increase in state expenditures.

That is the same "unprecedented and limitless approach" that this Court rejected in *Alliance*. 602 U.S. at 391–92. A State could challenge federal vehicle-safety standards because accidents may generate Medicaid or emergency-services costs; environmental or workplace-safety rules because illness or injury may increase public-health spending; immigration policies because some downstream costs may fall on state programs; or any FDA drug-approval or labeling decision because virtually all drugs "come with complications, risks, and side effects," which may lead to reimbursable care. *Id.* at 391–92.

Given the reality that "federal policies frequently generate indirect effects on state revenues or state spending," *Texas*, 599 U.S. at 680 n.3, under the Fifth Circuit's newly adopted theory, "virtually every" state would have "standing to challenge virtually every

government action that they do not like—an approach to standing that this Court has consistently rejected as flatly inconsistent with Article III," *Alliance*, 602 U.S. at 392.

Nor would the theory be limited to States. As the Ninth Circuit recognized in rejecting materially similar mifepristone standing theories, allowing standing based on downstream medical costs would also mean that any private entity that "provides health insurance or subsidized medical care" could "challenge any FDA decision approving a new drug" or loosening restrictions on an existing one. *Washington*, 108 F.4th at 1176. That would transform federal courts into "continuing monitors of the wisdom and soundness" of FDA's drug-safety judgments. *Alliance*, 602 U.S. at 384. Article III does not permit that result.

The "lack of historical precedent" for Louisiana's standing theory is a "telling indication of the severe constitutional problem." *Texas*, 599 U.S. at 677 (citation omitted). As this Court explained, "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." *Alliance*, 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." *Ibid.* (citation omitted). The Fifth Circuit's contrary approach unleashes precisely the kind of the "government by lawsuit" that the district court rightly abjured. App.21a (quoting *Texas*, 599 U.S. at 704 (Gorsuch, J., concurring)).

"[T]he federal courts are the wrong forum for addressing [Louisiana's] concerns about FDA's actions." *Alliance*, 602 U.S. at 396–97. Louisiana may still "present [its] concerns and objections to the President and FDA in the regulatory process, or to Congress and the President in the legislative process" and may "also express [its] views about abortion and mifepristone to fellow citizens, including in the political and electoral processes." *Id.* at 397. But "under Article III of the Constitution, those kinds of objections alone do not establish a justiciable case or controversy in federal court." *Id.* at 396. The Fifth Circuit identified no sound basis for departing from that straightforward rule.

B. FDA's Judgment that an In-Person Dispensing Requirement is Unnecessary for Safety is Correct and Lawful

FDA 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 was not arbitrary or capricious. The Fifth Circuit's contrary conclusion recycled reasoning from its prior, vacated *Alliance* opinions that this Court never endorsed, ignored key features of FDA's analysis, and substituted judicial skepticism—unmoored from the actual agency record—for FDA's scientific assessment.

The FDAAA directs FDA to make the "policy-laden" determination, *Seven Cnty. Infrastructure Coal.* v. *Eagle Cnty.*, 605 U.S. 168, 183 (2025), of whether a REMS will "ensure the benefits of the drug outweigh [its] risks"; "minimize the burden on the health care delivery system"; and "accommodate different, comparable aspects of the elements to assure safe use for a drug," 21 U.S.C. § 355-1(g)(4)(B). Congress also required that REMS elements 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).

FDA's application of those factors—which the Fifth Circuit's opinion does not acknowledge—easily satisfies the APA's standard for reasoned decisionmaking. 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."). FDA relied on multiple, independent lines of evidence in reaching its decision to remove the in-person dispensing requirement. It reviewed more than five years of adverse-event data, comparing periods when the in-person dispensing requirement was enforced with periods when it was not. Based on FAERS data and adverse event data submitted by Danco and GenBioPro, FDA found "no new safety concerns" related to the removal of the in-person dispensing requirement, and concluded "there does not appear to be a difference in adverse events between [those] periods"—which "suggests that mifepristone may be safely used without an in-person dispensing requirement." D. Ct. Doc. 1-50 at 63. FDA also analyzed 15 studies that evaluated the safety and efficacy of mifepristone when dispensed to more than 55,000 patients by a variety of means not involving in-person dispensing in a clinic or hospital, finding that their cumulative results corroborated that removing the in-person dispensing requirement did not pose safety risks.[1] See D. Ct. Doc. 1-50 at 65–66, 69, 73–74, 77.

[1] The mountain of studies overwhelmingly supporting mifepristone's safety—including the studies upon which FDA relied and the studies published after the 2023 REMS—are all included in GenBioPro's citizen petition and the accompanying appendices. D. Ct. Doc. 231-3–231-12.

Neither the Fifth Circuit nor Louisiana identified any scientific evidence FDA failed to consider—no clinical trials, adverse event reports, post-approval studies, peer-reviewed literature, or other scientific data. Instead, the panel relied on vacated Fifth Circuit decisions to fault FDA for considering adverse-event data after FDA's 2016 change to prescriber reporting requirements that it claimed made FAERS data unreliable. In the panel's view, it was "unreasonable" for FDA to "use the resulting absence of data to support its decision." App.13a (quoting *Alliance II*, 78 F.4th at 249).

That reasoning is incorrect. Setting aside that FDA maintained a mifepristone-specific reporting requirement for fatalities, which this Court has recognized to be "more stringent than the requirements for most other drugs," *Alliance*, 602 U.S. at 376, FDA's 2016 change simply brought the adverse event reporting for mifepristone closer in line with the protocol applicable to *virtually all other prescription drugs*, including many drugs with a REMS in place, under which prescribers are permitted (but not required) to report non-fatal adverse events. D. Ct. Doc. 1-11 at 26–28; 21 C.F.R. § 314.80(c) (imposing reporting requirements on manufacturers but not providers). FDA recognized that, as with other drugs, "serious adverse events other than deaths" continue to reach FDA through manufacturers' "periodic safety update reports and annual reports," D. Ct. Doc. 1-11 at 28, through which manufacturers are required to report all adverse-event reports that they receive, including from a variety of different sources that are not limited to physician reports. See 21 C.F.R. § 314.80(b)–(c). Significantly, adverse event reports are overinclusive by nature: they include all adverse experiences when taking a drug and do not incorporate any kind of causation analysis. See *id.* § 314.80(a).

The FAERS database FDA considered incorporates those reports. See D. Ct. Doc. 1-11 at 28; App.59a. Thus FDA's decision to remove the in-person dispensing requirement incorporated information about all adverse event reports it had received, including non-fatal adverse events. Importantly, the relative numbers of non-fatal adverse events in the FAERS database for years after 2016 are comparable to those for years prior to the 2016 change. And FDA had more than ample post-2016 data to make an apples-to-apples comparison of adverse event reports when in-person dispensing was required versus when it was not. The Fifth Circuit's suggestion that FAERS data is somehow unreliable without a requirement that physicians report non-fatal adverse events ignores the reality that most drugs have no such reporting requirement, see D. Ct. Doc. 1-11 at 26–28; 21 C.F.R. § 314.80(c), yet Congress still directed FDA to rely on "adverse event reports" as one source of data when making its safety determinations, see 21 U.S.C. § 355-1(a)(1)(E), (b)(3); see also *FCC* v. *Prometheus Radio Project*, 592 U.S. 414, 427 (2021) (agencies must have the freedom to make "a reasonable predictive judgment" based on the available evidence when, as is often the case, it is operating without "perfect empirical or statistical data"). For all of these reasons, the 2023 REMS is fully consistent with FDA's duty to consider "adverse event report[s]." 21 U.S.C. § 355-1(a)(1)(E), (b)(3).

The panel also erred in concluding that FDA relied on literature that "did not affirmatively support its position." App.13a (quoting *Alliance II*, 78 F.4th at 250). That conclusion ignores the surrounding context of FDA's analysis. FDA reviewed the results of 15 studies that evaluated medication abortion outcomes for over 55,000 patients, and each study reached the conclusion that dispensing by mail, courier, or through pharmacies was

safe and effective. See D. Ct. Doc. 1-50 at 65–81. The 15 studies did not identify any new or increased risks when mifepristone is dispensed outside a clinic or hospital. *Ibid.* In particular, 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 pharmacies and those who received it in-person. *Id.* at 74. 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." *Id.* at 80.

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. *Ibid.* And those studies' conclusions as to safety fully supported FDA's predictive judgment that "mifepristone will remain safe" without requiring in-person dispensing at a clinic or hospital. *Ibid.* While no one study may be perfect, any limitations in the specific studies that FDA examined were outweighed by the fact that all the studies it examined supported the safety of removing the in-person dispensing requirement, *ibid.*, and by the fact that FDA imposed additional requirements on pharmacies and physicians to ensure compliance with the mifepristone REMS, *id.* at 80–81.

Finally, the panel erred by basing its conclusion on FDA's purported concession that it had "failed to adequately study whether remotely prescribing mifepristone is safe." App.2a, 13a. Contrary to the panel's suggestion, FDA has never conceded that its determination that mifepristone can be safely prescribed via telehealth and distributed by mail was wrong or that the review that precipitated it was unlawful. Rather, in announcing

that it would undertake a review of the 2023 REMS, FDA simply stated that it would study "the safety of the current REMS[] in order to determine whether modifications are necessary." D. Ct. Doc. 1-110 at 2. Although it stated that "prior REMS approvals" "lack[ed] adequate consideration," *ibid.*, FDA did *not* state that the review that led to the 2023 REMS unreasonably weighed the scientific evidence and real-world data before the agency. Nor did it suggest that the ultimate predictive judgment reflected in the 2023 REMS—that mifepristone could be safely used when prescribed and distributed remotely—was incorrect: a fact reinforced by FDA's judgment that it was safe to allow the 2023 REMS to remain in effect while it undertook its review. Indeed, as recently as this morning, FDA stated that "Mifepristone is safe when used as indicated and directed and consistent with the Mifepristone Risk Evaluation and Mitigation Strategy (REMS) Program." FAQ #4, https://perma.cc/Z5TD-MHL7.

II. The Remaining Factors Overwhelmingly Favor A Stay

Absent relief from this Court, the Fifth Circuit's § 705 stay pending appeal will upend the status quo that has for more than five years permitted mifepristone to be dispensed outside of a clinic. Prior to yesterday's order, patients nationwide, in states where abortion is broadly permitted and in states where abortion is banned but exceptions permitting that care remain, were able to receive mifepristone from a pharmacy or by mail. That nationwide access matters because mifepristone has permissible medical uses in all 50 States. The Fifth Circuit's order immediately suspends that status quo, harming patients, providers, the national healthcare system, and GenBioPro. Louisiana's alleged harms, by contrast, are attenuated, speculative, and belied by its years-long delay in seeking emergency relief. The district court found that imbalance dispositive. The Fifth Circuit

gave it no meaningful weight.

A. GenBioPro Will Be Immediately and Irreparably Harmed

Most notably, the Fifth Circuit did not address GenBioPro's irreparable harm. The court acknowledged only that the manufacturers had asserted "compliance costs and mifepristone profits," yet dismissed those harms as "potential financial losses" that "pale beside" Louisiana's asserted interests. App.16a. But GenBioPro's unrebutted evidence demonstrates 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. App.57a–58a ¶¶ 5, 10. Suspending the 2023 REMS also creates immediate 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. App.58a–59a. Beyond compliance costs, the Fifth Circuit's order will 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 the Fifth Circuit's interim order is later lifted, modified, vacated, or reversed. App.57a–59a. The Fifth Circuit nowhere grappled with those concrete operational harms.

B. The Public Interest Demands A Stay

The Fifth Circuit likewise discounted the broader public harms, which are grave, immediate, and nationwide. Its stay eliminates 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. Patients and clinicians have, for years, relied on dispensing mifepristone without an in-clinic visit, particularly for women from rural areas and those for whom transportation, childcare, or occupational constraints make it difficult to see providers in person. As a direct result of the Fifth Circuit's order, patients nationwide may face delay or denial of access to time-sensitive medical care, supply-chain disruptions, and attendant health risks. *See* D. Ct. Doc. 1-50 at 58–59. Some patients may instead seek procedural abortions or may be forced to continue pregnancies against their will, including in circumstances that endanger their health. See, *e.g.*, D. Ct. Doc. 231-18 at 9–11, 19–20.

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 the Fifth Circuit imposed those burdens itself—without the administrative record and before FDA completed its ongoing review. That kind of judicial override impairs FDA's ability to carry out its statutory mandates and undermines the integrity of the drug-approval and distribution process as a whole. The Fifth Circuit's stay thus harms the *federal* government's sovereign interest in the uniform, nationwide implementation of its regulatory judgments. See *CASA*, 606 U.S. at 859 (a court order that "prevents the Government from enforcing its policies against nonparties" is an "improper[] intru[sion]" on "a coordinate branch of the Government" and "is enough to justify interim relief" (quotation omitted)).

That disruption is especially improper because a § 705 stay is a status-preserving tool, not a mechanism for retroactively undoing years-old agency action. Once an agency action has been operative for years and regulated parties, patients, providers, pharmacies,

and States have structured their conduct around it, a § 705 "stay" of its long-elapsed effective date no longer preserves the status quo. It inverts it, imposing the very kind of abrupt, court-ordered regulatory upheaval that interim relief is supposed to avoid.

The Fifth Circuit compounded those harms by making its order effective immediately. Courts routinely provide breathing room before disrupting complex regulatory regimes. Indeed, when a district court in the Northern District of Texas entered a comparable order staying the mifepristone REMS in 2023, it included a seven-day administrative stay to allow for orderly review and transition—a stay this Court then extended while it considered the emergency application before it. See *Alliance for Hippocratic Med.* v. *FDA*, 668 F. Supp. 3d 507, 560 (N.D. Tex. Apr. 7, 2023); *Alliance*, 602 U.S. at 377. GenBioPro requested the same here. The Fifth Circuit refused, leaving manufacturers, pharmacies, prescribers, and patients no time to adjust—even though the unrebutted record shows that unwinding five years of distribution infrastructure cannot be done overnight without serious disruption.

C. 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, and 72 more days after filing suit 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.

The Fifth Circuit dismissed that delay in a footnote as "beside the point," reasoning that Louisiana had shown "daily irreparable harm" from the 2023 REMS. App.15a n.8.

Even putting aside the entirely speculative nature of these claims, discussed above, see pp.17–22, *infra*, equity does not work that way. Louisiana's years of inaction are 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.

That conclusion is reinforced by Louisiana's telling isolation. Even among the six States that are currently challenging the mifepristone REMS based on identical assertions of injury, Louisiana is alone in seeking this sweeping nationwide relief on an emergency basis.[2] The Fifth Circuit's order therefore gets the equities backwards: the only concrete and imminent harms flow from its order. The balance of harms and the public interest overwhelmingly favor preserving the longstanding status quo.

D. Request for Relief

Issues of such public importance should not be litigated in this "rushed, high-stakes, [and] low-information" manner. D. Ct. Doc. 258 at 32. This Court should vacate the Fifth Circuit's § 705 stay and preserve the long-settled status quo while FDA completes its ongoing review of the mifepristone REMS. At minimum, given the grave disruption the Fifth Circuit's order would produce, that order should not take effect without further review. If this Court declines to stay the order, it should grant an immediate administrative

[2] 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 recently 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 *Florida* v. *FDA*, No. 7:25-cv-00126-O (N.D. Tex.), Pls.' Resp. to Mot. to Stay or to Dismiss 6, D.Ct.Doc. 56 (N.D. Tex. Apr. 24, 2026).

stay, construe this application as a petition for a writ of certiorari before judgment, grant the petition, and set this case for briefing and argument.

CONCLUSION

The application should be granted.

Respectfully Submitted.

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