No. 23-__

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In 2000, the Food and Drug Administration (FDA) approved Danco's drug Mifeprex for termination of early pregnancy based on the agency's expert judgment that clinical data showed the drug to be safe and effective. The agency later modified certain conditions of use for mifepristone in 2016 and 2021, again relying on clinical data and the agency's expert judgment that the drug would remain safe and effective under the modified conditions of use. In 2022, associations of doctors who have never prescribed Mifeprex sued FDA, arguing that FDA's actions modifying the drug's conditions of use in 2016 and 2021 violated the Administrative Procedure Act. The questions presented are:

1. Whether an association can demonstrate Article III standing to enjoin a government action by arguing that some unspecified member may be injured at some future time by the challenged action; and

2. Whether the Fifth Circuit erred in upholding the preliminary injunction of FDA's 2016 and 2021 actions based on the court's review of an incomplete administrative record.

PARTIES TO THE PROCEEDING

Petitioner in this Court is Danco Laboratories, LLC, who was an intervenor-appellant below.

Respondents were plaintiffs-appellees below. They are 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.; and George Delgado, M.D.

Defendants-appellants below were the U.S. Food and Drug Administration (FDA); Robert M. Califf, M.D., in his official capacity as Commissioner of Food and Drugs; Janet Woodcock, M.D., in her official capacity as Deputy Commissioner of Food and Drugs; Patrizia Cavazzoni, M.D., in her official capacity as Director of FDA's Center for Drug Evaluation and Research; the U.S. Department of Health and Human Services (HHS); and Xavier Becerra, in his official capacity as Secretary of HHS.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Danco Laboratories, LLC hereby states that it is a wholly-owned subsidiary of Danco Investors Group, LP. No publicly held corporation owns 10% or more of the stock of either entity.

RELATED PROCEEDINGS

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

- *Danco Laboratories, LLC* v. *Alliance for Hippocratic Medicine, et al.*, No. 22A901 (Apr. 21, 2023) (granting application for stay)
- *Food & Drug Administration, et al.* v. *Alliance for Hippocratic Medicine, et al.*, No. 22A902 (Apr. 21, 2023) (granting application for stay)

United States Court of Appeals (5th Cir.):

- *Alliance for Hippocratic Medicine, et al.* v. *U.S. Food & Drug Administration et al.*, No. 23-10362 (Aug. 16, 2023)
- *Alliance for Hippocratic Medicine, et al.* v. *U.S. Food & Drug Administration et al.*, No. 23-10362 (Apr. 12, 2023) (partially granting and partially denying stay pending appeal)

United States District Court (N.D. Tex.):

- *Alliance for Hippocratic Medicine, et al.* v. *U.S. Food & Drug Administration et al.*, No. 2:22-cv-223 (Apr. 7, 2023)

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Danco Laboratories, LLC respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit.

INTRODUCTION

This case presents a serious question: whether courts can disregard constitutional and statutory limits on judicial review of executive action in order to overrule an agency decision they dislike. The Fifth Circuit's decision upends FDA-approved conditions of use for Danco's drug Mifeprex. It does so at the

request of a group of plaintiffs who do not prescribe or use the drug and whose real disagreement with FDA is that they oppose all forms of abortion. When a stay panel of the Fifth Circuit similarly invalidated FDA's 2016 and 2021 changes to the mifepristone conditions of use, this Court granted emergency relief, issuing a stay that extends through disposition of this timely filed petition for certiorari. *See* Pet. App. 111a. The merits panel's ruling again failed to follow this Court's precedent on standing and review of administrative agency action. Both errors warrant this Court's review.

First, the panel found standing where there is none. Respondents—associations of doctors who are opposed to abortion and do not prescribe mifepristone—are not themselves "the object of the government action or inaction [they] challenge[]." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 562 (1992). The panel nevertheless held that Respondents established associational standing by showing that (1) other doctors prescribe mifepristone, (2) some women may seek emergency care in some circumstances after taking mifepristone, and (3) some member of a Respondent association might be working in that same emergency room and provide the care. Pet. App. 17a. The court attempted to forge the links in this "highly attenuated chain of possibilities," *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 410 (2013), by reasoning that the associations have hundreds of members, and that FDA's actions increased the risk that some unidentified member might be forced at some future time to personally provide care that he or she objected to providing. But "a statistical probability that some of those members are threatened with concrete injury,"

Summers v. *Earth Island Inst.*, 555 U.S. 488, 495, 497 (2009), is insufficient to create associational standing.

That is why, after *Summers*, circuit after circuit has rejected claims of associational standing to seek injunctive relief where an association cannot identify a member who faces injury traceable to the challenged action. Six circuits have flatly rejected what the Fifth Circuit sanctioned here, reasoning that an assertion *some* members of a large group will inevitably be affected by a regulation—without clear allegations regarding "who these members are or how exactly the [regulation] will harm them individually"—"trends too closely to the statistical probability theory of associational standing rejected in *Summers*." *Prairie Rivers Network* v. *Dynegy Midwest Generation, LLC*, 2 F.4th 1002, 1009-10 (7th Cir. 2021). No other circuit defies *Summers* to permits associational standing based on facts like those here.

Second, the Fifth Circuit's merits ruling was just as flawed, and equally in conflict with this Court's decisions. Judicial review under the APA asks whether an agency acted "within a zone of reasonableness," does not permit a court to "substitute its own policy judgment for that of the agency," *Federal Commc'ns Comm'n* v. *Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021), does not require an agency to incant "magic words," *Garland* v. *Ming Dai*, 141 S. Ct. 1669, 1679 (2021), and permits an agency to make "predictive judgments," *Lingle* v. *Chevron U.S.A. Inc.*, 544 U.S. 528, 544 (2005). Here, even the limited set of materials available at this stage includes hundreds of pages of careful, detailed, scientific analysis bearing on FDA's decisions in 2016 and 2021. In mining the incomplete record for purported flaws, the Fifth

Circuit abandoned the standard this Court has prescribed in APA cases.

The Fifth Circuit also parted ways with the D.C. Circuit, which, in contrast, has long held that preliminary relief should not be decided without a review of the administrative record. *See American Bioscience, Inc.* v. *Thompson*, 243 F.3d 579, 580 (D.C. Cir. 2001). There is good reason for the D.C. Circuit's position—a court cannot determine that an agency has "fail[ed] to consider an important aspect of the problem," Pet. App. 54a, or offered an explanation for its decision that "runs counter to" the evidence before the agency, *id.* at 62a, without examining the full agency record.

This Court should also grant review because this is a case of indisputable importance. For the women and teenage girls, health care providers, and States that depend on FDA's actions to ensure safe and effective reproductive health care is available, this case matters tremendously. And for the pharmaceutical and biotechnology industry, permitting judicial second-guessing of FDA's scientific evaluations of data will have a wildly destabilizing effect.

This Court should grant the writ and reverse.

OPINIONS BELOW

The Fifth Circuit's opinion is reported at ___ F.4th ___, and available at 2023 WL 5266026 (5th Cir. Aug. 16, 2023). Pet. App. 1a-110a. The District Court's memorandum opinion and order is reported at ___ F. Supp. 3d ___, and available at 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023). Pet. App. 164a-249a.

JURISDICTION

The Fifth Circuit entered judgment on August 16, 2023. *See* Pet. App. 1a-2a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent provisions are set out in the appendix to the petition. *See* Pet. App. 250a-251a.

STATEMENT OF THE CASE

A. Factual Background

Danco holds the FDA-approved New Drug Application (NDA) for Mifeprex (mifepristone) Tablets for use in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Mifeprex is Danco's only product.

1. 2000 Approval

In 2000, FDA approved Mifeprex as safe and effective for the medical termination of intrauterine pregnancy through 49 days' pregnancy. That approval was based on data from three clinical trials with thousands of participants showing that mifepristone was effective for 92.1% to 95.5% of women, meaning further intervention to terminate the pregnancy was not required. ROA.642-647, ROA.591-598.

FDA imposed certain use restrictions with its approval, including that the drug would be dispensed by a doctor in-person and that there would be an in-person follow-up appointment. Those use restrictions were deemed a Risk Evaluation and Mitigation Strategy (REMS) by a 2007 amendment to the Food, Drug, and Cosmetic Act (FDCA). *See* Identification of Drug and Biological Products, 73 Fed. Reg. 16313

(Mar. 27, 2008). The statute also required Danco to submit a supplemental New Drug Application (sNDA) for its REMS, which Danco did and FDA approved in 2011. ROA.672-675.

2. 2016 Changes

In 2015, Danco submitted an sNDA to modify certain aspects of Mifeprex's indication and dosing regimen, also implicating the REMS. FDA approved these changes after considering both dozens of studies reporting the outcomes for tens of thousands of women under various combinations of the proposed changes and 15 years of safety data. ROA.689-696, ROA.2142-2337.

i. Dosing and gestational age

FDA approved lowering the mifepristone dose from 600 mg to 200 mg and increasing the misoprostol dose from 400 mcg to 800 mcg, changing the misoprostol route of administration from oral to buccal (in the cheek pouch), and extending the approved gestational age from 49 to 70 days. FDA considered 20 studies of over 30,000 women supporting the conclusion that this new dosing regimen was safe and more effective, ROA.2170-2174, ROA.2202-2203, and seven studies of 934 women, which supported increasing the gestational-age cutoff, many of which also used the proposed dosing regimen, ROA.2179-2180, ROA.2203.

FDA summarized these studies with one table for the 16,794 subjects in U.S. studies and another table of the 18,425 subjects in non-U.S. studies. These tables reflected that "97.4% (US) and 96.1% (non-US)" of the patients required no further intervention, which the FDA reviewer concluded "strongly support the proposed new dosing regimen and the extension of the acceptable gestational age." ROA.2173.

Table 3: Efficacy- Mifepristone 200 mg with Buccal Misoprostol 800 mcg 24-48 Hours Later - US Studies

Study &Year	Design, Location	Gestation (maximum days)	M-M Interval (hrs)	Evaluable Subjects (N)	Success - no intervention (%)
Middleton 2005[24] US	Prospective	56	24-48	216	94.9
Winikoff 2008[23] US	Prospective	63	24-36	421	96.2
Fjerstad 2009[27] US	Retrospective	59	24-48	1,349	98.3
Grossman 2011[36] US - Clinic Mife v. Tele-med	Prospective	63	24-48	449	Clinic: 96.9% Telemed: 98.7%
Winikoff 2012[19] US	Prospective	57-70	24-48	629	93.2
Gatter 2015[13] US	Retrospective	63	24-48	13,373	97.7
Chong 2015[17] US	Prospective	63	24-48	357	96.7
TOTALS	7 Studies	56-70 days	24-48 hr	16,794	97.4

Source: Modified from Table 3, page 14-15, Chen-Creinin 2015 Review and submitted articles. All subjects had 200 mg oral mifepristone followed by 800 mcg buccal misoprostol.

Success percentages calculated by clinical reviewer.

Table 4: Efficacy- Mifepristone 200 mg with Buccal Misoprostol 800 mcg 24-48 Hours Later- Non- US Studies

Study &Year/Country	Design, Location	Gestation (maximum)	M-M Interval (hrs)	Evaluable Subjects (N)	Success - no intervention (%)
Alam 2013[37] Bangladesh	Prospective	63	24	629	92.7
Blum 2012[70]	Prospective	63	24	210	92.9
Boersma 2011[22] Curacao	Prospective	70	24-48	307	97.7
Chai 2013[38] Hong Kong	Prospective	63	48	45	95.6
Dahiya 2012[39] India	Prospective	50	24	50	92
Chong 2012[40] Georgia, Vietnam	Prospective	63	36-48	560	96.4
Giri 2011[41] Nepal	Prospective	63	24	95	93.6
Goldstone 2012[20] Australia	Retrospective	63	24-48	11,155	96.5
Louie 2014[14] Azerbaijan	Prospective	63	24-48	863	97.3
Ngo 2012[42] China	Retrospective	63	36-48	167	91.0
Ngoc 2011[43] Vietnam	Prospective	63	24	201	96.5
Ngoc 2014[16] Vietnam	Prospective	63	24-48	1,371	94.7
Olavarietta 2015[85] Mexico	Prospective	70	24	884	98.2
Pena 2014[44] Mexico	Prospective	70	24-48	971	97.3
Sanhueza 2015[48] Mexico	Prospective	70	24-48	896	93.3
TOTALS	15 Studies	56-70 days	24-48 hrs	18,425	96.1%

Source: Modified from Table 3, page 14-15, Chen-Creinin 2015 Review and submitted articles. All subjects had 200 mg oral mifepristone followed by 800 mcg buccal misoprostol.

Success percentages calculated by clinical reviewer.

ROA.2171-2173 (emphasis added).

This data showed that the revised dosing regimen resulted in increased effectiveness—meaning fewer women needing additional intervention such as a surgical abortion—through 70 days than had supported the initial approval through 49 days. *See* ROA.2175 ("[T]he proposed new dosing regimen is considerably more effective for all gestations through 70 days" compared to data submitted to support the initial approval.).

After carefully analyzing the data and literature, FDA concluded that "[s]erious adverse events" were "exceedingly rare," "generally far below 1.0% for any individual adverse event." ROA.2198. Among the numerous studies FDA considered, one found that only "29 women of 13,221 (0.1%) undergoing medical abortion experienced a major complication," meaning "emergency department presentation, hospitalization, infection, perforation and hemorrhage requiring transfusion"; another found only 4 of 1,172 patients (0.3%) prescribed a medication abortion through telemedicine required a blood transfusion, compared to 0.1% of 2,384 in-person patients; and a third found tiny numbers (0-0.5%) of hospitalizations, serious infections, or blood transfusions through 70 days gestation. ROA.2198.

ii. Number of in-person clinical visits

The pre-2016 Mifeprex label required three in-person clinical visits: one to receive Mifeprex; one to receive misoprostol 1-2 days later; and one for follow-up. After analyzing numerous studies involving tens of thousands of women, FDA determined there was no safety or efficacy reason to require patients be handed misoprostol in a prescriber's office or to mandate an in-person follow-up visit given the "variety of follow-

up modalities that can adequately identify the need for additional intervention." ROA.2268; *see also* ROA.2203-2204, ROA.2206-2209.

In considering the change for misoprostol, FDA reviewed 11 studies involving 30,763 women who took misoprostol at home. ROA.2182-2183. The two largest studies "showed 97% success using the new proposed dosing regimen with home use of buccal misoprostol," and even the lowest success rate (91.9%) "does not differ significantly from results with misoprostol taken in the clinic/office." ROA.2183. Many of these same studies were also "evaluated as part of the proposed dosing regimen," ROA.2190, and showed "adverse events equal to *or lower than* those with the approved regimen requiring in-office dispensing of misoprostol," ROA.2204 (emphasis added).

FDA found that the studies, including one of over 45,000 women, supported allowing multiple methods of follow-up. Based on FDA's consideration of the data, the agency reasoned that "[t]he exact timing and method [of follow up] should be flexible and determined jointly by the healthcare provider and the individual woman being treated[.]" ROA.2186. Of the several available options, "no single option is superior to the others." *Id.*

iii. Prescribing provider

FDA also approved changing the terminology on the labeling from "doctor" to "health care provider" so that health care providers licensed to prescribe drugs under state law could do so with mifepristone, as they do with other drugs. FDA reviewed four studies of 3,200 women prescribed mifepristone by nurses and certified midwives; none showed a statistical difference in outcomes from physician-prescribed

mifepristone—which, as FDA concluded, "clearly demonstrates that efficacy is the same with non-physician providers compared to physicians." ROA.2185-2186.

iv. Adverse event reporting

When it evaluated Danco's sNDA, FDA had more than 15 years of data from the adverse event reporting by prescribers that was initially mandated. Those years of data showed "the safety profile of Mifeprex is well-characterized, that no new safety concerns have arisen in recent years, and that the known serious risks occur rarely." ROA.2150. Of the more than 2.5 million women who had taken mifepristone, fewer than *one-tenth of one percent* experienced *any* adverse event, and only 878 women—0.035%—had been hospitalized. ROA.2225-2226. FDA accordingly modified a requirement that prescribers agree to report certain serious adverse events to Danco.

Because FDA determined that extensive data showed using mifepristone under the changes would be at least as safe and even more effective as under the original approved conditions, FDA also concluded that the proposed changes would not unacceptably increase "the numbers of hospitalizations, severe infections, blood loss requiring transfusion and ectopic pregnancy." ROA.2226.[1]

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[1] Of the more than 5.4 million women who have taken Mifeprex, there have been a total of 32 deaths within 30 days for any reason. FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2022*, https://www.fda.gov/media/164331/download. Of those, many were caused by circumstances with no connection to mifepristone—including homicide and drug overdose. *Id.*

With this change, anyone can report an adverse event for Mifeprex to Danco directly by calling a 1-800 number on the labeling and company website, or to FDA through the online form on FDA's website. By regulation, Danco is obligated to report to FDA any adverse drug experience information obtained or received from any source. 21 C.F.R. §§ 314.80, 314.81. Mifeprex prescribers also remain required to report to Danco—and Danco required to report to FDA—any patient deaths within 30 days of taking the drug, "whether or not considered drug related." REMS for Mifepristone Tablets, 200 mg, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf.

3. 2021 Non-Enforcement Decision

In April 2021, FDA determined that it would temporarily exercise enforcement discretion during the COVID-19 public health emergency as to whether mifepristone must be dispensed in person. ROA.787-788. Although no FDA review documents for this action are in the record, FDA stated that its decision was based on medical literature, postmarketing adverse event reporting from earlier in the COVID-19 pandemic, and available information about deviations or noncompliance events associated with the REMS. *E.g.*, ROA.787-788, ROA.827-829.

In December 2021, in response to a citizen petition challenging the 2016 changes, FDA reiterated its view that "mifepristone may be safely used without in person dispensing" and directed Danco to propose modifications to the REMS effectuating that change. ROA.829. FDA pointed to safety data from an eight-month period during which in-person dispensing was not enforced due to the COVID-19 pandemic, which

showed "no indication" that relaxing the in-person dispensing requirement "contributed to * * * adverse events." ROA.827-828. In addition, it pointed to three studies permitting mail-order pharmacy dispensing and five studies allowing clinic dispensing by mail, all of which supported the conclusion that mifepristone remains safe and effective without mandatory in-person dispensing. ROA.832-836.

4. 2023 REMS Modification

On January 3, 2023, FDA approved Danco's application to modify the REMS, including removing mandatory in-person dispensing. *See* Ctr. for Drug Evaluation & Rsch., *Approval Package for: Application Number 020687Orig1s025* (Jan. 3, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/020687Orig1s025.pdf. Respondents did not amend their complaint or otherwise challenge FDA's approval of the 2023 REMS modification, and no FDA review documents are in the record.

B. Procedural History

1. In November 2022, several organizations and doctors opposed to abortion brought an APA suit challenging four FDA actions: FDA's 2000 approval of mifepristone, FDA's 2016 approval of certain changes to Mifeprex's labeling and REMS, FDA's 2019 approval of a generic mifepristone product, and FDA's 2021 non-enforcement decision. They also challenged FDA's denial of citizen petitions related to the 2000 approval and 2016 changes. Respondents' declarations do not state that Respondents and their members prescribe Mifeprex, want to prescribe Mifeprex, or provide other abortion care. ROA.81-85, ROA.230-297, ROA.935-962. Respondents sought a preliminary injunction, and Danco intervened.

All parties agreed to defer ruling on Respondents' preliminary injunction until after the administrative record was produced. ROA.3240-3252, ROA.3588-3596, ROA.3801-3811. The District Court, however, declined to do so. ROA.4192. Based on only a fraction of the documents in the administrative record for the 2000 approval and 2016 changes and *none* of the agency documents for the 2021 non-enforcement decision, the District Court granted a preliminary injunction.

The District Court enjoined FDA's 23-year-old approval of mifepristone and all subsequent FDA actions related to it by purporting to "stay" the long-passed effective dates of these actions. Pet. App. 247a-249a (citing 5 U.S.C. § 705). The court ignored the portions of the limited preliminary injunction record showing FDA's consideration of available clinical trial data, medical literature, and real-world experience. *See, e.g.*, ROA.635-667, ROA.698-725, ROA.787-788, ROA.803-842, ROA.2142-2249, ROA.2251-2337, ROA.2381-2423. Instead, the court relied on materials never presented to FDA, including a 2021 "study" analyzing anonymous blog posts on the "Abortion Changes You" website. Pet. App. 173a-174a.

2. Danco and the Government appealed and sought an emergency stay of the injunction. The Fifth Circuit granted relief as to the 2000 approval, concluding that Respondents' challenge was likely untimely, but left in place the District Court's "stay" of FDA's 2016 and 2021 actions. Pet. App. 163a.

Danco and the Government submitted emergency stay applications to this Court. The Court stayed the preliminary injunction in full through the disposition of this petition. Pet. App. 111a.

3. The Fifth Circuit merits panel affirmed the District Court's decision to enjoin FDA's 2016 and 2021 actions.[2]

The panel first found that Respondents had established associational standing.

On injury-in-fact, the panel reasoned that "given the millions of women who take mifepristone, the number of women who experience complications from taking the drug, and the high number of the Organizations' members who treat such women," "it is highly likely that one or more of their members will be required to provide emergency care to a mifepristone patient in the near future."[3] Pet. App. 18a, 24a. The panel identified three "threatened injuries": First, the panel stated that a member might face "economic harm" from having to "divert time and resources away from their regular patients," even though emergency-room doctors lack "regular" patients and are paid to provide care to all comers. *Id.* at 32a. Second, the panel stated that a member might face a risk of "greater liability and increased insurance costs" from providing follow-up care to a woman who took

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[2] The merits panel reversed the District Court's injunction of FDA's 2000 approval as untimely. Pet. App. 52a. It also reversed the injunction of FDA's 2019 approval of a generic mifepristone product. *Id.* at 43a-45a.

[3] The panel repeatedly said that "the Medical Associations" include "hundreds" of "OB/Gyns or emergency-room doctors who treat women who experience severe adverse effects," Pet. App. 17a; *see also id.* at 24a, 27a, but no association provided membership numbers of doctors with these specialties practicing in U.S. emergency rooms. One is an association of pediatricians. Another is an association of dentists. A third is a global organization open to students, practicing and retired doctors of all specialties, and nurses.

mifepristone, even though no doctor said that had happened in the past. *Id.* at 26a. And third, the panel stated that a member could be forced to "choose between following their conscience and providing care," causing "mental and emotional stress," even though federal law allows individual doctors to decline care where they have a conscience objection. *Id.* at 25a, 33a. Such conscience protections might not be enough, the panel reasoned, "if no other doctor were available," even though no doctor offered evidence that had ever occurred. *Id.* at 34a.

On traceability, the panel concluded that these injuries are traceable to the 2016 changes and 2021 nonenforcement decision based on certain declarant-doctors who do not prescribe mifepristone or regularly treat patients who have taken mifepristone, saying that more complications can occur toward the 70-day gestational limit approved in 2016 and more emergency-room follow-up care might occur without mandatory in-person appointments and midwife or advanced practice nurse prescribing. *Id.* at 37a-39a. The panel thus found traceability because the asserted injuries—i.e., potential economic harm from treating one patient instead of another, potential liability and malpractice costs, and potential conscience violations—are at "increased risk" of occurring after the challenged 2016 and 2021 actions. *Id.* at 39a.

The panel never addressed redressability at all, even after stating that "rigorous evidence [is] needed to prove traceability and redressability." *Id.* at 36a. The panel did not point to any "pro[of]" that "enjoining enforcement of the [2016 and 2021 challenged actions] would cause there to be fewer" injuries to Respondents' members. *Id.*

On the merits, although it lacked the administrative record, the panel found the 2016 and 2021 modifications were likely arbitrary and capricious because FDA had not sufficiently considered certain aspects of its actions.

The panel held FDA failed to consider two issues in its 2016 changes. First, even though FDA materials in the record showed that FDA carefully analyzed data where multiple changes were made in concert, the panel concluded (without citation) that FDA had not sufficiently reflected on the "cumulative effect" of the 2016 changes, which it saw as "unquestionably an important aspect of the problem." *Id.* at 54a. Second, the panel said FDA should have considered whether to continue mandatory prescriber reporting of all adverse events—instead of using the voluntary prescriber reporting system used by *every other FDA-approved drug* (plus the still-mandatory additional requirement to report patient deaths for any reason)—because, according to the panel, "the 2016 Amendments might alter the risk profile." *Id.* at 56a.

As to the 2021 non-enforcement decisions, the panel rejected the argument that the challenge was moot because the non-enforcement decision was no longer in effect and had been superseded by the 2023 REMS, which Respondents did not challenge. *Id.* at 58a-60a. The panel asserted FDA lacked supporting evidence to permit dispensing other than in person because prescribers had not been required to report all adverse events to Danco since 2016. *Id.* at 60a-63a. The panel also faulted FDA for describing medical literature as "not inconsistent with its conclusion" that in-person dispensing was unnecessary instead of

saying the literature "supported" that conclusion. *Id.* at 63a.

The panel held that enjoining FDA's actions was warranted and that remand without vacatur would be inappropriate because it did not think FDA could remedy what the panel saw as errors. *Id.* at 73a.

REASONS FOR GRANTING THE PETITION

I. THE FIFTH CIRCUIT'S STANDING DECISION CONFLICTS WITH THIS COURT'S PRECEDENT AND SPLITS FROM OTHER CIRCUITS.

A. The Fifth Circuit's Standing Decision Conflicts With This Court's Precedent.

1. "The 'law of Art. III standing is built on a single basic idea—the idea of separation of powers.' " *TransUnion LLC* v. *Ramirez*, 141 S. Ct. 2190, 2203 (2021) (citation omitted). Therefore, "[r]elaxation of standing requirements is directly related to the expansion of judicial power." *Clapper*, 568 U.S. at 408-409 (quoting *United States* v. *Richardson*, 418 U.S. 166, 188 (1974) (Powell, J., concurring)). To guard against this possibility, plaintiffs seeking injunctive relief must show they will be "concrete[ly]" injured by an action "fairly traceable" to the defendant and "redressable" by the court. *Id.* at 409 (citation omitted).

The injury requirement demands that "the party seeking review [must] be himself among the injured," *Lujan*, 504 U.S. at 563 (citation omitted), and the injury "must affect the plaintiff in a personal and individual way," *Spokeo, Inc.* v. *Robins*, 578 U.S. 330, 339 (2016) (citation omitted). Neither "[a]llegations of *possible* future injury," *Clapper*, 568 U.S. at 409 (citation omitted), nor "past wrongs * * * amount to that

real and immediate threat of injury necessary to make out a case or controversy," *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 103 (1983). That remains the rule even when claims of past harm are coupled with "a statistical probability that some [plaintiffs] are threatened with concrete injury." *Summers*, 555 U.S. at 495, 497. The "threatened injury" alleged "must be certainly impending to constitute injury in fact." *Clapper*, 568 U.S. at 409 (citation omitted).

The traceability and redressability requirements mean that the defendant must be the cause of the plaintiff's injury—not intervening third-party actions. For that reason, "when the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish." *Lujan*, 504 U.S. at 562. To satisfy that burden, the plaintiff must show "that third parties will likely react in predictable ways." *Department of Commerce* v. *New York*, 139 S. Ct. 2551, 2566 (2019). Without "strong[] evidence" to "trace the necessary connection" between the challenged policy and the injury, a court cannot find standing. *California* v. *Texas*, 141 S. Ct. 2104, 2118-19 (2021). Plaintiffs cannot satisfy Article III by "speculat[ing] about 'the unfettered choices made by independent actors not before the court.'" *Clapper*, 568 U.S. at 414 n.5 (quoting *Lujan*, 504 U.S. at 562).

2. This Court rigorously holds litigants to these requirements. The Fifth Circuit did not. Respondents did not establish a certainly impending injury traceable to FDA's 2016 or 2021 actions. The Fifth Circuit's analysis conflicts with this Court's precedent in at least three ways—any one of which should have disqualified Respondents from bringing this suit.

First, the Fifth Circuit found injury based on statistical possibility, which *Summers* prohibits. In the panel's own words, Respondents' proof of injury rested on three pieces of evidence: (a) "data show[ing] that a definite percentage of women who take mifepristone will require emergency-room care"; (b) data "show[ing] that millions of women take mifepristone"; and (c) Respondents' "testi[mony] that hundreds of their members are OB/Gyns and emergency-room doctors who care for women in these circumstances." Pet. App. 27a.

Such a "probabilistic" standing analysis ignores the requirement that organizations must "make specific allegations establishing that at least one identified member had suffered or would suffer harm." *Summers*, 555 U.S. at 498-499. That case held an environmental organization lacks standing to challenge a Forest Service Regulation even though it has "thousands of members * * * who use and enjoy" areas affected by the regulation and "there [wa]s a statistical probability that some of those members are threatened with concrete injury." *Id.* at 497-498 (citation omitted). *Summers* makes clear that even where it is "likely" that "one individual" among an organization's members will suffer injury, "speculation does not suffice." *Id.* at 499.

Second, the Fifth Circuit leaned on past injury as a predictor of future injury, which *Lyons* prohibits. In the Fifth Circuit's view, "prior instances" of care "to women suffering complications from mifepristone," and "mifepristone's continued availability," showed that Respondents' "members are reasonably likely to be injured again." Pet. App. 29a. Even setting aside whether pre-*Dobbs* instances would recur in

jurisdictions that have since outlawed nearly all abortions, "past exposure" lacking a continuing effect "does not in itself show a present case or controversy regarding injunctive relief." *Lyons*, 461 U.S. at 102 (alteration and citation omitted). Just as the *Lyons* plaintiff's allegations that he had been the victim of an unlawful chokehold in the past and that Los Angeles police officers "routinely apply chokeholds" were insufficient to show that he had standing to enjoin future chokeholds, *id.* at 105, the plaintiffs here lack standing to enjoin future dispensing of mifepristone.[4]

Third, the Fifth Circuit's analysis directly conflicts with *Clapper*'s holding that an injury is not "certainly impending" when it rests on "a highly attenuated chain of possibilities" and "speculation about 'the unfettered choices made by independent actors not before the court.'" 568 U.S. at 410, 414 n.5 (quoting *Lujan*, 504 U.S. at 562). Because Respondents' evidence cannot explain, for example, who will seek emergency-room care, whether she will do so at a time when a member doctor is practicing, or whether another physician will provide that care, Respondents' evidence "does not adequately trace the necessary connection" between FDA's actions and Respondents' injury. *California*, 141 S. Ct. at 2118-19. As in *Clapper*, the challenged government action here "at most authorizes—but does not mandate or direct" a particular action by anyone, making allegations of harm from

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[4] Respondents stand on even shakier ground because their claims of past injury frequently rest on care provided by *other doctors* in their practice, *undated* experiences that may pre-date FDA's 2016 and 2021 actions, or care provided to women *without specifying* that a patient was properly prescribed and took FDA-approved mifepristone. *E.g.*, ROA.267-269, ROA.277-279.

independent actors' discretionary choices "necessarily conjectural." 568 U.S. at 412; *see also California*, 141 S. Ct. at 2119 (distinguishing *Commerce*, 139 S. Ct. at 2565-66, because the standing allegations in that case relied "not only on 'the predictable effect of Government action on the decisions of third parties' but also on comprehensive studies, rather than mere 'speculation'").

3. The Fifth Circuit also erred at every stage of its calculation of the existence of an injury to an association member that was traceable to FDA's actions in 2016 and 2021.

First, the court started from the premise that "millions of women" have taken mifepristone, but that number counts all women who have taken the drug in the 23 years since its initial approval—not the incremental number of additional women who have taken or will take it as a result of the conditions of use that FDA changed in 2016 or 2021. Yet any reliable statistical analysis of injury linked to the 2016 and 2021 changes would necessarily have to exclude women who would or will take it based on the 2000 approval and focus instead on how many women have and will take the drug *because of the 2016 and 2021 changes* that Respondents seek to enjoin. *See, e.g.*, *TransUnion*, 141 S. Ct. at 2208 ("[P]laintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek."). There is no such evidence in the record. And given the substantial changes in many States' laws to restrict abortion since this Court's decision in *Dobbs* v. *Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022), there is no possible way to determine how many women will do so in the future.

Second, there is no evidentiary support—and the court pointed to none—for the notion that "a significant percentage of women who take mifepristone experience adverse effects." Pet. App. 18a. Danco and FDA have disputed that statement with scientific data at every turn. From its 2000 approval forward, serious adverse events associated with Mifeprex have been "exceedingly rare," ROA.2189, including a rate of hospitalization well below 1%. *E.g.*, ROA.839-840, ROA.2189, ROA.2192, ROA.2197-2198. The record shows that for the overwhelming majority of women who take Mifeprex under the current dosing regimen, the drug is completely safe (over 99%) and effective (over 96%). As a result, any reliable statistical analysis would have to start from the tiny fraction of the unknown number of women who took Mifeprex because of the 2016 and 2021 changes and then experienced an adverse event for which she sought emergency care.

Third, any reliable statistical analysis would have to calculate how often a Respondent association member would be the on-call doctor in an emergency room in which the tiny fraction of the unknown number of women taking Mifeprex because of the 2016 and 2021 changes went for that emergency care. This in turn would require knowing, among other things, where and how often those members practice, how many doctors make up the staff in those locations, and what alternative facilities or practitioners could provide emergency care to any given individual when she needs it.

In sum, to even attempt computing a statistical likelihood that Respondents will be harmed by FDA's 2016 and 2021 modifications, one would need to know

the relevant numerator (the number of women who will be prescribed mifepristone as a result of FDA's 2016 and 2021 decisions *and* would not have been prescribed it otherwise *and* who subsequently need follow-up care *and* who seek that care from an emergency room) and the relevant denominator (all possible health care professionals who could provide follow-up care in an emergency room in the geographic area where a given woman is located at the time care is needed). No facts about any part of this equation exist, which is why the Fifth Circuit could only say that it viewed the 2016 and 2021 challenged actions as causing an "increased risk" of injury. Pet. App. 39a. All of the flaws in the Fifth Circuit's reasoning underscore the speculative nature of the asserted injuries here.

4. The Fifth Circuit attempted to paper over the flaws in Respondents' standing evidence by invoking the size of the associations, but that too conflicts with this Court's precedent.

Organizational plaintiffs must satisfy the same Article III requirements as individuals. *E.g.*, *Summers*, 555 U.S. at 495, 498; *Havens Realty Corp.* v. *Coleman*, 455 U.S. 363, 378-379 (1982); *Sierra Club* v. *Morton*, 405 U.S. 727, 739-740 (1972). An organization can borrow its individual members' standing, but it cannot rely on the size of its membership to create standing for a hypothetical composite member. It would "make a mockery" of standing doctrine to permit courts to find standing based on a statistical chance "that some (unidentified) members" are affected by the challenged activity "and will suffer (unidentified) concrete harm as a result." *Summers*, 555 U.S. at 497-498.

The Fifth Circuit's envelope-pushing decision is particularly problematic because this Court "has yet to reconcile its associational-standing test with its more recent guidance" regarding "the Constitution's separation of powers." *Association of Am. Physicians & Surgeons* v. *FDA*, 13 F.4th 531, 534, 538 (6th Cir. 2021). Associational standing lacks the historic roots that this Court has recently explained must support injury-in-fact. *See id.* at 538 (citing *TransUnion*, 141 S. Ct. at 2204). And associational standing leads to an inevitable mismatch between the requested remedy (which, here, results in a nationwide injunction) and the asserted injury (which, here, could involve just one unknown doctor in an unknown location at an unknown future time). *See id.* at 540 (citing *Gill* v. *Whitford*, 138 S. Ct. 1916, 1930 (2018)). At the least, this Court's recent "guidance should lead [lower courts] to vigilantly ensure that an association's members have incurred a personal injury." *Id.* at 534. As the decision below illustrates, the Fifth Circuit failed to do that here.

B. The Fifth Circuit's Standing Decision Conflicts With Other Courts Of Appeals.

Many other circuits have faced the question whether standing can be based "on the likelihood that some members of a discrete group, but not all, will be injured," where the plaintiff organization cannot identify any member who will be injured. Pet. App. 29a. Demonstrating how far afield from this Court's settled principles the Fifth Circuit's decision is, six circuits flatly disagree with the Fifth Circuit and recognize that *Summers* forbids finding associational standing without identifying members who will be injured by the policy they seek to enjoin. The Ninth Circuit's

decisions reflect "tension" in its application of *Summers*. *California Rest. Ass'n* v. *City of Berkeley*, 65 F.4th 1045, 1062-63 (9th Cir. 2023) (Baker, J., concurring). The Fifth Circuit alone has held that a court can calculate for itself whether it thinks the probability is sufficiently high that some unidentified association member might someday be injured. This Court's review is warranted to clarify *Summers*' requirements.

Six courts of appeals—the First, Second, Sixth, Seventh, Eighth, and D.C. Circuits—hold that associations cannot pin their standing on the assertion that "there is a substantial likelihood that at least one member" of their group will be injured by a challenged regulation. *American Chemistry Council* v. *Department of Transp.*, 468 F.3d 810, 820 (D.C. Cir. 2006). Although an increased risk of harm to the plaintiff—as opposed to certain injury—may constitute a cognizable injury-in-fact, these courts recognize that increased risk cannot eliminate the causation and redressability requirements. *See, e.g.*, *Public Citizen, Inc.* v. *National Highway Traffic Safety Admin.*, 513 F.3d 234, 237 (D.C. Cir. 2008) (explaining that a plaintiff must demonstrate that due to the challenged conduct there is "*both* (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm [to the plaintiff] with that increase[d risk] taken into account").

An association therefore cannot claim standing based on statistics regarding the "historical" rate of harm, *Memphis A. Philip Randolph Inst.* v. *Hargett*, 978 F.3d 378, 387-388 (6th Cir. 2020); cannot invoke only "generalized harm to a group of individual members," *Prairie Rivers*, 2 F.4th at 1010; and cannot

assert standing "on behalf of unnamed members," *Religious Sisters of Mercy* v. *Becerra*, 55 F.4th 583, 602 (8th Cir. 2022). A plaintiff's assertion that a large group will inevitably be affected by a regulation, without clear allegations regarding "who these members are or how exactly the [regulation] will harm them individually," "trends too closely to the statistical probability theory of associational standing rejected in *Summers*." *Prairie Rivers*, 2 F.4th at 1009-10; *accord Faculty* v. *New York Univ.*, 11 F.4th 68, 76 (2d Cir. 2021) (association lacked standing because it failed to "identify[] members who have suffered the requisite harm"); *Draper* v. *Healey*, 827 F.3d 1, 3 (1st Cir. 2016) (Souter, J., sitting by designation) (gun advocacy group lacked standing because it did not identify "any member of the group whom the regulation prevented from selling or purchasing a Glock").

The Ninth Circuit, by contrast, has at times suggested confusion about *Summers*' reach. *Compare National Council of La Raza* v. *Cegavske*, 800 F.3d 1032, 1041 (9th Cir. 2015) (permitting organization to leave unidentified two allegedly injured members because "the defendant need not know the identity of a particular member to understand and respond to an organization's claim of injury"), *with Associated Gen. Contractors of Am., San Diego Chapter, Inc.* v. *California Dep't of Transp.*, 713 F.3d 1187, 1194 (9th Cir. 2013) (holding *Summers* "requires, first, specific allegations establishing that at least one *identified member* had suffered or would suffer harm") (internal quotation marks omitted); *see also, e.g.*, *California Rest. Ass'n*, 65 F.4th at 1062-63 (Baker, J., concurring) (noting "tension" in Ninth Circuit's precedents on this point).

The Fifth Circuit's decision goes where no circuit has gone. It endorses a theory of associational standing that combines probabilistic injury to unnamed members (prohibited by *Summers*) with evidence of past injury (irrelevant under *Lyons*) to parties unregulated by the challenged action (discredited by *Clapper*). *See* Pet. App. 29a-32a. This Court should rein in now such unmoored Article III theories.

II. THE FIFTH CIRCUIT'S MERITS DECISION CONFLICTS WITH THIS COURT'S PRECEDENT, CREATES A CIRCUIT SPLIT, AND OVERREACHES.

A. The Fifth Circuit's Merits Decision Conflicts With This Court's Precedent.

This Court has explained that in APA cases the question is whether the reviewing court can "reasonably discern[]" the agency's path and, if so, the reviewing court "must 'uphold' " that decision. *Ming Dai*, 141 S. Ct. at 1679 (quoting *Bowman Transp., Inc.* v. *Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974)). The court's role is to ensure that an agency has "acted within a zone of reasonableness," not to "substitute its own policy judgment for that of the agency." *Prometheus*, 141 S. Ct. at 1158. Agencies are also allowed to make predictive judgments. *See id.* at 1160; *Lingle*, 544 U.S. at 544. And an agency need not use "magic words" to show its work. *Ming Dai*, 141 S. Ct. at 1679. The Fifth Circuit disregarded these rules.

First, contrary to the Fifth Circuit's conclusions, FDA's path to the 2016 changes is clear. The Fifth Circuit enjoined the changes that FDA approved in 2016 because FDA "did not consider the cumulative effect of the 2016 amendments" and did not consider

whether it should continue the same mandatory adverse event reporting after the changes, and therefore failed "to consider an important aspect of the problem." Pet. App. 54a-56a.

But Section 1 of FDA's Medical Review document lists the eleven changes to the Mifeprex approval that Danco sought, ROA.2147; Section 1.1 "recommend[s] an approval action for this efficacy supplement," *id.*; and the remainder of the 100-page document explains why the reviewers recommended approval after detailing the many dozens of studies that addressed various combinations of the changes, ROA.2142-2243. The Cross-Discipline Team Leader Review "concur[red]" in approving the set of changes, ROA.2254, and explained that the review's 60 pages of analysis was organized as "a topic-centered discussion of the totality of the data," ROA.2259.

FDA also explained its conclusion that the pre-2016 mandatory prescriber adverse event reporting was no longer necessary because of the drug's established safety profile—which FDA had determined would not be altered with the 2016 changes, including after considering data about the less-than-1% rate of serious adverse events in tens of thousands of study participants from the clinical trials supporting those changes. ROA.2272. Danco would still "be required by law, as is every NDA holder, to report serious, unexpected adverse events as 15-day safety reports, and to submit non-expedited individual case safety reports, and periodic adverse drug experience." ROA.2230.

Second, the Fifth Circuit failed to defer to FDA's predictive judgments. The Fifth Circuit enjoined FDA's 2021 non-enforcement decision based on its

view that if the agency had continued to mandate serious adverse event reporting, rather than use the same voluntary reporting for serious adverse events that other drugs use, it might have found additional adverse events. The court provided no reason to think this would be true; in any event, this Court's precedent plainly permits an agency to make predictions based on the evidence before it. *See Prometheus*, 141 S. Ct. at 1158; *Federal Commc'ns Comm'n* v. *WNCN Listeners Guild*, 450 U.S. 582, 595 (1981). That is especially so on an issue within an agency's scientific expertise.

Third, the Fifth Circuit required "magic words" where no such mantra is required. *Ming Dai*, 141 S. Ct. at 1679. It faulted FDA for saying that the medical literature was "not inconsistent with" its conclusion that Mifeprex would remain safe and effective without an in-person-dispensing requirement, rather than saying the literature "affirmatively support[s]" FDA's decision. Pet. App. 63a. This judicial wordplay raises the same sort of "magic words" conflict as is at play in the 2016 decision.

Even on the limited record available at this stage, it is clear that FDA considered all the changes Danco sought and sufficiently explained its reasoning for approving them. And yet the Fifth Circuit found otherwise.

B. The Fifth Circuit's Merits Decision Creates A Circuit Split.

The Fifth Circuit's decision to partially uphold the District Court's grant of a preliminary injunction to Respondents creates a circuit split. The D.C. Circuit has long held that courts should not decide preliminary injunctions when the court has not reviewed the

full administrative record. *American Bioscience*, 243 F.3d at 580. Courts can, of course, make decisions without the benefit of the record in cases where the argument "can be resolved with nothing more than the statute and its legislative history," *American Bankers Ass'n* v. *National Credit Union Admin.*, 271 F.3d 262, 266 (D.C. Cir. 2001), or where a plaintiff alleges that an agency's action was not a "formal administrative determination" such that no record exists, *Allied Pilots Ass'n* v. *Pension Benefits Guar. Corp.*, 334 F.3d 93, 97-98 (D.C. Cir. 2003). But where a plaintiff complains that the agency failed to draw a " 'rational connection between the facts found and the choice made,' " *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted), the D.C. Circuit requires a court's assessment of that connection to rest on the "full administrative record that was before the [agency]," *Walter O. Boswell Mem'l Hosp.* v. *Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) (quoting *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 420 (1971)).

In *American Bioscience*, for example, the D.C. Circuit vacated and remanded a district court decision denying a pharmaceutical company's request for a preliminary injunction because the district court had assessed the probability of success on the merits without the administrative record. 243 F.3d at 580. The district court had denied the plaintiffs' request based on its assessment that FDA's interpretation and application of a regulation were not plainly erroneous or inconsistent. *Id.* at 582. But the appellate court reversed, holding that the district court had improperly failed to "call[] for the administrative record," and had instead "relied on the parties' written or oral representations to discern the basis on which the FDA

acted." *Id.* "Surely that was not sufficient," the D.C. Circuit concluded, because the APA directs courts to perform judicial review "by review[ing] the whole record or those parts of it cited by a party." *Id.* (quoting 5 U.S.C. § 706; *Overton Park*, 401 U.S. at 419). Without the record, a court "cannot tell on what basis the Food and Drug Administration took the agency action the plaintiff seeks to enjoin." *Id*. at 580.

The Fifth Circuit here, in contrast, did *not* require review of the full administrative record before concluding that the agency's analysis of that record was insufficient. In an APA case, "the focal point for judicial review should be the administrative record[.]" *Camp* v. *Pitts*, 411 U.S. 138, 142 (1973). Bits of the record were presented to the courts below, but the full record remains unproduced—despite all parties' agreement before the District Court to file cross-motions for summary judgment after an administrative record was produced. *See* ROA.3240-3252, ROA.3588-3596, ROA.3801-3811, ROA.4192. Instead, the courts below rushed to award preliminary injunctive relief in an APA case lacking an administrative record. When the basis for undoing final agency action is that the agency acted arbitrarily and capriciously, the reviewing court cannot comply with the APA when it enters a mandatory preliminary injunction without an administrative record.

C. The Fifth Circuit's Merits Decision Awarded Far-Reaching Relief.

The Fifth Circuit's divergence from this Court's APA precedent extends beyond its resolution of the merits. By ordering a return to the pre-2016 labeling and use restrictions, the Fifth Circuit has ordered Danco to ask FDA for approval to put an obsolete and

less-effective dosing regimen on the labeling, including taking *three times* the amount of Mifeprex that is on the current labeling, along with outmoded guidance on the timing for the misoprostol. The Fifth Circuit also purported to affirm a stay of the 2023 REMS, which FDA and Danco raised to point out that any question about the correctness of the non-enforcement decision had become moot. *See* Pet. App. 58a, 76a. Plaintiffs never challenged the 2023 REMS in the District Court, making a stay of this agency action irreconcilable with the limits of APA review.

The Fifth Circuit also erred in decreeing that FDA could not fix the alleged flaws in its decision on remand and that the agency's actions must be vacated. *See id.* at 73a. At most, the appropriate remedy would be remand without vacatur: "[W]here there is an incomplete record and 'it is not at all clear that the agency's error incurably tainted the agency's decisionmaking process, the remedy of remand without vacatur is surely appropriate.' " *Sierra Club* v. *EPA*, 60 F.4th 1008, 1022 (6th Cir. 2023) (quoting *Black Warrior Riverkeeper, Inc.* v. *U.S. Army Corps of Eng'rs*, 781 F.3d 1271, 1290 (11th Cir. 2015)). Because FDA "may be able readily to cure a defect in its explanation of a decision," *Heartland Reg'l Med. Ctr.* v. *Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009), and because "the disruptive consequences" occasioned by "an interim change that may itself be changed" are significant when it comes to Mifeprex's conditions of use, *Allied-Signal, Inc.* v. *U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 150-151 (D.C. Cir. 1993) (citation omitted), remand without vacatur is the proper course if there are indeed errors to remedy.

III. THIS CASE IS AN EXCELLENT VEHICLE TO ADDRESS QUESTIONS OF NATIONAL SCOPE AND EXCEPTIONAL IMPORTANCE.

The Court should grant review given the national importance of the questions presented. The decision below affects the availability of a drug with lawful uses in States across the country. It raises questions about whether a single federal court can limit abortion access in the States that protect it. And it destabilizes the pharmaceutical and biotechnology industries by questioning when scientific studies—accepted by FDA—are sufficient to support conditions of use, invaliding FDA's conclusions based on untested, unscientific, and non-record evidence *without even evaluating* the administrative record. There are no barriers to this Court's review.

1. The panel conceded that it was "not insignificant" that eliminating access to Mifeprex, even temporarily, "may pose health risks to women, including those who use the drug to manage miscarriage," and will burden state and local health care systems. Pet. App. 69a-70a.

As numerous States, localities that run public health facilities, the medical establishment, and individual doctors have detailed, the panel's injunction will create tremendous negative effects, including pushing women to later gestational age surgical abortions or unapproved regimens with more complications, and impeding access to miscarriage management. *See, e.g.*, Doctors for America Amicus Br. 7, 10, Nos. 22A901, 22A902 (U.S. Apr. 14, 2023) (rural communities); *id.* at 8-11 (miscarriage management); *id.* at 14-16 (pregnancies from rape); Medical & Public

Health Societies Amicus Br. 22-23, Nos. 22A901, 22A902 (U.S. Apr. 14, 2023) (burdens on health care system); States' Amicus Br. 5-6, Nos. 22A901, 22A902 (U.S. Apr. 14, 2023) (investment in medication abortion access); Local Gov'ts Amicus Br. 7-12, 15-18, Nos. 22A901, 22A902 (U.S. Apr. 14, 2023) (burdens on understaffed and underfunded hospitals); Goldberg Decl. ¶¶ 10-22 & Schreiber Decl. ¶¶ 17-20, ECF No. 29, *Alliance for Hippocratic Med.* v. *FDA*, No. 23-10362 (5th Cir. Apr. 10, 2023).

2. The Pharmaceutical Research and Manufacturers of America (PhRMA) and hundreds of pharmaceutical companies told the Fifth Circuit that enjoining FDA's actions would severely destabilize the pharmaceutical industry and stifle innovation in drug development. *See* PhRMA Amicus Br., ECF No. 312, *Alliance for Hippocratic Med.* v. *FDA*, No. 23-10362 (5th Cir. May 2, 2023); Pharmaceutical Companies, Executives, and Investors Amicus Br., ECF No. 309, *Alliance for Hippocratic Med.* v. *FDA*, No. 23-10362 (5th Cir. May 2, 2023). As these briefs make clear, review is necessary to prevent the chaos that will ensue "[i]f every FDA drug approval decision is subject to an appreciable risk of being upended by a court based on flawed assessments of studies, reliance on anecdotes, and judicially added requirements." PhRMA Amicus Br. 26. The Fifth Circuit's ruling undermines "the durability of FDA drug approvals" and "diminish[es] the incentives for biopharmaceutical companies to invest in new medications." PhRMA Amicus Br. 20-21, Nos. 22A901, 22A902 (U.S. Apr. 14, 2023). It will force a "seismic shift in the clinical development and drug approval processes—erecting unnecessary and unscientific barriers to the approval of lifesaving medicines, chilling drug development and investment,

threatening patient access, and destabilizing the rigorous, well-established, and long-standing drug approval process." Pharmaceutical Companies Amicus Br. 18, Nos. 22A901, 22A902 (U.S. Apr. 14, 2023).

3. The Fifth Circuit's decision also has serious consequences for Danco. Mifeprex is Danco's only product. And the decision below will remove Mifeprex from the market entirely for an extended period of time.

The panel recognized that because it ordered Mifeprex to be marketed with the 2011 labeling and under the 2011 REMS, access to medication abortion would be disrupted for the months it would take Danco to prepare, and FDA to approve, an application to revert to the 2011 labeling and REMS, and longer still for Danco to then relabel Mifeprex, implement the modified REMS, re-certify prescribers, and update its distribution model. Pet. App. 67a-70a; Long Decl. 112a-120a, *Danco Labs., LLC* v. *Alliance for Hippocratic Med.*, No. 22A901 (U.S. Apr. 14, 2023); Woodcock Decl. 113a-116a, *FDA* v. *Alliance for Hippocratic Med.*, No. 22A902 (U.S. Apr. 14, 2023). All this assumes that FDA *can* legally approve an application based on outdated scientific information, including a less-effective dosing regimen—which is far from certain. And adding to the confusion, FDA is currently enjoined in 17 States and the District of Columbia from taking any action that would change the terms of Mifeprex's availability under the 2023 REMS. *See* Order Granting in Part Plaintiffs' Motion for Preliminary Injunction 30, ECF No. 80, *Washington* v. *FDA*, No. 1:23-cv-03026-TOR (E.D. Wash. Apr. 7, 2023). Only this Court's decisions are binding nationwide in the face of competing injunctions.

Even if FDA could approve marketing Mifeprex under the labeling used before the 2016 changes, that labeling would instruct women to take *three times* the amount of Mifeprex currently prescribed and would instruct providers to use a dosing regimen that has lower effectiveness rates. As part of the 2016 changes, FDA lowered the dose from three 200 mg tablets to one 200 mg tablet and increased the misoprostol dose from 400 mcg to 800 mcg—which data showed was more effective. ROA.2170-2174. Without further review, the Fifth Circuit's decision could cause women prescribed mifepristone to require *more*, rather than fewer, additional interventions including surgical abortions.

Although the case arrives at the Court in an interlocutory posture, the petition presents "important and clear-cut issue[s] of law" that are "fundamental to the further conduct of the case." Stephen M. Shapiro et al., *Supreme Court Practice* § 4.18 (11th ed. 2019) (citing cases). Indeed, this Court has already recognized the importance of the standing question by granting certiorari on it ten years ago. *See United States Forest Service* v. *Pacific Rivers Council*, No. 12-623 (U.S. Mar. 18, 2013).[5] And the merits question is inherently interlocutory because it deals with the preliminary injunction standard. There are no barriers to this Court's review.

* * *

[5] The Court was deprived of a chance to rule on that question due to the respondent's dismissal of its complaint. *See U.S. Forest Serv.* v. *Pacific Rivers Council*, 570 U.S. 901 (2013). The intervening decade has not resolved the split.

The risks and confusion that result from the Fifth Circuit's decision are not ones that women, teenage girls, and the public health system should be forced to bear without this Court's review. Denying review of the Fifth Circuit's opinion would eviscerate the sovereign authority of States that have chosen to expand and protect access to medication abortion in their jurisdictions. This Court has taken care to "not prevent the numerous States that readily allow abortion from continuing to readily allow abortion." *Dobbs*, 142 S. Ct. at 2305 (Kavanaugh, J., concurring). *Dobbs* returned the issue of abortion "to the people," *id.* at 2279, not a panel.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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