No. 25A1207

IN THE

Supreme Court of the United States

DANCO LABORATORIES, L.L.C.,

Applicant,

v.

THE STATE OF LOUISIANA, ET AL.,

Respondents.

REPLY IN SUPPORT OF APPLICATION TO STAY THE JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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INTRODUCTION

The Fifth Circuit's decision last Friday evening "introduced a profoundly destabilizing force into the Nation's drug regulatory regime," the consequences of which "extend far beyond the particular drug or regulatory action at issue here." PhRMA Br. 2. The court "improperly dismissed, and fundamentally misunderstood, the significant reliance interests that patients and providers have on the statutorily mandated process by which FDA must direct or approve updates to a drug's conditions of use," and "in less than two pages addressing the merits, the Fifth Circuit effectively rewrote those conditions of use overnight." Blood Cancer United Br. 2-3. The impact was direct, immediate, and chaotic. Patients could not pick up prescriptions even in-person at pharmacies; providers did not know if they could continue prescribing mifepristone; and Danco, as Mifeprex's sponsor, lost—without any of the administrative process Congress prescribed—its right to market its product consistent with FDA's judgment about what use restrictions are supported by the statutory REMS factors. The nationwide ruling ran "roughshod over [this] Court's recognition in *Dobbs* that 'the people of the various States may evaluate' the interests of a woman who wants an abortion and the interests in fetal life differently, 597 U.S. at 256, and the Court's determination to 'return the issue of abortion to the people's elected representatives,' *id.* at 232." New York Br. 3.

This emergency application does not come to this Court on a blank slate. Almost exactly three years ago, this Court granted Danco's emergency application to stay a similarly disruptive ruling upending a many years' old status quo—involving

this same drug, the same defendant agency's judgment under the same statutory scheme, and the same merits analysis. After granting certiorari, this Court then unanimously held that the plaintiffs lacked Article III standing and therefore did not reach the merits issues on which it also had granted certiorari. This Court should grant Danco's emergency application again, and if it does so, Plaintiffs "acquiesce in certiorari before judgment." Opp. 5.

Plaintiffs' efforts to avoid a stay from this Court fall apart upon examination. The Executive Order they quote (at 6) to say that President Biden "promised 'abortion care, including medication abortion'—'especially for those who live in States that are banning or severely restricting abortion care,' " La.Appx.233, says no such thing. And another source they quote from June 2022 (Opp. 6) speaks to keeping mifepristone accessible "*in light of the FDA's determination that the drug is safe and effective including when prescribed through telehealth and sent by mail*," La.Appx.242 (emphasis added), which was a scientific judgment FDA reached over a year earlier, in April 2021, and reiterated in December 2021, La.Appx.120-122, 146-186—flatly contradicting Plaintiffs' preferred narrative.[1]

And Plaintiffs' assertion that being handed the drug packet at a provider's office is "the only opportunity to screen for dangerous conditions like ectopic pregnancy, to accurately access gestational age, to screen for coercion and trafficking,

[1] Notably, the *Alliance* Plaintiffs—represented by the same counsel as Plaintiffs here—told this Court that "FDA's December 2021 action * * * permanently removed the in-person dispensing requirement." No. 23-235, Alliance Merits Br. 57-58. So did Louisiana. Mississippi et al. *Alliance* Br. 13.

and to ensure informed consent" relies entirely on the declaration of an *Alliance*-plaintiff doctor who is opposed to medication abortion and who has never treated patients seeking that care. Opp. 10 (citing La.Appx.606-608, 612-613, 615); *compare Alliance*, No. 2:22-cv-00223 (N.D. Tex.), ECF No. 1-8. In reality, FDA has said for the last decade that it is "inappropriate" "to mandate how providers clinically assess women," and that providers may conclude that obtaining a medical history or reviewing medical records suffices, La.Appx.157—meaning Mifeprex-certified providers can assess, and for years have assessed, the appropriateness of mifepristone for a given patient without a physical examination, independent of where the patient ultimately is handed or receives a medication packet (at a clinic, in a pharmacy, through the mail). *See* Physicians for Reproductive Health Br. 9 ("[P]hysicians report that in-person and telehealth assessments for prescribing mifepristone are substantially similar, and emphasize their ability to date a pregnancy using the patient's last menstrual cycle, recognize the symptoms of ectopic pregnancy, and counsel patients about their available options via telehealth.").

Plaintiffs' standing theories face the same flaws that the *Alliance* plaintiffs' did—and then some. Louisiana's asserted pocketbook injuries are both *more* attenuated than those of the doctors in *Alliance* and are based on the assertion that federal law has an indirect effect on state spending—neither of which are bases for standing. Louisiana's asserted "sovereign" injury is not a judicially remediable injury at all, and Plaintiffs can point to no case allowing a state to claim sovereign injury based on a state's desire for a federal regulatory approach that would advance the

state's own policy preferences. The Court should apply the same neutral principles here that it did in *FDA* v. *Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) and *United States* v. *Texas*, 599 U.S. 670, 678 (2023). That adheres to this Court's guidance that "in 'many cases the standing question can be answered chiefly by comparing the allegations of the particular complaint to those made in prior standing cases.' " *Alliance*, 602 U.S. at 384 (citation omitted).

On the merits, Plaintiffs wrongly suggest (at 38) that Danco gave "short shrift" to the merits by spending only five pages on those issues. Danco Appl. 27-31. But the Fifth Circuit spent 10 lines addressing exhaustion, Danco Appx. 8a, and less than 20 analyzing the merits of Plaintiffs' APA claims, *id.* at 13a-14a. The entirety of the court's analysis was to summarize the Fifth Circuit's holdings in its two *Alliance* decisions, both reversed by this Court after it found the plaintiffs lacked standing.

Those Fifth Circuit decisions misconstrued the basis for FDA's decision in two fundamental ways. Under the Fifth Circuit's approach, which Plaintiffs embrace, FDA's adverse-event reporting data "cannot be used to indicate drug safety." Opp. 39. The REMS statute, however, directs FDA to look for "new safety information" in "adverse event report[s]." 21 U.S.C. § 355-1(b)(3). And FDA regularly considers FAERS data as an information source about drug safety. *See, e.g.*, Fmr. FDA Comm'rs Br. 13-14 (FDA "uses FAERS data for virtually all approved drugs," and "[i]f FDA were not entitled to rely on the lack of adverse-event data regarding mifepristone from FAERS because FAERS relies on voluntary physician reporting—as it does for virtually all other approved drugs—it would upend FDA's rigorous, well-

established system for drug approvals and other regulatory decisions"). Plaintiffs offer no basis for their assertion (at 41) that "adverse event reports" "are not the same thing as FAERS data" when FAERS is an acronym for FDA Adverse Event Reporting System. In addition, neither the Fifth Circuit nor Plaintiffs acknowledge that FDA's conclusion was "supported by [its] review of the published literature," no study "raised serious safety concerns" about non-in-person dispensing, "the efficacy of medical abortion is maintained with mail order pharmacy dispensing," and several studies "support that dispensing by mail is safe and effective." Danco Appl. 30 (citing La.Appx.171, 293, 315-323).

Finally, the equitable factors support a stay from this Court to maintain what has been the status quo for more than five years, just as they did in April 2023 when the same equitable factors were at play and the Court granted a similar stay. *See Danco Lab'ys* v. *Alliance for Hippocratic Med.*, 143 S. Ct. 1075 (2023).

ARGUMENT

I. DANCO IS LIKELY TO SUCCEED ON THE MERITS.

This Court granted certiorari in *Alliance* to consider both a standing and a merits question. By ruling on standing, it did not reach the merits. There is a fair prospect this Court will agree to hear both the standing and merits questions again. Indeed, Plaintiffs acquiesce in cert before judgment if a stay is granted. Opp. 58.

A. Louisiana's Standing Theories Lack Merit.

Alliance established that "when determining whether an unregulated party has standing," a plaintiff cannot "challenge FDA's drug approvals simply on the

theory that use of the drugs by others may" lead to downstream "monetary and related injuries." *Alliance*, 602 U.S. at 384, 390-392. Such harms are "simply too attenuated" from FDA's actions—and recognizing them as a basis for standing would fashion "a novel standing doctrine out of whole cloth." *Id.* at 391. The Fifth Circuit sped past these "clear rules." *See id.* at 384. Louisiana's arguments here are incompatible with this Court's decision.

1. Plaintiffs invite this Court to abandon *Alliance* and find that Louisiana's claimed financial injuries create Article III standing because they are the "predictable effect" of FDA's 2023 REMS. Opp. 28 (citation omitted). Their response brief devotes a great deal of space to discussing cases like *Department of Commerce* v. *New York*, 588 U.S. 752 (2019), *Diamond Alternative Energy, LLC* v. *EPA*, 606 U.S. 100 (2025), and *First Choice Women's Resource Centers, Inc.* v. *Davenport*, No. 24-781, 2026 WL 1153029 (U.S. Apr. 29, 2026), which assess this aspect of causation. Opp. 27-29. And they attempt to retrofit the prior administration's statements into support for their narrative that FDA intended to injure Louisiana when it approved the 2023 REMS change, formalizing the policy in place since April 2021 that mifepristone need not be picked up in person at a provider's office. *Id.* at 30; *see supra*, n.1.

All this misses the issue. *Alliance* recognized that the predictability aspect of Article III causation guards against parties asserting injuries that are too speculative. As the Court put it, predictability "precludes speculative links—that is, where it is not sufficiently predictable how third parties would react to government action or cause downstream injury to plaintiffs." 602 U.S. at 391-392. But "the line

of causation between the illegal conduct and injury—the links in the chain of causation, *Allen* [v. *Wright*], 468 U.S. [737,] 752, 759 [(1984)]—must not be too speculative *or too attenuated*, *Clapper*[v. *Amnesty Int'l USA*], 568 U.S. [398,] 410-411 [(2013)]." *Alliance*, 602 U.S. at 383 (emphasis added and quotation marks omitted). Claims are too attenuated "where the government action is so far removed from its distant (even if predictable) ripple effects that the plaintiffs cannot establish Article III standing." *Id.*

Downstream financial affects from treating complications of an FDA-approved drug fell on the "too attenuated" side of the line for the unregulated *Alliance* plaintiffs, and they are no less attenuated here. *Id.* at 383, 391. Louisiana is likewise unregulated by FDA and "suffer[s] no direct monetary injuries from FDA's actions relaxing regulation of mifepristone." *Id.* at 385-386. For Louisiana to incur the Medicaid expenses it asserts, it must pay doctors for treating patients who experience rare complications after taking mifepristone. Just as in *Alliance*, accepting such a chain between FDA's actions and "downstream economic injuries [via] the doctors" would leave "no principled way to cabin" it. *Id.* at 386, 392. Every state and every insurance provider could trace similar costs to the government's loosening of "general safety regulations"—from "roll[ing] back emissions standards" to loosening "restrictions on guns"—merely by aggregating statistical evidence showing the regulatory change could have predictable impacts on people's health and welfare. *Id.* at 391; Danco Appl. 23.

Plaintiffs' proposed causation shortcut—simply presuming causation is

satisfied if a plaintiff says vacatur of an agency decision would avoid an asserted harm—proves too much. It would elevate all sorts of speculative and attenuated harms to Article III standing—contrary to any standing analysis this Court has endorsed. *See* Opp. 31. This Court has always separately addressed causation and redressability for just this reason. *Alliance*, 602 U.S. at 383-384. The fact that enjoining a government action may redress an attenuated injury does not mean that the injury meets the causation requirement. If it were otherwise, the *Clapper* plaintiffs should have had standing to enjoin the surveillance program: The injunction would have ensured their communications stayed private. *Clapper*, 568 U.S. at 410-412. The *Lyons* plaintiff should have had standing to enjoin the chokehold policy: The injunction would have ensured his safety. *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 105-106 (1983). And on and on.

Unlike the Fifth Circuit, the Ninth Circuit declined an invitation from another state to find Article III standing to challenge the 2023 REMS on similar theories. *Washington* v. *FDA*, 108 F.4th 1163, 1174-76 (9th Cir. 2024). That holding faithfully applied this Court's precedent.

2. Louisiana's "sovereign injury" theory likewise lacks merit. FDA's approval of the 2023 REMS does not stop Louisiana from "creat[ing] and enforc[ing] a legal code." Opp. 21 (citing *Alfred L. Snapp & Sons, Inc.* v. *Puerto Rico*, 458 U.S. 592, 601 (1982)). As Louisiana puts it, "[n]obody disputes" it criminalizes abortion, *id.* at 23, and it has "outstanding arrest warrants" for individuals whom it believes violated Louisiana law, *id.* at 11.

Louisiana asserts injury from "out of state prescribers who mail mifepristone into Louisiana while avoiding capture in Louisiana," which Louisiana compares to the United States' injury in a False Claims Act suit. *Id.* at 22, 24. But the two are not remotely the same. In a False Claims Act suit, the United States' injury is *the defendant's violation of the federal law*. *Contra* Opp. 22 (citing *Vt. Agency of Nat. Res.* v. *U.S. ex rel. Stevens*, 529 U.S. 765 (2000)). Here, there is no contention that FDA's exercise of its statutory authority in 21 U.S.C. § 355-1 to approve REMS modifications violated any Louisiana law.

That is likely why Louisiana quickly pivots to arguing that FDA's approval of the 2023 REMS is an "obstacle" to enforcing Louisiana law. Opp. 22. But unlike the "storied tradition" Louisiana invokes, *id.*, FDA's approval of the 2023 REMS does not "expressly prevent[]" Louisiana from taking any action—as was the case in *Bowen* v. *Public Agencies Opposed to Social Security Entrapment*, 477 U.S. 41, 48 (1986) ("[t]he [federal statutory] amendment expressly prevents States from" taking specific actions). And the other cases Louisiana cites were all actions in which the federal government asserted that a state or local law was preempted or otherwise unconstitutional under the Supremacy Clause. Opp. 23 (citing *Arizona* v. *United States*, 567 U.S. 387 (2012) (preemption); *United States* v. *Missouri*, 114 F.4th 980, 984 (8th Cir. 2024) (Supremacy Clause); *United States* v. *King County*, 122 F.4th 740, 750 (9th Cir. 2024) (Supremacy Clause). Neither Louisiana nor the federal government has taken the position that FDA's approval of the 2023 REMS preempts Louisiana law under the Supremacy Clause.

Louisiana has no case endorsing an "obstacle" theory like it asserts here. That is unsurprising, because nothing about FDA's approval of the 2023 REMS requires out-of-state providers to take any action with respect to Louisiana, allows anonymous prescribing, grants immunity to out-of-state providers who violate Louisiana law, legally invalidates Louisiana law, or commandeers Louisiana to administer federal law. Nothing about the 2023 REMS "require[s] the State[] to govern according to Congress' instructions" or "commandeers [the] State's legislative or administrative apparatus for federal purposes." *Nat'l Fed'n of Indep. Bus.* v. *Sebelius*, 567 U.S. 519, 577 (2012) (citations omitted). Nor does Louisiana assert that the 2023 REMS tramples on its power to enact laws in a way that gives rise to standing like in the cases it cites. *Maine* v. *Taylor*, 477 U.S. 131, 137 (1986) (state interest in contesting "adjudication that its import ban is unconstitutional"); *Cameron* v. *EMW Women's Surgical Ctr.*, 595 U.S. 267, 271 (2022) (interest in "defending the constitutionality" of state law). As this Court has made clear, "for standing purposes, the absence of coercive power over the [State] makes a difference." *Texas*, 599 U.S. at 678.

It speaks volumes that Louisiana has "not cited any precedent, history, or tradition of" this Court accepting voluntary third-party decisions to violate state criminal law as an Article III injury that a state can vindicate in a suit against the federal government. *Texas*, 599 U.S. at 677; *see TransUnion LLC* v. *Ramirez*, 594 U.S. 413, 424 (2021) ("'[H]istory and tradition offer a meaningful guide to the types of cases that Article III empowers federal courts to consider.' ") (citation omitted); *Saginaw County* v. *STAT Emergency Med. Servs., Inc.*, 946 F.3d 951, 956 (6th Cir.

2020) (Sutton, J.) ("That someone violates a law * * * does not by itself injure the government in an Article III way. Only 'actual or threatened interference with [its] authority' does" (quoting *United States* v. *West Virginia*, 295 U.S. 463, 473 (1935)). Louisiana's suggestion that a third-party's violation of state law "injure[s] the community" in a way that amounts to sovereign injury, *Ellingburg* v. *United States*, 146 S. Ct. 564, 574 (2026) (Thomas, J., concurring) (cited at Opp. 22, 24), runs headlong into established prohibitions against states bringing *parens patriae* suits against the federal government, *see Haaland* v. *Brackeen*, 599 U.S. 255, 295 (2023) ("[A] State does not have standing as *parens patriae* to bring an action against the Federal Government.").

In any event, Louisiana's formulation of sovereign injury merely runs it right back into the original *Alliance* causation problem. Like its Medicaid expenses, the State's claimed violations of Louisiana law involve (at a minimum) a multi-step daisy chain of third-party discretionary actions, including someone in Louisiana choosing to seek FDA-approved medication abortion from an out-of-state provider via telemedicine (as opposed to traveling out of state); the out-of-state provider electing to prescribe and mail the drug to someone in Louisiana; and the patient taking the drug while physically in Louisiana.[2] The daisy chain is further elongated by other states' independent decisions to enact "shield" laws, which affect providers' behavior.

[2] Because Louisiana is not challenging mifepristone's approval generally, it must establish that the injury flows from the elimination of in-clinic dispensing given that there are other ways an individual could receive the product. *See California* v. *Texas*, 593 U.S. 659, 669 (2021) (plaintiff must trace its injury to the specific " 'allegedly unlawful conduct' of which they complain").

Contrary to what Louisiana suggests (at 35), this causal chain is no less attenuated than that alleged by the doctors in *Alliance*. 602 U.S. at 386.

Louisiana's asserted "obstacles" amount to a claimed logistical burden on law enforcement—at bottom, an argument that pursuing and prosecuting violations requires additional state resources. Opp. 26. That is the same type of "indirect effects on state revenues or state spending" this Court has cautioned against as a basis for standing in "our system of dual federal and state sovereignty." *Texas*, 599 U.S. at 680 n.3. Caution is especially apt here because—as Louisiana does not deny—much of the logistical difficulty and cost derives from *other* states enacting conflicting laws.

Louisiana's logic would automatically grant standing to states any time the federal government deregulates in a context in which some state wants more regulation. But this Court has rejected the proposition that states have a protected interest in having the federal government make state policies easier to implement or enforce. *See, e.g., Texas*, 599 U.S. at 678 (states lack standing to contest "that the Executive Branch has made an insufficient number of arrests or brought an insufficient number of prosecutions"). Louisiana has enacted into state law its "general legal, moral, ideological, or policy objection to" abortion, but that does not create Article III standing to challenge FDA's approval of the 2023 REMS. *Alliance*, 602 U.S. at 381; *see, e.g.*, *Haaland*, 599 U.S. at 295 (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).

The Ninth Circuit correctly rejected this theory of standing also, holding that

the 2023 REMS does not infringe on state sovereign interests because it does not "interfere[] with [a State's] authority to enact or enforce restrictions on medical abortion within its boundaries." *Washington,* 108 F.4th at 1177. Louisiana attempts to distinguish that decision by claiming that it did not consider the exact record and theories here. Opp. 37. But, once again, the Ninth Circuit correctly applied this Court's precedent. Louisiana remains free to prohibit abortion and to enforce those prohibitions. Neither the downstream violations of its laws nor the practical difficulties it faces in enforcement gives it Article III standing to sue FDA.

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

Like the Fifth Circuit, Plaintiffs do not identify any evidence FDA failed to consider in approving the 2023 REMS. Plaintiffs instead take issue with FDA's assessment of the evidence before it and wrongly claim (at 18) that FDA "now concedes" that its 2023 REMS approval violated the APA. But FDA actually said that its ongoing review of the REMS "obviate[ed] any need to consider the merits of Plaintiffs' arguments." La.Appx.690. Plaintiffs rely on a letter Secretary Kennedy sent to state attorneys general opposed to abortion that referenced a supposed "lack of adequate consideration underlying the prior REMS approvals." La.Appx.478. But there is a mandatory process FDA must use to change a drug's REMS. A cabinet official cannot circumvent that process by sending a letter to political stakeholders and thereby somehow invalidate FDA's years-earlier conclusion—one that FDA told this Court was "the result of a thorough scientific review by agency experts." FDA

Alliance Br. 42-43 (quoting FDA Dec. 2021 citizen petition response, La.Appx.151).[3]

In any event, the 2023 REMS approval must stand or fall on the record before the agency at the time. *Vt. Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 549 (1978) (citation and quotation marks omitted). FDA's contemporaneous explanations in 2021 and 2023—finding after "comprehensive review[s]" that "mifepristone will remain safe and effective" without an in-clinic dispensing requirement, La.Appx.293, 328—amply satisfy the APA's "deferential arbitrary-and-capricious standard." *Seven Cnty. Infrastructure Coal.* v. *Eagle County*, 605 U.S. 168, 180 (2025).

Because the Fifth Circuit's sparce treatment of these issues included no independent analysis, Plaintiffs spend page after page trying to backfill. Opp. 38-45. But offering Plaintiffs' say-so that FDA gave "dispositive weight' to FAERS data" and relied on literature that was "not adequate on [its] own to establish the safety" of dispensing mifepristone by mail, Opp. 39, is insufficient to show an APA violation. It is Plaintiffs who err by siloing the many considerations FDA took into account in its decision—REMS assessment data, FAERS data, studies, literature, and other information, *see* La.Appx.328—combined.

[3] Deviating from that prior position would require specific actions by FDA. *See FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (agency "must" "provide a more detailed justification" if its changed position "rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests"); Opp. 38 (agreeing with this principle). That would be an especially high hurdle, where "[t]he scientific evidence collected and published since 2023 has only further confirmed the safety and effectiveness of removing the in-person dispensing requirement," Reproductive Health Researchers Br. 16-19; *see also id.* at 20-25 (debunking the EPPC "study" referenced in Secretary Kennedy's letter); ACOG Br. 7-12.

FAERS data does not contain every adverse event, to be sure, but it is still a "useful tool for FDA for activities such as looking for new safety concerns that might be related to a marketed product." La.Appx.392 (FDA website). FDA "regularly" uses this data to look for trends in adverse reporting following a change in a drug's conditions of use. FDA Scholars Br. 11; *see* Fmr. FDA Comm'rs Br. 14 ("FDA routinely relies on data reported through the FAERS system to support its decision to modify or remove REMS"). FDA explained that the mifepristone FAERS data showed no "new safety concerns * * * during the time when in-person dispensing was not enforced," La.Appx.171-172, 263, 328—which, along with other post-marketing assessments and published literature, supported finding that in-person dispensing was "no longer necessary to ensure that the benefits of the drug outweigh the risk" and should be modified "to reduce the burden on the health care delivery system," La.Appx.168, 171. Those are exactly the "kinds of speculative assessments or predictive or scientific judgments" where "[b]lack-letter administrative law instructs" "a reviewing court must be at its most deferential." *Seven Cnty.*, 605 U.S. at 182 (citation and quotation marks omitted).

Plaintiffs' complaint that FDA acknowledged limits in the studies it reviewed does not show an APA violation either. Under 21 U.S.C. § 355-1, which articulates the factors to be considered in a REMS modification (*contra* Opp. 43, wrongly invoking the standard in 21 U.S.C. § 355(d)), FDA is instructed to modify a REMS where an existing use condition is no longer necessary to "ensure the benefits of the drug outweigh the risks," or to "minimize the burden on the health care delivery

system." 21 U.S.C. § 355-1(g)(4)(B)(i), (ii); *see id.* § 355-1(f)(2)(C), (D). Those are precisely the reasons FDA gave for its decisions in 2021 and 2023, La.Appx.259, 269; *see* FDA Scholars Br. 14-15, and defended in this Court. Agencies "must have the freedom to make 'a reasonable predictive judgment' based on the available evidence." FDA *Alliance* Br. 44 (quoting *FCC* v. *Prometheus Radio Project*, 592 U.S. 414, 427 (2021)); *contra* Opp. 43 (misstating that FDA "never made" the argument "that agencies may make decisions in the absence of data").[4]

Plaintiffs do not excuse their failure to exhaust—particularly given that other states and interested parties exhausted their claims, and FDA is conducting an ongoing review of the mifepristone REMS that takes into account their views. FDA's regulations specify that anyone who "wishes to rely upon information or views not included in the administrative record" must independently "submit * * * a new petition to modify the action under § 10.25(a)." 21 C.F.R. § 10.45(f). That applies here. It is not an "abuse of process," *contra* Opp. 46, for FDA to provide a tentative response within 180 days, as required by its regulation, before providing a *final*

[4] Louisiana's parsing of the literature also gets the science wrong, underscoring why courts defer to agencies on these sorts of decisions. For instance, Louisiana claims the literature reflects "more frequent ED/urgent care visits," Opp. 43, but omits FDA's explanation that this may have been due to "significant distances" study participants lived from their providers, and that the study reported that "half of the participants who had an ED/urgent care visit did not require medical treatment." La.Appx.323; *see also* FemInEM Br. 18 ("numbers linked with emergency department visits capture patient behavior, not clinical harm"); Yale L. Sch. Info. Soc'y Br. 15. Women seeking follow-up care for observation, pain medication, or to confirm that they are no longer pregnant does not suggest the method of dispensing was somehow problematic. *See* Reproductive Health Researchers Br. 6-13.

decision. 21 C.F.R. § 10.30(e)(2).[5] Plaintiffs cannot show it would have been futile to ask FDA to consider Louisiana's views and evidence as part of the ongoing review. And Plaintiffs' "irreparable injury" exception tries to have it both ways; Louisiana cannot sit on its hands for years only to say now that it had no time to go to FDA.

II. THE REMAINING STAY FACTORS SUPPORT RELIEF.

A. This Case Warrants Review.

Review is warranted for the reasons explained in Danco's application. A lower court all but ignored this Court's reasoning and analysis in *Alliance*. *See, e.g.*, *Mallory* v. *Norfolk S. Ry. Co.*, 600 U.S. 122, 146 (2023) (vacating and remanding when decision below plainly conflicted with Supreme Court precedent). This case implicates a question of "national importance." *Trump* v. *CASA*, 606 U.S. 831, 876-877 (2025) (Kavanaugh, J., concurring); *see also FDA* v. *Alliance for Hippocratic Med.*, 144 S. Ct. 537 (2023) (mem.) (granting certiorari on all three questions presented, including "[w]hether FDA's 2016 and 2021 actions were arbitrary and capricious").[6] And there is an irreconcilable split of authority among the circuits. *See* Danco Appl. 34.

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

Plaintiffs brush away the substantial collateral harm flowing from the Fifth Circuit's order. That order "sets a precedent that—if left undisturbed—could

[5] The student note on which Louisiana relies admittedly did "not consider" "tentative decisions" by FDA. Michael Krupka, *Exasperated But Not Exhausted*, 77 Vand. L. Rev. 937, 956 n.144 (2024) (cited at Opp. 46).

[6] Plaintiffs attempt to recast (at 19-20) this Court's decision to grant certiorari in *Alliance* as a function of only the "significant standing issue," but the Court had no choice but to stop after it held the plaintiffs there lacked standing. "Article III require[d]" as much. *Alliance*, 602 U.S. at 379.

significantly disrupt the biopharmaceutical industry, harm patients, and stifle innovation in drug development." PhRMA Br. 2. "Opening the door to state-by-state second-guessing of drug regulation would place [drug] sponsors in an untenable position between potentially conflicting state positions," which has the consequence of "impact[ing] the pharmaceutical industry's decision-making in a manner that hurts innovation and public health." *Id.* at 14. The ruling below has upended access already—and without a stay from this Court will do so again—of a drug that is "used in the standard protocol for medication abortion and miscarriage management," and that for decades "has been found safe and effective when used for abortion care and miscarriage management, *regardless of whether it is dispensed in person*." ACOG Br. 2-3. The Fifth Circuit's order has affected states and localities far from Louisiana that have chosen a different policy—upsetting whether individuals in those states can obtain mifepristone in all of the ways permitted under those states' laws. New York Br. 13-14; Local Gov't Br. 14-15.

Plaintiffs suggest that it is not irreparable harm for Danco to lose its right to market a product in line with an agency's determination of required restrictions. But irremediable losses like that—without any of the statutory process that Congress said is required for a drug sponsor before a REMS can be altered—are classic irreparable harm. *E.g.*, *Ala. Ass'n of Realtors* v. *HHS*, 594 U.S. 758, 765 (2021) (per curiam) (recognizing "risk of irreparable harm" from "significant financial cost[s]" and loss of "elements of property ownership"); *CFTC* v. *British Am. Commodity Options Corp.*, 434 U.S. 1316, 1320 (1977) (Marshall, J., in chambers) (concluding that stay pending

application for certiorari was warranted where challenged regulation "may well" drive respondents out of business). Because no court-injunction of a REMS modification has ever taken effect, Plaintiffs' claim (at 47) that this situation presents "a run-of-the-mill business chore" is ridiculous. *See also* Opp. 47-48 n.3, 53-54. FDA's only statements on the path forward are those in the Woodcock Declaration previously submitted to this Court, and they faulted the Fifth Circuit for previously assuming—just as this panel did below—that a prior REMS would "snap back." Danco Appl. 35 (citing Woodcock Declaration).

C. The Balance of Equities Strongly Favors Danco.

Much of Plaintiffs' balance-of-equities argument collapses into their view of the merits. For the reasons Danco and many amici have explained, the 2023 REMS is lawful and adequately supported by the evidence before FDA. *See supra*, pp. 13-17; Reproductive Health Researchers Br. 4; Food and Drug Law Scholars Br. 2-4; FDA Comm'rs Br. 7. They are also safe. *See, e.g.*, FDA Comm'rs Br. 9; ACOG Br. 7-13; Physicians for Reproductive Health Br. 6-14. The balance of equities and public interest therefore favor maintaining the 2023 REMS for the duration of this case.

FDA has never suggested otherwise. *Contra* Opp. 50. If FDA were to identify an emergent health risk caused by 2023 REMS, it has tools to respond—like initiating labeling changes, 21 U.S.C. § 355(o)(4), or directing Danco to submit a new proposed REMS, *id.* § 355-1(g)(4)(B). That FDA has not done so necessarily reflects the agency's judgment that the current REMS ensures mifepristone's benefits outweigh its risks while "minimiz[ing] the burden on the health care delivery system." *See id.*

§ 355-1(g)(2)(C), (g)(4)(B). And because courts presume that government officials properly discharge their duties, the Court should not credit Plaintiffs' claim (at 51) that FDA is not undertaking its review seriously or expeditiously. *See Bracy* v. *Gramley*, 520 U.S. 899, 909 (1997).

Plaintiffs' breathless arguments about safety risks miss the mark for another reason. Contrary to Plaintiffs' assertions (which are based on only the views of a doctor who does not treat patients seeking medication abortions), *see* Opp. 3, 10, FDA's approval of the 2023 REMS did not remove an in-person medical *examination* requirement. FDA has repeatedly stressed it is "inappropriate" to "mandate how providers clinically assess women" because "[t]hese decisions should be left to the professional judgment of each provider." La.Appx.157. Consistent with that position, the prior REMS required in-person *dispensing*, not in-person *medical examination*. *See* ACOG Br. 4 (the 2023 REMS "dictates only where a patient must be standing when handed a medication that she will take later at home or at the location of her choice"). Plaintiffs' passing appeals to public health are thus unavailing. That interest neither weighs against the 2023 REMS, nor is advanced by "[f]orcing patients to navigate medically unnecessary in-person appointments." RHITES Br. 22.

Plaintiffs' other equities arguments are no better. Louisiana has not shown how—given its five-year delay in seeking relief and FDA's ongoing internal review—the Fifth Circuit's injunction is necessary to protect its interests. Plaintiffs blame their delay in bringing this lawsuit (and further delay in seeking preliminary relief) on a lack of clarity about the amount of mifepristone use within Louisiana. Opp. 49.

But that position conflicts with Louisiana's claim that every abortion within its borders causes it "blindingly clear" irreparable injury. *See id.* at 12. And, as explained above, Plaintiffs' attempt to discredit FDA's ongoing review is unfounded. *See Bracy*, 520 U.S. at 909.

Nor can it possibly be in the public interest to have federal courts sit as super-legislatures deciding between states' competing policy views. As 22 states and the District of Columbia explain, "[i]n finding that nationwide preliminary relief was in the public interest, the Fifth Circuit improperly elevated the policy preferences of States that have banned or restricted abortion over the preferences of other States that have made the different but equally sovereign determinations to promote access to abortion care."[7] New York Br. 16. Danco, on the other hand, does not ask the Court to arbitrate a policy dispute. Danco simply asks to restore the status quo and allow FDA's regulatory process to operate as Congress intended.

D. The Fifth Circuit Failed To Craft An Equitable Remedy.

Even if Plaintiffs were entitled to relief, the Fifth Circuit's decision to enjoin the 2023 REMS is both unprecedented and unlawful. No court has ever ordered that a drug immediately revert to conditions of use that FDA has found are unwarranted under the REMS statutory framework. The District Court's more limited order allowed it to retain jurisdiction over the case while FDA completes its review. And

[7] Of course, the Fifth Circuit's order interferes with health care activities entirely within those states' territories. *See, e.g.*, Physicians for Reproductive Health Br. 20 (explaining that only three of Hawaii's eight islands have abortion clinics, so an in-person dispensing requirement would require some patients to fly to get care).

FDA's statutory obligations already ensure that FDA must "promptly review and act upon" any "new safety information" that FDA believes "should be included in the labeling of the drug." ECF No. 250 at 3.

The APA did not require the Fifth Circuit to issue an injunction. *Contra* Opp. 55. Even if a court determines after review of the administrative record that an agency's analysis "falls short in some respects, that deficiency may not necessarily require a court to vacate the agency's ultimate approval." *Seven Cnty.*, 605 U.S. at 185; *see also EME Homer City Generation, LP* v. *EPA*, 795 F.3d 118, 132 (D.C. Cir. 2015) (Kavanaugh, J.) (finding "remand without vacatur" "appropriate" where "vacatur could cause substantial disruption to the trading markets that have developed"); *Apache Corp.* v. *FERC*, 627 F.3d 1220, 1223 (D.C. Cir. 2010) (Kavanaugh, J.) (similar). As Plaintiffs concede (at 55), the APA was enacted against a backdrop of general equitable principles. Applying those equitable principles, the courts of appeals have consistently recognized that "vacatur * * * is not inevitable." *Gulf Restoration Network* v. *Haaland*, 47 F.4th 795, 804 (D.C. Cir. 2022).[8] The reviewing court should consider "the disruptive consequences of an interim change that may itself be changed," *Allied-Signal, Inc.* v. *U.S. Nuclear Regul. Comm'n*, 988

[8] *See also, e.g.*, *Cent. Me. Power Co.* v. *FERC*, 252 F.3d 34, 48 (1st Cir. 2001); *NRDC* v. *EPA*, 808 F.3d 556, 584 (2d Cir. 2015); *Prometheus Radio Project* v. *FCC*, 824 F.3d 33, 52 (3d Cir. 2016); *Cent. & S.W. Servs., Inc.* v. *EPA*, 220 F.3d 683, 692 (5th Cir. 2000); *U.S. Steel Corp.* v. *EPA*, 649 F.2d 572, 577 (8th Cir. 1981); *Cal. Cmtys. Against Toxics* v. *EPA*, 688 F.3d 989, 994 (9th Cir. 2012); *Diné CARE* v. *Haaland*, 59 F.4th 1016, 1048-49 (10th Cir. 2023); *Black Warrior Riverkeeper, Inc.* v. *Army Corps of Eng'rs*, 781 F.3d 1271, 1289 (11th Cir. 2015); *Nat'l Org. of Veterans' Advocs., Inc.* v. *Sec'y of Veterans Affs.*, 260 F.3d 1365, 1380 (Fed. Cir. 2001).

F.2d 146, 150-151 (D.C. Cir. 1993), and whether "equity demands" that agency action "be left in place" while the agency corrects its error, *NRDC*, 808 F.3d at 584 (citation and quotation marks omitted). *Cf. Corner Post, Inc.* v. *Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 837 n.6 (2024) (Kavanaugh, J., concurring) ("Remand without vacatur is essentially a shorthand way of vacating a rule and staying the vacatur pending the agency's completion of an additional required action, such as providing additional explanation or issuing a new, more stringent rule.").

For all the reasons explained above, whether nominally called a § 705 stay or an injunction, the Fifth Circuit's ordered relief is an inappropriate remedy here. That relief imposes steep costs on Danco; causes regulatory instability for providers, pharmacies, and manufacturers; and disrupts patients' access to the standard regimen for medication abortion in ways that FDA determined are appropriate under the REMS considerations, no matter where they live. Those considerations may ultimately lead the court to conclude that vacatur is inappropriate. *See, e.g.*, *Vecinos para el Bienestar de la Comunidad Costera* v. *FERC*, 6 F.4th 1321, 1332 (D.C. Cir. 2021) (concluding agency erred but refusing to order vacatur because "vacating the orders would imperil [regulated party's] ability to obtain funding necessary to complete the projects in a timely fashion"); *Cent. Me. Power*, 252 F.3d at 48 (concluding agency erred but refusing to order vacatur because uncertainty from "[a]n on again-off-again" change would cause harm); *Cent. & S.W. Servs.*, 220 F.3d at 692 (concluding agency erred but refusing to order vacatur because "it would be disruptive to vacate a rule that applies to other members of the regulated community"); *Wild*

Fish Conservancy v. *Quan*, No. 23-35322, 2024 WL 3842101, at *1-2 (9th Cir. Aug. 16, 2024) (concluding agency's errors were "serious" but refusing to order vacatur given "significant economic consequences"). The equities demand a less disruptive remedy here, too.

It was also legal error to impose a stay under § 705 of a years' old agency action. Section 705, by its plain text, permits courts to "postpone" only those agency actions which have not yet taken "effect[]." 5 U.S.C. § 705. Congress's authorization to "preserve status or rights" does not suggest that the statute *also* permits courts to retroactively postpone the effective date of an agency action that has been in place for years. *Contra* Opp. 57 n.6. "Different potential perspectives of the relevant status quo," *id.*, should not have affected the Fifth Circuit's decision where "the situation on the ground before enactment of the" 2023 REMS, "the situation after enactment of the [2023 REMS], but before any judicial injunction," and "the situation after any district court ruling on a preliminary injunction," were identical: in-person dispensing was not required, *Labrador* v. *Poe*, 144 S. Ct. 921, 930 (2024) (Kavanaugh, J., concurring in the grant of stay).

Plaintiffs' reading of the statute does not make sense as a practical matter, either. The statute applies to district courts and appellate courts alike. *See* 5 U.S.C. § 705 (referencing "the court to which a case may be taken on appeal"). Yet an injunction that alters existing conditions will often require close judicial management of the facts on the ground. Courts of appeals generally do not engage in that type of inquiry. *See* Fed. R. Civ. P. 52(a)(2); Fed. R. App. P. 8(a); *see also* 16 Wright and

Miller, Fed. Prac. & Proc. § 3921.2 (3d ed. 2026 update) ("These provisions reflect the superior abilities of the district court to hear evidence, draw from prior experience with the case, and frame and enforce an injunction."). The Fifth Circuit can hardly hold an evidentiary hearing about the contested status of warehouse stock, or the validity of agreements that regulated parties entered into while governed by the 2023 REMS, or how FDA will exercise its enforcement discretion. Its unmanageable order should therefore be vacated.

CONCLUSION

This Court should vacate the Fifth Circuit's order or stay that order pending the conclusion of this litigation before the Fifth Circuit, and any subsequent petition for a writ of certiorari from Danco, and any further proceedings in this Court. Alternatively, this Court should stay the Fifth Circuit's order and grant certiorari before judgment.

Respectfully submitted,

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