No. 25A___

IN THE

Supreme Court of the United States

DANCO LABORATORIES, L.L.C.,

Applicant,

v.

THE STATE OF LOUISIANA, ET AL.,

Respondents.

APPLICATION TO STAY THE JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT AND REQUEST FOR AN IMMEDIATE ADMINISTRATIVE STAY

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RULE 29.6 STATEMENT

Danco Laboratories, LLC is 100% owned by Danco Investors Group, LP.

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PARTIES TO THE PROCEEDING

Applicant in this Court is Danco Laboratories, LLC, who was an intervenor-defendant-appellee below.

Respondents were plaintiffs-appellants below. They are the State of Louisiana and Louisiana resident Rosalie Markezich.

Defendants-appellees below were the U.S. Food and Drug Administration (FDA); Martin Makary, in his official capacity as Commissioner of Food and Drugs at FDA; Tracy Beth Høeg, in her official capacity as Acting Director of FDA's Center for Drug Evaluation and Research; the U.S. Department of Health and Human Services (HHS); and Robert F. Kennedy, Jr., in his official capacity as Secretary of HHS.

GenBioPro, Inc. was also intervenor-defendant-appellee below.

RELATED PROCEEDINGS

Supreme Court of the United States:

- *Danco Laboratories, LLC* v. *Alliance for Hippocratic Medicine*, No. 22A901 (Apr. 21, 2023) (granting emergency application for administrative stay and stay pending appeal)
- *FDA* v. *Alliance for Hippocratic Medicine*, No. 22A902 (Apr. 21, 2023) (granting emergency application for administrative stay and stay pending appeal)
- *Danco Laboratories, LLC* v. *Alliance for Hippocratic Medicine*, No. 23-236 (June 13, 2024) (vacating stay of FDA decisions regarding mifepristone because plaintiffs did not have standing to challenge agency actions)
- *FDA* v. *Alliance for Hippocratic Medicine*, No. 23-235 (June 13, 2024) (vacating stay of FDA decisions regarding mifepristone because plaintiffs did not have standing to challenge agency actions)

United States Court of Appeals for the Fifth Circuit:

- *Alliance for Hippocratic Medicine* v. *FDA*, No. 23-10362 (Apr. 12, 2023) (partially granting stay pending appeal)
- *Alliance for Hippocratic Medicine* v. *FDA*, No. 23-10362 (Aug. 16, 2023) (partially affirming stay of FDA decisions regarding mifepristone)
- *Alliance for Hippocratic Medicine* v. FDA, No. 23-10362 (Sept. 16, 2024) (vacating stay of FDA decisions regarding mifepristone on remand)

United States Court of Appeals for the Ninth Circuit:

- *Washington* v. *FDA*, No. 23-35294 (May 1, 2023) (holding that, under Supreme Court precedent, several states did not have standing to intervene in challenge to FDA decisions regarding mifepristone)

United States District Court for the District of Hawaii:

- *Purcell* v. *Kennedy*, No. 1:17-cv-00493 (Oct. 30, 2026) (remanding without vacatur to FDA to reconsider 2023 REMS)

United States District Court for the Western District of Louisiana:

- *Louisiana* v. *FDA*, No. 6:25-cv-01491 (Apr. 7, 2026) (denying Louisiana's and Ms. Markezich's motion for preliminary injunction and granting stay of litigation pending completion of FDA review)

United States District Court for the Eastern District of Missouri:

- *State of Missouri* v. *FDA*, No. 4:25-cv-01580-CMS (Oct. 23, 2025) (pending challenge to mifepristone's conditions of use and REMS)

United States District Court for the Northern District of Texas:

- *Alliance for Hippocratic Medicine* v. *FDA*, No. 2:22-cv-00223 (Apr. 7, 2023) (ordering a stay of FDA decisions regarding mifepristone)

- *Alliance for Hippocratic Medicine* v. *FDA*, No. 2:22-cv-00223 (Jan. 16, 2025) (allowing Missouri, Kansas, and Idaho to file amended complaint following voluntary dismissal by original *Alliance* plaintiffs)

- *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:

- *Whole Woman's Health Alliance* v. *FDA*, No. 3:23-cv-00019 (May 8, 2023) (challenge to 2023 REMS as unlawfully restrictive)

United States District Court for the Eastern District of Washington:

- *Washington* v. *FDA*, No. 1:23-cv-03026 (July 8, 2025) (upholding 2023 REMS)

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

Pursuant to Rule 23 of this Court and the All Writs Act, 28 U.S.C. § 1651, Danco respectfully files this application to stay the judgment of the United States Court of Appeals for the Fifth Circuit (App., *infra*, 1a-18a), pending the consideration and disposition of Louisiana's appeal and Danco's cross-appeal to the Fifth Circuit and, if the Court of Appeals alters the District Court's judgment in any way other than to order dismissal, pending the timely filing and disposition of Danco's petition for a writ of certiorari and any further proceedings in this Court. Alternatively, the Court should treat this application as a petition for a writ of certiorari before judgment and set this case for expedited briefing and argument before the summer recess. In addition, Danco respectfully requests an immediate administrative stay pending the Court's consideration of this application.

INTRODUCTION

This application presents a particularly clear case for intervention. Just three years ago, this Court stayed an injunction analogous to the stay the Fifth Circuit entered below, *Danco Lab'ys* v. *Alliance for Hippocratic Med.*, 143 S. Ct. 1075 (2023) (*Danco I*), before unanimously holding that the prior plaintiffs' challenge to FDA's regulation of Danco's drug Mifeprex was non-justiciable, *FDA* v. *Alliance for Hippocratic Med.*, 602 U.S. 367 (2024) (*Alliance*). This Court's ruling was unambiguous: doctors who don't prescribe mifepristone lack Article III standing to challenge the drug's regulatory approvals because they are not regulated by those

approvals, and accepting their attenuated theories of harm would defy bedrock Article III constraints. *Alliance*, 602 U.S. at 391-392.

The Fifth Circuit is, of course, familiar with *Alliance*. In the decision below, it relied extensively on its own prior rulings in that litigation. Yet it declined to apply key portions of this Court's analysis in which the Court explained why the plaintiffs there lacked Article III standing. In doing so, the Fifth Circuit split from the Ninth Circuit, which faithfully applied *Alliance* in rejecting identical theories of state standing. *Washington* v. *FDA*, 108 F.4th 1163, 1174 (9th Cir. 2024).

Like the *Alliance* plaintiffs, Louisiana is not required to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything" as a result of FDA's actions. *Alliance*, 602 U.S. at 385. In fact, Louisiana largely prohibits the termination of pregnancy. The Fifth Circuit nevertheless found that Louisiana has standing to challenge FDA's 2023 changes to mifepristone's conditions of use based on "$92,000 it paid in Medicaid costs from two women who needed emergency care in 2025 from complications caused by out-of-state mifepristone." App., *infra*, 11a; *see also* Compl. ¶ 109, *Louisiana* v. *FDA*, No. 6:25-cv-01491 (W.D. La. Oct. 6, 2025), ECF No. 1 (alleging that use of that drug by others will cause "pocketbook injuries" for Louisiana through "Medicaid payments" and "the ordinary costs that arise when uninsured or underinsured patients seek services at public hospitals").[1] But this Court rejected the idea that a plaintiff can claim Article III standing based on an

[1] Unless otherwise noted, "ECF" refers to the District Court's electronic docket, *Louisiana* v. *FDA*, No. 6:25-cv-01491 (W.D. La. 2025).

assertion that "FDA's relaxed regulation of mifepristone may cause downstream economic injuries." *Alliance*, 602 U.S. at 386. "The chain of causation is simply too attenuated." *Id.* at 391.

The Fifth Circuit also concluded that Louisiana had standing because there is a mismatch between the state's policies prohibiting abortion, the federal government's determination of how to balance the statutory factors that Congress directed the agency to consider in modifying a drug's conditions of use, and other states' laws that diverge from Louisiana's in how they regulate abortion. According to the Fifth Circuit, that mismatch supposedly frustrates the enforcement of Louisiana's laws and causes it "sovereign injury." App., *infra*, 9a-10a. But states have no sovereign interest in having *other* sovereigns' policies match theirs. *See, e.g.*, *Massachusetts* v. *EPA*, 549 U.S. 497, 519 (2007) (a state "surrenders certain sovereign prerogatives" such as "forc[ing]" other sovereigns to conform with its chosen policy). And a divergence in abortion policy at the state level is a natural result of "return[ing]" abortion policy to the states. *Dobbs* v. *Jackson Women's Health Org.*, 597 U.S. 215, 292 (2022).

Doubling down on its error, the Fifth Circuit concluded that Louisiana also meets the other injunction factors—and granted Plaintiffs relief that the District Court deemed inappropriate. Though the Fifth Circuit styled its order as a stay under 5 U.S.C. § 705, it operates as an injunction because it renders inoperable an agency action that has already been in effect for years. *See Alliance*, 602 U.S. at 377 (district court order "in effect enjoined FDA's approval of mifepristone"). The panel's

eagerness to enter an injunction was evident: The panel fast-tracked stay briefing when Louisiana did not ask to alter the ordinary briefing schedule (and even though Louisiana had waited 10 days to even seek a stay pending appeal); the panel fast-tracked its ruling when Louisiana did not ask for that either (and even though Louisiana had indicated that it was not requesting a stay decision for more than another week); and the panel upended the status quo by *immediately* staying a REMS modification that FDA approved *over three years ago* (even though that FDA decision served to formalize a *five*-year old agency decision).

Like the *Alliance* plaintiffs' complaint, Louisiana's complaint should have been dismissed outright. At the very least, the Fifth Circuit's injunction should be stayed pending the final resolution of this case.

It bears emphasis how unprecedented the Fifth Circuit's order is. Never before has a federal court purported to immediately enjoin a several years' old drug approval; restrict a distribution system for that drug that manufacturers, providers, patients, and pharmacies have all been using for years; or reinstate conditions that FDA determined do not meet the mandatory statutory criteria. The *Alliance* district court provided for time to appeal before its injunction would take effect, and when the Fifth Circuit later ruled on the merits, the Court of Appeals specifically highlighted the time FDA and Danco would have to prepare before any injunction took effect as a result of this Court's stay. *Alliance for Hippocratic Med.* v. *FDA*, 668 F. Supp. 3d 507, 560 (N.D. Tex. 2023); *Alliance for Hippocratic Med.* v. *FDA*, 78 F.4th 210, 252 (5th Cir. 2023) (*Alliance CA5 Panel*).

In contrast, the panel's ruling injects immediate confusion and upheaval into highly time-sensitive medical decisions—and it forces Danco, FDA, certified Mifeprex providers, patients, and pharmacies all to guess at what is allowed and what is not. What happens when patients arrive for scheduled appointments this weekend and beyond, or walk into pharmacies in New York, Minnesota, Washington, and many other states today to obtain Mifeprex that was prescribed by a provider yesterday? What should a patient do if she cannot obtain an in-person appointment immediately? And what are Danco's obligations as Mifeprex's sponsor? When explaining the error of the Fifth Circuit's stay ruling in *Alliance*, FDA told this Court that the governing REMS does *not* "simply snap back" to some previous version. *See* Declaration of FDA Principal Deputy Commissioner Janet Woodcock, M.D., in support of Emergency Stay Application, Appendix 113a-116a, ¶ 11, *FDA* v. *Alliance for Hippocratic Med.*, No. 22A902 (U.S.), https://tinyurl.com/muvakjc4. The resulting chaos for patients, providers, pharmacies, and the drug-regulatory system is a quintessential irreparable harm that underscores the need for emergency relief from this Court.

A stay is warranted. This Court stayed an order that had granted analogous preliminary relief during the *Alliance* litigation and then unanimously concluded that the plaintiffs there lacked Article III standing. And, as the Fifth Circuit recognized just days ago, "[f]ederal courts have a solemn responsibility to apply neutral principles, such as standing, to the cases that come before them and must resist the temptation to confer Article III standing any time an advocacy group or political subdivision challenges a law it passionately dislikes." *United States* v. *Texas*, No. 24-

50149, 2026 WL 1122127, at *6 (5th Cir. Apr. 24, 2026) (en banc); *see also id.* at *4-6 (applying *Alliance* to reject a challenge by an immigrant advocacy group and a political subdivision to a state criminal law targeted at immigrants). Yet three of the judges who joined the majority in that en banc decision took the exact opposite approach here. The decision below is not an application of neutral principles. It is an abdication of lower courts' duty to adhere to decisions of this Court. *See Hutto* v. *Davis*, 454 U.S. 370, 375 (1982) (per curiam).

Danco therefore requests that this Court issue an immediate administrative stay pending the resolution of this application. Danco also requests a stay of the Fifth Circuit's judgment pending the consideration and disposition of Louisiana's appeal and Danco's cross-appeal to the United States Court of Appeals for the Fifth Circuit and, if the Court of Appeals alters the District Court's judgment in any way other than to order dismissal, pending the timely filing and disposition of Danco's petition for a writ of certiorari and any further proceedings in this Court. Alternatively, this Court should treat this application as a petition for a writ of certiorari before judgment.

STATEMENT

A. Statutory Background

Through the Food, Drug, and Cosmetic Act of 1938 (FDCA), Congress has vested FDA with exclusive governmental authority to "protect the public health by ensuring that * * * drugs are safe and effective" and to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on

the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b). In furtherance of that mission, the FDCA establishes a comprehensive regulatory framework for the review and approval of new drugs through the new drug application (NDA) process. *Id.* § 355. The application process requires that FDA undertake a rigorous, science-driven evaluation of any application, as well as any new conditions for use of a previously approved drug submitted under a supplemental new drug application (sNDA), to determine whether the drug is "safe for use" and will have the "effect[s] it purports or is represented to have" under the conditions of use prescribed in the labeling. *Id.* § 355(d).[2]

FDA may also impose certain use restrictions on drugs through its risk evaluation and mitigation strategy (REMS) authority if "necessary to ensure the benefits of the drug outweigh" the risks. 21 U.S.C. § 355-1(a)(1)-(a)(2). A REMS may include medication guides, communication plans, disposal requirements, limitations on dispensing, or elements to assure safe use. *Id.* § 355-1(e)-(f). Congress directed FDA to periodically evaluate a REMS and determine whether the use restrictions in place "assure safe use of the drug," "are not unduly burdensome on patient access to the drug," and "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(5)(B)(i)-(iii).

[2] Because "[f]ew if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk," in this context, "safe" means that "the expected therapeutic gain justifies the risk entailed by its use." *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979); *see* 21 U.S.C. § 355(d).

B. Factual Background

1. Danco, a small pharmaceutical company incorporated in Delaware, holds the NDA for Mifeprex (mifepristone) Tablets for use in a regimen with misoprostol for the medical termination of early intrauterine pregnancy. FDA approved Mifeprex in 2000 for use through 49 days' gestation, with certain use restrictions. ECF No. 1-24 (2000 Approval Letter). Mifeprex's original use restrictions were deemed a REMS. *See* 73 Fed. Reg. 16,313 (Mar. 27, 2008).[3]

2. In 2016, FDA approved an sNDA that modified certain aspects of Mifeprex's labeling and REMS based on numerous studies and 15 years of data. *See* ECF No. 1-11 (FDA Mar. 29, 2016 Summary Review). "FDA deemed Mifeprex safe to terminate pregnancies up to 10 weeks," "approved a dosing regimen that reduced the number of required in-person visits [to] a single visit to receive Mifeprex," and "changed prescribers' adverse event reporting obligations to require prescribers to report only fatalities." *Alliance*, 602 U.S. at 375-376. In 2019, certain entities (not including Plaintiffs) filed a citizen petition requesting FDA undo the 2016 changes, which FDA denied in 2021. *See id.* at 376; ECF No. 1 at ¶ 52.

3. In 2020, during the COVID-19 pandemic, the American College of Obstetricians and Gynecologists (ACOG) asked FDA to not enforce a requirement that mifepristone be dispensed in-person. ECF No. 1-32 at 2. Before FDA responded,

[3] FDA approved a generic version of Mifeprex in 2019 and another in 2025. *See* ECF Nos. 1-25, 1-109. The mifepristone REMS today applies to all three companies' mifepristone products.

ACOG sued to enjoin that requirement. *ACOG* v. *FDA*, 472 F. Supp. 3d 183 (D. Md. 2020).

Louisiana (and several other states) moved to intervene. The district court denied Louisiana's motion because Louisiana did "not have a direct interest in th[e] case that would be impaired by its outcome." *ACOG* v. *FDA*, 467 F. Supp. 3d 282, 288 (D. Md. 2020). Louisiana's laws, the court explained, were not "linked in any way to the enforcement of FDA's" in-person dispensing requirement, so the "case would not impair those States' ability to enforce their own laws." *Id.* at 286. Nor would any judgment "eliminate any state's ability to continue to regulate medication abortion, as they choose, above and beyond the FDA's requirements." *Id.* at 289. The district court preliminarily enjoined the in-person dispensing requirement, *see ACOG*, 472 F. Supp. 3d at 233, but this Court stayed the injunction, *FDA* v. *ACOG*, 141 S. Ct. 578 (2021).

4. In April 2021, FDA responded to ACOG's petition. That response analyzed medical literature, postmarketing adverse event reporting, and information about deviations or noncompliance events associated with the REMS. ECF No. 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. *Id.* at 3. FDA's response to ACOG's petition therefore stated the agency would exercise enforcement discretion as to the in-person dispensing requirement during the public health emergency. *Id.*

In December 2021, FDA came to the same conclusion when responding to a 2019 citizen petition seeking to undo the 2016 changes. FDA explained that "mifepristone may be safely used without in-person dispensing," ECF No. 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. FDA relied on safety data from the nonenforcement periods, which showed "no indication" that suspending in-person dispensing "contributed to" adverse events. ECF No. 1-51 at 38. FDA pointed to three studies analyzing pharmacy mail dispensing and five studies analyzing clinic mail dispensing, all of which supported finding that mifepristone remains safe and effective without in-person dispensing. *Id.* at 26-28. FDA directed Danco (and GenBioPro, a manufacturer of generic mifepristone) to submit an sNDA proposing to remove the in-person dispensing requirement from the REMS.

Danco complied, and FDA approved Danco's sNDA in January 2023. *See* ECF No. 1-50 at 1, 3. Some entities, but not Louisiana, filed citizen petitions asking FDA to reassess in-person dispensing. *See* ECF No. 230-1 at 4; ECF No. 51 at 7 & n.3. Other states have submitted citizen petitions highlighting recent studies that reinforce the safety and effectiveness of mifepristone dispensed by means other than in person. *E.g.*, Citizen Petition from Attorney General of Massachusetts, et al. (June 6, 2025), https://tinyurl.com/yc6xaxk5.

5. This past September, responding to an inquiry from certain state Attorneys General, Secretary Kennedy said that HHS is conducting "a study of the safety of the current REMS, in order to determine whether modifications are necessary." ECF No.

1-110 at 1. A month later, a federal district court in Hawaii held that certain restrictions in the 2023 REMS were unlawful under the Administrative Procedure Act (APA) because FDA "fail[ed] to provide a reasoned explanation for its restrictive treatment of the drug" in light of the available evidence that mifepristone is objectively safe. *Purcell* v. *Kennedy*, No. 1:17-cv-00493, 2025 WL 3101785, at *2 (D. Haw. Oct. 30, 2025). That court did not enjoin the 2023 REMS in whole or part; it "remand[ed]" the matter to FDA and ordered that "the mifepristone REMS * * * will remain in place pending the outcome of the Agency remand." *Id.* at *28. Separately, the Hawaii court also ordered FDA to address pending citizen petitions asking the agency to reconsider aspects of the 2023 REMS. *Id.*

C. Procedural History

1. In November 2022, a group of physicians opposed to abortion sued in the Northern District of Texas over various FDA decisions related to mifepristone, including FDA's decision in April 2021 to not enforce in-person dispensing during COVID and its decision in December 2021 to direct amendment of the mifepristone REMS to remove in-person dispensing. *See Alliance for Hippocratic Med.* v. *FDA*, No. 2:22-cv-00223 (N.D. Tex.). Some of the physicians asserted that they provided pregnancy-related health care, including emergency care after unsuccessful medication abortions using mifepristone. The district court issued a preliminary injunction, which this Court stayed before it took effect and ultimately reversed, unanimously holding the plaintiffs lacked standing. *Alliance*, 602 U.S. at 374.

This Court explained that Article III's case-or-controversy requirement limits federal judicial power to disputes in which the plaintiff has a "personal stake." *Id.* at 379. Because FDA's actions did not require the plaintiffs to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything" with mifepristone, their asserted downstream injuries were too attenuated to establish standing. *Id.* at 385-386. The Court recognized that, for any drug, FDA's approval or lifting of use restrictions may "yield more visits to doctors" because "virtually all drugs come with complications, risks, and side effects." *Id.* at 392. But it emphasized that plaintiffs cannot show Article III standing by pointing to such "distant (even if predictable) ripple effects" of an FDA drug-approval decision. *Id.* at 383.

Over a year after this Court's decision, Louisiana and Rosalie Markezich moved to intervene in the *Alliance* suit. *Alliance* ECF No. 264. The Northern District of Texas denied their intervention motion as moot when it transferred a different complaint filed far earlier by three other states to the Eastern District of Missouri. *Alliance* ECF No. 273.[4]

2. On October 6, 2025, Louisiana and Ms. Markezich filed suit in the Western District of Louisiana challenging the 2023 REMS, which had formalized in January 2023 the nonenforcement policy in place since April 2021. ECF No. 1. Months passed. Plaintiffs then moved for preliminary relief, asking the court to postpone the (long-

[4] The Texas district court did not analyze whether those three intervenor states had standing, and FDA, Danco, and GenBioPro each have a pending motion to dismiss that complaint for lack of standing (among other things).

passed) effective date of the 2023 REMS or enjoin the 2023 REMS. ECF Nos. 20, 20-26.

FDA opposed Plaintiffs' motion and moved for a stay of the litigation while FDA independently reconsiders the 2023 REMS in connection with the *Purcell* court's order to do so, several citizen petitions seeking different forms of relief, and the REMS statute itself. ECF No. 51.

Danco intervened, moved to dismiss the complaint, and opposed Plaintiffs' motion for preliminary relief. ECF Nos. 52, 230. Danco argued that, like the original *Alliance* plaintiffs, Plaintiffs lack standing. ECF No. 230-1 at 5-12. Danco also argued that Plaintiffs failed to satisfy threshold APA requirements; that the dispute is not ripe; and that their claims fail on the merits. *Id.* at 13-15, 16. And Danco emphasized the nationwide harm to the public and to Danco that would result from an injunction of the mifepristone REMS. *Id.* at 24-25. GenBioPro also moved to intervene and to dismiss the complaint. ECF Nos. 54, 231.

The District Court held a hearing on the motions. ECF No. 229. During the hearing, the court probed the asserted potential harms, noting that there have been "many cases" when a safety signal about a drug "comes to the attention of the FDA," and the agency is able to "do something quickly." Dkt. 12-3, Ex. B, D. Ct. Hr'g Tr. 54-55.[5] The court also asked if "during [FDA's] review process," the agency "sees a public health issue with the 2023 REMS—particularly the * * * in-person dispensing

[5] "Dkt." refers to a document on the Fifth Circuit's electronic docket, *Louisiana* v. *FDA*, No. 26-30203 (5th Cir. 2026).

requirement—is there a way for FDA to take immediate action to change it, to restore it, or to alter the 2023 REMS to meet the public health concern?" Tr. 53:25-54:4; *see also* Tr. 54:21-55:6 (requesting briefing). Following the hearing, the court received a supplemental brief from FDA confirming its authority to take immediate action in the event of an exigent public health crisis. ECF No. 250.

The District Court denied Plaintiffs' motion for preliminary relief without prejudice; denied Danco's and GenBioPro's motions to dismiss without prejudice; and granted the government's motion to stay the litigation during the agency's REMS review. *See* App., *infra*, 19a-55a. The District Court thought that Louisiana has standing and is likely to succeed on the merits, *id.* at 34a-46a, but concluded that the equities and public interest "weigh heavily in favor of FDA completing the job that the law requires it to do," and so declined to engage in " 'government by lawsuit.' " *Id.* at 21a (quoting *United States* v. *Texas*, 599 U.S. 670, 704 (2023) (Gorsuch, J., concurring)); *see also id.* at 46a-54a.

3. Ten days later, Plaintiffs sought a stay or injunction pending appeal from the Fifth Circuit. *See* Dkt. 12-1 (Mot.). They did not request expedited briefing and asked for a ruling by May 11. Dkt. 12 (docket text). Danco, FDA, and GenBioPro filed opposition briefs. Dkts. 72, 74, 76. Several organizations, including disability and veterans' advocacy groups, submitted amicus briefs in support of defendants. Dkts. 68, 92, 93, 94.

Just before 5:00 p.m. on Friday evening, May 1, and ten days before Plaintiffs' requested deadline, the Fifth Circuit granted their motion for a stay of the 2023

REMS. Dkt. 119-1; App., *infra*, 1a-18a. The Fifth Circuit first concluded that Plaintiffs were not obligated to ask the District Court for a stay or exhaust administrative remedies with FDA before seeking the appellate court's intervention. App., *infra*, 7a-8a. It then held that Louisiana has standing because by determining that in-person dispensing was not legally necessary, FDA "opened the door for mifepristone to be remotely prescribed to Louisiana women," and because Louisiana said its Medicaid program paid for emergency room care for two women after they experienced "complications caused by out-of-state mifepristone" and sought follow-up care.[6] *Id.* at 10a, 11a. According to the Fifth Circuit, the former amounts to intentional federal interference with Louisiana's enforcement of its state laws and is thus a judicially remediable "sovereign" harm to Louisiana, and the latter is a "financial injury" sufficient to create Article III standing for the state.

The Fifth Circuit also concluded that the stay factors favored Louisiana. On likelihood of success, the court held that FDA "conceded" that it "had failed to adequately study whether remotely prescribing mifepristone is safe" when announcing a new mifepristone REMS review last fall. *Id.* at 2a, 12a-14a. The court also proceeded to "briefly summarize" the *Alliance* stay and merits panel rulings that had found FDA violated the APA by looking to the same adverse event reporting system for mifepristone that FDA looks to for virtually every other FDA-approved

[6] Both the Fifth Circuit and the district court declined to address whether Ms. Markezich has standing. App., *infra*, 12a n.6, 43a n.15. Plaintiffs did not rely on her standing in the Fifth Circuit. *See* Dkts. 12 at 12; 76 at 9 n.7.

drug and by relying on literature that the Fifth Circuit deemed insufficient "on [its] own" to show dispensing by mail was safe. *Id.* at 13a-14a.[7]

On irreparable harm, the court held that Louisiana is suffering such harm because abortions that occur cannot be undone "by legal remedy" and because sovereign immunity makes Medicaid expenditures unrecoverable from the federal government. *Id.* at 14a-15a.

The appeals court rejected the District Court's assessment of the balance-of-harms and the public interest, *id.* at 15a-16a, and asserted that Danco was wrong that a stay of the 2023 REMS would leave no governing legal framework for distributing mifepristone. The court ignored the FDA declaration submitted to this Court that said exactly that. *Id.* at 16a-17a; *see id.* at 57a ¶ 9 (explaining that Danco was relying on "the declaration that FDA submitted to the Supreme Court of the United States in connection with seeking emergency relief in the *Alliance* litigation" in order to understand what FDA would expect of Danco if the court were to order the requested stay or injunction of the 2023 REMS); App., *infra*, 58a-59a ¶¶ 10-17

[7] As the District Court rightly pointed out, "the substance of the alleged deficiencies" in FDA's analysis, even if true, would "show only that the 2023 REMS was 'taken without sufficient consideration of the effects those changes would have on patients' due to a lack of underlying data." App., *infra*, 51a. As a result, nothing about these asserted deficiencies would show that in-person dispensing "is scientifically necessary to ensure mifepristone is 'safe' and 'effective.' " *Id.* Agencies, after all, can and do regularly make predictive judgments about scientific matters within their expertise on less-than-100%-perfect data. *See Seven Cnty. Infrastructure Coal.* v. *Eagle County*, 605 U.S. 168, 182 (2025) ("Black-letter administrative law instructs that when an agency makes those kinds of speculative assessments or predictive or scientific judgments, * * * a reviewing court must be at its most deferential.") (citation and quotation marks omitted).

(discussing FDA declaration and application to this case); Woodcock Decl., *supra*, pp. 113a-116a ¶¶ 11-16.

Finally, the Fifth Circuit shrugged off the District Court's concerns about judicial interference with FDA's statutory authority to make science- and medicine-based judgments, especially while FDA's own review is ongoing; the risks of conflicting judgments across the country; and the sweeping scope of Louisiana's requested relief which would invalidate the 2023 REMS nationwide. App., *infra*, 17a-18a.

Although the Fifth Circuit had ignored GenBioPro's request for a 7-day stay if the court were inclined to grant relief to Plaintiffs, Dkt. 72 at 24, Danco moved for an administrative stay immediately after the court ruled and reiterated the chaos from the order, the lack of prejudice to Plaintiffs from a short stay, and this Court's prior grant of an emergency stay of the similarly disruptive *Alliance* injunction. Dkt. 123. Because the time by which Danco requested an administrative stay has passed without a ruling, and Danco had informed the Fifth Circuit that Danco would seek emergency relief from this Court if the Fifth Circuit declined to rule, Danco now seeks an immediate administrative stay from this Court as well as a stay of the Fifth Circuit's judgment through the conclusion of that appeal and cross-appeal and, if warranted, the disposition of a timely filed petition for a writ of certiorari by Danco.

ARGUMENT

Under Rule 23 of the Rules of this Court and the All Writs Act, 28 U.S.C. § 1651, the Court may stay a court of appeals' preliminary ruling. *See, e.g.*, *Dep't of*

State v. *Aids Vaccine Advoc. Coal.*, 146 S. Ct. 19 (2025). To obtain a stay, an applicant must show a likelihood of success on the merits, a reasonable probability of certiorari, and a likelihood of irreparable harm. *See Hollingsworth* v. *Perry*, 558 U.S. 183, 190 (2010) (per curiam). In "close cases," "the Court will balance the equities and weigh the relative harms." *Id.* Those factors overwhelmingly support a stay here, not least because of the recent, controlling ruling of this Court that resolves those factors in Danco's favor. *See Danco I*, 143 S. Ct. at 1075; *Alliance*, 602 U.S. at 391-392.

I. DANCO IS LIKELY TO SUCCEED ON THE MERITS.

Danco makes the necessary showing that there is a "fair prospect that a majority of this Court will * * * grant a petition for a writ of certiorari and reverse the order below." *See Hollingsworth*, 558 U.S. at 191. The Fifth Circuit declined to apply this Court's standing analysis in *Alliance*, in derogation of the decision itself and of this Court's instruction that federal courts should "chiefly" evaluate standing "by comparing the allegations of the particular complaint to those made in prior standing cases." *Alliance*, 602 U.S. at 383-384. Contrary to what the Fifth Circuit concluded, the "causal link" between Plaintiffs' alleged injuries and "FDA's regulatory actions is * * * too attenuated to establish standing," and some of Plaintiffs' alleged injuries are not cognizable at all. *Id.* at 390. That is precisely what the Ninth Circuit held in *Washington* v. *FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024), a decision the Fifth Circuit never engaged with despite creating a circuit split by reaching the opposite conclusion. In *Washington*, the court of appeals held that under this Court's *Alliance* decision, Idaho lacked standing to challenge the 2023 REMS based on the same type

of sovereign and financial injuries asserted by Louisiana. Further, Plaintiffs have no viable merits claims.

A. Like the *Alliance* Plaintiffs, Louisiana Lacks Standing.

Nothing in FDA's 2023 REMS requires Louisiana to "prescribe or use mifepristone" or to "do anything or to refrain from doing anything." *Alliance*, 602 U.S. at 391-392. Thus, to establish Article III standing as an unregulated party, Louisiana faces the "substantially more difficult" task of showing that the 2023 REMS caused it some judicially cognizable injury. *Id.* at 382-383. This Court has already held that claims of downstream financial harm by doctors who provide follow-up care for treating complications after a medication abortion is too attenuated to create Article III standing. Louisiana's theory—that it can base standing on having to pay those doctors if someone who received FDA-approved mifepristone through the mail seeks follow-up care to treat a complication—is a *more* attenuated version of the doctor-standing theories *Alliance* expressly rejected. And a supposed sovereign injury resulting from federal law not mapping onto a particular state's law is not "legally and judicially cognizable" at all. *Texas*, 599 U.S. at 676 (citation omitted).

1. In *Alliance*, this Court unanimously held that the "chain of causation" between FDA's "safety regulations" and people "show[ing] up at emergency rooms or in doctors' offices with follow-on injuries" is "simply too attenuated" for Article III purposes. *Alliance,* 602 U.S. at 391-392. Allowing 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 be an "unprecedented" expansion of Article III requirements and

would have no "principled" endpoint. *Id.* at 392. That is why, as this Court emphasized, there "is no Article III doctrine of 'doctor standing' that allows doctors to challenge" any government action "affecting public health." *Id.*

It necessarily follows that a state cannot establish standing based on having to pay doctors for providing follow-up care if some individuals who are prescribed a drug "show up at emergency rooms or in doctors' offices" seeking that care. Such costs are indistinguishable from the innumerable other forms of "indirect effects on state revenues or state spending" that are ever present "in our system of dual federal and state sovereignty"—which both this Court and lower courts have made clear cannot form the basis for standing without eroding "Article III constraints." *Texas*, 599 U.S. at 680 n.3; *see also California* v. *Texas*, 593 U.S. 659, 675-678 (2021) (expressing skepticism of predictive effects on state budgets); *Maryland* v. *Dep't of Agric.*, 151 F.4th 197, 210 (4th Cir. 2025) (because "[i]nnumerable federal actions impact state budgets and programs," a state's "alleged decline[] in tax revenue" does not constitute "cognizable injury"); *Arizona* v. *Biden*, 40 F.4th 375, 386 (6th Cir. 2022) ("peripheral costs imposed on States" not "cognizable").

Faced with the same theory of standing, the Ninth Circuit correctly recognized that the expenditure of Medicaid dollars on follow-up care is insufficient *as a matter of law* to establish Article III standing to challenge FDA's regulation of mifepristone. *Washington*, 108 F.4th at 1174. Allowing states "to proceed based on predictions of increased emergency-room visits alone would give not just states, but every entity that provides health insurance or subsidized medical care, standing 'to challenge any

FDA decision approving a new drug,' " contrary to the Supreme Court's admonition. *Id.* at 1176 (quoting *Alliance,* 602 U.S. at 392). The Fifth Circuit never recognized, let alone engaged with, this consequence of its reasoning.

Nor did the Fifth Circuit (or the District Court) engage with the relevant portion of *Alliance*'s reasoning. App., *infra*, 11a-12a; *see id.* at 41a-42a. Instead, like the District Court, the Fifth Circuit sought to distinguish *Alliance* on the ground that, unlike the doctors in that case, "Louisiana provided hard evidence linking thousands of dollars in Medicaid costs to care stemming from out-of-state mifepristone." *Id.* at 12a. But Louisiana's evidence is irrelevant. This Court in *Alliance* expressly recognized that FDA's drug approvals may "yield more visits to doctors" because "virtually all drugs come with complications, risks, and side effects." 602 U.S. at 392. Nonetheless, the unanimous Court held, as a categorical rule, that FDA's loosening of safety requirements "is so far removed from its distant (even if predictable) ripple effects that the plaintiffs cannot establish Article III standing." *Id.* at 383.

Alliance thus squarely forecloses a state from basing Article III standing on a "downstream" invoice a doctor submits to a Medicaid program after providing care to someone who takes mifepristone. *Id.* at 383. "Lower court judges may sometimes disagree with this Court's decisions, but they are never free to defy them." *NIH* v. *Am. Pub. Health Ass'n*, 145 S. Ct. 2658, 2663 (2025) (Gorsuch, J., concurring in part and dissenting in part). "[I]ncreased costs to the state's Medicaid system" does not create Article III standing to challenge the 2023 REMS. *Washington*, 108 F.4th at 1174-76.

2. Louisiana cannot circumvent *Alliance*'s central holding by recasting the various downstream effects of the 2023 REMS as "sovereign" injury. The types of harms Louisiana asserts have not been " 'traditionally' recognized as providing a basis for a lawsuit in American courts." *TransUnion LLC* v. *Ramirez*, 594 U.S. 413, 424 (2021).

First, *Alliance* forecloses this "sovereign-harm" standing theory, too. The alleged harm to Louisiana's "sovereign interest in the power to create and enforce a legal code," App., *infra*, 9a, relies on the same attenuated causal link that *Alliance* rejected. In *Alliance*, this Court resisted the "sweeping doctrinal change" that would have been required to find standing for anyone with an interest in enforcing a regulation to sue to challenge it: "Firefighters" do not have standing "to object to relaxed building codes that increase fire risks;" "Police officers" do not have standing "to challenge a government decision to legalize certain activities that are associated with increased crime;" and "Teachers in border states" do not have standing "to challenge allegedly lax immigration policies that lead to overcrowded classrooms." *Alliance*, 602 U.S. at 392. The state governments are not better situated than the state employees that this Court highlighted in those examples. A "logistical burden on law enforcement" simply does not establish standing. *Washington*, 108 F.4th at 1177. "Holding 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.*

The types of harms to Louisiana that the Fifth Circuit accepted therefore contravene this Court's admonition in *Alliance* that the "downstream" consequence from some doctors choosing to prescribe mifepristone is an impermissibly "distant (even if predictable) ripple effect[]" of FDA's regulation. *Alliance*, 602 U.S. at 383. This is especially true here, where—as Louisiana's filings below made clear—the alleged frustration of Louisiana's laws occurs because other "states have enacted 'shield laws' to protect medical practitioners in their states from extradition for prescribing" mifepristone. App., *infra*, 41a; ECF No. 253 at 10-11. This difference in state policies is yet again a natural result of this Court "return[ing]" abortion policy to the states. *Dobbs*, 597 U.S. at 292.

Nor can Louisiana sidestep *Alliance* by conflating traceability with redressability. App., *infra*, 10a. The fact that enjoining a government action may stop indirect, attenuated "harms" does not mean that the harm is sufficiently non-attenuated to create Article III standing. *See, e.g.*, *Murthy* v. *Missouri*, 603 U.S. 43, 74 n.11 (2024) ("[W]hile traceability and redressability are *often* flip sides of the same coin, that is not *always* the case.") (citation and internal quotation marks omitted). Were it otherwise, the plaintiffs would have had standing in *Clapper* v. *Amnesty International USA*, because enjoining the government surveillance program would eliminate any risk of injury. 568 U.S. 398, 414 (2013). And every boundless hypothetical this Court invoked to show why the *Alliance* plaintiffs lacked standing—from doctors challenging air quality standards to firefighters suing over "relaxed building codes"—would come out the other way. 602 U.S. at 391-392.

Second, even setting *Alliance*'s causation analysis aside, Louisiana's standing theory must fail because it relies on an injury that is not cognizable. The states' sovereign interests derive from their status as "independent sovereigns" within the Constitutional framework. *Nat'l Fed'n of Indep. Bus.* v. *Sebelius*, 567 U.S. 519, 577-578 (2012) (*NFIB*). As independent sovereigns, states cannot be "require[d] * * * to govern according to Congress' instructions," *New York* v. *United States*, 505 U.S. 144, 162 (1992); cannot have their officers "command[ed] * * * to administer" federal law, *Printz* v. *United States*, 521 U.S. 898, 935 (1997); and cannot be coerced "to implement a federal program," *NFIB*, 567 U.S. at 577-578. *See generally Alfred L. Snapp & Son, Inc.* v. *Puerto Rico*, 458 U.S. 592, 601 (1982) (noting that a sovereign interest includes "the power to create and enforce a legal code."). An "invasion of a legally protected interest" thus occurs when the federal government violates those principles. *Spokeo, Inc.* v. *Robins*, 578 U.S. 330, 339 (2016) (quoting *Lujan* v. *Defs. of Wildlife*, 504 U.S. 555, 560 (1992)).

But FDA's approval of the 2023 REMS does not force Louisiana to implement a federal program, command Louisiana's officers, or otherwise interfere with Louisiana's status as an independent sovereign. To the contrary, Louisiana has repeatedly emphasized that it continues to exercise its authority to investigate and prosecute violations of its laws. *See* ECF No. 1 ¶¶ 100-102, 115. And, as the District Court noted, FDA's 2023 REMS "does not mean that medical providers * * * [are] free to ignore the laws of [their] states." App., *infra*, 40a n.13; s*ee also GenBioPro, Inc.* v. *Raynes*, 144 F.4th 258, 276 (4th Cir. 2025) (rejecting challenge that 2023 REMS

preempted a West Virginia law restricting abortion). Louisiana thus suffers no sovereign injury because nothing in the REMS undermines Louisiana's ability to legislate and enforce abortion restrictions as it sees fit. *See Washington*, 108 F.4th at 1177 (rejecting identical theory of injury).

The Fifth Circuit nevertheless thought Louisiana suffered sovereign harm because "the 2023 REMS sanctions and facilitates conduct with the express purpose of undermining Louisiana's legal restrictions on abortion." App., *infra*, 10a. As a purely factual matter, that central premise is wrong. FDA had already determined that in-person dispensing was not required for safe and effective use of mifepristone back in April 2021, before this Court's decision in *Dobbs*. And nothing in FDA's analysis of the scientific data that was before the agency demonstrates that FDA's decision was driven by an intent to stymie abortion law in any state or was based on any factors other than those Congress expressly told FDA to consider when designing a REMS program. ECF Nos. 1-10, 1-50.[8]

[8] The Fifth Circuit's opinion refers to materials outside the record. App., *infra*, 9a (citing Exec. Order No. 14076, 87 Fed. Reg. 42,053 (July 8, 2022). These materials are not referenced in any FDA decision documents that are in the record. And there is no evidence that these materials were a basis for FDA's decision-making. However, "[t]he grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based." *SEC* v. *Chenery Corp.*, 318 U.S. 80, 87 (1943). And "agencies are entitled to a presumption of regularity." *FDA* v. *Wages & White Lion Invs., LLC*, 604 U.S. 542, 577 (2025). That presumption of regularity serves as a "general working principle" that means courts will "insist on a meaningful evidentiary showing" before entertaining doubts about the integrity of official acts or documents. *Nat'l Archives & Records Admin.* v. *Favish*, 541 U.S. 157, 174-175 (2004). The Executive Order falls far short of suggesting that FDA's decision-making, in approving a change in the 2023 REMS that had already been in effect for almost three years, was so irregular that it warrants looking beyond the record. *See Biden* v. *Texas*, 597 U.S. 785, 812-813 (2022) (referencing the "strong showing of bad

More fundamentally, the Fifth Circuit's analysis makes a basic category error. Louisiana's abortion laws unquestionably remain enforceable as a legal matter; Louisiana's core complaint is that it has to work harder and expend more resources to pursue violations. *Contra, e.g.*, *Maine* v. *Taylor*, 477 U.S. 131, 137 (1986) (recognizing that a state has standing to defend its law against a constitutional challenge). But states having to devote resources to pursue their chosen policies does not undermine their status as co-equal sovereigns—states expending such resources is the *default* for health and safety laws. *See, e.g.*, *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475 (1996) (protecting citizens' "health and safety" is "primarily" a "matter of local concern" (citation and quotation marks omitted)). And a state has no "legally protected interest" in having federal policy match or facilitate its own. *Spokeo*, 578 U.S. at 339 (citation omitted); *see, e.g.*, *Haaland* v. *Brackeen*, 599 U.S. 255, 295 (2023) (rejecting allegation that federal statute "injures Texas by requiring it to break its promise to its citizens that it will be colorblind in child-custody proceedings" under state law). Were it otherwise, some state "would always have standing" to challenge every federal policy. *Brackeen*, 599 U.S. at 295. The "lack of historical precedent" for that standing theory is a "telling indication of the severe constitutional problem." *Texas,* 599 U.S. at 677 (citation omitted).

Applying these principles, the Ninth Circuit correctly recognized that the mere fact that the 2023 REMS may "mak[e] it easier for [state] residents to obtain and use

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faith or improper behavior" necessary to rebut the presumption of regularity) (quotation marks omitted).

mifepristone" cannot create standing because courts "have never held that a logistical burden on [state] law enforcement constitutes a cognizable Article III injury." *Washington,* 108 F.4th at 1177. A state's general "interest in the preservation of sovereign authority" does not confer "standing to challenge federal action that affects state law enforcement indirectly, by making violations of state law more difficult or costly to detect." *Id.* at 1176. The Fifth Circuit never engaged with this reasoning either, further underscoring that Danco is likely to show that Plaintiffs lack standing.

B. Danco Is Likely To Prevail On The Merits For Additional Reasons.

Beyond jurisdiction, Danco is also likely to show that Plaintiffs cannot succeed on their APA claims for other reasons. *See Hollingsworth*, 558 U.S. at 190.

1. Although parties must "exhaust[] all administrative remedies expressly prescribed" before seeking APA review, Plaintiffs never did so before seeking judicial relief. *See Darby* v. *Cisneros*, 509 U.S. 137, 146, 153 (1993). FDA's regulations mandate that any request for FDA to "take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a [citizen] petition" before suit is filed, 21 C.F.R. §§ 10.45(b), 10.25(a), but Plaintiffs never filed a citizen petition regarding either the 2023 REMS or the 2021 nonenforcement decisions. Courts in other circuits have routinely dismissed suits in such circumstances. *See, e.g.*, *Ctr. for Food Safety* v. *Hamburg*, 696 F. App'x 302, 303 (9th Cir. 2017) (mem. op.); *Ass'n of Am. Physicians & Surgeons* v. *FDA*, 358 F. App'x 179, 180-181 (D.C. Cir. 2009) (per curiam). This failure to exhaust is an independent

shortcoming that shows Plaintiffs are unlikely to succeed on the merits of their APA claims.

The District Court "decline[d] to substantively address" Plaintiffs' failure to exhaust. App., *infra*, 20a-21a n.3. The Fifth Circuit sought to excuse that failure based on its prior conclusion in the *Alliance* litigation that exhaustion by the *Alliance* plaintiffs would have been futile. *Id.* at 8a. That conclusion was wrong three years ago—and is doubly so now, when FDA has indicated it is conducting a thorough review of the mifepristone REMS as a result of, among other things, several citizen petitions—the exact thing that Plaintiffs say would have been futile to submit. The fact of FDA's ongoing review and consideration of citizen-petition arguments and materials plainly shows that this is not the "exceptional" case when "a *certainty* of an adverse decision" can excuse exhaustion. *Tesoro Refin. & Mktg. Co.* v. *FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009) (citations omitted). Other states did not seek to jump the line, and they submitted citizen petitions that FDA is in the process of addressing. ECF No. 51 at 7 & n.3. Louisiana should be held to the same standard.

2. Substantively, the Fifth Circuit was equally off-base. Without engaging in the substance of any arguments, the court simply summarized the panel decisions in *Alliance* that this Court reversed when it found the suit jurisdictionally deficient—and then declared them "persuasive." App., *infra*, 13a-14a. But those decisions—like the decision below—were made in an accelerated posture without the benefit of the full administrative record. And they misconstrue the basis for FDA's decision to remove in-person dispensing in two fundamental ways.

First, those earlier decisions wrongly faulted FDA for relying on the absence of reported adverse events as one supporting data point because such reporting has been voluntary for prescribers since 2016. App., *infra*, 13a; *see Alliance for Hippocratic Med.* v. *FDA*, No. 23-10362, 2023 WL 2913725, at *17 (5th Cir. Apr. 12, 2023) (per curiam). But, as Danco explained below, voluntary adverse event reporting by prescribers and patients is the norm for virtually all FDA approved drugs. Danco, like other drug manufacturers, must report every adverse event that it learns of from any source to FDA, and patients and providers can report any adverse events directly to FDA too. *See* App., *infra*, 59a-60a; 21 C.F.R. §§ 314.80, 314.81. FDA's approval of the 2023 REMS is thus fully consistent with FDA's duty to consider "adverse event report[s]." 21 U.S.C. § 355-1(a)(2)(A), (b)(3).

Although adverse event reporting surely does not capture every adverse event, FDA routinely relies on these data (or the lack thereof) as part of analyzing whether to modify or discontinue a REMS for all types of drugs. *E.g.*, FDA, Lotronex sNDA Approval 2 (Sep. 8, 2023), https://tinyurl.com/bdh82ftc. If consideration of voluntary adverse event reporting invalidates REMS-related decisions, virtually every REMS modification would be unlawful. FDA Scholars Br. 24-25, *Alliance for Hippocratic Med.* v. *FDA*, No. 23-235, 2024 WL 400099 (U.S. Jan. 30, 2024). Plaintiffs do not even attempt to justify this radical standard. As this Court has made clear, it "is not unusual" for agencies to act without "perfect empirical or statistical data." *FCC* v. *Prometheus Radio Project*, 592 U.S. 414, 427 (2021). And it is "[b]lack-letter" law that "a reviewing court must be at its most deferential" when considering an agency's

"predictive or scientific judgments." *Seven Cnty.*, 605 U.S. at 182 (citation and quotation marks omitted).

Second, the prior Fifth Circuit decisions faulted FDA's discussion of the scientific literature before the agency in December 2021, on the basis that FDA conceded that "the studies neither confirmed nor rejected" the necessity of in-person dispensing. App., *infra*, 13a-14a; *see Alliance CA5 Panel*, 78 F.4th at 250. That characterization is incorrect. FDA said its conclusion was "supported by [its] review of the published literature." ECF No. 1-10 at 25. And it was. FDA reviewed three studies permitting pharmacy dispensing by mail, none of which "raised serious safety concerns." ECF No. 1-50 at 45, 67-69. These studies supported finding "that the efficacy of medical abortion is maintained with mail order pharmacy dispensing." *Id.* at 69. In addition, FDA examined five studies allowing clinic dispensing by mail, which further "support that dispensing by mail is safe and effective." *Id.* at 69-75. Moreover, any limitations in the specific studies FDA examined were outweighed by the fact that *all* the studies supported that it was safe to remove the in-person dispensing requirement. Exercising its expert judgment, FDA determined this evidence collectively showed the "benefits of" lifting the in-person dispensing requirement "outweigh[ed] the risks." *Id.* at 11.

Further, even an agency decision that relies on the *absence* of data can be upheld if the agency makes a "reasonable predictive judgment." *Prometheus*, 592 U.S. at 427. Here, FDA reviewed the data and—based on the lack of real-world adverse events and multiple supporting studies—reasonably predicted that the in-

person dispensing requirement could be "modified * * * without compromising patient safety." ECF No. 1-10 at 22.

Contrary to what the Fifth Circuit held, FDA's decision to consider anew all evidence available today does not suggest (let alone establish) that its prior analysis fell short of the APA's standards. *Contra* App., *infra*, 13a. "Embedded in an agency's power to make a decision is its power to reconsider that decision." *ConocoPhillips Co.* v. *EPA*, 612 F.3d 822, 832 (5th Cir. 2010). "[A]n agency is free to alter its past rulings and practices, and even to reverse its course." *E. Columbia Basin Irrigation Dist.* v. *FERC*, 946 F.2d 1550, 1560 (D.C. Cir. 1991) (citations and quotation marks omitted). The mere fact that FDA is looking at additional years of evidence and conducting a new study is not a concession that its prior analysis was deficient under the APA. That is especially true given that FDA has not yet responded to the complaint or taken a position on the merits. *See* ECF No. 51; *contra* App., *infra*, 2a (wrongly stating that "FDA conceded" the merits).

II. THE REMAINING STAY FACTORS SUPPORT RELIEF.

The Fifth Circuit's ruling is extremely disruptive. Far from seeking an ordinary stay of a new agency action that has not yet gone into effect, the court immediately—upon the issuance of its order—stayed conditions on the distribution of mifepristone that have been in effect for over *five years*. This is unprecedented. Even in the prior *Alliance* litigation, the district court stayed its order for seven days to allow the federal government and Danco to seek emergency relief. *Alliance*, 668 F. Supp. 3d at 560.

Suspending the 2023 REMS, as the Fifth Circuit has done, causes immediate confusion and dramatic upheaval for manufacturers, distributors, providers, pharmacies, and patients around the country. App., *infra*, 18a. The harm to Danco and the public interest from the Fifth Circuit's order overwhelmingly favor a stay and significantly outweigh any downstream and attenuated injury to Louisiana—and warrant this Court's intervention. *See Hollingsworth*, 558 U.S. at 190. This Court has already concluded as much: Three years ago, this Court granted a stay before it granted certiorari and resolved the jurisdictional question in a virtually indistinguishable suit against Danco and FDA. *See Danco I*, 143 S. Ct. at 1075 (stay); *Alliance*, 602 U.S. at 391-392 (merits). At a minimum, this Court's earlier decisions indicate that the equities favor Danco.

A. This Case Warrants Review.

For at least three reasons, the issues presented in this application warrant this Court's review under its traditional certiorari criteria. *See Hollingsworth*, 558 U.S. at 190; *John Does 1-3* v. *Mills*, 142 S. Ct. 17, 18 (2021) (Barrett, J., concurring in the denial of application for injunctive relief).

To start, this Court regularly grants review when lower courts contravene this Court's precedents, and the decision below does exactly that. "[W]hen this Court issues a decision, it constitutes a precedent that commands respect in lower courts." *NIH*, 145 S. Ct. at 2663 (Gorsuch, J., concurring). Indeed, "unless we wish anarchy to prevail within the federal judicial system, a precedent of this Court must be followed by the lower federal courts no matter how misguided the judges of those

courts may think it to be." *Hutto*, 454 U.S. at 375. "[D]efiance of vertical *stare decisis*, if allowed to stand, substantially erodes confidence in the functioning of the legal system." *Andrus* v. *Texas*, 142 S. Ct. 1866, 1879 (2022) (Sotomayor, J., dissenting from denial of stay). This Court has not hesitated to intervene when it believes a lower court has sought to circumvent a decision that should have "squarely controlled." *See, e.g.*, *Trump* v. *Boyle*, 145 S. Ct. 2653, 2654 (2025) (per curiam) (intervening where decision below did not differ from an earlier decision "in any pertinent respect"); *DHS* v. *D.V.D.*, 145 S. Ct. 2627, 2630 (2025) (per curiam) (intervening where "a lower court has failed to give effect to an order of this Court"); *NIH*, 145 S. Ct. at 2661-62 (Barrett, J., controlling opinion) (intervening where party's argument attempted an "end-run" around previous decision).

The Court should do the same here. "[A] litigant who"—like Danco—"has obtained judgment in this Court after a lengthy process of litigation, involving several layers of courts, should not be required to go through that entire process again to obtain execution of the judgment of this Court." *D.V.D.*, 145 S. Ct. at 2630 (quoting *Gen. Atomic Co.* v. *Felter*, 436 U.S. 493, 497 (1978)). This Court's decision in *Alliance* was unanimous.

Review is also warranted because the decision below has injected "tremendous uncertainty" around the "interim legal status of * * * mifepristone rules," which is an issue of "national importance." *Trump* v. *CASA, Inc.*, 606 U.S. 831, 875-877 (2025) (Kavanaugh, J., concurring). "Keep[ing] in mind how much time it takes for the litigation process to run its course," the only way for Danco, doctors, patients, and the

public to have any clarity is for this Court to step in. *See Labrador* v. *Poe*, 144 S. Ct. 921, 929-930 (2024) (Kavanaugh, J., concurring). As Justice Kavanaugh has explained, "[o]ne of this Court's roles" is to "resolve major legal questions of national importance and ensure uniformity of federal law." *CASA*, 606 U.S. at 876 (Kavanaugh, J., concurring). And, rather than "abdicat[e]" that duty, this Court should speak "the final word on whether to green-light or block major new federal statutes and executive actions for the several-year interim until a final ruling." *Id.* Not only is that what "the American people appropriately expect"; it is what is required here. *Id.* at 877-878. Anything else would risk "severely harming the Government and would-be beneficiaries of" the challenged regulation. *Id.* at 875 (again identifying nationwide injunctions involving "mifepristone" as an archetypal example of cases where this Court must step in).

Review is also warranted for a third reason: The decision below creates a division among the courts of appeals. The Ninth Circuit—faithfully applying this Court's decision in *Alliance* and other recent precedents—held that states lack standing to challenge the 2023 REMS based on the same theories of sovereign and financial harm that Louisiana raises. *See Washington*, 108 F.4th at 1168 ("We are guided in our decision by the Supreme Court's recent decision on standing and the FDA's regulation of mifepristone in [*Alliance*]."); *see also supra*, pp. 20-21 (discussing Ninth Circuit decision). And because the Fifth Circuit has now "entered a decision in conflict with the decision of another United States court of appeals on the same important matter," Sup. Ct. R. 10(a), this Court's review is called for.

B. The Fifth Circuit's Order Inflicts Substantial, Certain, Unrecoverable Harm On Danco And The Public.

Both Danco and the public would be harmed in the absence of a stay. Danco—like any pharmaceutical manufacturer—is subject to a strict and complex regulatory regime. Danco understands the law to require Mifeprex to have an approved REMS and to be distributed in accordance with that REMS. Because there has never been a court-enjoined REMS, Danco faces substantial uncertainty as to what its obligations are, which could include revising product labels, packaging, and promotional materials; recertifying providers; and amending its supplier- and distributor-contracts and policies (among other things). App., *infra*, 57a-58a. None of these changes can occur without FDA signing off on a new REMS. FDA told this Court that the Fifth Circuit was wrong in *Alliance* when it assumed an old REMS would just "snap back" to some prior version. *Id.* at 58a-59a; Woodcock Decl., *supra*, p. 113a ¶ 11.

What can pharmacies do with the stock on their shelves? Louisiana's complaint is about mail-order pharmacies, but does the stay prevent brick-and-mortar pharmacies from dispensing drugs in-person to a patient? What acts of distribution by Danco or others in the supply chain could lead to civil and criminal penalties? *See* 21 U.S.C. § 333. There are no answers to these questions (and many others), leaving Danco—and others—to face a "Hobson's choice" between possible exposure "to potentially huge liability" or "suffer[ing] the injury of obeying the law during the pendency of the proceedings," which itself is irreparable harm. *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992). The impact here extends far

beyond Louisiana, because the FDCA does not envision or permit different drug approvals or REMS in different states.

Mifeprex is Danco's *only* product. Without a valid legal framework for distributing that product, Danco will lose its only source of revenue and may be unable to continue operating. App., *infra*, 60a. That harm, too, is irreparable. *See Wis. Gas Co.* v. *FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (economic harms irreparable when "the loss threatens the very existence of the movant's business").

A stay would also benefit the public. The Fifth Circuit's unprecedented order forces patients, providers, and pharmacies into immediate uncertainty, with no transition period and no practical guidance. Patients who have appointments—as soon as this morning—are in limbo. Providers who have already screened, counseled, and prepared patients for care may have to stop midstream, potentially unable to complete treatment plans that were set in motion days earlier. Pharmacies—many of which have already verified prescriptions and prepared medication for pickup—may be forced to suspend dispensing with virtually no notice, leaving staff uncertain about their obligations. The public interest thus adds to the weighty considerations favoring a stay.

C. The Balance of Equities Strongly Favors Danco.

On the other side of the ledger, Plaintiffs' asserted harms merely rehash their flawed theories of standing. But even if Louisiana had standing, Plaintiffs have still failed to make the "clear showing" of irreparable injury required for their "drastic remedy." *Mazurek* v. *Armstrong*, 520 U.S. 968, 972 (1997). Plaintiffs' litigation

conduct confirms it. "[A] party requesting a preliminary injunction must generally show reasonable diligence." *Benisek* v. *Lamone*, 585 U.S. 155, 159 (2018) (per curiam). But Plaintiffs waited nearly *three years* after FDA approved the 2023 REMS—and almost *five years* after FDA first applied the relevant policy—to bring this lawsuit. They then delayed months before seeking a preliminary injunction. This Court has made clear such delays should have weighed against Plaintiffs' belated assertion of a need for immediate injunctive relief. *E.g.*, *id.* at 160 (plaintiffs' "years-long delay in asking for preliminary injunctive relief weighed against their request"); *Texas* v. *EPA*, No. 23-60069, 2023 WL 7204840, at *11 (5th Cir. May 1, 2023) ("multi-year delay" "undercuts any claim that time is of the essence"); ECF No. 52-4 at 23 (collecting cases).

Nor do respondents need a sweeping injunction to protect their interests. FDA has already committed to engaging in further review of the 2023 REMS to address the kinds of concerns Louisiana raises. FDA has asserted that, given the recent litigation and "numerous citizen petitions," FDA wishes "to reconsider the restrictions on mifepristone based on all the evidence before the agency." ECF No. 51 at 2-3. In FDA's own words, this "review may eliminate any need for the Court's" intervention—presumably because the agency could decide to re-impose the kinds of restrictions Plaintiffs are seeking or to analyze the underlying data in a way that satisfies Plaintiffs. *Id.* at 10.

The Fifth Circuit's order short-circuits that process and imposes immediate and grave harm on the public. As multiple amici explained during the proceedings

below, the injunction Louisiana sought means that women across the nation—including from states with abortion policies that differ significantly from Louisiana's—will face medically unnecessary barriers to access a drug that FDA has repeatedly deemed safe and effective and that is the standard of care. *See, e.g.*, ECF No. 208 at 1, 5-9 (amicus brief of nine former FDA Commissioners and Acting Commissioners explaining that the agency's decisions with respect to mifepristone, including the 2023 REMS, were "consistent with sound science"); ECF No. 224 at 5, 20 (amicus brief of the American College of Obstetricians and Gynecologists and fourteen other medical societies, explaining that "the overwhelming weight of scientific evidence" shows that mifepristone is safe and that restricting it will "endanger pregnant patients").

Hospitals, clinics, and patients have, for years, relied on telemedicine in prescribing mifepristone, particularly for women from rural areas and those for whom transportation, childcare, or occupational constraints make it difficult to see providers in person. *See* 21 U.S.C. § 355-1(f)(2)(C)(i)-(iii) (obligating FDA to ensure that REMS are not "unduly burdensome on patient access to the drug"). For many women across the country, mifepristone is the best method to lawfully terminate a pregnancy. *See* ECF No. 210 (amicus brief of 19 states and the District of Columbia, describing importance of medication abortions). Enjoining the 2023 REMS would significantly limit those patients' abilities to obtain mifepristone in the time-sensitive fashion this context demands. Such a deprivation of "necessary medical care" thwarts

the public's interest. *Jones* v. *Tex. Dep't of Crim. Just.*, 880 F.3d 756, 759-760 (5th Cir. 2018) (per curiam).

D. The Fifth Circuit's Order Mandates Nationwide Chaos In The Guise Of An Equitable Remedy.

At a minimum, the stay factors show that the public interest and equities weigh against allowing the Fifth Circuit to change the availability of a drug nationwide at the request of a single state.[9] *See* App., *infra*, 18a (acknowledging that the stay has a nationwide effect). The Fifth Circuit's decision is unprecedented: Until now, no federal court has *ever* immediately commanded a drug revert to conditions of use that FDA has found are unwarranted under the REMS statutory framework. Given the equities at stake, the District Court denied Louisiana's request for a preliminary injunction but noted that the court's analysis may "change" if FDA did not "complete its review and make any necessary revisions to the REMS within a reasonable timeframe." *Id.* at 54a. That order represents the outer boundaries of appropriate relief in a case like this one.

1. The Fifth Circuit's order unquestionably disrupts a many-years-long status quo. A Section 705 stay is not an available remedy for agency action that has already gone into effect. It makes little sense to "postpone the effective date of an agency action" that has been operative for more than two years (and applied through enforcement discretion even longer). 5 U.S.C. § 705. Postponement must be

[9] As noted above, *supra*, pp. 31-32, although the Fifth Circuit styles its order as a stay under 5 U.S.C. § 705, a "stay" of an agency action that has already been in effect for five years is indistinguishable from an injunction. *Cf. Starbucks Corp.* v. *McKinney*, 602 U.S. 339, 346-348 (2024).

contemporaneous with or predate the effective date of the challenged agency action. *See, e.g.*, Webster's New International Dictionary 1682 (1927) (def. 1) ("postpone" means "to defer to a future or later time; to put off; delay"). Relatedly, a preliminary injunction is not an appropriate remedy where it alters the pre-litigation posture of the parties. The "limited purpose" of such relief "is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex.* v. *Camenisch*, 451 U.S. 390, 395 (1981). Yet the Fifth Circuit has upended the status quo that has been in place for nearly five years.

An alteration of the status quo is particularly inappropriate here because it runs the risk of "operat[ing], in effect, as a final judgment" by short-circuiting FDA's ongoing review and pre-ordaining the outcome. *See Trump* v. *Sierra Club*, 588 U.S. 930, 931-932 (2019) (Breyer, J., concurring in part and dissenting in part). Further, and in any event, the injunction offers Plaintiffs interim relief they would not automatically secure "in any final injunction that may be entered." *See De Beers Consol. Mines* v. *United States*, 325 U.S. 212, 220 (1945). Given "the disruptive consequences of an interim change that may itself be changed," the appropriate remedy if Plaintiffs were to prevail on the merits would be to remand without vacatur to allow FDA to consider and address any issue with its decision-making that the court identifies. *Allied-Signal, Inc.* v. *U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 150-151 (D.C. Cir. 1993). For example, another district court that considered the 2023 REMS and found it too "restrictive"—given available evidence that mifepristone is objectively safe—remanded back to FDA without vacatur. *See Purcell*, 2025 WL

3101785, at *2. A preliminary injunction should not award a party more relief than that.

2. The Fifth Circuit's order is also overbroad because it reaches beyond the parties to this litigation. The FDCA does not envision or permit different drug approvals or REMS in different states. *E.g.*, 21 U.S.C. §§ 355, 355-1. The Fifth Circuit's order is therefore incompatible with this Court's repeated instructions that remedies "must of course be limited to the inadequacy that produced the injury in fact." *Lewis* v. *Casey*, 518 U.S. 343, 357 (1996). Any court-ordered remedy "must not be 'more burdensome [to the defendant] than necessary to redress the complaining parties.' " *Texas*, 599 U.S. at 702 (Gorsuch, J., concurring) (quoting *Califano* v. *Yamasaki*, 442 U.S. 682, 702 (1979)). An order of vacatur can improperly "stymie the orderly review of important questions," "sweep up nonparties who may not wish to receive the benefit of the court's decision," and "facilitate efforts to evade the APA's normal rulemaking processes." *Id.* at 703 (Gorsuch, J., concurring).

Illustrating the point: Other, similarly-situated states have consented to a stay of litigation while FDA performs its review. In *Florida* v. *FDA*, No. 7:25-cv-00126 (N.D. Tex.), Florida and Texas bring APA claims against FDA challenging, *inter alia,* the same FDA mifepristone REMS that Louisiana challenges here, based on the same theories of harm and standing. And just days ago, Florida and Texas filed a brief consenting to a seven-month stay pending FDA's ongoing review. They explained that "[b]ecause the FDA is substantively reconsidering all the Challenged Actions, the States agree that a time-limited stay would promote 'economy of time

and effort for [the Court], for counsel, and for litigants.' " Pls.' Resp. to Mot. to Stay or to Dismiss 6, *Florida* v. *FDA*, No. 7:25-cv-00126 (N.D. Tex. Apr. 24, 2026), ECF No. 56. As the District Court in this case rightly acknowledged, "this case arises amid multiple parallel lawsuits across the country addressing the same regulatory issues surrounding access to mifepristone," and the "substantial risk of inconsistent judicial outcomes" counsels in favor of a stay. App., *infra*, 49a. The Fifth Circuit's intervention deprives Florida, Texas, and FDA of their agreed-upon relief and disrupts the court's proceedings in that parallel suit.[10]

Nor is there anything in the text of the APA that required the Fifth Circuit to enter a sweeping remedy. The APA preserves "the power or duty of the court to * * * deny relief on any * * * equitable ground." 5 U.S.C. § 702(1). And Section 705 of the APA itself adopts the general rule that preliminary injunctive relief should be limited as "necessary to prevent irreparable injury"—*i.e.*, the injury to the parties who brought the suit. *Id.* § 705. Moreover, Congress enacted the APA against a background rule that statutory remedies should be construed in accordance with "traditions of equity practice." *Hecht Co.* v. *Bowles*, 321 U.S. 321, 329 (1944). Consistent with that background rule, the relief available in an action under the APA includes traditional forms of equitable actions and relief. *Cf. Arizona*, 40 F.4th at 396

[10] Before the Fifth Circuit, Louisiana dismissed the District Court's concern for other litigants and other decision-makers as "not the proper judicial role." Dkt. 12-1 at 22. But "a district court should 'think twice—and perhaps twice again—before granting' such sweeping relief." *Texas*, 599 U.S. at 703 (Gorsuch, J., concurring) (citation omitted). And that is what the District Court here did. App., *infra*, 50a-52a (citing *Texas*, 599 U.S. at 702-703 (Gorsuch, J., concurring)).

(Sutton, C.J., concurring) (noting that there is no sound reason to conclude that Congress "meant to upset the bedrock practice of case-by-case judgments with respect to the parties in each case" by adopting the "unremarkable" "set aside" language in 5 U.S.C. § 706).

III. THIS COURT SHOULD ISSUE AN ADMINISTRATIVE STAY.

Given the sweeping and immediate nature of the Fifth Circuit's order, Danco also requests that this Court grant an administrative stay while it considers this application. As in *Danco I*, an administrative stay is warranted to preserve the status quo. Since the amended REMS was announced in 2023, Danco has been free to rely on the procedures set by FDA to distribute its product. The Fifth Circuit's decision immediately ends that. A stay should issue to prevent the disruption and confusion that will result if the decision below were to remain operative. And that is all the more true here, where this Court has already addressed the jurisdictional question (in a decision the Fifth Circuit has now defied) and is likely to reverse, *see supra*, pp. 19-21. An administrative stay is thus warranted to avoid subjecting the public to that sort of regulatory whiplash on this important issue. Importantly, Louisiana appears to agree that permitting the 2023 REMS to remain in effect at least until May 11 would not cause it irreparable harm. *See* Dkt. 12 (docket text) (requesting relief by "05/11/2026"). And "[u]nless and until this Court grants * * * an application for stay," "tremendous uncertainty" will surround the legal status of mifepristone "throughout the country." *See CASA*, 606 U.S. at 875 (Kavanaugh, J., concurring).

CONCLUSION

The Court should stay the Fifth Circuit's injunction pending the consideration and disposition of Louisiana's appeal and Danco's cross-appeal to the Fifth Circuit and, if the Court of Appeals alters the District Court's judgment in any way other than to order dismissal, pending the timely filing and disposition of Danco's petition for a writ of certiorari and any further proceedings in this Court. Alternatively, the Court should grant certiorari before judgment and set this case for expedited briefing and argument before the summer recess. In addition, Danco respectfully requests an immediate administrative stay of the Fifth Circuit's judgment pending the Court's consideration of this application.

Respectfully submitted,

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