Nos. 23-235 and 23-236

In the Supreme Court of the United States

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

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

DANCO LABORATORIES, L.L.C., PETITIONER

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

ON WRITS OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRIEF FOR THE FEDERAL PETITIONERS

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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

The federal petitioners were 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., petitioner in No. 22-236, 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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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-110a) is reported at 78 F.4th 210.[1] 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 pub-

[1] All references in this brief to "Pet. App." are to the appendix to the petition for a writ of certiorari filed in No. 23-235.

lished in the Federal Reporter but is available at 2023 WL 2913725.

JURISDICTION

The judgment of the court of appeals was entered on August 16, 2023. The petition for a writ of certiorari was filed on September 8, 2023 and granted on December 13, 2023. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent statutory provisions are reproduced in the appendix to this brief. App., *infra*, 1a-6a.

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. 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. And the courts ordered that sweeping preliminary relief even though it would upend the regulatory regime for mifepristone, with disruptive consequences for FDA, mifepristone's sponsors, and women who need access to the drug.

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 demonstrates 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 framework, 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).

The FDAAA allows either the drug sponsor or the FDA to initiate the process of modifying an existing REMS. 21 U.S.C. 355-1(g) and (h). FDA, for example, may require submission of a proposed modification if it determines that the modification should be made to en-

sure that the benefits of the drug outweigh the risks or to minimize the burden of complying with the REMS. 21 U.S.C. 355-1(g)(4).

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. J.A. 224-232. 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. J.A. 485-487. 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. J.A. 230. The original approved conditions of use called for women to make three clinical visits: An initial visit to take mifepristone; a second visit two days later to take misoprostol; and a follow-up visit two weeks after the initial visit to confirm the termination of the pregnancy. J.A. 296. 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. J.A. 225-232.

When Congress adopted the REMS framework in 2007, it deemed each drug with existing Subpart H 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). In 2011, FDA approved a REMS for mifepristone providing for essentially the same requirements that had previously been imposed under Subpart H. Pet. App. 9a.

2. In 2016, FDA approved a supplemental new drug application from mifepristone's sponsor, petitioner Danco Laboratories, L.L.C., that sought to alter the drug's conditions of use, including the REMS. J.A. 284-291. FDA's approval was based on a comprehensive review of the safety and efficacy of the proposed changes 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." J.A. 435; see J.A. 418-519.

Based on safety and efficacy data from numerous studies, FDA approved three changes to mifepristone's conditions of use that are relevant here: (1) increasing the gestational age limit from seven to ten weeks, J.A. 283-291, 298-300, 450-456; (2) reducing the number of in-person visits from three to one, J.A. 300-302, 456-457; and (3) modifying the REMS to allow mifepristone to be prescribed by non-physician healthcare providers licensed under state law to prescribe drugs, such as nurse practitioners, J.A. 309-310, 461-462.[2]

In addition, FDA modified a prior requirement under the REMS that prescribers of mifepristone agree to report certain adverse events such as hospitalizations and blood transfusions to the drug's sponsor. J.A. 319. FDA determined based on "15 years of reporting" that the REMS requirement to report non-fatal adverse events was no longer warranted and that, as with all other approved drugs, information on such events could be "col-

[2] FDA also altered the approved dosing regimen, including reducing the amount of mifepristone from 600 mg to 200 mg, increasing the amount of misoprostol, and changing the administration of misoprostol from oral to buccal (dissolved in the cheek pouch). J.A. 424. Those changes were not challenged in this litigation.

lected in the periodic safety update reports and annual reports" submitted by the drug's sponsor to FDA pursuant to FDA regulations. *Ibid.*

In approving the 2016 changes, FDA concluded that the use of mifepristone under the revised conditions would be "safe," emphasizing that serious adverse events "are exceedingly rare." J.A. 465. Specifically, FDA explained that published studies involving tens of thousands of women who had taken mifepristone found that hospitalization occurs in between 0% and 0.7% of cases; that serious infections occur in between 0% and 0.2% of cases; and that bleeding requiring transfusion occurs in between 0% and 0.5% of cases. J.A. 303-304. Studies also show that those rates of adverse events are comparable to the rates of the same adverse events following surgical abortions. J.A. 410.

3. In 2019, FDA approved an application from another sponsor, GenBioPro, to market a generic version of mifepristone. J.A. 348-354; see 21 U.S.C. 355(j). The same REMS covers both versions of the drug. J.A. 349-351.

4. In July 2020, during the COVID-19 public health emergency, a district court enjoined FDA from enforcing the requirement that mifepristone be dispensed in person. *American Coll. of Obstetricians & Gynecologists* v. *FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020). The injunction remained in place until January 2021, when it was stayed by this Court. *FDA* v. *American Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).

In April 2021, FDA announced that, in light of the continued risk that dispensing mifepristone in person would expose patients to COVID-19, the agency intended to exercise enforcement discretion as to the in-

person dispensing requirement during the public health emergency. J.A. 377. FDA explained that its decision "was the result of a thorough scientific review by [agency] experts" who evaluated evidence including "clinical outcomes data and adverse event reports." *Ibid.*

5. In December 2021, based in part on its experience during the pandemic, FDA determined that the in-person dispensing requirement was not necessary to assure mifepristone's safe use. FDA thus directed Danco and GenBioPro to initiate the process of modifying the REMS accordingly. J.A. 378-379; see J.A. 397-412; 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. The REMS continues to provide that the drug may be dispensed only on a prescription from a certified prescriber who has ensured that the patient has reviewed and signed a patient agreement form providing information on the drug, including its risks, and instructions on when and how to seek follow-up care if necessary. *Ibid.*

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 have filed two citizen petitions concerning mifepristone.

First, in 2002, two respondents filed a petition asking FDA to withdraw its 2000 approval of mifepristone. J.A. 201-223. FDA denied the petition in March 2016, on the same day it approved the changes to mifepristone's conditions of use. J.A. 237-270. In the denial, FDA ex-

plained 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." J.A. 254.

Second, in 2019, two respondents filed a petition challenging FDA's 2016 changes to mifepristone's approved conditions of use and urging the agency to retain the in-person dispensing requirement. J.A. 321-347. In December 2021, FDA denied that petition in relevant part. J.A. 372-412. FDA determined that respondents' various criticisms of the 2016 changes were unfounded. J.A. 379-393. The agency also explained that "the in-person dispensing requirement is no longer necessary to assure the safe use of mifepristone." J.A. 378. In addition to reviewing the available scientific literature, FDA reviewed the available data and found no evidence of "a difference in adverse events when in-person dispensing was and was not enforced." J.A. 399; see J.A. 398-408.

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. J.A. 97-112. 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 time-barred, *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. 701 *et seq*. Pet. App. 171a-187a. The court separately held that statutory provisions derived from the 1873 Comstock Act prevented FDA from removing the in-person dispensing requirement. *Id.* at 151a-159a; see Act of Mar. 3, 1873, ch. 258, 17 Stat. 598 (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 the relevant FDA actions—even though those actions had already been in effect for years. Pet. App. 194a (capitalization and emphasis omitted).

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 otherwise denied relief. Pet. App. 196a-244a. The government and Danco then sought a stay from this Court. The Court 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 and affirmed 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' unidentified 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 be required to 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-32a. The court further determined that respondents had demonstrated traceability by sufficiently establishing that FDA's 2016 and 2021 actions "cause[] an increased risk of injury." *Id.* at 40a. 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 those 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. He also would have held that removal of the in-person dispensing requirement violated the Comstock Act, an issue that the majority did not reach. *Id.* at 98a-104a; see *id.* at 63a n.8.

SUMMARY OF ARGUMENT

To the government's knowledge, this case marks the first time any court has restricted access to an FDA-approved drug by second-guessing FDA's expert judgment about the conditions required to assure that drug's safe use. 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. The Court should reverse.

I. Respondents lack Article III standing. They do not prescribe mifepristone, and FDA's actions allowing *other* providers to prescribe the drug do not require them to do or refrain from doing anything. The Fifth Circuit nonetheless held that the respondent associations have standing based on what the court viewed as a statistical probability that some of their unidentified members might be called upon to treat women who are prescribed mifepristone and then suffer exceedingly rare serious adverse events. But 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).

Even respondents have now abandoned that statistical approach, conceding that they must identify at least

one member who faces an imminent, cognizable injury. But respondents have not come close to carrying that burden. Their primary theory is that their members could be required to violate their consciences by completing an abortion for a woman who presents in an emergency room with an ongoing pregnancy. But that hypothetical scenario cannot establish an imminent injury because it rests on a long and speculative chain of contingencies. Indeed, although mifepristone has been on the market for decades, respondents cannot identify even a single case where any of their members has been forced to provide such care. Respondents' other theories are likewise speculative. And those theories are independently foreclosed because they rest on the untenable premise that emergency-room doctors suffer an Article III injury whenever they provide emergency care.

Respondents also lack standing because they have not shown that their asserted injuries are fairly traceable to FDA's challenged actions. If those injuries occur at all, they will be linked to FDA's actions only by a long and attenuated causal chain involving independent actions by other providers, patients, and third parties. In addition, respondents have scarcely even attempted to show that their asserted injuries are attributable to the incremental effects of FDA's 2016 and 2021 changes to mifepristone's conditions of use.

Respondents' attempt to defend the judgment below on the alternative ground that they have organizational standing likewise fails. This Court has never accepted respondents' suggestion that an organization can manufacture standing to challenge an agency action merely by expending resources on that challenge.

II. FDA's actions were lawful.

A. FDA's 2016 changes to mifepristone's approved conditions of use 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 did not suggest that FDA overlooked any material in the record and did not point to any evidence suggesting that any of the 2016 changes would be unsafe, either alone or in combination. Instead, the court overturned FDA's actions solely because it believed FDA had failed to cite a study examining the combined effect of all of the relevant changes. But there is no basis for that novel requirement—and in any event, FDA *did* cite a study that combined the relevant changes.

B. FDA lawfully changed mifepristone's adverse-event reporting requirement in 2016, bringing that requirement more in line with the reporting mechanism that applies to nearly all other FDA-approved drugs. Based on more than 15 years of experience, the agency determined that a heightened reporting requirement previously applicable to mifepristone was no longer needed because the drug's safety profile was well-established and serious adverse events were exceedingly rare.

C. FDA lawfully decided to eliminate the in-person dispensing requirement in 2021. The agency concluded, based in part on actual experience during the pandemic, that the requirement was no longer necessary to ensure mifepristone's safe use and thus no longer justified under the FDCA. The Fifth Circuit faulted FDA for relying on available adverse-event data and published studies because it viewed those sources as flawed. But the APA does not require agencies to act based on perfect

data, which seldom exists. Instead, it requires them to act reasonably based on the information available. That is what FDA did here.

III. Even if respondents had standing and some likelihood of success on the merits, the Fifth Circuit erred in affirming sweeping preliminary relief. The district court's invocation of 5 U.S.C. 705 to "postpone" agency actions that had been in effect for years contravenes that provision's plain text. And there is no equitable justification for allowing parties whose asserted injuries are at best attenuated—and whose relevant claims assert only that FDA failed adequately to explain its actions—to secure disruptive nationwide relief that threatens profound harms to the government, the healthcare system, patients, and the public.

ARGUMENT

I. RESPONDENTS LACK ARTICLE III STANDING

Article III standing is a "bedrock constitutional requirement that this Court has applied to all manner of important disputes." *United States* v. *Texas*, 599 U.S. 670, 675 (2023). It is "built on a single basic idea—the idea of separation of powers." *Ibid.* (citation omitted). The requirement that a plaintiff demonstrate standing "helps safeguard the Judiciary's proper—and properly limited—role in our constitutional system," *ibid.*, by ensuring that federal courts do not become "forums for the ventilation of public grievances" more properly resolved through the democratic process, *Valley Forge Christian Coll.* v. *Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 473 (1982).

To demonstrate Article III standing, a plaintiff must "show that she has suffered an injury in fact that is 'fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested re-

lief.'" *Haaland* v. *Brackeen*, 599 U.S. 255, 291-292 (2023) (citation omitted). The asserted injury must be "legally and judicially cognizable," *Texas*, 599 U.S. at 676 (citation omitted), and "concrete, particularized, and actual or imminent," *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (citation omitted). And where, as here, an association asserts standing to sue on behalf of its members, it must show that "at least one identified member ha[s] suffered or would suffer" the requisite injury. *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 498 (2009).

Those familiar Article III principles resolve this case. Respondents' claim of associational standing fails because they have not shown that any identified member faces any imminent, judicially cognizable injury—much less an injury fairly traceable to FDA's 2016 and 2021 actions. And respondents' alternative assertion of organizational standing is likewise meritless.

A. Respondents Have Not Established A Cognizable Injury

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 those actions by third parties do not impose any cognizable harms on respondents. *Coalition 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.

In attempting to avoid that straightforward result, respondents have asserted that the respondent associations have Article III standing to sue on behalf of their

members on the theory that *other* doctors will prescribe mifepristone to women who choose to take it; that some fraction of those women will seek emergency care; that some fraction of that fraction will seek care from respondents' member-doctors; and that those doctors will suffer cognizable injuries as a result. The Fifth Circuit endorsed that theory, reasoning that because many women take mifepristone and respondents claim that their members include many doctors, it is statistically likely that some members will suffer the asserted injuries. But respondents have now abandoned that statistical approach, correctly acknowledging that they must identify at least one specific member who faces an imminent injury to a legally protected interest.

Respondents have not come close to meeting that burden. Their primary theory is that their members could be forced to violate their consciences by completing an abortion for a woman with an ongoing pregnancy, but that scenario rests on a chain of speculative contingencies. Indeed, although mifepristone has been on the market for decades, respondents have not identified even a single case in which any association member has been required to provide such treatment. Respondents' other theories of injury are equally unpersuasive. Among other things, they reduce to the assertion that doctors suffer Article III injury whenever they are presented with patients in need of care—an unprecedented and limitless theory that would allow doctors to challenge virtually any policy affecting public health.

1. Respondents cannot rely on statistics and must instead identify at least one member who satisfies Article III

The Fifth Circuit did not purport to identify any particular individual respondent or member of a respond-

ent organization who faces actual or imminent injury. Instead, the court relied on a statistical approach to associational standing: It reasoned that "a definite percentage of women who take mifepristone will require emergency-room care"; that respondents had "testified that hundreds of their members are OB/Gyns and emergency-room doctors"; and that respondents' members—in the aggregate—thus face what the court viewed as a "substantial risk" of future injury. Pet. App. 26a-27a. That statistical approach flatly contradicts this Court's precedent, and even respondents have now abandoned it.

a. This Court's associational-standing precedents hold that a membership organization can sometimes sue "as the representative of its members." *Students for Fair Admissions, Inc.*, v. *President & Fellows of Harvard Coll.*, 600 U.S. 181, 199 (2023) (citation omitted). "The possibility of such representational standing, however, does not eliminate or attenuate the constitutional requirement of a case or controversy." *Warth* v. *Seldin*, 422 U.S. 490, 511 (1975). An organization seeking to represent its members thus must show that those members "would otherwise have standing to sue in their own right." *Harvard*, 600 U.S. at 199 (quoting *Hunt* v. *Washington State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977)). Put differently, the organization must identify "at least one member with standing." *United Food & Commercial Workers Union Local 751* v. *Brown Grp., Inc.*, 517 U.S. 544, 555 (1996).

The Fifth Circuit's statistical approach flouts that requirement. Instead, it mirrors the "novel" approach this Court emphatically rejected in *Summers*. 555 U.S. at 498. There, the Court 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 [unidentified] 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," but rather "that the organizational plaintiffs failed to prove that their members would be injured." Pet. App. 28a. But an invalid theory of standing was precisely the problem this Court identified in *Summers*. After holding that no identified member had standing, see *Summers*, 555 U.S. at 495-497, the Court faulted the dissent for "propos[ing] a hitherto unheard-of test for organizational standing" that relied on statistics to elide the requirement that an organization "make specific allegations establishing that at least one identified member" will suffer cognizable harm, *id.* at 497-498. The Court emphasized that the "requirement of naming the 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.

b. Although respondents themselves relied on a statistical theory earlier in this litigation, see, *e.g.*, Pet. App. 23a-24a, they declined to defend it in opposing certiorari, see Br. in Opp. 26-27. Instead, respondents appeared to concede that they must show that "at least

one identified member" satisfies Article III. *Summers*, 555 U.S. at 498. Below, respondents offered evidence about just seven specific members who described themselves as practicing doctors who could suffer the kinds of injuries on which respondents rely. See J.A. 150-200 (declarations of Drs. Francis, Skop, Wozniak, Johnson, Frost-Clark, Delgado, and Jester). Respondents' standing thus depends on showing that at least one of those seven members faces an imminent Article III injury.

2. Respondents have not identified any member who faces an imminent conscience injury

Respondents' primary theory of injury is that the availability of mifepristone could give rise to circumstances in which their members could be required to provide treatment that "conflicts with their sincerely held moral beliefs and violates their rights of conscience." Pet. App. 17a. But respondents have not shown that any member faces any imminent threat of such an injury. To the contrary, respondents' asserted conscience injury rests on a long chain of contingencies so speculative that respondents have not identified even a single case in which it has materialized during the decades that mifepristone has been available.

a. Just two of respondents' seven identified members offered any evidence about their religious or moral beliefs; both stated that they oppose "being forced to end the life of a human being in the womb" by completing "an incomplete elective chemical abortion." J.A. 155; see J.A. 167. The declarations from the leaders of the respondent organizations that discuss conscience injuries likewise stated that respondents' members generally object to being forced to perform or complete

an abortion for a patient who presents with an ongoing pregnancy. J.A. 121, 135-136, 142-143.

For such an injury to come to pass, all of the following contingencies would have to occur: (i) a woman chooses to take mifepristone after consultation with another provider; (ii) the woman suffers an exceedingly rare serious adverse event requiring emergency care; (iii) rather than returning to the prescribing provider, the woman seeks care from one of respondents' members or presents in an emergency room where a member is working; (iv) when the woman does so, her pregnancy is still ongoing; (v) it would violate the member's conscience to complete an abortion in such urgent circumstances; and (vi) the member is unable to seek assistance from another doctor or invoke federal conscience protections and is instead forced to complete an abortion.

To state that theory is to refute it. This Court has "repeatedly reiterated that 'threatened injury must be *certainly impending* to constitute injury in fact,' and that 'allegations of *possible* future injury' are not sufficient." *Clapper*, 568 U.S. at 409 (brackets and citation omitted). Time and again, therefore, the Court has rejected theories of standing that rest on a "speculative chain of possibilities," *id.* at 414, 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, the 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 explained that such an approach is "inconsistent with [the] requirement that 'threatened injury must be certainly

impending.'" *Ibid.* (citation omitted). Similarly, in *Summers*, the Court explained that an organization member's assertion that he planned to visit "unnamed" national forests was insufficient to establish standing to challenge regulations exempting certain Forest Service projects from notice, comment, and appeal procedures. 555 U.S. at 495; see *id.* at 490. The Court explained that because the theory of standing depended on a chain of contingencies, it might have demonstrated "a chance" of injury, but "hardly [the] likelihood" necessary to satisfy Article III. *Id.* at 495.

So too here. Respondents' theory relies on a long chain of contingencies involving independent actions by third parties, including other providers, patients, and respondents' employers. And key links in that chain are particularly speculative. As the Fifth Circuit acknowledged, for example, mifepristone's rates of serious adverse events such as hospitalization, blood transfusion, or serious infection are extremely low. Pet. App. 18a; see J.A. 303-304. And by definition, the risk that a woman experiencing such an adverse event would present in an emergency room with an ongoing pregnancy is even lower.

In addition, even if such a woman happened to present in an emergency room where a respondent doctor was working, respondents have not explained how or why the doctor would be compelled to provide an abortion against her conscience. A variety of federal laws prohibit employers from requiring employees to perform or participate in abortions or other procedures to which they object. 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. V, §§ 506-507, 136 Stat. 496. Respondents' two declarations addressing identified

members' religious or moral objections do not explain why those protections would not be available to the declarants. See J.A. 155, 167. Indeed, those declarations do not include *any* information about employer policies or other circumstances that could compel the declarants to provide care to which they object.[3]

b. Decades of experience confirm that none of respondents' member doctors face any realistic threat—much less a certainly impending threat—of being forced to complete an abortion for a mifepristone patient. Standing to seek prospective relief, of course, cannot be based on mere "past injury"; instead, a plaintiff must show an "imminent future injury." *Summers*, 555 U.S. at 495. Here, however, the striking *absence* of any past conscience injury powerfully underscores that respondents' theory is speculative.

Mifepristone has been on the market for more than 23 years. During that time, more than five million American women have relied on the drug to end their pregnancies. Pet. App. 19a. And respondents claim

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[3] The Fifth Circuit stated that federal conscience protections did not "alleviate the Doctors' conscience injury" because the court believed 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. Pet. App. 34a; see *id.* at 33a-34a. The government has argued that, in some circumstances, the emergency care required by EMTALA may include abortion care; this Court has granted certiorari to review that question in *Moyle* v. *United States*, cert. granted, No. 23-726 (Jan. 5, 2024). But EMTALA imposes obligations on covered "hospital[s]," not individual doctors. 42 U.S.C. 1395dd(b)(1). And in the separate litigation on which the Fifth Circuit relied, the government specifically disclaimed the suggestion that "EMTALA would compel individuals to perform abortions contrary to their sincerely held religious or moral beliefs." Gov't Reply Br. at 25, *Texas* v. *Becerra*, 89 F.4th 529 (5th Cir. 2024).

that their members include "thousands of doctors and hundreds of OB/Gyns and emergency-room doctors." *Id.* at 23a. Yet neither respondents nor the Fifth Circuit have pointed to even a single instance in which a member of a respondent organization was required to terminate an ongoing pregnancy.

Instead, the Fifth Circuit primarily relied on Dr. Francis's description of the experience of her unidentified "partner." Pet. App. 19a (quoting J.A. 154); see *id.* at 24a; Br. in Opp. 33-34. Notably, nothing in the declaration states that the partner is a member of a respondent organization. Nor does the declaration explain why the partner chose to provide treatment rather than refer the patient to another, non-objecting doctor or invoke federal conscience protections.

The other declarations on which the Fifth Circuit and respondents have relied also do not substantiate their asserted conscience injury. Those declarations recount only that at some point in the more than two decades mifepristone has been on the market, the declarants or other doctors treated patients who experienced "complications" after using mifepristone to end a pregnancy. Br. in Opp. 21. But none of those declarations states that the declarant had a religious or moral objection to providing such care.

Respondents focus (Br. in Opp. 21) on the declaration of Dr. Skop, which describes one incident in which she performed a procedure to remove pregnancy tissue from a patient's uterus but does not suggest that the pregnancy was ongoing at the time. See J.A. 164. The declaration neither states that Dr. Skop conscientiously objected to providing such care, nor explains why, if she did object, she chose to proceed rather than invoking applicable conscience protections. Dr. Skop's other spe-

cific allegations state that she or someone in her "group practice" "cared for" patients who required certain treatments other than the termination of an ongoing pregnancy, without explaining whether she personally performed any particular medical procedure or whether she objected to doing so. J.A. 163. Respondents' remaining declarations are similarly vague and lacking in evidence of a conscience injury.[4]

Again, even demonstrated instances of past injury would not necessarily establish standing to seek prospective relief. See *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 105-106 (1983). But particularly given the lack of any showing of such past incidents here, respondents cannot satisfy Article III with bare speculation that the availability of mifepristone "*could* force [them] to have to surgically finish an incomplete elective chemical abortion." Pet. App. 24a (quoting J.A. 167) (emphasis added).

3. Respondents' remaining theories of injury likewise fail

In addition to their asserted conscience injury, respondents contend that providing emergency care to women who have taken mifepristone will cause the individual respondents or members of respondent organizations "mental and emotional stress"; that it will require them to "divert time and resources away from their ordinary practice"; and that it will "expose[] [them] to greater malpractice liability and increased in-

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[4] See Pet. App. 22a (citing J.A. 173-174) (relying on Dr. Wozniak's declaration, which describes one instance in which she treated a patient for "adverse effects," without suggesting any objection); *id.* at 28a (citing J.A. 198) (relying on Dr. Jester's statement that he treated a woman with a uterine infection, without suggesting any objection).

surance costs." Pet. App. 24a-26a. But like the conscience theory, those theories fail at the outset because respondents have not identified any doctor who faces an imminent risk of being forced to treat a mifepristone patient. And each of respondents' other theories has additional flaws.

a. Respondents first assert that treating women who have taken mifepristone causes them to experience feelings of "stress and pressure." Pet. App. 34a (quoting J.A. 172). But even the Fifth Circuit rejected the suggestion that those feelings are a judicially cognizable injury. Instead, the court found that such "mental and emotional stress" is "best understood as additional to the Doctors' conscience injuries, not independent from them." *Id.* at 34a-35a.

The Fifth Circuit correctly recognized that respondents' feelings of "stress and pressure" are not themselves Article III injuries. Pet. App. 35a. Respondents' identified members are doctors who have chosen to provide emergency care in hospital settings. "Stress and pressure" are inherent in that vocation, and respondents have not cited any authority suggesting that simply being presented with a person in need of emergency care qualifies as an Article III injury to a doctor whose chosen profession is treating patients in an emergent setting.

Endorsing that novel theory would open the courthouse doors to an endless parade of suits. Doctors could sue to challenge virtually any policy that allegedly increased the risk that they would be presented with patients whose cases they find distressing—a category that could include everything from gun regulations to automobile or workplace safety standards. Nor would the logic be limited to doctors; lawyers and other pro-

fessionals could likewise sue to challenge any policy that allegedly caused them to be presented with potential clients whose cases they found stressful. The Fifth Circuit correctly rejected that limitless conception of Article III.[5]

b. Respondents' reliance on a "diversion of resources" theory, Pet. App. 25a, is equally limitless and equally flawed. Emergency medicine necessarily requires triaging patients and thereby diverting resources from some patients to others. If that were sufficient for standing, then emergency-room doctors could challenge any regulation (or lack thereof) that threatened to increase the number of patients with a particular condition. Nor do respondents provide any basis for defining one group of patients as their "regular" ones, *id.* at 31a, and thereby labeling treatment of those in the disfavored class a source of diversion. And while respondents have suggested vague harm to their "business interests," Br. in Opp. 35 (brackets and citation omitted), they provide no support for the counterintuitive proposition that doctors suffer cognizable economic harm when they are presented with patients requiring care.

c. Finally, respondents and the Fifth Circuit provide no basis for concluding that FDA's regulatory actions with respect to a drug that respondents' members do not prescribe exposes them to malpractice claims or higher insurance costs. Pet. App. 28a, 31a. They do not identify any instance in which respondents or any of

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[5] The Fifth Circuit stated that respondents' standing theory was not "'limitless,'" but that was because the court treated the stress-related injury as "augment[ing]" the conscience-based theory rather than "provid[ing] a separate basis for Article III standing." Pet. App. 35a (citation omitted).

their members have ever been sued, threatened with a lawsuit, or required to pay increased insurance premiums because they treated women who had taken mifepristone. See *id.* at 31a-32a (citing J.A. 141-142, which simply speculates as to this possible chain of events). Respondents' unadorned speculation cannot demonstrate an imminent injury in fact.

B. Respondents Have Not Shown That Their Asserted Injuries Are Fairly Traceable To FDA's 2016 And 2021 Actions

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

1. As an initial matter, FDA's challenged actions simply authorized Danco and GenBioPro to distribute mifepristone under 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 mifepristone—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 exceedingly rare cases where the result of those independent actions is a serious adverse event requiring emergency medical treatment, FDA's actions neither require patients to seek treatment from respondents nor require respondents to provide it. Accordingly, even if respondents' asserted future harms were cognizable, they would not be fairly traceable to FDA's actions because they rest on a "line of causation" that is "attenuated at best" and that turns on the independent decisions of multiple third parties who are strangers to this litigation. *Allen* v. *Wright*, 468 U.S. 737, 757 (1984).

Nor have respondents suggested that Congress has attempted to "elevate[]" their asserted injuries "to the status of legally cognizable injuries redressable by a federal court," *Texas*, 599 U.S. at 681-682, or to "articulate chains of causation that will give rise to a case or controversy where none existed before," *Spokeo* v. *Robins*, 578 U.S. 330, 341 (2016) (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.

2. The Fifth Circuit's traceability holding also fails on its own terms.

a. As the Fifth Circuit 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 LLC* v. *Ramirez*, 594 U.S. 413, 431 (2021). Here, the Fifth Circuit held that respondents' challenge to FDA's original 2000 approval of mifepristone is likely time barred, and this Court has declined to grant certiorari on that question. Respondents thus cannot establish traceability by simply asserting that all adverse events associated with mifepristone "are traceable to FDA because it approved the drug." Pet. App. 16a. Instead, respondents must demonstrate that they face imminent injury due to the incremental effects of FDA's 2016 and 2021 actions addressing mifepristone's conditions of use.

That poses a serious hurdle because respondents' evidentiary presentation in the district court focused almost entirely on their assertion that they are injured by the availability of mifepristone in general—an assertion

that depended on respondents' recounting of undated and sporadic encounters with women who took the drug, and that 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 made the required traceability showing on the theory 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 it is implausible that the incremental effects of FDA's actions cause enough additional serious adverse events to establish a certainly impending injury to respondents. To the contrary, the record demonstrates that serious adverse events remain extremely infrequent with the relevant actions in place. See, *e.g.*, J.A. 442-500; see also FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2022* (*Adverse Events Summary*).

b. The Fifth Circuit did not cite any studies or other scientific evidence to support its conclusion that the 2016 Amendments will cause more women to experience complications from mifepristone. Instead, the court simply repeated the "three reasons" asserted in respondents' declarations. Pet. App. 36a. None of those reasons withstands scrutiny.

First, the court echoed respondents' assertion that "the risk of complication increases with gestational age" and raising the gestational age limit from 49 to 70 days will thus result in additional complications. Pet. App. 36a. That contention rested on respondents' own conclusory declarations; respondents have not supported it with studies or other evidence. And the available scientific evidence demonstrates that mifepristone remains extremely safe throughout the full 70-day period: As

FDA explained in 2016, "[i]ncreased gestational age was not associated with an increased incidence of [serious adverse events]." J.A. 304.

Second, the court reasoned that the removal of the second and third in-person visits would result in an "increase" in "the percentage of women who experience complications that present to [an] emergency room." Pet. App. 37a. But again, respondents did not cite any statistics demonstrating such an increase in the seven years the 2016 changes had been in effect—much less an increase sufficient to put any identifiable respondent or member at imminent risk of being required to treat a mifepristone patient she would not have had to treat under the framework that existed prior to 2016.

Third, the Fifth Circuit stated that "the percentage of women who present to the emergency room will increase because the [2016 changes] allow non-physicians to prescribe mifepristone," and the court believed that patients who receive a prescription from such a practitioner "'cannot possibly go back to their non-doctor-prescribers for surgical abortions.'" Pet. App. 37a (citation omitted). But the court's premise was wrong. In fact, non-physician practitioners who were authorized to prescribe mifepristone were *already* providing abortion care, including follow-up surgical care, before the 2016 changes. See, *e.g.*, J.A. 309-310, 497; National Ass'n of Nurse Practitioners Cert. Amicus Br. 10-11, 14-17.

c. The Fifth Circuit likewise erred in determining that FDA's 2021 decision that the in-person dispensing requirement was no longer warranted "contributes to [respondents' alleged] injury." Pet. App. 38a. Again, the court relied on respondents' unsupported allegations that—contrary to FDA's findings—that decision would result in "more complications" requiring emer-

gency care. *Id.* at 41a. And again, the court did not attempt to quantify that supposed increase, nor explain how it would be significant enough to demonstrate that any particular doctor would imminently be required to treat a patient suffering such a complication despite the doctor's objection.[6]

C. Respondents Lack Organizational Standing

The Fifth Circuit relied solely on associational standing and did not decide whether the respondent associations have "organizational standing" to sue on their own behalf. Pet. App. 41a. Respondents have advanced an organizational theory as an alternative basis for upholding the Fifth Circuit's decision (Br. in Opp. 37-39), but that theory is equally meritless.

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[6] The Fifth Circuit repeated respondents' assertion that the effects of the 2021 decision would be particularly great "in cases of ectopic pregnancy." Pet. App. 39a (citing J.A. 165-166). But mifepristone does not exacerbate ectopic pregnancy; it simply is not effective in treating that condition. As FDA recognized, ectopic pregnancies may be diagnosed without an in-person examination. J.A. 255. And as with respondents' other theories of injury, their reliance on the possibility of undiagnosed ectopic pregnancies attributable to FDA's 2021 decision rests on a speculative chain of events: that a woman with an ectopic pregnancy will be prescribed mifepristone by another provider who fails to diagnose that condition; that the ectopic pregnancy would have been caught during an in-person visit; that the woman's ectopic pregnancy will rupture before she confirms with her provider that she is still pregnant; and that she will ultimately seek emergency care from a member of a respondent organization—despite the fact that ectopic pregnancy occurs in just 0.005% of women who use mifepristone. U.S. Gov't Accountability Office, GAO-08-751, *FDA: Approval and Oversight of the Drug Mifeprex* 39 (2008), https://perma.cc/JZW33J8N. Moreover, the risks associated with ectopic pregnancy provide no support for respondents' principal theory of injury because no respondent has asserted any conscience objection to treating an ectopic pregnancy.

Respondents assert that FDA's 2016 actions caused them to "expend[] 'considerable time, energy and resources' on their 26-page citizen petition challenging" those actions. Br. in Opp. 38 (citation omitted). But if the cost of opposing agency action were sufficient to satisfy Article III, any party could bootstrap its way into standing to challenge any agency action merely by doing so. That is not the law.

Respondents also assert that FDA's 2021 decision regarding the in-person dispensing requirement "'impaired'" their "'ability to provide [chemical abortion] counseling' to pregnant women." Br. in Opp. 38 (quoting *Havens Realty Corp.* v. *Coleman*, 455 U.S. 363, 379 (1982)) (brackets in original). But FDA's action in no way prohibited respondents from providing counseling to any women willing to receive it. And respondents do not explain how a change in the way *other* providers dispense mifepristone to women who decide to seek it has any effect on *respondents*' counseling efforts.[7]

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"No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *Simon* v. *Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 37 (1976); see *TransUnion*, 141 S. Ct. at 2203. The lower courts lost sight of

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[7] Although the Fifth Circuit did not reach the question (Pet. App. 41a-42a), respondents have briefly suggested (Br. in Opp. 20 n.2) that they "satisfy the requirements for third-party standing." But those requirements are *additional* showings that must be made when a party seeks to assert the rights of a third party. Third-party standing is not a substitute for the "irreducible constitutional minimum of standing," which requires "the plaintiff" to have "suffered an 'injury in fact.'" *Lujan*, 504 U.S. at 560.

that principle in drawing on the conclusory assertions in respondents' declarations to credit their highly speculative and attenuated claims of Article III injury. This Court should reject respondents' profoundly flawed theories and put an end to this case by holding that respondents lack Article III standing.

II. FDA'S ACTIONS WERE LAWFUL

The Fifth Circuit compounded its standing errors by holding that FDA acted arbitrarily and capriciously in approving changes to mifepristone's conditions of use in 2016, in modifying the adverse-event reporting requirements under the REMS 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." *FCC* v. *Prometheus Radio Project*, 592 U.S. 414, 423 (2021). 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." *Ibid.* And 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 the grant of application for stay) (citation omitted). The Fifth Circuit's decision ignored those foundational principles.

A. FDA Lawfully Changed The Conditions Of Use In 2016

1. In 2016, FDA approved Danco's 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 office visits

from three to one; and (c) allowing certain licensed nonphysician health care providers to prescribe mifepristone. J.A. 283-291. 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 "experience and data gained in the last 20 years from millions of women in the US and abroad," among other information. J.A. 451; see J.A. 436-437 (listing 14 "major studies and review articles covering over 45,000 women"); J.A. 509-516 (listing over 70 publications examining safety and efficacy). And FDA carefully explained how that scientific evidence supported its conclusion that the changes would not result in "a safety profile different from the original approved Mifeprex dosing regimen." J.A. 304; see J.A. 292-320; 418-525.

Increase in gestational age. FDA relied on "[f]our studies" and a "systematic review" including "over 30,000" women, all of which had "evaluated the exact proposed dosing regimen through 70 days gestation." J.A. 299. These publications showed that mifepristone's success rate between 49 and 70 days gestation—still well within the first trimester—was "comparable to (and in several studies, greater than) the success rates for medical abortion in the initial 2000 decision for Mifeprex up to 49 days gestation." J.A. 456. The data also indicated "that the rates of * * * serious adverse events are not clinically different from that of other gestational age ranges." J.A. 304.

Reduction in office visits. FDA relied on nearly a dozen studies involving "large numbers of women in the U.S." and other countries, all of which showed that completing the two-drug protocol at home was "associated with exceedingly low rates of serious adverse events,

and with rates of common adverse events comparable to those in the studies of clinic administration of misoprostol that supported the initial approval in 2000." J.A. 308; see J.A. 458 (citing studies); J.A. 466 (discussing "studies including well over 30,000 patients"). FDA explained that "there is no medical rationale" for a woman to return to the clinic to be given misoprostol and that "it is preferable for the woman to be in a convenient, safe place"—rather than in transit home from a second visit—for the onset of the cramping and bleeding that typically occur shortly after taking misoprostol. J.A. 459. FDA likewise concluded that there is no medical reason for an in-person follow-up visit to confirm the termination of the pregnancy and that the method of follow up should instead be "determined jointly by the healthcare provider and the individual woman being treated." J.A. 462.

Prescriptions by non-physician providers. FDA relied on "four studies with 3,200 women in randomized controlled clinical trials and 596 women in prospective cohorts." J.A. 302. Those studies found "no differences in efficacy, serious adverse events, ongoing pregnancy or incomplete abortion" depending on whether a physician prescribed the drug. J.A. 497.

2. The Fifth Circuit's sole basis for holding that the 2016 changes were arbitrary and capricious was its assertion that FDA purportedly failed to "consider the cumulative effect of the 2016 amendments" because it did not 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*, 592

U.S. at 423. Here, FDA explicitly determined that the approved conditions of use after the 2016 changes would "continue to assure safe use" of the drug and that "the benefit-risk profile for Mifeprex continues to be favorable" with the changes. J.A. 319. 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. J.A. 307-310, 478-485.

The Fifth Circuit did not conclude that FDA ignored any study in the administrative record. Nor did it identify any evidence suggesting that any of the changes would be unsafe, either alone or in combination. Instead, the court faulted FDA for "neither consider[ing] the effects as a whole"—by which the court meant citing a study that "examined the effect of implementing all of [the 2016] changes together"—nor "explain[ing] why it declined to do so." Pet. App. 53a. But FDA was not required to commission or conduct scientific studies. And 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*, 592 U.S. at 425.

The Fifth Circuit's contrary conclusion ignored the realities of the drug-approval process. As FDA has explained, "[m]any clinical trial designs are more restrictive * * * than will be necessary or recommended in postapproval clinical use; this additional level of caution is exercised until safety and efficacy of the product is

demonstrated." J.A. 265. The pharmaceutical industry has underscored this point, noting that "[t]here are virtually always differences between clinical trial conditions and approved labeling," in part because studies typically include extra conditions intended to assure data quality. Pharm. Cos. Cert. Amici Br. 15. Requiring sponsors to provide a single study exactly matching all of the approved conditions of use would thus impose "an impossibly rigid new standard." *Id.* at 12 (emphasis omitted); see PhRMA Cert. Amicus Br. 12-19.

Nor did the Fifth Circuit posit any reason to think that three changes that were shown to be safe individually would somehow be dangerous in combination. Respondents have not attempted to make such a showing either. To the contrary, their citizen petition challenging the 2016 changes never suggested that the changes could 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 J.A. 321-347. FDA can scarcely be faulted for failing to more explicitly consider an issue that respondents themselves failed to raise before the agency.

Second, and in any event, the Fifth Circuit's conclusion that FDA did not rely on studies considering 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 J.A. 299 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 J.A. 299 n.1) (same); Olavarietta 2015 (cited at J.A. 299 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." J.A. 298. 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, the FDCA, nor any other source of law required FDA to use the phrase "as a whole" or otherwise "incant 'magic words.'" *Garland* v. *Ming Dai*, 593 U.S. 357, 369 (2021).

3. Respondents and the district court—but not the Fifth Circuit—also questioned the substance of FDA's assessment of the data before the agency. But the deferential arbitrary and capricious standard does not give litigants or the courts a license to second-guess highly technical determinations that Congress has assigned to an expert agency. In any event, respondents' and the district court's objections lack merit.

a. The district court highlighted some reports of particularly serious events in patients who had taken mifepristone, including deaths. *E.g.*, Pet. App. 178a. But the fact that a drug is associated with an adverse event for reporting purposes does not mean that it actually caused that event. As of December 2022, 32 deaths had been reported among nearly six million women who have taken mifepristone, and some of those had obvious alternative causes—including homicide, drug overdose, and other factors entirely unrelated to mifepristone. See *Adverse Events Summary*. In addition, pregnancy itself entails a significantly higher risk of serious adverse events, including a death rate 14 times higher than that associated with legal abortion. J.A. 241.

Regardless, the FDCA does not limit FDA to approving drugs only when they are without risk—a standard no drug could satisfy. Instead, FDA must consider whether "the expected therapeutic gain justifies the risk entailed by [the drug's] use." *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979); see 21 U.S.C. 355(d). That is what FDA did here. Although FDA has acknowledged that serious adverse events can occur with mifepristone use, it found that they are "exceedingly rare." J.A. 465. And it concluded that the evidence relating to the proposed changes "d[id] not suggest a safety profile different from the original approved Mifeprex dosing regimen," J.A. 304, and that "the benefit-risk profile for Mifeprex continues to be favorable" with the changes, J.A. 319.

b. For their part, respondents have criticized (Br. in Opp. 43) various features of a handful of the dozens of studies on which FDA relied. For example, respondents object (*ibid.*) that FDA's decision extending mifepristone's gestational limit from seven to ten weeks was based on studies involving "ultrasounds and follow-up visits," even though FDA did not impose those requirements in the approved 2016 conditions of use. To the extent respondents suggest that FDA failed to consider the potential necessity of ultrasound and follow-up, they are mistaken. FDA addressed both points at length in its review of Danco's application and when responding to respondents' citizen petitions. See J.A. 254-256, 265, 285-341, 466, 482-485. With respect to ultrasound, FDA explained that such a requirement was unnecessary because "in clinical practice, pregnancies can also be (and frequently are) dated using other clinical methods." J.A. 255; see J.A. 482-485. And FDA explained that a requirement of in-clinic follow-up care was unnecessary

because "appropriate follow-up * * * may be accomplished in multiple ways and not all require an in-clinic visit." J.A. 385-386. These aspects of the record, which respondents simply ignore, demonstrate that FDA did not "fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).[8]

B. FDA Lawfully Changed The Adverse Event Reporting Requirements In 2016

FDA's 2016 action also changed the requirement under the REMS 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. J.A. 319, 392. FDA determined that "after 15 years of reporting serious adverse events, the safety profile for Mifeprex is essentially unchanged," J.A. 319, 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," J.A. 392. But FDA made clear that mifepristone's sponsors

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[8] In addition, FDA's 2016 action also changed mifepristone's approved dosing regimen, including reducing the amount of mifepristone from 600 mg to 200 mg; increasing the amount of misoprostol; reducing the amount of time between taking mifepristone and misoprostol; and changing the route of administration of the misoprostol. J.A. 295. FDA explained that those changes would more closely align with clinical practice. J.A. 443-450. Respondents have not specifically challenged those changes. Accordingly, even if the Court determines that FDA acted arbitrarily in approving other changes in 2016, it should make clear that any resulting relief does not require FDA to revert to an outdated dosing regimen.

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, 21 C.F.R. 314.80(c)(1)(i); see 21 C.F.R. 314.98. J.A. 392.

The Fifth Circuit held that FDA's change to the reporting requirements 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 unnecessary 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.

C. FDA Lawfully Decided To Remove The In-Person Dispensing Requirement In 2021

The Fifth Circuit likewise erred in concluding that FDA acted arbitrarily and capriciously by deciding to remove the in-person dispensing requirement after determining it was no longer needed to assure mifepristone's safe use—and thus no longer justified under the FDCA. J.A. 397-408. FDA's decision "was the result of a thorough scientific review" by agency experts who

evaluated "available clinical outcomes data and adverse event reports." J.A. 377.

The Fifth Circuit suggested that because FDA had, as part of the 2016 changes, eliminated the REMS requirement for prescribers to report certain non-fatal serious 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 as noted, see pp. 41-42, *supra*, FDA's 2016 changes left undisturbed the reporting requirements governing mifepristone's sponsors. And as FDA explained, adverse event reports are contained in the FDA Adverse Event Reporting System (FAERS) database, which FDA "routinely monitors." J.A. 398. 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, which is 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 information from the drug's sponsors and concluded that the nonenforcement of the in-person dispensing requirement during much of 2020 and 2021 (due to an injunction and, later, enforcement discretion) did not appear to affect adverse events. J.A. 397-399. 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." J.A. 399-400. FDA's analysis of those studies spans nearly ten full pages in the agency's 2021 petition response. J.A. 399-408. And FDA further analyzed the issue in another contemporaneous document explaining its decision. See FDA, *REMS Modification Rationale Review* 19-36, 38-40 (2021), https://perma.cc/W4U3-L38P (document beginning on PDF page 41).

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 J.A. 407). But FDA acknowledged those limitations and went on to explain why, "[d]espite the limitations of the studies [it] reviewed," the available evidence supported its conclusion that "mifepristone will remain safe and effective if the in-person dispensing requirement is removed." J.A. 400, 407. The deferential arbitrary and capricious standard does not give litigants or the courts a license to "unduly second-guess" the agency's "scientific judgments." *Cytori Therapeutics, Inc.* v. *FDA*, 715 F.3d 922, 923 (D.C. Cir. 2013) (Kavanaugh, J.). 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*, 592 U.S. at 427. The lower courts violated this fundamental administrative-law principle in overriding FDA's predictive judgments here.

III. THE DISTRICT COURT'S REMEDY WAS IMPROPER

Even if the Fifth Circuit were correct that respondents have standing and a likelihood of success on the

merits, the court erred in affirming the portions of the district court's order suspending FDA's 2016 and 2021 actions. The district court erroneously invoked 5 U.S.C. 705 to "postpone" the effective date of agency actions that had long been in effect. And especially given the nature of the errors the lower courts identified, there was no basis for imposing disruptive preliminary relief that would harm women, the Nation's healthcare system, FDA, and mifepristone's sponsors.

A. The District Court Erred In Relying On 5 U.S.C. 705

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 to "stay" the effective date of FDA's challenged actions. Pet. App. 194a. Section 705 provides in relevant part that, "to the extent necessary to prevent irreparable injury," a reviewing court "may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. 705. But the lower courts never explained how a court could "postpone" the effective date of actions that became effective years before the litigation began.

To "postpone" means "to defer to a future or later time; to put off; delay." *Webster's New International Dictionary* 1682 (1928) (def. 1); see *Black's Law Dictionary* 1389 (3d ed. 1933) ("To put off; defer; delay"). Section 705 thus requires that any postponement be contemporaneous with or predate the effective date of the challenged agency action; otherwise there would be no way for a court to postpone that effective date. Here, however, FDA's challenged decisions with respect to mifepristone became effective in 2016 and 2021—years before the district court issued its order. Neither the

district court nor the Fifth Circuit made any effort to reconcile the district court's order "postpon[ing]" FDA's already-effective actions with the text of Section 705.

The lower courts thus erred in interpreting Section 705 to authorize "an interim * * * form of vacatur" and in treating that relief as the default interim remedy in suits seeking review of agency action, Pet. App. 194a (citation omitted)—a theory that departs from background principles requiring party-specific remedies and would improperly make universal relief the norm. Instead, courts reviewing agency action must apply the traditional equitable principles governing the propriety and scope of any preliminary relief. See, *e.g.*, *Winter* v. *NRDC, Inc.*, 555 U.S. 7, 20, 24 (2008).

B. The Balance Of The Equities And The Public Interest Do Not Support Preliminary Relief

The Fifth Circuit correctly recognized that the availability of any preliminary relief in this case 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 an 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 legal 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 more restrictive pre-2016

conditions of use could unnecessarily impair 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 the approved conditions would call for women to complete three office visits—even though FDA has found those conditions to be unnecessary and unjustified.

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. ROA 2468-2470, 2478-2485, 2510-2511. Surgical abortion is an invasive procedure that can have greater health risks for some patients, such as those who are allergic to anesthesia. J.A. 228-230, 242.

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. ROA 3250. 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, 312-314, 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 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 ex-

perience with the continued safe and effective use of mifepristone under the challenged conditions. At a minimum, FDA should have the opportunity to address the Fifth Circuit's concerns before the entry of sweeping preliminary relief that would alter a years-long status quo and inflict profound harm on women, the medical system, the agency, and the public.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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APPENDIX

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APPENDIX

1. 5 U.S.C. 705 provides:

Relief pending review

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

2. 21 U.S.C. 355 provides in relevant part:

New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

* * * * *

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said sub-

section, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled in-

vestigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.

3. 21 U.S.C. 355-1 provides in relevant part:

Risk evaluation and mitigation strategies

(a) Submission of proposed strategy

(1) Initial approval

If the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, determines that a risk evaluation and mitiga-

tion strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and informs the person who submits such application of such determination, then such person shall submit to the Secretary as part of such application a proposed risk evaluation and mitigation strategy. In making such a determination, the Secretary shall consider the following factors:

(A) The estimated size of the population likely to use the drug involved.

(B) The seriousness of the disease or condition that is to be treated with the drug.

(C) The expected benefit of the drug with respect to such disease or condition.

(D) The expected or actual duration of treatment with the drug.

(E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.

(F) Whether the drug is a new molecular entity.

(2) Postapproval requirement

(A) In general

If the Secretary has approved a covered application (including an application approved before the effective date of this section) and did not when approving the application require a risk evaluation and mitigation strategy under paragraph (1), the Secretary, in consultation with the

offices described in paragraph (1), may subsequently require such a strategy for the drug involved (including when acting on a supplemental application seeking approval of a new indication for use of the drug) if the Secretary becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug.

(B) Submission of proposed strategy

Not later than 120 days after the Secretary notifies the holder of an approved covered application that the Secretary has made a determination under subparagraph (A) with respect to the drug involved, or within such other reasonable time as the Secretary requires to protect the public health, the holder shall submit to the Secretary a proposed risk evaluation and mitigation strategy.

* * * * *

(g) Assessment and modification of approved strategy

(4) Modification

(A) On initiative of responsible person

After the approval of a risk evaluation and mitigation strategy by the Secretary, the responsible person may, at any time, submit to the Secretary a proposal to modify the approved strategy. Such proposal may propose the addition, modification, or removal of any goal or element of the approved strategy and shall include an adequate rationale to support such proposed addition, mod-

ification, or removal of any goal or element of the strategy.

(B) On initiative of Secretary

After the approval of a risk evaluation and mitigation strategy by the Secretary, the Secretary may, at any time, require a responsible person to submit a proposed modification to the strategy within 120 days or within such reasonable time as the Secretary specifies, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that 1 or more goals or elements should be added, modified, or removed from the approved strategy to—

(i) ensure the benefits of the drug outweigh the risks of the drug;

(ii) minimize the burden on the health care delivery system of complying with the strategy; or

(iii) accommodate different, comparable aspects of the elements to assure safe use for a drug that is the subject of an application under section 355(j) of this title, and the applicable listed drug.