No. 23-236

IN THE

Supreme Court of the United States

DANCO LABORATORIES, L.L.C.,

Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

REPLY IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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CORPORATE DISCLOSURE STATEMENT

The disclosure made in the petition for a writ of certiorari remains accurate.

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INTRODUCTION

This case has all the hallmarks of one warranting this Court's review. The Fifth Circuit's decision directly conflicts with this Court's precedents on Article III standing and judicial review of agency action. It splits from other courts of appeals that hew to those precedents. And the fourteen amicus briefs on behalf of prominent medical and public health societies; providers; patient advocacy organizations; States; localities; public health systems; scholars;

pharmaceutical companies, executives, and investors; the leading pharmaceutical industry group; faith-based organizations; and federal and state legislators leave no dispute about whether this case is nationally important. It is.

Respondents barely engage with these points. On standing, they do not defend the Fifth Circuit's actual holding: a purported probabilistic analysis of the likelihood that a Respondent association member will be (1) working in an emergency room where a woman arrives experiencing an adverse event or incomplete abortion after taking Mifeprex, and (2) forced to provide care—despite federal and state conscience laws—because no other provider is available. Respondents' reluctance to defend the Fifth Circuit's speculative reasoning is understandable, because it contradicts this Court's precedents four times over: It combines probabilistic future injury to unnamed members (contra *Summers*) with evidence of past injury (irrelevant under *Lyons*) for parties unregulated by the challenged action (discredited by *Clapper*), without requiring traceability to the challenged action (improper under *TransUnion*). In so doing, the Fifth Circuit broke with how every other circuit has applied those precedents.

Respondents suggest certiorari is not warranted because the Fifth Circuit held the individual named providers also satisfy Article III standing, or because there might be standing under some *other* theory like organizational standing. The first is untrue and the second is not a valid argument against certiorari.

On the merits, Respondents' argument is equally unavailing. The panel's complaints about supposed shortcomings in FDA's explanations are insufficient

under this Court's precedents to justify an injunction. FDA detailed—across hundreds of pages of careful scientific analysis—the reasoning for its conclusion that Mifeprex would remain safe and effective with the proposed changes. Indeed, FDA's predictive judgment has proven correct in the years since those changes were approved.

Neither the APA nor the FDCA preclude FDA from analyzing and synthesizing the information before the agency to make predictive judgments about what conditions are (or are not) necessary for a drug's benefits to outweigh its risks. Contrary to Respondents' contentions, FDA is not limited to matching its approval to a clinical study protocol. And here, FDA fully explained why it approved each specific change based on years of real-world experience and the agency's conclusion that the changes it was approving involved no new safety risks. By faulting FDA's reasoning as insufficient without even *reviewing* the administrative record, the panel split from the D.C. Circuit's established, commonsense rule that courts must do so before ordering this sort of injunctive relief.

Without a hint of irony, Respondents suggest review is unwarranted now because the injunction is based "on an incomplete factual and administrative record" and "further factual development" might support Respondents' position. BIO 1, 11. But the fact the lower courts deemed FDA's explanations wanting *without* reviewing the full record is precisely why certiorari is warranted—not a reason to deny it. Nor can the Court credibly accept Respondents' take-our-word-for-it assertion that mifepristone "will remain widely available" if this Court denies review.

BIO 13-14. FDA and Danco have described in detail why that is not so.

Certiorari should be granted.

ARGUMENT

I. THE STANDING QUESTION WARRANTS REVIEW.

1. The Fifth Circuit found associational standing without identifying any individual member with standing to challenge FDA's 2016 and 2021 actions. Instead, it hypothesized that some member(s) of a Respondent association face "imminent injury" because "millions of women take mifepristone," some of them will later "require emergency room care," and, according to the court (but not the record), "hundreds" of the associations' members are emergency-room doctors. Pet. App. 27a.

Respondents do not reconcile the Fifth Circuit's decision with this Court's precedents. Respondents reprise the panel's statistical misadventure, BIO 23-25, but they offer no way to square the court's holding with *Summers*, which prohibits "probabilistic standing" theories. *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 499 (2009).

Respondents defend the panel's view that because some members claim "[p]ast injuries," "it is substantially likely that Respondent doctors will be harmed again." BIO 24, 27. But *Lyons* is clear: pointing to past injury as a predictor of future injury cannot establish standing for injunctive relief. *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 102-109 (1983).

As to *Clapper*, Respondents disclaim that any injury is based on "a highly attenuated chain of possibilities." BIO 27 (citation omitted). Yet their

claimed injury depends on the independent actions of multiple third parties—including a woman who wants a medication abortion and a provider who prescribes Mifeprex to her—and also on unknown, unpredictable circumstances about the woman's subsequent need for follow-up care and what role (if any) a Respondent association member plays in that care. *Clapper* was unconditional: "threatened injury must be *certainly impending* to constitute injury in fact"; "allegations of *possible* future injury are not sufficient." *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (citation, quotation marks, and brackets omitted).

2. The Fifth Circuit's decision is also inconsistent with *TransUnion*, which held that "plaintiffs must demonstrate standing for each claim" and "each form of relief." *TransUnion LLC* v. *Ramirez*, 141 S. Ct. 2190, 2208 (2021). Respondents never say they can trace an association member's impending injury-in-fact to either FDA's 2016 or 2021 actions, or that they can demonstrate redressability from enjoining those specific actions.

That is unsurprising. The record shows that for the overwhelming majority of women who take Mifeprex under the current dosing regimen, the drug is safe (over 99%) and effective (over 96%). ROA.2171-2174; ROA.2198-2199. There is no record evidence about how many women (if any) will be prescribed Mifeprex because of FDA's 2016 and 2021 actions (rather than the 2000 approval), and then experience an adverse event or need surgical follow-up, and then seek care at an emergency room where the only available medical staff who can treat the woman is an association member, and then receive medical care from that member. To state this line of hypotheticals

is to refute the presence here of impending injury, traceable to the challenged actions, and redressable by enjoining them.

Respondents' remaining traceability and redressability objections are just as wrong. Advanced practice nurses and midwives who prescribe mifepristone can and do provide follow-up care, including surgical abortions. *See* National Ass'n of Nurse Practitioners, et al. Amicus Br. 10-11, 14-17. FDA's considered decision to permit flexibility in how women receive follow-up care does not prevent women from choosing to return in-person to their prescribing clinic or provider, or from going to another clinic or provider rather than the emergency room. And the fact that a pharmacist dispenses mifepristone or a woman receives it by mail does not solve Respondents' traceability or redressability problems. Respondents would still have to trace a member's harm to *how the mifepristone was dispensed*, rather than some other reason. They have not and cannot.

3. In accepting precisely the kind of "statistical probability" theory of standing *Summers* rejected, 555 U.S. at 497, the Fifth Circuit deviated from every other circuit. Pet. 24-27. Respondents seek to avoid this split by saying the Fifth Circuit *also* concluded that individual Respondents "would be injured" and thus independently had standing. BIO 22, 26. It did not. In addressing whether the risk of harm was "speculative," the Fifth Circuit cited three doctors' declarations as support for concluding it was "not speculative" that "a *group of members* who claim future injury are really at risk." Pet. App. 28a-29a (emphasis added). The Fifth Circuit never found that these doctors—let alone any other association

member—*individually* had standing to challenge FDA's 2016 or 2021 actions.[1]

II. THE FIFTH CIRCUIT'S MERITS DECISION WARRANTS REVIEW.

1. An agency does not act arbitrarily and capriciously where it "reasonably considered the relevant issues and reasonably explained [its] decision[s]," including making "reasonable predictive judgment[s]." *FCC* v. *Prometheus Radio Project*, 141 S. Ct. 1150, 1158, 1160 (2021). Even a "decision of less than ideal clarity" stands "if the agency's path may reasonably be discerned." *Bowman Transp., Inc.* v. *Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974). The Fifth Circuit disregarded these administrative-law fundamentals—affirmed again and again by this Court and other circuits—and faulted FDA for not describing the agency's analysis in exactly the way the panel preferred. Pet. App. 54a-55a, 63a-64a.

Respondents do little more than paraphrase the decision below. They claim to agree that FDA did not need to "incant magic words," BIO 46 (citation and quotation marks omitted), but insist the Fifth Circuit rightly enjoined the 2016 changes because FDA did not use the word "cumulative" in explaining that the 2016 changes would not negatively affect Mifeprex's

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[1] Nor could the Fifth Circuit have found standing on this basis. Respondents highlight Dr. Skop, BIO 21-22, but her declaration is silent on *when* she previously provided care, so it cannot show the care was *traceable* to FDA's 2016 or 2021 decisions and would be *redressed* by enjoining those actions. ROA.277-283. Nor did Dr. Skop (or any other declarant) personally allege that she was forced to complete an elective abortion over her objection, or that she personally suffered a cognizable injury. *See* FDA Pet. 16-18.

safety or efficacy. BIO 42-43. Respondents also assert FDA erred by referring to the literature as "not inconsistent with" the agency's conclusion that Mifeprex would remain safe and effective without an in-person-dispensing requirement, rather than saying the literature "affirmatively support[ed]" FDA's conclusion. BIO 10, 48 (citation omitted).

FDA's 100-plus-page medical review fully supports the agency's 2016 decision. FDA meticulously considered each change; analyzed the many studies evaluating those changes—including in various combinations—and the resulting evidence of safety; and explained why FDA's clinical reviewers thought these "interrelated" changes should collectively be approved. ROA.2166; *see* ROA.2142-2243; ROA.2251-2337. The agency's "deductions [were] based on the [agency's] expert knowledge" and are reasonably discernible from the records available. *FCC* v. *National Citizens Comm. for Broad.*, 436 U.S. 775, 814 (1978) (citation omitted). Respondents cannot identify anything lacking from this explanation—except the word "cumulative." *See* BIO 42-43. And even that is misguided: FDA concluded that each of Danco's requested changes posed zero additional safety concerns. *See* ROA.2142-2243; ROA.2251-2337. Respondents offer no rationale for why adding zero-plus-zero-plus-zero-plus-zero additional safety concerns would equal anything other than zero "cumulative" safety concerns.

Respondents continue to insist that FDA is required to precisely match a drug's conditions of use with the protocols used in a single clinical study. BIO 43-44. Neither the FDCA nor APA say that. The FDCA requires FDA to determine whether there is

substantial evidence a drug is safe and effective for its intended use with the proposed labeling. 21 U.S.C. § 355(d). FDA reasonably explained why clinical trials conducted before a safety-and-efficacy finding often have more restrictive protocols than the approved labeling, why it did not rigidly mandate ultrasounds and instead deferred to provider discretion, and why it declined to mandate in-person follow-up care. ROA.2186; ROA.2206-2209. Nothing more is required. Indeed, "[t]he Fifth Circuit's novel, judicially imposed requirement" threatens to "cause real harm to healthcare providers, patients, and pharmaceutical innovation," because most clinical studies do not perfectly match a drug's conditions of use when approved. PhRMA Amicus Br. 14.

Respondents do not dispute that FDA was entitled to make "reasonable predictive judgment[s] based on the evidence" before it. *Prometheus*, 141 S. Ct. at 1160. Relying on FDA's "comprehensive review" of the "exceedingly rare" number of major adverse events associated with Mifeprex since 2000, ROA.2198; ROA.2224, and numerous studies evaluating the "new proposed regimen," ROA.2189, FDA reasonably concluded that the drug's benefits would continue to outweigh its risks under the modified conditions of use, ROA.2272. Respondents simply disagree with FDA's prediction. That is not a legitimate basis on which to find agency action arbitrary and capricious.

Respondents' defense of the panel's analysis of FDA's 2021 action also conflicts with this Court's precedents. FDA reasonably evaluated the evidence before it and elected to temporarily exercise enforcement discretion during the COVID-19

emergency with respect to in-person dispensing. FDA's determination rested on "a thorough scientific review" of two decades of evidence, "including available clinical outcomes data and adverse event reports." ROA.807; ROA.822-823. Respondents do not identify any evidence FDA ignored or misunderstood and offer nothing to show that FDA's predictive judgment based on the evidence before it was unreasonable. At most, Respondents' argument is that the evidence was not perfect, but agencies are not required to base their decisions on "perfect empirical or statistical data." *Prometheus*, 141 S. Ct. at 1160.

2. The Fifth Circuit's decision also created a split over whether a preliminary injunction can issue without review of the full administrative record. Respondents do not cite, let alone attempt to distinguish, the many D.C. Circuit cases on the other side of this split. *See* Pet. 30-31.

Respondents' own arguments make clear why the Fifth Circuit is on the wrong side of the split. Respondents urged the district court to find—without reviewing the full administrative record—that FDA acted arbitrarily and capriciously by failing to adequately consider aspects of its decision and not "reasonably explain[ing]" certain conclusions. BIO 40 (citation omitted). But Respondents—and the courts—are simply guessing about whether the full record supports FDA's reasoning. It takes chutzpah to say this Court's review is unwarranted "because FDA has not yet produced the administrative record," BIO 11, but also assert the district court properly enjoined FDA without it.

3. The Fifth Circuit also overreached on remedy. Respondents cannot explain how the APA plausibly permits courts to "postpone the effective date[s]" of already-in-effect agency actions. BIO 50-51 (citation omitted). Nor can they justify the panel's view that FDA could not remedy any purported shortcomings on remand. *See, e.g.*, *Heartland Reg'l Med. Ctr.* v. *Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) (when basis for arbitrary-and-capricious finding is inadequate explanation, agency should have opportunity, on remand, to cure any defect). That is unsurprising, given the picayune nature of the supposed flaws. Indeed, it is entirely possible the full administrative record alone will "substantiate [FDA's] decision[s]" without the need for additional explanation. BIO 52 (citation omitted).

III. THIS CASE IS OF NATIONAL IMPORTANCE.

1. The array of amici supporting certiorari demonstrate the national importance of this case.

The nation's leading medical associations emphasize that "[t]his Court should not allow the speculative fears of a handful of doctors to deprive patients throughout the country of an essential medication that is proven safe for use in early pregnancy." American College of Obstetricians & Gynecologists, et al. Amicus Br. 4. Denying review risks harms that are "rooted in the reality that mifepristone is an essential component of reproductive care, including miscarriage and abortion, without which a vast number of patients will suffer." *Id.* at 6.

Leading patient advocacy groups including the Leukemia and Lymphoma Society and the American

Cancer Society underscore the broad consequences at stake: The decision below "jeopardizes patients' and providers' ability to rely on FDA's expert process to deem drugs and their conditions of use safe and effective, and therefore available for treatment." Patient & Provider Advocacy Orgs. Amicus Br. 1.

And the leading pharmaceutical industry association reiterates that the decision below—"if left undisturbed—could significantly disrupt industry and stifle innovation in drug development." PhRMA Amicus Br. 2.

The list goes on. Two dozen States stress their "strong interest in the meaningful availability of mifepristone" and "in ensuring high-quality, science-driven patient care within their borders." New York, et al. Amicus Br. 1. Over 850 federal and state legislators; dozens of localities, including the operators of large municipal public hospital and health-care systems; food and drug law scholars; religious organizations; and national associations of nurse-practitioners and nurse-midwives urge review, too.

The Fifth Circuit's decision to upend FDA's scientific judgment based on a misunderstanding of the law and what Respondents freely admit is an incomplete record is both unprecedented and tremendously important.

2. None of Respondents' attempts to diminish the national importance of this case hold water.

The case's interlocutory posture is no barrier to review. Absent review, an unprecedented preliminary injunction will take effect nationwide, significantly altering the terms on which mifepristone is approved for use. The Court regularly grants certiorari in cases

involving preliminary injunctions, including to resolve threshold standing issues. *E.g.*, *Murthy* v. *Missouri*, 601 U.S. __, 2023 WL 6935337 (Oct. 20, 2023) (granting certiorari); *Biden* v. *Nebraska*, 143 S. Ct. 2355 (2023).

Respondents' plea to deny review because three States—after filing briefs as amici in the district court and Fifth Circuit—moved to intervene in the district court two weeks ago. BIO 11, 18. But intervention cannot revive a jurisdictionally-defunct suit, and the States' motion raises a host of separate issues, including standing, timeliness, and venue. In any event, the Fifth Circuit's preliminary injunction is not based on those States' claims or an analysis of whether they are properly asserted.

Respondents' invocation of supposed alternative grounds for affirmance is irrelevant to whether to grant certiorari. *See* BIO 20 n.2, 37-39, 49-50. The panel's deviation from this Court's precedents and its split from other circuits, in a case of national importance, is what makes this case appropriate for review. Respondents' attempt to distance themselves from the Fifth Circuit's faulty logic is a reason to grant review, not deny it.

Respondents' assertion that the administrative record or further factual development might someday support their claims is likewise not a credible basis to deny review of a mandatory, nationwide injunction that is unsupportable on the *current* record. That is particularly so where the mandatory injunction in question will upend the status quo, pose health risks to women and girls, burden health care systems, and disrupt access to a drug with lawful uses in States across the country. Pet. 33-37.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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