No.

In the Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

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

This case concerns mifepristone, a drug that the U.S. Food and Drug Administration (FDA) approved in 2000 as safe and effective for terminating early pregnancies. The Fifth Circuit held that respondents—doctors and associations of doctors who oppose abortion—have Article III standing to challenge FDA's 2016 and 2021 actions with respect to mifepristone's approved conditions of use and that those actions were likely arbitrary and capricious. The court therefore affirmed the district court's stay of the relevant agency actions. The questions presented are:

1. Whether respondents have Article III standing to challenge FDA's 2016 and 2021 actions.

2. Whether FDA's 2016 and 2021 actions were arbitrary and capricious.

3. Whether the district court properly granted preliminary relief.

PARTIES TO THE PROCEEDING

Petitioners were the defendants-appellants in the court of appeals. They are the U.S. Food and Drug Administration (FDA); Robert M. Califf, M.D., in his official capacity as FDA's Commissioner of Food and Drugs; Janet Woodcock, M.D., in her official capacity as Principal Deputy Commissioner of FDA; 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.

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.

Danco Laboratories, L.L.C. was an intervenor-appellant below.

RELATED PROCEEDINGS

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

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

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)

Supreme Court of the United States:

U.S. Food & Drug Administration, et al. v. *Alliance for Hippocratic Medicine, et al.*, No. 22A902 (Apr. 21, 2023)

Danco Laboratories, LLC v. *Alliance for Hippocratic Medicine, et al.*, No. 22A901 (Apr. 21, 2023)

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PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the U.S. Food and Drug Administration, et al., respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-110a) is not yet reported but is available at 2023 WL 5266026. The opinion and order of the district court (Pet. App. 111a-195a) is not yet reported but is available at 2023 WL 2825871. This Court's order granting a stay (Pet. App. 245a-248a) is reported at 143 S. Ct. 1075. The court of appeals' order granting a stay in part (Pet. App. 196a-244a) is not yet reported but is available at 2023 WL 2913725.

JURISDICTION

The judgment of the court of appeals was entered on August 16, 2023. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent statutory and regulatory provisions are reproduced in the appendix to this petition. Pet. App. 249a-254a.

STATEMENT

In 2000, the U.S. Food and Drug Administration (FDA) approved mifepristone for termination of early pregnancy based on the agency's scientific judgment that the drug is safe and effective. FDA has maintained that judgment across five presidential administrations, and it has modified the original conditions of mifepristone's approval as decades of experience have further confirmed the drug's safety. Today, more than half of American women who choose to terminate their pregnancies rely on mifepristone to do so. And study after study has shown that when mifepristone is taken in accordance with its approved conditions of use, serious adverse events are exceedingly rare.

Respondents are doctors and associations of doctors who oppose abortion on religious and moral grounds. They do not prescribe mifepristone, and FDA's approval of the drug does not require them to do or refrain from doing anything. Yet the lower courts held that respondents have Article III standing to challenge FDA's actions. And the courts then countermanded FDA's scientific judgment by suspending FDA's 2016 changes to mifepristone's approved conditions of use and FDA's 2021 decision to eliminate the requirement that the drug be dispensed in person. The effect of the lower

courts' decisions would be to compel FDA to return to a pre-2016 regulatory regime that imposes restrictions on distribution that FDA has found to be unnecessary and unjustified.

This Court previously stayed the district court's order in full. If the portions of that order affirmed by the Fifth Circuit are now allowed to take effect, it would upend the regulatory regime for mifepristone, with damaging consequences for women seeking lawful abortions and a healthcare system that relies on the availability of the drug under the current conditions of use. And the logic of the Fifth Circuit's unprecedented decision would threaten to severely disrupt the pharmaceutical industry and prevent FDA from fulfilling its statutory responsibilities according to its scientific judgment.

A. Statutory Background

Congress has entrusted FDA with the authority and responsibility to determine whether a "new drug" is safe and effective before it is distributed. 21 U.S.C. 321(p), 355; see 21 U.S.C. 393(b)(2)(B). The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, directs FDA to approve a new drug if, among other things, the sponsor's application contains evidence demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. 355(d); see 21 C.F.R. 314.50, 314.105(c).

In 2007, Congress codified and expanded FDA's prior regulatory regime by authorizing the agency to require a "risk evaluation and mitigation strategy" (REMS) when it determines that such a strategy is necessary to ensure that the benefits of a drug outweigh the risks. 21 U.S.C. 355-1; see Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, Tit. IX, § 901, 121 Stat. 922. Under the REMS frame-

work, FDA's approval of a drug may include "elements to assure safe use," such as a requirement that a drug's prescribers have particular training or that a drug be dispensed only in certain settings. 21 U.S.C. 355-1(f)(3). FDA may require submission of a proposed modification to an approved REMS if it determines that the modification should be made to ensure the benefits of the drug outweigh the risks. Modifications may include changes to requirements previously imposed to assure safe use of the drug. 21 U.S.C. 355-1(g) and (h).

B. FDA's Actions Addressing Mifepristone

1. In 2000, after a four-year review of the original sponsor's application, FDA approved mifepristone under the brand name Mifeprex. C.A. Add. 181-191.[1] Mifepristone is approved for use in a regimen with another drug, misoprostol, to end an early pregnancy. A patient who follows the two-drug regimen experiences cramping and bleeding similar to that associated with a miscarriage. *Id.* at 727-729. In approving mifepristone, FDA invoked regulations known as "Subpart H" to impose requirements to assure the drug's safe use, including a requirement that mifepristone be dispensed in person by or under the supervision of a doctor with specified qualifications. *Id.* at 186. FDA concluded based on a review of clinical trials and other scientific evidence that, under those conditions, mifepristone was safe and effective to terminate pregnancy through seven weeks of gestation. *Id.* at 181-188.

When Congress adopted the REMS framework in 2007, it deemed each drug with existing Subpart H

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[1] Like the government's stay application, this petition cites materials from the record below by referring to the addendum to the government's motion for a stay pending appeal in the Fifth Circuit.

restrictions—including mifepristone—to have an approved REMS imposing the same restrictions. FDAAA § 909(b), 121 Stat. 950-951 (21 U.S.C. 331 note). Since those amendments took effect, therefore, the requirements to assure mifepristone's safe use have been governed by the statutory REMS framework.

2. In 2016, FDA approved a supplemental new drug application from mifepristone's sponsor, Danco Laboratories, that sought to alter the drug's conditions of use (including the REMS). C.A. Add. 768-775. FDA's approval was based on a comprehensive review of the safety and efficacy of the modifications that considered "20 years of experience with [mifepristone], guidelines from professional organizations here and abroad, and clinical trials that have been published in the peer-reviewed medical literature." *Id.* at 677; see *id.* at 661-760. Three aspects of FDA's 2016 action are relevant here.

First, based on safety and efficacy data from numerous studies, FDA increased the gestational age limit from seven to ten weeks, C.A. Add. 689-698, 768-775, 790-791; reduced the number of required in-person clinical visits from three to one, *id.* at 698-701, 791-792; and approved a modification to the REMS to allow certain non-physician healthcare providers licensed under state law to prescribe and dispense drugs, such as nurse practitioners, to prescribe and dispense mifepristone, *id.* at 703-704, 791-793. FDA concluded that the use of mifepristone under the revised conditions would be "safe," emphasizing that major adverse events "are exceedingly rare." *Id.* at 707.

Second, FDA also changed the conditions of use by altering the approved dosing regimen. C.A. Add. 666. Among other things, FDA reduced the amount of mifepristone from 600 mg to 200 mg, increased the amount

of misoprostol, and called for the misoprostol to be administered buccally (dissolved in the cheek pouch) rather than orally. *Ibid.*

Third, FDA modified a prior requirement that prescribers of mifepristone agree to report certain adverse events such as hospitalizations and blood transfusions to the drug's sponsor. C.A. Add. 802. FDA determined based on "15 years of reporting" that the requirement was no longer warranted and that, as with the vast majority of other drugs, information on non-fatal adverse events could be "collected in the periodic safety update reports and annual reports" submitted by the drug's sponsor to FDA. *Ibid.*

3. In 2019, FDA approved an application from another sponsor, GenBioPro, to market a generic version of mifepristone. D. Ct. Doc. 1-37 (Nov. 18, 2022); see 21 U.S.C. 355(j). The same REMS covers both versions of the drug. D. Ct. Doc. 1-37, at 1-2.

4. In April 2021, FDA announced that, in light of the COVID-19-related risks associated with the in-person dispensing requirement, FDA intended to exercise enforcement discretion as to that requirement during the pandemic. C.A. Add. 841. FDA explained that its decision "was the result of a thorough scientific review by experts" who evaluated evidence including "clinical outcomes data and adverse event reports." *Ibid.*

5. In December 2021, FDA further determined that the in-person dispensing requirement was not necessary to ensure mifepristone's safe use. FDA thus directed Danco and GenBioPro to initiate the process of modifying the REMS. *Id.* at 842-843; see 21 U.S.C. 355-1(g)(4)(B). In 2023, after this suit was filed, FDA approved the sponsors' applications to remove the in-person dispensing requirement from the REMS. FDA,

Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg (Jan. 2023), https://perma.cc/MJT5-35LF.

C. Respondents' Citizen Petitions

Before challenging FDA's decision to take or refrain from taking action with respect to a drug, a party must file a citizen petition with the agency. 21 C.F.R. 10.45(b). Respondents filed two citizen petitions relevant here.

First, in 2002, two respondents filed a petition asking FDA to withdraw its 2000 approval of mifepristone. C.A. Add. 804. FDA denied the petition in March 2016, on the same day it approved modifications to mifepristone's indication, labeling, and REMS. *Id.* at 804-836. In the denial, FDA explained that "well-controlled clinical trials" had "supported the safety" of mifepristone at the time of the 2000 approval, and that "over 15 years of postmarketing data and many comparative clinical trials in the United States and elsewhere continue to support [its] safety." *Id.* at 820.

Second, in 2019, two respondents filed a petition challenging FDA's 2016 changes to mifepristone's indication, labeling, and REMS and urging the agency to retain the in-person dispensing requirement. C.A. Add. 192-217. In December 2021, FDA denied that petition in relevant part. *Id.* at 837-876. FDA determined that respondents' various criticisms of the 2016 changes were unfounded. *Id.* at 843-857. The agency further determined that "the in-person dispensing requirement"—which was already subject to enforcement discretion beginning in April 2021, and which had been enjoined during much of 2020—"is no longer necessary to assure the safe use of mifepristone." *Id.* at 842; see *id.* at 862. In addition to reviewing the available scientific literature, FDA reviewed the available data and found that "there

does not appear to be a difference in adverse events when in-person dispensing was and was not enforced." *Id.* at 863; see *id.* at 862-872.

D. Proceedings Below

1. In November 2022, respondents filed this suit challenging the 2000 approval of Mifeprex; the 2016 changes to the drug's conditions of use; the 2019 approval of generic mifepristone; the 2021 exercise of enforcement discretion; and the 2016 and 2021 denials of respondents' citizen petitions. C.A. Add. 161-177. Respondents sought a preliminary injunction ordering FDA to suspend those actions. Pet. App. 117a.

2. The district court granted respondents' motion. Pet. App. 111a-195a. The court rejected the government's arguments that respondents lack standing, *id.* at 118a-133a, and that their challenge to the 2000 approval of mifepristone was untimely, *id.* at 134a-141a. On the merits, the court held that FDA's actions were arbitrary and capricious under the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, 5 U.S.C. 701 *et seq*. Pet. App. 171a-187a. The court separately held that statutory provisions derived from the 1873 Comstock Act barred FDA from removing the in-person dispensing requirement. *Id.* at 151a-159a; see 18 U.S.C. 1461-1462.

Respondents had styled their motion as seeking a preliminary injunction. But the district court instead invoked 5 U.S.C. 705 to "stay" the effective date of "FDA's September 28, 2000, Approval of mifepristone and all subsequent challenged actions"—even though those actions had already been in effect for years. Pet. App. 193a-195a.

3. The government and Danco appealed and sought a stay pending appeal. The Fifth Circuit granted a stay as to FDA's 2000 approval of mifepristone, but other-

wise denied relief. Pet. App. 196a-244a. The government and Danco then applied to this Court for a stay of the district court's order pending appeal and, if necessary, the Court's consideration and disposition of a petition for a writ of certiorari. The Court granted the applications and stayed the district court's order in its entirety. *Id.* at 245a.

4. After further briefing and argument, the Fifth Circuit issued an opinion that largely tracked the stay panel's analysis, vacating the district court's order as to the 2000 approval of mifepristone but affirming the suspension of FDA's 2016 and 2021 actions. Pet. App. 1a-110a.

a. The Fifth Circuit first held that respondents have Article III standing to challenge FDA's decisions with respect to branded mifepristone. Pet. App. 14a-42a. Relying on a theory of associational standing, the court reasoned that "a certain percentage" of women who take mifepristone will experience adverse events or require surgical abortions, *id.* at 16a; that some percentage of that percentage will seek emergency care, *ibid.*; and that some of respondents' members are likely to treat women who experience such adverse events, *id.* at 17a; see *id.* at 26a-28a. The court accepted respondents' contention that treating women who take mifepristone and experience complications constitutes a cognizable injury because doctors who treat such patients may provide care that violates their consciences, may be "forced to divert time and resources away from their regular patients," and may be "expose[d] * * * to greater liability and increased insurance costs." *Id.* at 31a-36a. The court further determined that respondents had demonstrated traceability by sufficiently establishing that most of FDA's challenged actions "cause[] an in-

creased risk of injury." *Id.* at 40a-41a. But the court held that respondents had failed to introduce evidence showing they were injured by the approval of generic mifepristone, and the court therefore vacated the portion of the district court's order suspending FDA's approval of the generic version of the drug. *Id.* at 42a-44a.

The Fifth Circuit next held that respondents' challenge to FDA's original 2000 approval of mifepristone was likely untimely. Pet. App. 45a-51a. The court accordingly vacated the portion of the district court's order staying the 2000 approval. *Id.* at 51a.

b. Turning to the merits, the Fifth Circuit held that respondents are likely to succeed on their claims that FDA's 2016 and 2021 actions were arbitrary and capricious. Pet. App. 51a-63a. As to the 2016 changes to mifepristone's conditions of use, the court acknowledged that FDA had relied on studies establishing the safety of the relevant changes. But it nonetheless concluded that FDA acted arbitrarily because "none of the studies it relied on examined the effect of implementing all of those changes together." *Id.* at 53a. The court further held that FDA acted arbitrarily in changing the adverse-event reporting requirement in 2016. *Id.* at 54a-56a. The court stated that, although FDA had determined that the risks associated with mifepristone were "well known" by 2016, FDA had "failed to account for" the possibility that the 2016 changes "might alter the risk profile." *Id.* at 54a-55a.

The Fifth Circuit next concluded that FDA's 2021 decision to eliminate the in-person dispensing requirement was arbitrary and capricious because the agency had relied in part on adverse-event data that the court viewed as unreliable due to the 2016 change to the reporting requirement. Pet. App. 59a-63a. Although the

court identified no evidence that contradicted the agency's determination that the in-person dispensing requirement was no longer necessary to assure safe use, the court faulted FDA for citing studies that were "merely 'not inconsistent' with" FDA's conclusions, rather than studies that "affirmatively supported" the change. *Id.* at 63a.

c. As to remedy, the Fifth Circuit affirmed the district court's conclusion that respondents would be irreparably harmed absent relief and that the balance of the equities favored respondents. Pet. App. 63a-69a. The court also held that the district court properly invoked 5 U.S.C. 705 to "stay" the effective date of FDA's already-effective actions. Pet. App. 69a-74a. And the court concluded that the flaws it perceived in FDA's explanation for the 2016 and 2021 actions would justify vacatur of the challenged agency actions rather than a mere direction to consider the issues further because, in the court's view, "'it is far from certain' that FDA could cure its mistakes with further consideration." *Id.* at 72a (citation omitted).

d. Judge Ho concurred in part and dissented in part. Pet. App. 76a-110a. He agreed with the majority's analysis of the 2016 and 2021 actions, but would have suspended FDA's 2000 approval of mifepristone as well. *Id.* at 83a-97a. Judge Ho further concluded that removal of the in-person dispensing requirement violated the Comstock Act, an issue that the majority had declined to reach. *Id.* at 98a-104a; see *id.* at 63a n.8.

REASONS FOR GRANTING THE PETITION

To the government's knowledge, the decisions below mark the first time any court has restricted access to an FDA-approved drug based on disagreement with FDA's expert judgment about the conditions required

to assure that drug's safe use—much less done so after those conditions had been in effect for years. And the Fifth Circuit reached that unprecedented result through a series of errors that contradict this Court's precedents and violate black-letter Article III and administrative-law principles.

First, the Fifth Circuit erred in holding that the respondent associations have standing based on what it viewed as a statistical probability that some of their unidentified members might be asked to treat women who are prescribed mifepristone and who then suffer an exceedingly rare serious adverse event. This Court has emphatically rejected that statistical approach to associational standing, explaining that it would "make a mockery" of Article III. *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 498 (2009).

Second, the Fifth Circuit erred in holding that FDA's 2016 and 2021 actions were likely arbitrary and capricious. FDA's actions were supported by an exhaustive review of a record including dozens of scientific studies and decades of safe use of mifepristone by millions of women in the United States and around the world. The Fifth Circuit swept aside the agency's expert judgments based on novel requirements that have no basis in the FDCA or the Administrative Procedure Act.

Third, even if respondents had standing and some likelihood of success on the merits, the Fifth Circuit erred in affirming disruptive nationwide preliminary relief at the behest of parties whose asserted injury is at best highly attenuated and whose relevant claims primarily assert only that FDA failed adequately to explain its actions.

When the Fifth Circuit issued an opinion declining to stay the relevant portions of the district court's order,

this Court granted a full stay. The decision below relies on substantially similar reasoning, repeats many of the same legal errors, and threatens the same profound harms to the government, the healthcare system, patients, and the public. This Court should grant certiorari and reverse.

I. THE DECISION BELOW IS INCORRECT

A. Respondents Lack Article III Standing

To demonstrate Article III standing, "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC* v. *Ramirez*, 141 S. Ct. 2190, 2203 (2021). To establish injury in fact, respondents were required to show "an invasion of a legally protected interest" that is both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc.* v. *Robins*, 578 U.S. 330, 339 (2016) (citation omitted). And to satisfy the second prong of the standing test, respondents were required to demonstrate that their claimed injuries are "fairly traceable" to FDA's challenged actions. *Haaland* v. *Brackeen*, 143 S. Ct. 1609, 1638 (2023); see *California* v. *Texas*, 141 S. Ct. 2104, 2113 (2021). Respondents fell far short of making the requisite showings.

1. Respondents oppose abortion and therefore oppose the use of mifepristone. But respondents "are not required to receive" or prescribe mifepristone, and "[t]hey do not have standing to challenge FDA's decision to allow *other people* to receive" or prescribe the drug because that decision does not impose any concrete, particularized, or imminent harm on them. *Coa-*

lition for Mercury-Free Drugs v. *Sebelius*, 671 F.3d 1275, 1277 (D.C. Cir. 2012) (Kavanaugh, J.). "The Constitution therefore requires that [respondents] direct their objections to the Executive and Legislative Branches, not to the Judiciary." *Id.* at 1283.

To avoid that straightforward result, respondents have advanced theories of standing that concededly rest on a series of contingencies: that a woman will obtain mifepristone from another provider; that she will suffer an extremely rare serious adverse event; and that, rather than returning to her provider or another provider that was previously identified, she will seek care from one of respondents' members. Pet. App. 16a. The conscience-based theory on which the Fifth Circuit principally relied rests on two further contingencies: that the relevant woman will require an emergency abortion or other care to which respondents' unidentified member conscientiously objects, and that, despite federal conscience protections, the member will be forced to provide that care rather than referring the woman to a non-objecting doctor. *Id.* at 32a-34a; see, *e.g.*, 42 U.S.C. 238n, 300a-7(c) and (d); Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, Div H, Tit. VI, §§ 506-507.

To describe those theories is to refute them. This Court has repeatedly rejected theories of standing that rest on a "speculative chain of possibilities," *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 414 (2013), especially where, as here, those possibilities depend on "unfettered choices made by independent actors," *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 562 (1992) (citation omitted). In *Clapper*, for example, this Court reversed a decision finding standing based on "an objectively reasonable likelihood" that plaintiffs would suffer injury

from the challenged policy. 568 U.S. at 410. The Court rejected that approach as "inconsistent with [the] requirement that 'threatened injury must be certainly impending.'" *Ibid.* (citation omitted). So too here.

The Fifth Circuit relied on respondents' allegation that some of their members have treated complications from mifepristone in the past. Pet. App. 19a-24a. But even though millions of women have taken mifepristone and respondents claim to have thousands of members practicing around the country, C.A. Add. 75-77, respondents alleged only a handful of incidents. Standing to seek prospective relief cannot be based on such "past injury"; instead, a plaintiff must show an "imminent future injury." *Summers* v. *Earth Island Institute*, 555 U.S. 488, 495 (2009).

The Fifth Circuit attempted to cure that problem by relying on associational standing: Even if no particular doctor is sufficiently likely to be required to treat a mifepristone patient experiencing a complication, the court reasoned that because respondents "testified that hundreds of their members are OB/Gyns and emergency-room doctors," respondents' members in the aggregate face a "substantial risk" of future injury. Pet. App. 26a-27a. But that theory of standing mirrors the "novel" one this Court squarely rejected in *Summers*, 555 U.S. at 498. *Summers* explained that it "would make a mockery" of Article III to find standing whenever, based on an "organization's self-description of the activities of its members, there is a statistical probability that some of those members are threatened with concrete injury." *Id.* at 497-498. Yet that is precisely what the Fifth Circuit did here in "bas[ing] standing on the likelihood that some members of a discrete group, but not all, will be injured." Pet. App. 28a.

The Fifth Circuit purported to distinguish *Summers*, asserting that "[t]he problem in that case was *not* that plaintiffs' standing theory was invalid." Pet. App. 28a. In fact, an invalid theory of standing is exactly the defect this Court identified. The Court faulted the dissent for "propos[ing] a hitherto unheard-of test for organizational standing" that relied on probabilities to elide the requirement that an organization "make specific allegations establishing that at least one identified member" will suffer harm. 555 U.S. at 498. And the Court emphasized that the "requirement of naming affected members has never been dispensed with in light of statistical probabilities." *Id.* at 498-499. Contrary to the Fifth Circuit's assertion, therefore, the Court did not suggest that a stronger showing of "the facts upon which such probabilistic standing depends" could somehow satisfy Article III. *Id.* at 499. Instead, the Court rejected that probabilistic approach root and branch.

2. The Fifth Circuit suggested that respondents had provided "multiple examples" of doctors who have experienced harms from treating women who have taken mifepristone. Pet. App. 31a. Under *Summers* and this Court's other Article III precedents, those assertions of past injury could not establish standing to seek prospective relief even if they were supported by the record. But the Fifth Circuit's analysis of the record evidence was flawed on its own terms.

The Fifth Circuit principally focused on respondents' allegations that doctors had been required, against their conscience, to complete or facilitate an abortion for a patient who has taken mifepristone. But respondents and the Fifth Circuit failed to identify any doctor who imminently faces such harm. In fact, over the nearly 23 years mifepristone has been on the market—

and across the more than five million Americans who have used it to end a pregnancy—the Fifth Circuit identified only three doctors whose declarations purported to describe such a conscience injury. Pet. App. 19a-24a.

Even those isolated examples do not withstand scrutiny. The first cited declaration recounts the experience of the declarant's *partner*. Pet. App. 19a-20a (Dr. Francis); Resps. C.A. App. 6. Nothing in the declaration states that the unidentified doctor is a member of a respondent organization. The other declarations recount that the declarants personally (1) treated a patient for heavy bleeding; and (2) performed a procedure to resolve pregnancy tissue remaining in the uterus. Pet. App. 20a-22a (Drs. Skop and Wozniak); Resps. C.A. App. 16, 26-27. The declarations neither state that the declarants conscientiously objected to providing that care nor explain why, if they did object, they chose to proceed rather than invoking applicable conscience protections or allowing another doctor to step in.[2]

The Fifth Circuit's other grounds for finding imminent concrete injury were also flawed. The court held that respondents have standing because they have been "forced to divert time and resources away from their regular patients" to treat mifepristone patients. Pet.

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[2] The Fifth Circuit stated that federal conscience protections did not "alleviate the Doctors' conscience injury" because the court believed that the government's invocation of those protections here is inconsistent with its arguments in other litigation concerning the Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. 1395dd. See Pet. App. 34a. But in the separate litigation on which the Fifth Circuit relied, the government emphasized that EMTALA "'does not purport to displace the Religious Freedom Restoration Act,'" which would "inform EMTALA's application to individual providers." Gov't C.A. Reply Br. at 25, *Texas* v. *Becerra*, No. 23-10246 (5th Cir. Aug. 4, 2023).

App. 31a. There is substantial reason to doubt that simply being presented with a patient in need of care qualifies as an Article III injury to an emergency room doctor—someone whose chosen profession is treating patients in an emergent setting. But in any event, it is speculative that any particular doctor will experience such an effect in the future.

The Fifth Circuit similarly erred in speculating that FDA's regulatory actions with respect to a drug that respondents do not prescribe exposes them to malpractice allegations or higher insurance costs. Pet. App. 28a. Neither respondents nor the Fifth Circuit explained how or why such effects might occur. Nor did they identify any instance in which respondents or any of their members have ever been sued, threatened with a lawsuit, or required to pay increased insurance premiums.

3. Finally, the Fifth Circuit committed additional, independent errors in holding that respondents' alleged injuries were fairly traceable to FDA's actions in 2016 and 2021. Pet. App. 36a-41a.

a. As an initial matter, FDA's challenged actions simply authorized Danco and GenBioPro to distribute mifepristone subject to specified conditions. FDA did not require any healthcare provider to prescribe the drug or any patient to take it. A patient's decision to take the drug—in consultation with her provider and after being fully advised of the risks—is the product of independent actions by those third parties. And in the rare cases where the result of those independent actions is a serious adverse event requiring medical treatment, FDA's actions neither require patients to seek treatment from respondents' members nor require respondents' members to provide it. Respondents' assertion of future harm thus is not *fairly* traceable to FDA's ap-

proval of the distribution of the drug for prescription to women who choose to take it. See *Brackeen*, 143 S. Ct. at 1640.

Nor could respondents maintain that Congress has attempted to "elevate[]" their asserted injuries "to the status of legally cognizable injuries redressable by a federal court," *United States* v. *Texas*, 143 S. Ct. 1964, 1973 (2023) (citation omitted), or to "articulate chains of causation that will give rise to a case or controversy where none existed before," *Spokeo*, 578 U.S. at 341 (citation omitted). Nothing in the FDCA confers any rights on respondents or contemplates suits based on incidental and attenuated harms to doctors who oppose the availability of a drug and seek to prevent other doctors and patients from prescribing and using it.

b. The Fifth Circuit's traceability holding also fails on its own terms. As the court acknowledged (Pet. App. 36a), it is axiomatic that "standing is not dispensed in gross; rather, plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek." *TransUnion*, 141 S. Ct. at 2208. Here, the Fifth Circuit held that respondents' challenge to FDA's original 2000 approval of mifepristone is likely time barred, and that they can only challenge FDA's subsequent actions regarding the conditions of use. Respondents were thus required to show that they are injured by the incremental effects of those changes. That posed a serious hurdle, because respondents and the district court had focused almost entirely on respondents' assertion that they are injured by the availability of mifepristone in general—they made little or no effort to isolate the effects of FDA's 2016 and 2021 actions. Pet. App. 129a-131a.

The Fifth Circuit nonetheless held that respondents had made the required showing on the ground that FDA's 2016 and 2021 actions "will increase the number of women who suffer complications as a result of taking mifepristone." Pet. App. 36a. But that assertion disregards FDA's detailed findings to the contrary. See pp. 21-27, *infra*. And even accepting the Fifth Circuit's flawed mode of analysis, it is implausible that the incremental effects of FDA's actions cause enough adverse events to establish a certainly impending injury to respondents. The court of appeals pointed to no studies or other reliable evidence suggesting that FDA's 2016 and 2021 actions have had a substantial effect on the likelihood of adverse events that would require women to seek emergency care from respondents or their members. In fact, the record demonstrates that serious adverse events remain extremely infrequent with the relevant actions in place.[3]

In addition, the Fifth Circuit did not even purport to conclude that respondents suffer any Article III injury traceable to FDA's 2016 change to the reporting requirements. The district court held that respondents had standing to challenge that change because it caused them to spend "time, energy, and resources" to conduct their own research into adverse events. Pet. App. 126a. But the district court cited no precedent endorsing that boundless theory or otherwise suggesting that a party suffers an Article III injury when the government modifies reporting requirements applicable only to third parties. And because the Fifth Circuit did not endorse

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[3] See, *e.g.*, C.A. Add. 658-659 (reporting adverse events received by FDA through June 30, 2021); see also *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2022*, https://www.fda.gov/media/164331/download?attachment.

that holding or identify any other ground that would give respondents standing to challenge the 2016 changes to the reporting requirements, the court had no basis for reaching the merits of that challenge.

B. FDA's 2016 And 2021 Actions Were Reasonable And Reasonably Explained

The Fifth Circuit compounded its error by holding that FDA likely acted arbitrarily and capriciously in approving changes to mifepristone's conditions of use in 2016, in modifying the adverse-event reporting requirements at the same time, and in determining in 2021 that the in-person dispensing requirement was no longer necessary. The arbitrary and capricious standard is "deferential," and a reviewing court's only role is to ensure "that the agency has acted within a zone of reasonableness" and "has reasonably considered the relevant issues and reasonably explained the decision." *FCC* v. *Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Where, as here, the parties disagree on matters relating to public health, "courts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'" *FDA* v. *American Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring in grant of application for stay) (citation omitted). The Fifth Circuit's decision ignored those foundational principles.

1. 2016 Changes to Conditions of Use

a. In 2016, FDA approved an application to change mifepristone's conditions of use by, as relevant here, (a) increasing the gestational age limit from seven to ten weeks; (b) reducing the number of required clinical visits from three to one; and (c) allowing licensed non-

physician health care providers to prescribe and dispense mifepristone. C.A. Add. 768-775. FDA's approval of the 2016 changes was both "reasonable and reasonably explained." *Department of Commerce* v. *New York*, 139 S. Ct. 2551, 2571 (2019). FDA based its decision on an exhaustive review of "data gained in the last 20 years from millions of women in the US and abroad," among other information. C.A. Add. 693; see *id.* at 678-679 (listing 14 "major studies and review articles covering over 45,000 women"); *id.* at 751-758 (listing 79 total publications examining safety and efficacy). And FDA carefully explained how that scientific evidence supported each change. *Id.* at 660-761, 776-803.

b. The Fifth Circuit's sole basis for holding that the 2016 changes were arbitrary and capricious was its assertion that FDA failed to cite a study that evaluated the effects of those changes "as a whole." Pet. App. 53a. That holding was doubly wrong.

First, the APA requires an agency to review the record, "reasonably consider[] the relevant issues," and "reasonably explain[] [its] decision." *Prometheus*, 141 S. Ct. at 1158. Here, FDA grounded its judgment in a voluminous body of medical evidence on the widespread use of mifepristone over decades. And the agency carefully explained why the available data supported its conclusion that the 2016 changes would allow the drug to continue to be used safely and effectively—as in fact it has been since that time. C.A. Add. 720-727, 790-793.

The Fifth Circuit did not conclude that FDA ignored any study in the administrative record. Nor did it identify any evidence even suggesting that combining the proposed changes would lead to unsafe outcomes. Instead, the court faulted FDA for "neither consider[ing] the effects as a whole, nor explain[ing] why it declined

to do so." Pet. App. 53a. But as this Court explained in rejecting a similar argument, it was not arbitrary or capricious for FDA to "rel[y] on the data it had (and the absence of any countervailing evidence) to predict" that changes it had determined were safe individually would also be safe collectively. *Prometheus*, 141 S. Ct. at 1159. And the Fifth Circuit's criticism was particularly misplaced because respondents, in their 2019 citizen petition, never suggested that the changes could somehow be unsafe in combination even if they were safe individually or that FDA had erred because no study considered the changes "as a whole." See C.A. Add. 194-205.

Second, and in any event, the Fifth Circuit's conclusion that FDA did not consider the cumulative effect of the 2016 changes was wrong on the record. FDA considered numerous studies that examined the effect of multiple proposed modifications. Indeed, FDA considered at least three studies that closely mirrored challenged aspects of the 2016 conditions. See, *e.g.*, Sanhueza Smith et al. 2015 (cited at C.A. Add. 782 n.3) (up to 70 days gestation, same dose, dosing regimen, route of administration, and at-home administration of misoprostol); Winikoff et al. 2012 (cited at C.A. Add. 782 n.1) (same); Olavarietta 2015 (cited at C.A. Add. 782 n.4) (same, and also evaluating prescribing by nurses versus physicians). FDA explicitly stated that it was relying on data from those studies, and others, "to support multiple changes." C.A. Add. 781. Fairly read, therefore, the record makes plain FDA's conclusion that the combined changes would not affect the well-established safety or effectiveness profile of mifepristone. And neither the APA nor any other source of law required FDA to use the phrase "as a whole" or otherwise "incant

'magic words.'" *Garland* v. *Ming Dai*, 141 S. Ct. 1669, 1679 (2021).

2. 2016 Change To Reporting Requirements

FDA's 2016 action also changed the requirement that prescribers of mifepristone agree to report certain adverse events such as hospitalizations and blood transfusions to the drug's sponsor—a requirement that created obligations beyond FDA's standard reporting requirements for drug sponsors, which are applicable to all FDA-approved drugs. C.A. Add. 802, 856. FDA determined that "after 15 years of reporting serious adverse events, the safety profile for Mifeprex is essentially unchanged," *id.* at 802, and that the continued reporting of non-fatal adverse events by prescribers under the REMS was "not warranted" because mifepristone's "known risks occur[] rarely," *id.* at 856. FDA did not alter the detailed adverse event reporting requirements applicable to mifepristone's sponsors (Danco and, today, GenBioPro). As FDA explained (*ibid.*), those companies remained (and still remain) under an obligation to report *all* "serious and unexpected" adverse events to FDA within 15 days, and to report all other adverse events annually. See 21 C.F.R. 314.80, 314.98.

The Fifth Circuit held that FDA's change to the reporting requirement was arbitrary and capricious, asserting that FDA failed to acknowledge that the 2016 changes to the conditions of use "might alter the risk profile" of mifepristone. Pet. App. 55a. As explained above, however, FDA had already found that the 2016 changes *would not* affect mifepristone's safety profile. The APA did not compel FDA to maintain heightened reporting requirements it had determined were unnec-

essary to account for changes in risk that FDA had determined would not occur.

In any event, even if the Fifth Circuit were correct that FDA acted arbitrarily and capriciously in eliminating the special adverse-event reporting requirement that previously applied to mifepristone, the only relief that such an error could justify would be an order requiring FDA to reinstate that requirement or explain more fully why it is unnecessary. The asserted error would provide no basis for suspending the changes to mifepristone's approved conditions of use.

3. 2021 Decision To Remove The In-Person Dispensing Requirement

The Fifth Circuit likewise erred in concluding that FDA acted arbitrarily and capriciously by determining that the in-person dispensing requirement must be removed because it was no longer needed to assure mifepristone's safe use—and thus no longer justified under the FDCA. C.A. Add. 861-872. FDA's decision "was the result of a thorough scientific review" by agency experts who evaluated "available clinical outcomes data and adverse event reports." *Id.* at 841; see also *id.* at 861-872.

The Fifth Circuit suggested that because FDA had, as part of the 2016 changes, eliminated the special requirement for prescribers to report certain non-fatal adverse events to the sponsor, it was "unreasonable" for FDA to "use the resulting absence of data to support its decision." Pet. App. 59a (citation omitted). But FDA's 2016 changes left undisturbed the detailed reporting requirements governing mifepristone's sponsors. See p. 24, *supra*. And as FDA explained, adverse event reports are contained in the FDA Adverse Event Reporting System (FAERS) database, which FDA "routinely

monitors." C.A. Add. 862. FDA's decision to remove the in-person dispensing requirement thus incorporated information about all adverse event reports it had received, including non-fatal adverse events. *Ibid.*

The Fifth Circuit stated that FDA's FAERS database was "insufficient" because some "adverse events will go unreported." Pet. App. 59a-60a. By that logic, FDA acts arbitrarily whenever it relies on the adverse-event data yielded by the reporting regime applicable to all FDA-approved drugs. The Fifth Circuit did not even attempt to justify that startling conclusion.

Moreover, data from the FAERS system was not the only evidence FDA considered in 2021. FDA also specifically sought out data from the drug's sponsors and concluded that the nonenforcement of the in-person dispensing requirement during much of 2020 and 2021 did not appear to affect adverse events. C.A. Add. 861-863. FDA also relied on "an extensive review of the published literature," including studies that "examined replacing in-person dispensing in certain healthcare settings" with "dispensing at retail pharmacies" and "by mail." *Id.* at 864. FDA's analysis of those studies spans nearly ten full pages in the record. *Id.* at 863-872.

The Fifth Circuit focused on FDA's statement that the studies were "not adequate on their own to establish the safety of the model of dispensing mifepristone by mail." Pet. App. 63a (quoting C.A. Add. 871). But FDA acknowledged those limitations, and went on to explain why "[d]espite the limitations of the studies [it] reviewed," those studies (plus other real-world evidence) supported its conclusion that "mifepristone will remain safe and effective if the in-person dispensing requirement is removed." C.A. Add. 864, 871. The deferential arbitrary and capricious standard does not give liti-

gants or the courts a license to "unduly second-guess" the agency's "scientific judgments." *Pharmaceutical Mfg. Research Servs., Inc.* v. *FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020) (quoting *Cytori Therapeutics, Inc.* v. *FDA*, 715 F.3d 922, 923 (D.C. Cir. 2013)). And this Court has emphasized that an agency must have the freedom to make "a reasonable predictive judgment" based on the available evidence when, as is often the case, it is operating without "perfect empirical or statistical data." *Prometheus*, 141 S. Ct. at 1160. That is what FDA did here.

C. The District Court's Remedy Was Improper

Even if the Fifth Circuit were correct that respondents have standing and some likelihood of success on the merits, the court erred in affirming the district court's nationwide preliminary relief suspending FDA's 2016 and 2021 actions. Although respondents sought a preliminary injunction requiring FDA to withdraw or suspend the relevant agency actions, the district court instead invoked 5 U.S.C. 705—which authorizes a court in an APA action "to postpone the effective date of an agency action or to preserve status or rights pending conclusion of review proceedings"—to order what it termed a "stay" of the effective date of FDA's actions. The Fifth Circuit upheld the use of Section 705 as applied to FDA's 2016 and 2021 actions, but it never explained how a court could "postpone" the effective date of actions that became effective years before this litigation began.

In any event, the Fifth Circuit recognized that the availability of any preliminary relief is governed by "the traditional four-factor test for a preliminary injunction," including a balancing of the equities and consideration of the public interest. Pet. App. 44a. For at

least three reasons, the Fifth Circuit erred in holding that those considerations justified affirmance of a preliminary order upending a years-long status quo.

First, the portions of the district court's order affirmed by the Fifth Circuit would impose grave harms on the government, mifepristone's sponsors, women seeking medication abortions, and the public. Extant doses of mifepristone would become misbranded and FDA and the drug's sponsors would be required to bring its labeling and other conditions into compliance with the Fifth Circuit's decision. Even after FDA made the required changes, the substantially more restrictive pre-2016 conditions of use would unnecessarily impair or even eliminate access to mifepristone for many women who are seeking to lawfully terminate their pregnancies. The drug would be approved for a significantly shorter period of time (through seven, rather than ten, weeks' gestation), and women could obtain the drug only if they were able to complete three clinical visits—even though FDA has found those requirements to be unnecessary. In addition, it appears that the lower courts' orders would obligate FDA to reinstate a now-obsolete and unfamiliar dosing regimen that includes higher doses of mifepristone than FDA has determined are necessary.

The loss of access to mifepristone would be damaging for women and healthcare providers around the Nation. For many patients, mifepristone is the best method to lawfully terminate their early pregnancies. They may choose mifepristone over surgical abortion because of medical necessity, a desire for privacy, or past trauma. C.A. Add. 321-323, 330-337, 350-351. Surgical abortion is an invasive medical procedure that can have greater health risks for some patients, such as

those who are allergic to anesthesia. *Id.* at 184-186, 319-320, 330, 333, 342, 349-350, 808.

Second, respondents' asserted injuries cannot remotely justify the disruptive alteration of the status quo that the district court's preliminary relief would entail. Respondents' central contention is that if mifepristone were available under the pre-2016 conditions rather than the current conditions, the risk that one or more of their members would be called upon to treat a serious adverse event would be reduced to some marginal and unquantified extent. Even if that attenuated, probabilistic injury could satisfy Article III, it would not justify destabilizing nationwide preliminary relief. Respondents' own conduct underscores the point: They delayed for almost three years before petitioning FDA to reconsider the changes made in 2016; waited nearly a year to challenge the denial of that 2019 petition; and then disclaimed a need for preliminary relief and instead asked the district court to consolidate their preliminary-injunction motion with a full trial on the merits, C.A. Add. 362. That history belies any need for immediate relief, or any equitable basis for granting it.

Third, the grounds on which the Fifth Circuit held that respondents are likely to succeed further underscore the impropriety of preliminary relief. Unlike the district court, the Fifth Circuit did not conclude that mifepristone is unsafe. Instead, the court held that FDA did not adequately explain its 2016 and 2021 actions. Even if that were true, those asserted failures of explanation would at most have justified a direction to FDA to further consider the relevant issues, without additional relief that would bar distribution of mifepristone as presently approved. See, *e.g.*, *Weinberger* v. *Romero-Barcelo*, 456 U.S. 305, 312-313, 314, 320 (1982).

Lower courts sometimes order such limited equitable relief by describing the remedy as a "remand without vacatur." *Bloomberg L.P.* v. *SEC*, 45 F.4th 462, 466 (D.C. Cir. 2022). Whatever the form, that approach accords with traditional equitable principles by avoiding "needless[] disrupt[ion]" when an agency can likely cure a defect through further consideration and explanation. *Id.* at 477-478; see *Romero-Barcelo*, 456 U.S. at 320.

Here, the Fifth Circuit expressed doubt that "FDA could cure its mistakes with further consideration." Pet. App. 72a. But it offered no meaningful explanation for that conclusion. As to the 2016 changes, for example, the only flaw the Fifth Circuit identified is that FDA failed to explicitly state that it had concluded that three changes that it had exhaustively found to be safe by themselves would also be safe in combination. And if FDA considered either the 2016 or the 2021 actions again now, it would also be able to rely on years of experience with the continued safe and effective use of mifepristone under the challenged conditions.

II. THE DECISION BELOW WARRANTS REVIEW

The Fifth Circuit's decision warrants this Court's review because it would impose an unprecedented and profoundly disruptive result: Neither respondents nor the courts below identified any prior decision abrogating FDA's approval of a drug or limiting a drug's availability based on a disagreement with the agency's judgment about safety or effectiveness—much less doing so at the behest of plaintiffs with such an attenuated claim of standing and imminent harm.

In taking that step here, the Fifth Circuit countermanded a scientific judgment FDA has maintained across multiple administrations; imposed unnecessary restrictions on the distribution of a drug that has been

safely used by millions of Americans over more than two decades; and upset reliance interests in a healthcare system that depends on the availability of mifepristone as an alternative to surgical abortion for women who choose to lawfully terminate their early pregnancies. At earlier stages of this case, hundreds of amici filed briefs underscoring the harmful consequences of the lower courts' decisions.

Beyond those destabilizing practical consequences, the Fifth Circuit's decision also warrants this Court's review because of its serious legal errors. Under the Fifth Circuit's "novel" standing analysis, *Summers*, 555 U.S. at 498, associations of doctors could sue to challenge any government action that might incidentally affect the practices of one of their associations' members. Pulmonologists could sue the Environmental Protection Agency to challenge regulations that increased (or reduced) air pollution; pediatricians could sue the Department of Agriculture to challenge standards that imperiled (or improved) student nutrition; and emergency room doctors could sue the government to challenge regulations that loosened (or restricted) access to firearms.[4]

Neither the Fifth Circuit nor respondents have cited any prior decision, by any court, endorsing that extravagant concept of standing. And other courts of appeals

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[4] The Fifth Circuit sought to minimize the sweeping implications of its holding, suggesting that it applies only when a plaintiff faces "injury akin to being forced to violate his or her sincerely held conscience beliefs." Pet. App. 35a. But the Fifth Circuit did not limit its holding to conscience-based injuries; to the contrary, it explicitly held that respondents and their members "sustain a concrete injury" whenever "they are forced to divert time and resources away from their regular patients" or face "greater liability and increased insurance costs." *Id.* at 31a.

have correctly recognized that this Court's precedents foreclose a "statistical probability theory of associational standing" and instead require an associational plaintiff to show that "at least one individual member—and not those individual members as a group—has standing to sue." *Prairie Rivers Network* v. *Dynegy Midwest Generation, LLC*, 2 F.4th 1002, 1010 (7th Cir. 2021); see, *e.g.*, *Faculty, Alumni & Students Opposed to Racial Preferences* v. *New York Univ.*, 11 F.4th 68, 75-76 (2d Cir. 2021); *American Chemistry Council* v. *Department of Transp.*, 468 F.3d 810, 820 (D.C. Cir. 2006).

The Fifth Circuit's analysis of the merits was equally flawed. The court scarcely acknowledged FDA's detailed analysis of the available scientific evidence. Instead, it faulted FDA for failing to cite studies that do not exist and for failing to explicitly respond to unfounded objections that were not raised during the administrative process. Those holdings flatly contradict this Court's repeated admonitions about the "deferential" nature of the arbitrary-and-capricious standard and the dangers of judicial second-guessing of agency action. *Prometheus*, 141 S. Ct. at 1158.

The Fifth Circuit's application of those holdings in the context of FDA's drug approvals has especially disruptive implications for the pharmaceutical industry and those who depend upon the drugs it supplies. Indeed, a wide range of industry participants have warned that the lower courts' approach would "result in 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." Pharmaceu-

tical Companies Amicus Br. at 18, *FDA* v. *Alliance for Hippocratic Medicine*, No. 22A902 (Apr. 14, 2023).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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