No. 26-30203

IN THE

United States Court of Appeals for the Fifth Circuit

THE STATE OF LOUISIANA, *et al.*,
Plaintiffs-Appellants,

v.

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

and

DANCO LABORATORIES, LLC,
Intervenor-Defendant-Appellee.

On Appeal from the United States District Court for the Western District of Louisiana, No. 6:25-cv-01491-DCJ-DJA (Joseph, J.)

DANCO LABORATORIES, LLC'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR A STAY OR INJUNCTION PENDING APPEAL

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April 23, 2026

CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

1. **Case Number and Style**: No. 26-30203, *Louisiana v. U.S. Food and Drug Admin.*

2. **Plaintiffs-Appellants**: The State of Louisiana, by and through its Attorney General, Liz Murrill; and Rosalie Markezich

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4. **Defendants-Appellees**: U.S. Food and Drug Administration; Martin A. Makary, M.D., M.P.H., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; Tracy Beth Høeg, M.D., Ph.D., in her official capacity as Acting Director, Center For Drug Evaluation And

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5. **Counsel for Defendants-Appellees**: Brett A. Shumate; James W. Harlow; and Noah T. Katzen of the U.S. Department of Justice

6. **Intervenors-Defendants-Appellees**:

Danco Laboratories, LLC. Danco Laboratories, LLC states that its parent corporation is Danco Investors Group, LP. Danco is 100% owned by that parent corporation.

GenBioPro, Inc. In the District Court, GenBioPro, Inc. stated that "its parent company is Xenia Holdco LLC, and that there is no publicly held corporation that owns 10% or more of its stock." District Court ECF.55.

7. **Counsel for Intervenors-Defendants-Appellees**:

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[1] Pursuant to Federal Rule of Civil Procedure 25(d), Dr. Høeg has been automatically substituted for her predecessor.

8. **Amici and their Counsel in the District Court**:

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[2] A full list of participating amici can be found at District Court ECF.141.

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[3] A full list of participating amici can be found at District Court ECF.155-3. In the District Court, amici represented that: "One supporting signatory to the amicus brief, Endora, operates under a fiscal

Former Commissioners and Acting Commissioners of the U.S. Food and Drug Administration (David A. Kessler, M.D.; Jane E. Henney, M.D.; Margaret Hamburg, M.D.; Robert M. Califf, M.D.; Michael A. Friedman, M.D.; Joshua M. Sharfstein, M.D.; Stephen Ostroff, M.D.; Norman E. "Ned" Sharpless, M.D.; Janet A. Woodcock, M.D.)

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sponsorship arrangement with Aspiration Tech.; however no publicly traded corporation owns ten (10%) or more of its stock." District Court ECF.228.

Brown of the Washington Office of the Attorney General; Dan Rayfield of the Oregon Office of the Attorney General; Brian L. Schwalb of the District of Columbia Office of the Attorney General; and Peter F. Neronha of the Rhode Island Office of the Attorney General

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[4] A full list of amici appears at District Court ECF.167-2.

[5] A full list of amici appears at District Court ECF.170-2.

Intervenor-Defendant-Appellee reserves the right to supplement this disclosure with other financially interested persons or entities identified as the appeal progresses.

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth

Counsel for Intervenor-Defendant-Appellee Danco Laboratories, LLC

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INTRODUCTION

The District Court gave Plaintiffs the benefit of every doubt—yet still concluded that the extraordinary injunction they seek is unwarranted. That bottom-line conclusion is correct. Far from seeking an ordinary stay of a new agency action, Plaintiffs here are asking to enjoin conditions on the distribution of mifepristone that the Food and Drug Administration (FDA) first implemented *five years ago*. Suspending those conditions—codified since 2023 in the risk evaluation and mitigation strategy (REMS) for mifepristone—would cause immediate nationwide confusion and dramatic upheaval for manufacturers, distributors, providers, pharmacies, and patients around the country. The Supreme Court stayed an injunction granting analogous preliminary relief three years ago, *Danco Laboratories v. Alliance for Hippocratic Med.*, 143 S. Ct. 1075 (2023), before unanimously concluding that plaintiffs in that case lacked Article III standing, *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 391-392 (2024) (*Alliance*). Plaintiffs do not come close to justifying a different result.

In fact, Plaintiffs fare far worse than the District Court recognized. Ignoring *Alliance*'s reasoning, the District Court concluded that

Louisiana had standing because (1) FDA's REMS approval—based on the agency's determination of what "is necessary to ensure that the benefits of the drug outweigh the risks," "not unduly burdensome on patient access," and "minimize[s] the burden on the health care delivery system," 21 U.S.C. § 355-1(a)(1), (g)(5)(B)(ii), (iii)—differs from Louisiana's general policy of prohibiting abortions and (2) women can experience complications after a medication abortion for which they seek follow-up care, and providers may bill Medicaid for the follow-up care.

But *Alliance* expressly held that a plaintiff's assertion that it will incur "downstream" expenses related to FDA's approval of mifepristone use restrictions does not create Article III standing to challenge that approval. 602 U.S. at 383. And in other cases, the Supreme Court has rejected state-standing theories that turn on mere misalignment between state and federal policies. *See, e.g.*, *United States v. Texas*, 599 U.S. 670, 681 (2023). As the Ninth Circuit correctly recognized, it necessarily follows that states lack standing to challenge FDA's supposed under-regulation of a drug based on the types of financial or sovereign injuries Louisiana asserts. *Washington v. FDA*, 108 F.4th 1163, 1175-76 (9th Cir.

2024). Each of Louisiana's standing theories is either directly foreclosed by *Alliance*, or not cognizable under any existing doctrine.

The District Court made other significant errors. It never addressed Plaintiffs' failure to exhaust administrative remedies. It ignored the merits arguments Defendants-Intervenors presented. And its evaluations of Louisiana's claims of irreparable harm repeated its mistaken standing analysis.

Even so, the District Court correctly concluded that the Plaintiffs did not demonstrate a need for the District Court to address any of these issues in a rushed posture. Before Plaintiffs brought suit, FDA had already announced that it was undertaking an internal review of the mifepristone REMS that will consider the issues raised in Plaintiffs' complaint. Having waited years to bring this action, Plaintiffs cannot show that basic principles of prudence or equity favor a rushed and abbreviated judicial intervention. Plaintiffs' request for an extraordinary and disruptive injunction should be denied.

STATEMENT

1. Danco, a small pharmaceutical company incorporated in Delaware, holds the approved New Drug Application for Mifeprex

(mifepristone) Tablets. Mifepristone is used for the medical termination of early intrauterine pregnancy. ECF.1-24.[6] Mifeprex is Danco's only product. ECF.52-2 at 1 (Long Decl.).

Mifepristone is subject to certain use restrictions known as a "risk evaluation and mitigation strategy," or REMS, "to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). Congress instructed FDA to periodically evaluate a drug's REMS to ensure that it is "not unduly burdensome on patient access" and "minimize[s] the burden on the health care delivery system," *id.* § 355-1(g)(5)(B)(ii), (iii).

Under its original approval and REMS, patients were required to appear in person at a provider's office to receive mifepristone. During the COVID-19 pandemic, the American College of Obstetricians and Gynecologists asked FDA to lift that requirement. ECF.1-32 at 2. After studying the medical literature, adverse-event reporting, and other data, FDA found no indication that adverse events occurred with greater frequency when a patient received the drug by a method other than in-

[6] Unless otherwise specified, ECF references are to the District Court docket, No. 6:25-cv-01491 (W.D. La.). ECF page numbers reference the blue ECF headers.

person dispensing. ECF.1-3. In 2021, FDA decided to exercise enforcement discretion as to the in-person dispensing requirement during the public health emergency. *Id.*

2. In November 2022, a group of physicians that oppose abortion challenged various FDA decisions related to mifepristone, including the 2021 non-enforcement decision. *See Alliance for Hippocratic Med. v. FDA*, No. 2:22-ccv-00223-MJK (N.D. Tex. Nov. 18, 2022). That district court found the plaintiffs had standing and issued a preliminary injunction of FDA's approvals related to mifepristone from 2000 onward. *See Alliance*, 602 U.S. at 377. A stay panel of this Court affirmed that injunction for FDA's actions from 2016 onward, but the injunction never took effect. *See Alliance for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725 (5th Cir. Apr. 12, 2023) (per curiam) ("*Alliance* Stay"). The Supreme Court immediately granted emergency relief and stayed it. *Danco*, 143 S. Ct. 1075. Then, the Supreme Court unanimously reversed this Court's judgment in favor of the plaintiffs, and held that the plaintiffs lacked Article III standing. *Alliance*, 602 U.S. 367 (reversing *Alliance for Hippocratic Med. v. FDA*, 78 F.4th 210 (5th Cir. 2023) ("*Alliance* Merits")).

3. On January 3, 2023, based on additional data from the non-enforcement period, FDA approved a REMS modification eliminating the in-person dispensing requirement. *See* ECF.1-10, 1-50, 1-51.

On October 6, 2025, Plaintiffs here, Louisiana and Rosalie Markezich, filed a complaint in the Western District of Louisiana challenging the 2023 REMS, which had formalized the non-enforcement policy in place since April 2021. ECF.1. Months passed. Plaintiffs then moved for a preliminary injunction. ECF.20, 20-26.

The government opposed Plaintiffs' motion and moved for a stay while FDA independently reconsiders the 2023 REMS. ECF.51; *see also* ECF.1-110.

Danco intervened, moved to dismiss the complaint, and opposed Plaintiffs' preliminary injunction motion. ECF.52, 229. Danco argued that, like the original *Alliance* plaintiffs, Plaintiffs lack standing. ECF.52-4. 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.* And Danco emphasized the nationwide harm to the public and to Danco that would result from a stay. *Id.* at 24-25.

The District Court denied Plaintiffs' motion for preliminary relief without prejudice; denied Danco's motion to dismiss without prejudice; and granted the government's motion to stay the litigation during the agency's REMS review. ECF.258 (Dist.Ct.Opp). Though the District Court determined that Plaintiffs have standing and are likely to succeed on the merits, *id.* at 16-28, it also 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 3 (quoting *Texas*, 599 U.S. at 704 (Gorsuch, J., concurring)); *see also id.* at 28-36.

Plaintiffs now ask this Court to upend the status quo that has been in place for five years by granting them an injunction pending appeal. Pls.' Mot., Fifth Circuit Doc.12-1 (Mot.).

ARGUMENT

Injunctive relief pending appeal is an "extraordinary remedy." *Texas v. United States*, 40 F.4th 205, 215 (5th Cir. 2022) (per curiam) (quotation omitted). Unlike an ordinary stay that "simply suspend[s] judicial alteration of the status quo," this type of "injunctive relief 'grants judicial intervention that has been withheld by lower courts.'" *Nken v.*

Holder, 556 U.S. 418, 429 (2009). A party is not entitled to that remedy as a "matter of right, even if irreparable injury might otherwise result." *Texas Democratic Party v. Abbott*, 961 F.3d 389, 397 (5th Cir. 2020) (quotation omitted).

The Court considers four factors in deciding whether to grant an injunction or stay pending appeal: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties … and (4) where the public interest lies." *Nken,* 556 U.S. at 426 (citation omitted). Plaintiffs must "clearly carr[y] the burden of persuasion" that the District Court abused its discretion in analyzing those factors. *Anibowei v. Morgan*, 70 F.4th 898, 902 (5th Cir. 2023) (quotation omitted). They fall far short.

I. PLAINTIFFS LACK ARTICLE III STANDING.

Just as was the case with the *Alliance* plaintiffs, nothing in FDA's 2023 REMS requires Louisiana to "prescribe or use mifepristone" or to "do anything or refrain from doing anything" with mifepristone. *Alliance*, 602 U.S. at 391-392. That means, like the *Alliance* plaintiffs, Plaintiffs

have no non-attenuated, non-speculative cognizable injury-in-fact that is "'traditionally redressable in federal court.'" *Alliance*, 602 U.S. at 379, 381 n.1 (citation omitted).[7] The "pocketbook" harm Louisiana asserts from having to pay providers if someone enrolled in Medicaid seeks follow-up care after a medication abortion is a *more* attenuated version of the doctor-standing theories rejected in *Alliance*. And Louisiana's alleged sovereign injury from FDA's REMS determination is not a "legally and judicially cognizable" injury at all. *Texas*, 599 U.S. at 676 (quotation omitted).

A. *Alliance* Forecloses Standing Based On Downstream State Medicaid Payments.

Like the District Court, Plaintiffs mention *Alliance* only in passing, and ignore its reasoning. But—as the Ninth Circuit correctly recognized in a similar suit brought by Idaho challenging the 2023 REMS—*Alliance* squarely forecloses a state from basing Article III standing on a "downstream" invoice a doctor submits to a Medicaid program after

[7] Plaintiffs, rightly, have not maintained that Rosalie Markezich has standing to seek injunctive relief, ECF.111 at 2 n.2; *see also* Dist.Ct.Op.25n.15. Louisiana's requested injunction from this Court rests entirely on Louisiana's claim that it has standing. Mot.12. In any event, Markezich lacks standing, too. ECF.52-4 at 12-13.

providing follow-up care if someone takes mifepristone. *Washington*, 108 F.4th at 1175; *see also Alliance*, 602 U.S. at 384 (federal courts should "chiefly" evaluate standing "by comparing the allegations of the particular complaint to those made in prior standing cases").

Alliance 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 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. Indeed, 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 courts have made

clear cannot form the basis for standing without eroding "bedrock 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. Department 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").

For this reason, the Ninth Circuit held 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 District Court did not engage with *Alliance*'s reasoning—and neither does Louisiana. Dist.Ct.Op.23-24; Mot. 14-16. Instead, the

District Court reasoned that causation exists because "out-of-state medical providers … responded to the 2023 REMS by expanding mifepristone access to pro-life states like Louisiana in ways that were entirely predictable." Dist.Ct.Op.20. That doesn't work. *Alliance* did not turn on whether the "downstream" injury was predictable: Indeed, the Supreme Court expressly recognized that FDA's drug approvals can predictably "yield more visits to doctors" because "virtually all drugs come with complications, risks, and side effects." 602 U.S. at 392. But the 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. Were it otherwise, every one of the hypotheticals *Alliance* rejected as being outlandish—from firefighters challenging building safety codes to teachers challenging immigration policy, *id.* at 392—could come out the opposite way.

Ignoring the reasoning of a recent Supreme Court decision is remarkable in any circumstance. "Lower court judges may sometimes disagree with this Court's decisions, but they are never free to defy them." *NIH v. American Public Health Ass'n*, 606 U.S. __, 145 S. Ct. 2658, 2663

(2025) (Gorsuch, J., concurring in part and dissenting in part). *Alliance* dictates that "increased costs to the state's Medicaid system" does not create Article III standing for the state to challenge the 2023 REMS. *Washington*, 108 F.4th at 1174-76.

B. Louisiana Suffers No Cognizable Sovereign Injury.

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

This circuit has held that states can suffer cognizable "sovereign" harm if the federal government exerts "substantial pressure on them to change their laws." *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015); *see also Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015) (same). And it is true that in our system of federalism, states are "independent sovereigns" and cannot be "force[d] … to implement a federal program." *National Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 577-578 (2012).

But FDA's approval of the 2023 REMS does not stop Louisiana from being an independent sovereign, or force Louisiana to implement a federal program. Nor does Louisiana argue that FDA's action preempted any Louisiana law. To the contrary, Louisiana has repeatedly emphasized that it continues to exercise its authority to investigate and prosecute violations of its laws. *See* Mot.13 n.7; ECF.1 ¶¶ 100-102, 115. Indeed, as District Court noted, FDA's 2023 REMS "does not mean that medical providers … [are] free to ignore the laws of [their] states." Dist.Ct.Op.22n.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).

That should be the end of the matter. Louisiana suffers no sovereign injury because nothing in the REMS undermines Louisiana's "authority to regulate or to enforce its laws." *Harrison v. Jefferson Parish Sch. Bd.*, 78 F.4th 765, 770 (5th Cir. 2023); *see also Washington*, 108 F.4th at 1177 (Ninth Circuit reaching the same conclusion with respect to Idaho). Nor does the 2023 REMS otherwise "compel the State[] to require or prohibit" any conduct or to change its laws. *Printz v. United States*, 521 U.S. 898, 924 (1997).

The District Court nevertheless thought Louisiana suffered sovereign harm because the 2023 REMS could "undermine[] the enforcement" of Louisiana law in the sense of requiring more effort by Louisiana to enforce its policy against abortions. Dist.Ct.Op.17, 21-22. This approach misunderstands sovereign harm. As the Ninth Circuit explained, the mere fact that the 2023 REMS may "mak[e] it easier for [state] residents to obtain and use 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.

For good reason. Our system of dual sovereignty creates boundless variations between federal and state policy on issues ranging from immigration to voting rights to government provision of benefits. Every such variation can, at some level, be characterized as the federal government interfering with the state's chosen policy. *See, e.g.*, *Haaland v. Brackeen*, 599 U.S. 255, 295 (2023) (analyzing 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). But states have no cognizable interest in having federal policy match theirs. Otherwise, some state "would always have standing" to challenge every federal policy. *Id.* 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).

Louisiana cannot rescue its sovereign-harm theory by pointing to the District Court's statement that FDA supposedly approved the 2023 REMS to "circumvent anti-abortion states' ability to regulate abortion." Dist.Ct.Op.21; Mot. 15. FDA had already elected not to enforce the in-person dispensing requirement back in April 2021, and nothing in FDA's analysis of the scientific data that is before the Court demonstrates an intent to stymie abortion law or look beyond the factors Congress told FDA to consider. ECF.1-10, 1-50. In any event, even if FDA's decision made it "predictable" that mifepristone could be mailed to patients, Mot.15; Dist.Ct.Op.21, that does not—and cannot—elevate Louisiana's nebulous harms to a concrete Article III injury-in-fact.

Nor, for that matter, can the District Court's statement overcome the Supreme Court's admonition that the "downstream" consequences of 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. Dist.Ct.Op.23; ECF.253 at 10-11. Nothing in the 2023 REMS compels or directs any third party to violate Louisiana law, speaks to extradition, or grants immunity to those who violate Louisiana law. The difference in state policies that is the source of Louisiana's frustration is a natural result of the Supreme Court "return[ing]" abortion policy to the states. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 292 (2022).

II. PLAINTIFFS LACK A LIKELIHOOD OF SUCCESS FOR ADDITIONAL REASONS.

Plaintiffs also cannot make the requisite "strong showing" on the merits for other reasons. *Nken*, 556 U.S. at 434 (quotation marks omitted).

1. Although parties must "exhaust[] all administrative remedies expressly prescribed" before seeking APA review, Plaintiffs ran into Court without doing so. *See Darby v. Cisneros*, 509 U.S. 137, 146, 153 (1993). Other states, in contrast, did not seek to jump the line, and submitted citizen petitions that FDA is in the process of addressing. ECF.51 at 7 & n.3.

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); *see id.* § 10.25(a). Plaintiffs never filed a citizen petition regarding either the 2023 REMS or the 2021 non-enforcement decision. Courts routinely dismiss suits in such circumstances. *See, e.g.*, *Center for Food Safety v. Hamburg*, 696 F. App'x 302, 303 (9th Cir. 2017) (mem. op.); *Association of Am. Physicians & Surgeons v. FDA*, 358 F. App'x 179, 180-181 (D.C. Cir. 2009) (per curiam).

Dismissal is particularly appropriate because FDA has indicated it is conducting a thorough review of the REMS, based on, among other things, several citizen petitions. This alone is strong evidence that exhaustion would not be futile. *See generally Tesoro Refin. & Mktg. Co.*

v. FERC, 552 F.3d 868, 874 (D.C. Cir. 2009) (noting that the futility "exception is quite restricted" and should be applied only in the "exceptional" case when there is "a *certainty* of an adverse decision" (quotations omitted)).

The District Court "decline[d] to substantively address" Plaintiffs' failure to exhaust even as it concluded that Plaintiffs were likely to prevail on the merits of their APA claim. Dist.Ct.Op.2n.3. This was error. Plaintiffs' failure to exhaust is an independent and sufficient ground to deny Plaintiffs relief.

2. Plaintiffs also urge this Court to ignore the "particular judicial deference" owed to agencies on scientific matters and to second-guess FDA's judgment about the 2023 REMS based entirely on this Court's prior *Alliance* decisions. *Atchafalaya Basinkeeper v. U.S. Army Corps of Eng'rs*, 894 F.3d 692, 701 (5th Cir. 2018); *see* Mot.19-20. But those decisions—like the District Court's 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" since 2016. *Alliance* Stay, 2023 WL 2913725, at *17. But, as Danco explained below, adverse-event reporting is voluntary 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* Long Decl. ¶¶ 18-19; 21 C.F.R. §§ 314.80, 314.81.

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, *All. for Hippocratic Med. v. FDA*, No. 23-235, 2024 WL 400099 (5th Cir. Jan. 30, 2024). Plaintiffs do not even attempt to justify this radical standard. *See FCC v. Prometheus Radio Proj.*, 592 U.S. 414, 427 (2021) (it "is not

unusual" for agencies to act without "perfect empirical or statistical data").

Second, the prior 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. *Alliance* Merits, 78 F.4th at 250. Respectfully, this is incorrect. FDA said its conclusion was "supported by [its] review of the published literature." ECF.1-10 at 26. 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.1-10 at 23.

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. "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." *East Columbia Basin Irrigation Dist. v. FERC*, 946 F.2d 1550, 1560 (D.C. Cir. 1991) (quotations and citations 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.51; Mot.3.

III. THE BALANCE OF HARMS AND EQUITIES OVERWHELMINGLY FAVORS DEFENDANTS.

Plaintiffs also come up short on the remaining equitable factors. Although they, at times, characterize their request as a "stay," there is no question Plaintiffs functionally seek a nationwide injunction. *See* Mot.23-24.[8] Their requested relief would "'not simply suspend judicial alteration of the status quo," it would "grant[] judicial intervention that has been withheld by lower courts,' and therefore 'demands a significantly higher justification' than that required for a stay." *Lux v. Rodrigues*, 561 U.S. 1306, 1307 (2010) (Roberts, C.J., in chambers) (quoting *Ohio Citizens for Responsible Energy, Inc. v. NRC*, 479 U.S.

[8] Indeed, it makes little sense to "postpone the effective date of an agency action" that has been in effect for years. 5 U.S.C. § 705.

1312, 1313 (1986) (Scalia, J., in chambers)). Thus, even if the applicant shows a likelihood of success on the merits, no injunction should issue unless the applicant "sufficiently demonstrate[s] that the balance of harms and equities favors it at [the] time." *NetChoice, LLC v. Fitch*, 145 S. Ct. 2658 (2025) (Kavanaugh, J., concurring in denial of application to vacate stay). Here, Plaintiffs are asking this Court to upend a status quo that has been in place for five years. They do not come close to justifying that extraordinarily disruptive result.

1. The District Court's conclusion that Louisiana is facing ongoing irreparable harm relied exclusively on its erroneous standing analysis. Dist.Ct.Op.28. 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); *contra* Mot. 17-18.

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 implemented the relevant policy—to

bring this lawsuit. They then delayed months before seeking a preliminary injunction. Those delays are fatal to their request for injunctive relief. *E.g.*, *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.52-4 at 23 (collecting cases).

2. Likewise, the District Court gave minimal attention to Danco's harms, notwithstanding its duty to "consider the effect *on each party* of the granting or withholding of the requested relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008) (emphasis added).

In the *Alliance* litigation, FDA stated to the Supreme Court that an order suspending the mifepristone REMS would require FDA to approve a new REMS.[9] Long Decl. ¶¶ 8-14; Gov. Opening Br. 46-47, *Alliance* (U.S. Jan. 23, 2024). That costly and time-consuming process would likely be complicated by the fact that any proposal for a modified REMS would ask FDA to add a burden to the healthcare delivery system, in violation of FDA's statutory directive to minimize such burdens. *See* 21 U.S.C. § 355-1(f)(2)(C), (D). And unlike when the merits panel ruled in *Alliance*, there

[9] The mifepristone REMS also governs the two generic products on the market. *See* ECF.52-4 at 2 n.1.

is no Supreme Court stay in effect to give Danco or FDA "time … to arrange for mifepristone to be distributed" pursuant to a new REMS. *Contra Alliance* Merits, 78 F.4th at 253.

Because Mifeprex is Danco's only product, any order staying or suspending the current REMS would threaten Danco with certain, unrecoverable harm: without a valid legal framework for distributing its product, Danco will lose its only source of revenue and may be unable to continue operating. *See* Long Decl. ¶¶ 3, 11, 16-17, 20; *see generally Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021) (economic harms irreparable when the "alleged financial injury threatens the very existence of [a party's] business" (quotation marks omitted)).

3. Despite its errors in weighing Louisiana and Danco's harms, the District Court did correctly recognize that the equities weigh heavily against an injunction.

Plaintiffs are asking this Court to engage in "rushed, high-stakes, [and] low-information decision-making," even though, as the District Court recognized, the deficiencies they claim do not allow this Court to determine "whether FDA's in-person dispensing requirement is

scientifically necessary to ensure mifepristone is 'safe' and 'effective.'" Dist.Ct.Op.32. The several pending related lawsuits create the risk of conflicting judgments and direction. *Id.* at 35. Especially in the face of FDA's ongoing review of the current REMS, this type of disruption is entirely unwarranted. *See Texas v. United States*, 50 F.4th 498, 531 (5th Cir. 2022) (preserving the status quo given the "inevitable disruption that would arise from a lack of continuity and stability") (quotation omitted); *Campaign for S. Equal. v. Bryant*, 773 F.3d 55, 58 (5th Cir. 2014) (disruption from lack of continuity in an "important area of law" harms "the public interest at large").

Further, because the FDCA does not envision or permit different drug approvals or REMS in different states, "the relief sought by Plaintiffs would, as a practical matter, have a nationwide effect." Dist.Ct.Op.32. As a result, Louisiana's requested relief raises all the same concerns presented by nationwide injunctions, which tend to "stymie the orderly review of important questions …, facilitate efforts to evade the APA's normal rulemaking processes," and impose burdens on non-parties. *Texas*, 599 U.S. at 703 (Gorsuch, J., concurring).

And that's not all. Were this Court to grant an injunction, 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. 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"); *see also* ECF.148-2 (describing barriers). For many women across the country, mifepristone is the best method to lawfully terminate a pregnancy. *See* ECF.158-1. Enjoining the 2023 REMS would significantly limit those patients' ability to obtain mifepristone in the time-sensitive fashion this context demands. Such a deprivation of "necessary medical care" imposes irreparable harm. *Jones v. Texas Dep't of Crim. Just.*, 880 F.3d 756, 759-760 (5th Cir. 2018) (per curiam).

Presented with these same considerations, the Supreme Court in *Alliance* stayed an analogous order disrupting mifepristone distribution.

143 S. Ct. 1075. That decision necessarily reflected the Court's judgment that the equities weigh in favor of denying preliminary relief. *Nken*, 556 U.S. at 434. Plaintiffs are not entitled to a different result.

CONCLUSION

This Court should deny Plaintiffs' motion.

Respectfully submitted,

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April 23, 2026

CERTIFICATE OF COMPLIANCE

I hereby certify that this motion complies with the requirements of Federal Rule of Appellate Procedure 27(d) because it has been prepared in 14-point Times New Roman, a proportionally spaced font. I further certify that this motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 5,182 words, according to the count of Microsoft Word.

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CERTIFICATE OF SERVICE

I certify that on April 23, 2026, I electronically filed the foregoing response brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I certify that the participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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