NOS. 23-235, 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.,
Respondents.

and

DANCO LABORATORIES, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

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

RESPONDENTS' BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

In 2000, the Food and Drug Administration (FDA) approved mifepristone under Subpart H—the only regulatory pathway available for such approval—by labeling pregnancy a "serious and life-threatening illness." Because the drug could not safely be approved without restrictions, the agency conditioned its approval on numerous safeguards. Yet in 2016, FDA stripped away many safeguards, failing to explain why it was proper to eliminate them all without a study showing their cumulative safety. In 2021, FDA removed the last-remaining doctor's visit, allowing mail-order chemical abortions despite admitting the safety studies on which it relied were "insufficient." The questions presented are:

1. Whether the Fifth Circuit correctly held that individual doctors and medical associations have Article III standing to challenge an agency's removal of drug safeguards where: (1) the named Respondents have suffered repeated injury; (2) it is undisputed that complications result in emergency room visits for 2.9%–4.6% of women; and (3) relying on emergency room doctors like Respondents to treat those serious complications was a central part of FDA's plan to deal with those complications.

2. Whether the Fifth Circuit correctly required FDA to address important aspects of the problem and adequately explain its decisions to remove critical safeguards in 2016 and 2021, allowing chemical abortion drugs to be dispensed through the mail without any physical examination to diagnose gestational age or an ectopic pregnancy, both of which affect the health and safety of pregnant women.

RELATED DECISIONS

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

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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INTRODUCTION

The decision below faithfully applied the unremarkable principle that a federal agency must follow administrative law standards long set by Congress. This decision is not "unprecedented," but part of the basic compromise Congress has made in giving federal agencies power over nearly "every nook and cranny of daily life." *City of Arlington* v. *FCC*, 569 U.S. 290, 315 (2013) (Roberts, C.J., dissenting). When agencies exercise such significant authority, the Administrative Procedure Act (APA) requires that they sufficiently explain their decisions and consider important aspects of the problem. FDA failed to satisfy those standards here.

Immediate review of these interlocutory petitions—on an incomplete factual and administrative record—is not warranted. Petitioners are wrong to insinuate that the lower court's decision takes mifepristone off the market. It does no such thing. The modest decision below merely restores the common-sense safeguards under which millions of women have taken chemical abortion drugs. Women will still have access to chemical abortion under the same protections that existed for the first 16 years of mifepristone's use, including crucial examinations and ongoing monitoring for complications by a prescribing physician. And FDA had "no safety or efficacy concerns about the originally approved dosing regimen" when changing it in 2016. ROA.707. That Danco might need to revert to the prior approved label—something it has had over seven months now to prepare for—does not justify interlocutory review. If this litigation involved a drug unrelated to abortion, there would not even be a debate as to whether this Court should intervene mid-litigation stream.

The Fifth Circuit correctly determined that the named Respondent doctors and association members have standing. These doctors have suffered concrete and specific injuries, including forced participation in elective abortion, because of FDA's deregulation of chemical abortion. That emergency room physicians—like the Respondent doctors—will often be called upon to treat chemical abortion complications is not a bug in the system but part of its very design. FDA has always known that those doctors would be needed to respond to harms caused by chemical abortion. In 2021, for instance, when FDA eliminated the initial in-person doctor visit—the mechanism to diagnose a life-threatening ectopic pregnancy and confirm gestational age—it relied on the "common practice for healthcare providers to provide emergency care coverage for other healthcare providers' patients." ROA.814. Factor in the acknowledgment on mifepristone's current label that between 2.9% and 4.6% of women who take chemical abortion drugs end up in the emergency room, and Respondents' harms here are the furthest thing from speculative.

The Fifth Circuit was also correct on the merits of Respondents' challenge to FDA's 2016 and 2021 actions. FDA says that federal courts should grant "significant deference" to its "expertise" and must not "unduly second-guess" its decisions. FDA.Pet.21, 27. But no amount of deference can cure FDA's failure to engage in reasoned decision-making.

For the 2016 changes, not a single study that FDA relied on examined what would happen if the agency removed every safeguard at once. That's like the unlawful agency action in *Motor Vehicle Manufacturers Association of U.S., Inc.* v. *State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), where

the agency relied on data of cars with only automatic seatbelts but not airbags to conclude that neither provided a safety benefit. "That was obviously arbitrary and capricious in *State Farm*. And so too here." FDA.Pet.App.235a. Nor did FDA explain why it was appropriate not to consider any study assessing the changes as a whole.

FDA's 2021 decision to permanently remove the in-person dispensing requirement fares no better. In allowing for mail-order abortions, FDA relied heavily on its Adverse Event Reporting System (FAERS). But FDA abandoned reporting requirements for nonfatal adverse events years before. As the Fifth Circuit stay panel concluded, "[t]his ostrich's-head-in-the-sand approach is deeply troubling" and "unreasonable." FDA.Pet.App.236a. FDA also relied on studies that the agency admitted did not independently support its decision; indeed, the best that FDA could say about the studies was that they were "*not inconsistent with* [its] conclusion" to allow mail-order abortion. *Id.* at 57a (emphasis added). The APA and other statutes governing FDA's actions require more.

This challenge to FDA's 2021 actions, as the district court and Judge Ho's concurrence both recognize, is also likely to succeed for another reason: FDA violated the Comstock Act—a longstanding federal criminal law that prohibits the mailing, shipping, or delivery of "[e]very" and "any drug … designed, adapted, or intended for producing abortion." 18 U.S.C. 1461–62. FDA's 2021 approval of mail-order abortions directly contradicts the Comstock Act's prohibition on shipping abortion drugs in the mail. This provides an alternative basis for upholding the decision below. For these reasons, this Court should deny review.

STATEMENT

A. FDA's approval of mifepristone

For over 80 years, FDA has been subject to the statutes at issue in this case. First, the Food, Drug, and Cosmetic Act (FDCA) requires drug manufacturers to prove, and FDA to ensure, that any approved drug is "safe and effective" for its intended use. 21 U.S.C. 321(p), 355(d). Second, the APA subjects FDA's actions, no less than any other agency, to judicial review, ensuring that those actions are rational and adequately explained. 5 U.S.C. 702.

These statutes governed FDA's decision to approve a two-drug chemical abortion regimen involving mifepristone (also known as "RU-486" and "Mifeprex") and misoprostol. FDA.Pet.App.6a. Mifepristone is a synthetic steroid that blocks nutrition to an unborn child. *Id.* at 112a. And misoprostol induces contractions to expel the dead baby from the mother's womb. *Id.* at 6a.

In 1994, the Population Council—a nonprofit founded by John Rockefeller III to address supposed world "overpopulation"—obtained the U.S. patent rights to mifepristone. FDA.Pet.App.113a; ROA.107. The Council then granted Danco Laboratories, LLC—a Cayman Islands-based company with no other pharmaceutical products—an exclusive license to manufacture, market, and distribute mifepristone in the United States. FDA.Pet.App.6a; ROA.115.

In 2000, FDA approved mifepristone under an accelerated approval provision known as "Subpart H." 21 C.F.R. 314 subpt. H; FDA.Pet.App.7a. Subpart H allowed expedited approval of drugs that treat "serious or life-threatening illnesses." 21 C.F.R. 314.500. Before mifepristone, FDA had approved

fewer than 40 drugs under Subpart H—including 20 "for the treatment of HIV and HIV-related diseases," nine "for the treatment of various cancers and their symptoms," four "for severe bacterial infections," one for hypertension, and one for leprosy. FDA.Pet.App.163a.

As FDA has explained, Subpart H applies "where FDA 'determines that a drug, effective to the treatment of a disease, can be used safely only if distribution or use is modified or restricted.'" FDA.Pet.App.5a. Subpart H was the only path to mifepristone's approval because the drug "could not be administered safely without imposing certain use restrictions." *Id.* at 7a.

Yet Subpart H was a poor fit. To satisfy its requirements, FDA was required to label pregnancy a "serious or life threatening illness." FDA.Pet.App.7a. The agency also determined that mifepristone provided a "meaningful therapeutic benefit" over surgical abortions, *ibid.*, despite not comparing chemical abortion with surgical abortion to find such a "benefit," *Id.* at 167a.

Given mifepristone's acknowledged, serious, and adverse complications, FDA included safeguards. FDA.Pet.App.7a. These protections included a seven-week gestational limit, confining prescribing authority to physicians, and mandating three in-person office visits: (1) the Day 1 in-person dispensing and administration of mifepristone, (2) the Day 3 in-person dispensing and administration of misoprostol, and (3) the Day 14 office visit to confirm no fetal parts or tissue remains. Additionally, abortion providers were required to report all serious adverse events.

In response to FDA's 2000 Approval of mifepristone, Respondents American Association of Pro-Life Obstetricians & Gynecologists (AAPLOG) and Christian Medical & Dental Associations (CMDA) filed a citizen petition with FDA to explain why that approval lacked scientific and legal basis (2002 Citizen Petition). FDA.Pet.App.8a–9a.

While the 2002 Citizen Petition was pending before FDA, Congress, in the Food and Drug Administration Amendments Act (FDAAA), amended the FDCA to codify Subpart H. FDA.Pet.App.9a. Under the FDAAA, FDA must require a risk evaluation and mitigation strategy (REMS) when the agency determines that a REMS is "necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness" and its association "with a serious adverse drug experience." 21 U.S.C. 355-1(f)(1). The FDAAA further specified that drugs previously approved under Subpart H would temporarily be "deemed to have in effect an approved [REMS]." Pub. L. No. 110-85, tit. IX §909(b)(1), 121 Stat. 823, 950 (2007). This stop-gap measure said nothing about any specific drug approval. Danco subsequently submitted—and FDA approved—its REMS application.

B. FDA's removal of critical safeguards

Fourteen years elapsed before FDA finally rejected the 2002 Citizen Petition (2016 Petition Denial). FDA.Pet.App.10a. The same day, FDA approved "major changes" to the chemical abortion drug regimen (2016 Major Changes). *Id.* at 10a, 200a. Among other things, the agency (1) increased the maximum gestational age from seven weeks to ten, (2) allowed non-doctors to prescribe and administer chemical abortions, (3) decreased the mifepristone

dose from 600 mg to 200 mg, (4) increased the misoprostol dose from 400 mcg to 800 mcg, (5) amended the misoprostol administration period from 48 hours to 24–48 hours, (6) allowed a repeat 800 mcg dose of misoprostol, (7) switched to buccal administration of misoprostol, (8) removed the Day 3 in-person administration requirement for misoprostol, (9) eliminated the Day 14 in-person follow-up examination to identify complications, and (10) removed the requirement that prescribers report non-fatal adverse events. *Id.* at 10a.

FDA made these changes based on studies that examined "the safety consequences of eliminating *one* or *two* of the" safeguards simultaneously, but with "*zero*" studies on the safety consequences of removing all these safeguards at once. FDA.Pet.App.235a (emphasis added). In essence, FDA removed key safeguards it originally thought necessary to ensure mifepristone's safe use. Accordingly, in 2019, AAPLOG and Respondent American College of Pediatricians (ACPeds) filed another citizen petition requesting that FDA undo the 2016 Major Changes (2019 Citizen Petition). *Id.* at 11a.

One month later, FDA approved GenBioPro, Inc.'s abbreviated new drug application (ANDA) for a generic version of mifepristone, relying on the safety data for Danco's name-brand version (2019 Generic Approval). FDA.Pet.App.11a.

FDA then invoked the COVID pandemic to deregulate mifepristone further. FDA.Pet.App.11a. In April 2021, FDA stated that it would "exercise enforcement discretion" and allow "dispensing of mifepristone through the mail … or through a mail-order pharmacy" during the pandemic (2021 Non-

Enforcement Decision). *Ibid*. FDA took this action even though the Comstock Act expressly prohibits distribution of chemical abortion drugs by using the mail, an express company, a common carrier, or an interactive computer service. 18 U.S.C. 1461–62.

In December 2021, FDA denied almost all of the 2019 Citizen Petition (2021 Petition Denial). FDA.Pet.App.12a. It simultaneously announced that the agency had decided it would permanently allow chemical abortion by mail—requiring only that the sponsors of mifepristone submit updated REMS. *Ibid.* This national mail-order abortion scheme effectively federalized abortion access across the country.

C. Proceedings below

In November 2022, Respondents filed this lawsuit alleging that the 2000 Approval, 2016 Petition Denial, 2016 Major Changes, 2019 Generic Approval, 2021 Non-Enforcement Decision, and 2021 Petition Denial all violated the APA. FDA.Pet.App.202a. Danco intervened. *Id.* at 117a.

Respondents moved for a preliminary injunction to halt these actions pending judicial review. FDA.Pet.App.117a. The district court found that FDA's actions were all unlawful under the APA and granted the motion in part. *Id.* at 111a, 159a, 172a–174a. The court stayed the effective date of the challenged actions under 5 U.S.C. 705, imposing a preliminary injunction in the alternative. *Id.* at 193a–95a.

FDA and Danco appealed and moved to stay the district court's order. A Fifth Circuit motions panel stayed the district court's ruling as it applied to the 2000 Approval but did not disturb the rest. FDA.Pet.App.196a. The stay panel held that "the

individual plaintiffs and doctors in plaintiff associations have standing to challenge FDA's actions." *Id.* at 207a; see also *id.* at 218a (rejecting FDA's comparison of mifepristone to ibuprofen). The stay panel also concluded that FDA's 2016 and 2021 changes were arbitrary and capricious. *Id.* at 233a–236a. FDA and Danco sought, and this Court granted, a stay of that order through the ruling on any petition for certiorari. *Id.* at 245a.

After full briefing and argument, the Fifth Circuit affirmed in part and reversed in part. FDA.Pet.App.3a. The Fifth Circuit held that Respondent doctors and medical associations have standing. First, "FDA and Danco do not dispute that a significant percentage of women who take mifepristone experience adverse effects." *Id.* at 17a. A significant percentage of those women present to emergency rooms, *id.* at 18a, and the Fifth Circuit found that "FDA's data and the Doctors' testimony" established that the doctors and medical associations faced a "substantial risk" of future injury, *id.* at 26a–27a—a risk increased by FDA's 2016 and 2021 actions, *id.* at 36a–41a.

Exercising well-established principles of judicial review over agency actions, the court of appeals then held that the 2016 Major Changes and the 2021 actions violated the APA. FDA.Pet.App.51a–56a, 56a–63a. The court explained that, contrary to congressional command, FDA ignored important aspects of the problem and did not adequately explain its 2016 and 2021 decisions. *Ibid.* With respect to the 2016 Major Changes, the lower court faulted FDA for failing to consider a major aspect of the problem: "the cumulative effect of the 2016 Amendments." *Id.* at 53a. With respect to the 2021 actions, the lower court

criticized FDA for "g[iving] dispositive weight to adverse-event data in FAERS—despite the uncontested limitations of doing so," *id.* at 59a, and for "rel[ying] on various literature relating to remote prescription of mifepristone—despite [its] admission that the literature did not affirmatively support its position," *id.* at 61a.

The court of appeals, however, reversed the district court's ruling on the 2000 Approval, holding that Respondent's challenge was likely untimely. FDA.Pet.App.46a–51a. The court of appeals also vacated the district court's order on the 2019 Generic Approval for lack of standing. *Id.* at 43a. Respondents conditionally cross-petitioned for certiorari on these points. FDA's and Danco's petitions for certiorari challenge the 2016 and 2021 portions of the Fifth Circuit's ruling.

REASONS FOR DENYING THE PETITION

This Court's review of the decision below is unwarranted. The APA's most basic principle—that courts must set aside unlawful agency action—governs this case. FDA complains that the decision below is "unprecedented," urges this Court to "defer[ ]" to its expertise, and suggests the Fifth Circuit erred by second-guessing its decisions. FDA.Pet.21, 30. That is an invitation for judicial abdication. But no agency—including FDA—is infallible. This Court should deny review.

First, the fact-bound decision below is in an interlocutory posture and merely restores the basic safeguards to a chemical drug regimen that existed for sixteen years. Petitioners are wrong to imply that mifepristone will be unavailable under the lower court's decision. To the contrary, the reinstated safe-

guards simply restore modest protections for women's health that FDA deemed crucial until just seven years ago.

Immediate review is also unwarranted because FDA has not yet produced the administrative record. And further factual development would allow Respondents to introduce additional evidence of their ongoing harm from FDA's deregulation of chemical abortion drugs.

Judicial economy will also be served if this Court denies review now. The proposed State intervenors press sovereign and economic harms that are distinct from Respondents'. Suggestions in Supp. of Mot. to Intervene (N.D. Tex. Nov. 3, 2023), ECF No. 152. They assert, for example, that "a wide network of persons—in reliance on the FDA's challenged [2016 and 2021] actions—mail[ ] abortion pills into [those] States," thereby undermining their pro-life laws and imposing serious economic harms on them. *Id.* at 1. The States should be able to establish their harms and litigate their claims before this Court grants review.

Second, the lower court correctly analyzed the challenged 2016 and 2021 actions. To begin, Respondent doctors and medical associations have standing. Throughout this litigation, FDA has advanced a radical view of standing that would mean only the parties who profit from a drug can sue over its unlawful deregulation. See FDA.CA5.Br.24 (arguing that standing does not exist even if "hundreds of thousands of women *will* … need emergency care" and even if "plaintiff doctors and their associations *will* necessarily be injured by the consequences" of chemical abortion) (emphasis added).

Before this Court, Petitioners suggest that the Fifth Circuit erred by relying on a speculative theory of injury based solely on a possibility of future harm. FDA.Pet.App.12a. But the Fifth Circuit properly found that *named* Respondent doctors and association members have suffered past harm and are likely to suffer future harm. *Id.* at 16a–41a. Those harms are not speculative. They have already occurred, and there is a "substantial risk" they "will occur" again. *Susan B. Anthony List* v. *Driehaus*, 573 U.S. 149, 158 (2014) ("*SBA List*") (cleaned up). Indeed, according to FDA's own evidence, hundreds of thousands of women have suffered adverse events. FDA.Pet.App.210a, 215a. Further, "FDA's data and the Doctors' testimony show that women will continue to present to the emergency room after taking mifepristone, requiring urgent treatment. That trend is not speculative—it is 'predictable' and 'consistent[ ].'" *Id.* at 27a. (citation omitted).

Traceability also exists. As the Fifth Circuit found, risks to women increased after FDA eliminated safeguards like in-person visits—removing the opportunity for a doctor to diagnose dangerous ectopic pregnancies and accurately assess gestational age. FDA.Pet.App.36a–41a. And it is no answer to say, as Petitioners do, that a woman's decision to take the drug absolves the agency of responsibility to ensure the drug's safety under the FDCA. See FDA.Pet.18.

On the merits, FDA failed to engage in the reasoned decision-making the APA requires. It is hornbook law that when an agency acts, it must "reasonably consider[ ] the relevant issues and reasonably explain[ ]" its actions. *FCC* v. *Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)

("*Prometheus*"). FDA failed both precepts in making the 2016 and 2021 actions.

FDA acknowledged that the 2016 Major Changes were "interrelated." FDA.Pet.App.10a. And while the cumulative effect of the changes is an important aspect of the problem, none of the studies on which the agency relied examined the safety of the changes as a whole. *Id.* at 53a; ROA.128. Nor did the agency offer any explanation as to why such a study was unnecessary. Similarly, FDA failed to evaluate mifepristone's safety under the conditions of use in the proposed labeling—as required by the FDCA. 21 U.S.C. 355(d). It was arbitrary and capricious for FDA to rely only on studies that included additional safeguards not found under the approved 2016 label. FDA.Pet.App.54a, 235a.

FDA's 2021 actions were also arbitrary. In removing the in-person dispensing requirement, FDA relied heavily on FAERS and on studies that it admitted were insufficient to find mail-order abortion safe. FDA.Pet.App.59a–63a. As to FAERS, FDA abandoned requirements for prescribers to report nonfatal adverse events years before. *Id.* at 10a. And as to the studies, FDA admitted that, at most, they were not "inconsistent" with its safety finding. *Id.* at 57a. But the FDCA and the APA require more. Further, the district court correctly held, and Judge Ho's concurrence agreed, that FDA's mail-order abortion regimen is unlawful for an additional reason—it violates the Comstock Act. *Id.* at 98a–104a, 159a.

I. Review of the fact-bound and interlocutory decision below is unwarranted.

The decision below does not warrant immediate review. First, mifepristone will remain widely avail-

able under the Fifth Circuit's decision. Petitioners are wrong to suggest otherwise. The modest safeguards for women's health restored by two different court of appeals panels do not remove chemical abortion drugs from the market. Rather, they simply ensure that women will take the drug only after being seen by a doctor and screened for dangerous contraindications. Second, the interlocutory nature of the decision below counsels against review. This is especially true, where as here, FDA has not produced the administrative record, additional factual development would showcase the continuing harms Respondents have suffered since filing suit, and proposed State intervenors' claims have yet to be litigated in the lower courts.

A. The lower court's fact-bound analysis reimposes modest, common-sense safeguards that protected women's health for 16 years.

Petitioners overstate the practical effects of the decision below. They contend that the Fifth Circuit's opinion, left undisturbed, will have disastrous effects on the judiciary, abortion providers, pharmaceutical companies, and women across America. Nothing could be further from the truth.

First, Petitioners put much emphasis on the Fifth Circuit's "unprecedented decision" and assert that the court "unduly second-guess[ed] the agency's scientific judgments." FDA.Pet.3, 27 (cleaned up). But the lower court acted consistent with Article III and the APA. As even Petitioner Danco admits, the Fifth Circuit "min[ed] the … record," Danco.Pet.3, carefully fulfilling the role assigned it by Congress under the APA. 5 U.S.C. 706(2). What the lower court did here is not unprecedented. Instead, it is Petitioners who

seek the extraordinary—for this Court to blindly defer to FDA's determinations and rubber-stamp them as unimpeachably "scientific." Yet that would abdicate the judicial role under the APA. See FDA.Pet.App.105a–09a (Ho, J., concurring and dissenting in part) (rehearsing many of FDA's prior "mistakes" and acknowledging "Congress's clear directive that courts conduct independent legal review of FDA action under the APA").

Second, Petitioners assert that the decision below will "upset [the] reliance interests" of abortion providers who "depend[ ] on the availability of mifepristone" FDA.Pet.31. That drastically overstates matters. The court below did *not* take mifepristone off the market.[1] Rather, the court returned mifepristone to a regulatory regime that operated in this country for *16 years*, spanning three different presidential administrations. See FDA.Pet.App.71a ("Danco will have legal authority to market and sell Mifeprex under the conditions that were in effect before 2016."). Petitioners have pointed to nothing suggesting that abortion providers could not return to the regulatory regime that existed for the overwhelming majority of mifepristone's time on the market.

Third, Petitioners contend that the decision below will have "especially disruptive implications for the pharmaceutical industry and those who depend upon

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[1] Danco alleges that "the decision below will remove [mifepristone] from the market entirely for an extended period of time." Danco.Pet.35. If that were to happen, Danco has no one to blame but itself. The company has long known that it might need to return to the 2016 labeling.

the drugs it supplies." FDA.Pet.32. Not so. That decision applies to only *two* companies, Danco and GenBioPro, the only FDA-approved manufacturers of mifepristone. FDA.Pet.App.71a. What's more, the lower court simply did what courts have done since Congress enacted the APA: exercised "judicial review," 5 U.S.C. 702, and determined that an agency failed to consider important aspects of the problem and to adequately explain its decision. It is a fact-bound decision that applied well-established APA principles to FDA's actions involving one drug. That holding—which has no application beyond the specific agency actions at issue here—in no way imperils other drug approvals, past or future.

What Petitioners are really seeking is immunity for FDA from legal review. Petitioners desire a world where FDA acts, and no matter what the underlying evidence shows, courts defer to its judgments (or, better yet, eschew review altogether). That's not the world Congress created when it passed the APA. See FDA.Pet.App.108a–09a (Ho, J., concurring and dissenting in part) (citing cases invalidating FDA action). It was Congress that subjected FDA's actions to judicial review. And it was Congress that tasked FDA with the responsibility of affirmatively demonstrating that every drug it reviews is safe and effective. 21 U.S.C. 355(d). Petitioners' pleas for FDA immunity belong in the halls of Congress—not before this Court.

Finally, Petitioners castigate the decision below as harmful to women. FDA.Pet.28; Danco.Pet.3. That turns reality on its head. Since the 2000 Approval, mifepristone has harmed countless women—not, as Petitioners would have this Court believe, a "tiny fraction." Danco.Pet.22. As the district court found,

chemical abortions "are over fifty percent more likely than surgical abortion to result in an emergency room visit within thirty days," and chemical abortions produce "far higher rates of hemorrhaging, incomplete abortion, and unplanned surgical evacuation, … pain, nausea, vomiting[,] and diarrhea." FDA.Pet.App.167a–68a. And since FDA's 2016 and 2021 actions removing critical safeguards, the harms have only grown. Without the oversight and involvement of physicians during the chemical abortion process, women are now at a greater risk of experiencing adverse effects. *Id.* at 36a–41a (discussing evidence that "more women will suffer serious adverse events" because of the 2016 and 2021 actions).

B. The interlocutory posture of this case weighs against certiorari.

These petitions challenge an interlocutory decision in an ongoing case—a well-recognized reason to deny certiorari. This Court "generally await[s] final judgment in the lower courts before exercising [its] certiorari jurisdiction." *Va. Military Inst.* v. *United States*, 508 U.S. 946, 946 (1993) (statement of Scalia, J.); accord Eugene Gressman et al., Supreme Court Practice § 4.18, at 282 (9th ed. 2007) ("[T]he interlocutory nature of a lower court judgment will generally result in a denial of certiorari.").

Reviewing the questions presented at this preliminary juncture risks deciding them based on an incomplete record. FDA has yet to produce the full administrative record, which often sheds light on the agency's decision-making. Indeed, FDA has asserted in this very case that the administrative record is "absolutely" necessary to provide full review. Oral

Arg. at 23:07 (5th Cir. May 17, 2023). That record is particularly crucial here because Respondents expect it will show further politicization of FDA's decisions and reviewer concerns over the quality of clinical investigations. Despite having had almost a year to prepare the administrative record, FDA has dragged its feet, most recently telling the court of appeals that the record remained in "cold storage." Oral Arg. at 24:49 (5th Cir. May 17, 2023). This glaring deficiency is a reason to deny certiorari.

In addition, further litigation in the lower courts will better develop the factual record showing the harms to Respondents. Litigation through final judgment will allow Respondents to submit evidence of their ongoing harm since they filed this lawsuit, bolstering their standing. Ensuring that the parties can build a full evidentiary record in the lower courts is another reason to pass on interlocutory review.

A recent development in the district court further justifies this Court denying review. The States of Missouri, Kansas, and Idaho have moved to intervene. Mot. to Intervene (N.D. Tex. Nov. 3, 2023), ECF No. 151. These States have alleged injuries caused by FDA's actions and interests in the outcome of this case different from those asserted by Respondents. Suggestions in Supp. of Mot. to Intervene (N.D. Tex. Nov. 3, 2023), ECF No. 152. The Court would benefit from the lower courts first considering the States' claims alongside Respondents' and awaiting a consolidated final judgment.

Otherwise, the Court may find itself reviewing challenges to the same FDA actions multiple times. This is particularly true given Petitioners' emphasis on standing. For Petitioners to prevail on those

arguments and insulate FDA's unlawful actions from judicial review, it is not enough to show that Respondents lack standing. Petitioners must also establish that the States do too.

This Court should follow its usual approach, deny interlocutory review, and allow this case to proceed to final judgment.

II. This Court should deny interlocutory review because the Fifth Circuit was correct on the merits of the 2016 and 2021 actions.

The Fifth Circuit correctly found that both the Respondent doctors and medical associations possess standing because they have endured past harm and are likely to experience future harm. That court put forth the proper legal standards, FDA.Pet.App.14a, and acknowledged that standing does not exist based "on a highly attenuated chain of possibilities," nor does it allow "guesswork as to how independent decisionmakers will exercise their judgment," *ibid.* (quoting *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 410, 413 (2013)). This Court does not typically review the misapplication of undeniably correct principles of law, Sup. Ct. R. 10, but in any event, the court below did not err in its analysis. Plus, organizational standing also exists—an issue the Fifth Circuit didn't reach, FDA.Pet.App.41a. This Court may affirm on that alternative standing rationale. *Biden* v.

Nebraska, 143 S. Ct. 2355, 2365 (2023) ("If at least one plaintiff has standing, the suit may proceed.").[2]

On the merits, the Fifth Circuit rightly concluded that FDA violated federal law when the agency made sweeping changes to the mifepristone regimen in 2016 and authorized mail-order chemical abortions in 2021. The lower court's analysis fits squarely within this Court's APA jurisprudence holding agencies accountable for arbitrary and capricious actions when they fail to consider an important aspect of the problem or adequately explain their decisions. See *State Farm*, 463 U.S. at 43.

A. Respondents possess individual, associational, and organizational standing.

The lower court properly found that the individual Respondent doctors and medical associations have standing. See *Hunt* v. *Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977) (associational standing exists where a named plaintiff member has standing).

Petitioners suggest that the Fifth Circuit erred by failing to "identify any [association] member who will be injured." Danco.Pet.24; FDA.Pet.12. But the Fifth

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[2] Respondents also satisfy the requirements for third-party standing. Indeed, the Fifth Circuit stated that if "it were necessary to consider third-party standing, it is likely that emergency-room doctors have a sufficiently close relationship with mifepristone patients." FDA.Pet.App.41a (cleaned up). "In many respects, such a relationship may be closer than those previously recognized by [this] Court." *Id.* at 42a (citations omitted).

Circuit's opinion details at length the harm suffered by the *named* Respondent doctors and association members. After reviewing their declarations, the Fifth Circuit "conclude[d] that the Medical Organizations *and* Doctors have made a 'clear showing' that *their* members face injury with sufficient likelihood to support entering a preliminary injunction." FDA.Pet.App.14a (emphasis added); see also *id.* at 26a ("We conclude that the Medical Organizations and Doctors have made a 'clear showing' of associational standing.").

In particular, the lower court relied on testimony from "multiple doctors who have personally given emergency care to women suffering complications from mifepristone." FDA.Pet.App.28a. The court painstakingly summarized Respondents' declarations. Take just one: Dr. Ingrid Skop's. A member of Respondent AAPLOG, Dr. Skop "testified to caring for many women experiencing severe complications due to mifepristone." *Id.* at 20a. She has "cared for at least a dozen women who have required surgery to remove retained pregnancy tissue" including "the embryo or fetus" "after a chemical abortion." *Id.* at 20a–21a. On one occasion, when treating a "young woman who had been bleeding for six weeks after she took the chemical abortion drugs," Dr. Skop "performed a sonogram, identified a significant amount of pregnancy tissue remaining in her uterus, and performed a suction aspiration procedure to resolve her complication." *Id.* at 21a.

Given that Dr. Skop has often treated women suffering serious complications from chemical abortion drugs, the Fifth Circuit was on firm ground to find it likely that she, as well as other doctors, "will continue treating women who experience severe

complications after taking mifepristone." FDA.Pet.App.26a; see also *id.* at 28a (finding that the "record amply supports" Respondent doctors' claims they are likely to be injured again). So Petitioners are simply wrong to claim that the court below did not identify an association member who would be injured and that it opened a circuit split by failing to identify such a person. See Danco.Pet.24. The court below did no such thing.

Moving beyond their mistaken view on harms to individual association members, Petitioners focus their other standing arguments on two points. They claim that Respondents' injuries are (1) too speculative and (2) not traceable to FDA's 2016 and 2021 actions. Petitioners are wrong on both counts.

1. Respondents' injuries are not speculative.

The Fifth Circuit recognized that Respondents are required to show that "the threatened injury is 'certainly impending,' or there is a 'substantial risk' that the harm will occur." FDA.Pet.App.14a (quoting *SBA List*, 573 U.S. at 158 (quoting in turn *Clapper*, 568 U.S. at 414 n.5)). And the court was surely correct when it held that a "substantial risk" does not require that the threatened injury be "literally certain." *Id.* at 15a (citing *Clapper*, 568 U.S. at 414 n.5). See also *Massachusetts* v. *EPA*, 549 U.S. 497, 526 n.23 (2007) ("Even a small probability of injury is sufficient … provided of course that the relief sought would, if granted, reduce the probability.") *Lujan* v. *Defs. of Wildlife*, 504 U.S. 555, 564 n.2 (1992) (acknowledging imminence "is concededly a somewhat elastic concept"); *Babbitt* v. *United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (requiring plaintiff to

"demonstrate a realistic danger of sustaining a direct injury"); *Kolender* v. *Lawson*, 461 U.S. 352, 355 n.3 (1983) ("a credible threat"). Otherwise, standing for a prospective injury would never exist.

The Fifth Circuit correctly applied this Court's precedents to find "a 'substantial risk' that the harm will occur." *SBA List*, 573 U.S. at 158 (quoting *Clapper*, 568 US at 414 n.5). This was based both on FDA's own data and Respondents' testimony: "FDA's data and the Doctors' testimony show that women will continue to present to the emergency room after taking mifepristone, requiring urgent treatment." FDA.Pet.App.27a.

The data. FDA cannot deny that many women will require surgery and emergency follow-up care because of chemical abortion complications. See FDA.Pet.App.18a ("[A]bout 5–8 out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding."); see also ROA.593 ("access to health care and emergency services is critical for the safe … use of [mifepristone]"). The current Mifeprex patient agreement discloses that chemical abortion "will not work" in "about 2 to 7 out of 100 women." FDA Pet.App.18a. And according to the most updated medication guide, between 2.9% and 4.6% of women who take mifepristone end up in the emergency room. *Ibid*. Some women experience especially severe conditions, such as sepsis, hospitalization, or a blood transfusion because of heavy bleeding. *Ibid.* This data led the lower court to conclude that the need for future treatment was both "predictable and consistent." *Id.* at 27a (cleaned up).

Doctor testimony. The evidence also shows, as already discussed, that "many Doctors have already been required to treat patients experiencing complications due to mifepristone." FDA.Pet.App.27a (citing *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 102 (1983)). Drs. Johnson, Frost-Clark, and Skop, for example, each testified to treating emergency medical conditions caused by mifepristone a dozen times or more. ROA.277–82, 938, 945. Indeed, as noted above, Dr. Skop has been required to perform emergency surgery to remove embryos, fetuses, and pregnancy tissue in at least 12 different cases. FDA.Pet.App.20a–21a. These facts confirm that Respondents face a substantial risk of future injury.

Petitioners next suggest that, even if many women will need care due to chemical abortion complications, it is speculative that Respondents will be called upon to treat them. FDA.Pet.14. But as the Fifth Circuit found, Respondents have repeatedly suffered harm already and given the thousands of women who will undeniably need emergency care, it is substantially likely that Respondent doctors will be harmed again. FDA.Pet.App.26a–28a.

In fact, FDA has long acknowledged that treatment by emergency room physicians like Respondents is "*critical for the safe*" use of mifepristone. ROA.593 (emphasis added). That emergency room physicians will treat women harmed by chemical abortion drugs is not "speculative" but the *acknowledged* effect of FDA's removal of chemical abortion safeguards. See *ibid.* From the drug's initial approval to the agency's decision to allow mail-order abortions, emergency room physicians (such as named Respondent doctors) have been part of FDA's solution to chemical abortion complications.

The 2000 Approval Memorandum, for instance, acknowledges that "access to health care and emergency services *is critical for the safe* and effective use of the drug." ROA.593 (emphasis added). In determining that prescribing physicians need not have hospital admitting privileges or surgical intervention skills, that Memo relies on the "current medical practice" of "referr[ing] patients who need surgery … to a physician possessing the skills to address the problem." ROA.595. FDA thus required that the prescriber need only "direct patients to hospitals" for "emergency services." *Ibid.* It's unsurprising then that the 2016 Black Box label contemplates women seeking out emergency room treatment. FDA.Pet.App.219a (requiring prescribers to inform patients when to go to the "emergency room"). And when FDA removed the requirement that a woman see a doctor before a chemical abortion, it again relied on the "common practice for healthcare providers to provide emergency care coverage for other healthcare providers' patients." ROA.814. FDA further justified its reliance on emergency room care by explaining that hospitals frequently "employ 'hospitalists' to provide care" for other physicians' patients. *Ibid*.

Many of the named Respondents are hospitalists who work in emergency rooms. The harm caused to them by chemical abortion complications is not only predictable but embedded in FDA's plan to fill the care gap caused by removing physician visits from the chemical abortion protocol. Respondents' harm is not speculative at all but the anticipated result of FDA's decision to remove safeguards in 2016 and 2021.

One of this Court's seminal APA decisions involved a similar challenge to the U.S. Department of

Transportation's removal of a car safety standard. See *State Farm*, 463 U.S. at 29. Because the automobile manufacturers benefited from the safeguard's removal, they brought no challenge. Instead, the parties who would be responsible for remedying the injuries caused by the change—State Farm Insurance and the National Association of Independent Insurers—filed suit. *Id.* at 39. Article III standing is even stronger here where FDA has acknowledged that emergency room doctors will need to treat chemical abortion complications. ROA.595, 814.

Taking aim at a straw man, Petitioners lean on *Summers* v. *Earth Island Institute*, 555 U.S. 488 (2009), and allege that the Fifth Circuit found standing based solely on a "statistical possibility" of harm. Danco.Pet.19; FDA.Pet.15–16. This criticism misses the mark. This case is unlike *Summers* because Respondents assert "specific allegations establishing that at least one identified member had suffered or would suffer harm." 555 U.S. at 498. In *Summers*, the government conceded that standing would exist where a member alleged injury to "interests in viewing the flora and fauna," affirmed that he "had repeatedly visited [a certain park]," and expected "to do so again." *Id.* at 494. Yet "no plaintiff in *Summers* had standing because none had alleged specific plans to observe nature in one of the areas at issue." *Dep't of Educ.* v. *Brown*, 143 S. Ct. 2343, 2354 n.3 (2023).

Summers is inapposite here because, as discussed above, "testimony was offered from multiple doctors who have personally given emergency care to women suffering complications from mifepristone." FDA.Pet.App.28a (citing multiple declarations). See also *Monsanto Co.* v. *Geertson Seed Farms*, 561 U.S.

139, 153–54 (2010) (finding standing based on a "reasonable probability" and a "substantial risk" that an agency's deregulatory action would impact non-regulated parties). And it is blackletter law that "past wrongs are evidence bearing on whether there is a real and immediate threat of repeated injury." *O'Shea* v. *Littleton*, 414 U.S. 488, 496 (1974). The Fifth Circuit thus correctly held that the record "amply supports" standing because Respondents "are reasonably likely to be injured again." FDA.Pet.App.28a.

Past injuries also distinguish this case from *Clapper*, which Petitioners cite, because the plaintiffs there could not show that they already experienced the harm alleged. And *Clapper* is inapposite for another reason: the harms here are *not* based on "a highly attenuated chain of possibilities", 568 U.S. at 410, but rather on a medical reality repeatedly acknowledged by FDA. Throughout FDA's regulation of mifepristone, including the 2021 actions allowing mail-order abortions, FDA has admitted that emergency room doctors will be crucial to addressing chemical abortion complications. ROA.814.

2. Respondents' injuries are traceable to FDA's removal of chemical abortion safeguards.

The Fifth Circuit correctly determined that FDA's 2016 and 2021 actions—which include increasing gestational age, removing doctor's visits, and allowing mail-order abortion—created a substantial risk of harm to Respondent doctors and medical associations.

FDA first suggests that the harms are not traceable to its removal of chemical abortion safeguards because *women* make an independent decision to take the drugs. FDA.Pet.18 ("A patient's decision to take

the drug … is the product of independent actions"); Danco.Pet.17 (similar). But FDA is charged with protecting public health by ensuring that drugs on the market are "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. 355(d). It would be absurd to insulate an agency's deregulation of a dangerous drug simply because women reasonably rely on those actions.

Plus, standing often rests on "choices made by independent actors." FDA.Pet.App.27a (quoting *Lujan*, 504 U.S. at 562). Indeed, in *Department of Commerce* v. *New York*, 139 S. Ct. 255, 2566 (2019), this Court rejected the government's claim that harm was not traceable because it depended on the actions of third parties. Standing may depend, the Court explained, "on the predictable effect of Government action on the decisions of third parties." *Ibid.* So too here. That women will take chemical abortion drugs under the currently existing safety protocol is an entirely predictable effect of FDA's actions. Millions of women have done just that. FDA.Pet.App.26a.

Danco also suggests that traceability requires this Court to consider the number of women who will take the drug "because of" the 2016 and 2021 safeguard removals but wouldn't have taken it if those protections remained in place. Danco.Pet.21–22. Not so. The removal of those safeguards increases the risk of complications from *all* chemical abortions—not just any additional abortions that occur because the safeguards are gone. See FDA.Pet.App.36a–41a. As the Fifth Circuit stay panel noted, FDA's "virtual elimination of controls" has led to "an increasing number of women coming to the emergency room with complications from chemical

abortions." *Id.* at 215a; see also ROA.149 ("Since the 2016 Major Changes, the rate of women and girls who have suffered complications from chemical abortion and required critical medical treatment has increased and will continue to increase."). Danco's cramped traceability analysis is unwarranted.

a. The 2016 Major Changes have increased the risk of harm to Respondents.

FDA's 2016 Major Changes eliminated critical safeguards and thus predictably led to more women needing emergency care. Those changes increase the risk of harm to Respondents in three ways.

First, the risk of chemical abortion complications consistently rises with gestational age. ROA.92. It is undisputed that the need for follow-up surgery "increases with advancing gestational age through 70 days of gestation." *Medication Abortion up to 70 days of Gestation*, Am. Coll. of Obstetrics & Gynecology Clinical Practice Bulletin (Oct. 2020), https://bit.ly/3VB36vK. The U.S. study on which FDA relied to approve mifepristone, for example, found that surgical intervention was needed for 17% of women at 50–56 days' gestation and 23% of women at 57–63 days' gestation—confirming that "the regimen is less effective and the incidence of adverse events is higher" for gestational ages over 49 days. Irving M. Spitz, et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, New England J. of Med. (Apr. 30, 1998). Even the systematic review that Danco touts, Danco.Pet.6, showed a significant increase in the failure rate as the baby's gestational age increases: 1.9% failed under 7 weeks, 3.3% failed between 7–8 weeks, 4.5% failed

between 8–9 weeks, and 6.9% failed between 9–10 weeks. Melissa J. Chen and Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review*, U.C. Davis (July 2015), https://bit.ly/44wQ2vo.

Second, FDA's removal of the 14-day follow-up visit puts Respondents at an "increased risk" of treating a woman experiencing chemical abortion complications. FDA.Pet.App.37a. Without a follow-up exam by a physician, women "are simply left to report to the emergency room when they experience adverse effects." *Ibid*. Again, Dr. Skop has been required to perform emergency surgeries to remove embryos, fetuses, and pregnancy tissue in a dozen different cases, *Id.* at App.20a–21a—many of which could have been avoided if FDA had not removed the follow-up exam.

Third, the 2016 Major Changes discontinued the requirement that doctors prescribe chemical abortion. As a result, "women who use this drug cannot possibly go back to their non-doctor-prescribers for surgical abortions" and "must instead seek 'emergency care' from a qualified physician." FDA.Pet.App.210a. When emergencies occur—as FDA concedes they will—it is emergency room doctors like Respondents and their members "who must manage the aftermath." *Id.* at 217a; see also ROA.278 ("FDA's actions in 2016 and 2021 have increased the frequency of complications from chemical abortion.").

Given the myriad ways FDA's 2016 removal of safeguards increase the risk of emergency care, it is no surprise that the 2016 Black Box label requires prescribers to inform patients when they need to seek such care. FDA.Pet.App.219a. For all these reasons,

Respondents' injuries are traceable to the 2016 Major Changes.

b. The 2021 actions have increased the risk of harm to Respondents.

FDA's decision to allow mail-order chemical abortions in 2021, as the Fifth Circuit stay panel explained, "enabled women to (1) get the drug without *ever* talking to a physician, (2) take the drug without *ever* having a physical exam to ensure gestational age and/or an ectopic pregnancy, and (3) attempt to complete the chemical abortion regimen at home." FDA.Pet.App.215a. Respondent doctors testified that the increase in mail-order abortions "means that more women will suffer complications from unsupervised use of mifepristone," *id.* at 40a, "because without proper oversight, chemical abortions can become even more dangerous than when they are supervised." ROA.280. FDA's own studies confirm "there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail." ROA.836.

Realizing this, FDA knew in 2021 that its mail-order chemical abortion regimen depended on the "common practice" of healthcare providers "provid-[ing] emergency care coverage for other healthcare providers' patients." ROA.814. In other words, FDA knew that its regulatory changes would burden emergency room physicians like Respondent doctors and association members.

Mail-order chemical abortions heighten the risk for women—and thus the harms on Respondents—in at least two ways. First, it is impossible to accurately diagnose dangerous contraindications like ectopic pregnancy without an in-person doctor's visit.

FDA.Pet.App.213a. Ectopic pregnancies occur in about one out of every 50 pregnancies. *Id.* at 23a. FDA currently requires that ectopic pregnancies be excluded prior to a chemical abortion. 2023 Mifeprex Label, at 1, https://bit.ly/46Zix63. This is because chemical abortion drugs do not end an ectopic pregnancy and instead risk masking its life-threatening complications. FDA.Pet.App.23a. Delivering mifepristone through the mail "will cause some women to remain undiagnosed [for ectopic pregnancies] and at high risk for these adverse outcomes." *Ibid.*

Second, because FDA removed in-person prescribing, "many women are now being prescribed mifepristone … without a sonogram to verify the gestational age of the unborn child." ROA.288. As noted, complication risks steadily increase with gestational age, and without an in-person dispensing requirement, women may underestimate gestational age and thus take the drugs past the FDA-approved limit. ROA.149–50, 281, 958–59. If beyond ten weeks' gestation, women have higher "chances of complications due to the increased amount of tissue, leading to hemorrhage, infection and/or the need for surgeries or other emergency care." ROA.281.

Indeed, as the Fifth Circuit stay panel observed, several doctors "testified that they have seen an increasing number of women coming to the emergency room with complications from chemical abortions due to FDA's virtual elimination of controls on the dispensing and administration of the drugs." FDA.Pet.App.215a. One doctor testified that "[d]eregulated chemical abortion … increases the number of women who come to the emergency department with complications." ROA.282. Another Respondent doctor

testified that the frequency of "[t]hese emergency situations are becoming more common … as the FDA has relaxed its regulations." ROA.938. And still another testified that the frequency of complications from chemical abortion increased when FDA stopped enforcing the in-person dispensing requirement. ROA.267.

On this record, the court below had more than enough evidence to connect the challenged 2021 actions to Respondents' asserted injuries.

3. Respondents face concrete and cognizable injuries.

The Fifth Circuit properly held that increasing the instances where Respondents are called upon to facilitate an abortion (1) violates their conscience rights, (2) interferes with their medical practices by consuming limited resources, and (3) increases their exposure to malpractice actions, along with higher insurance costs. FDA.Pet.App.31a–36a. These asserted injuries are concrete and cognizable. Petitioners do not appear to contest that.

Conscience rights. Respondent doctors and medical association members, the Fifth Circuit rightly held, "face a concrete injury when they are forced to choose between following their conscience and providing care to a woman experiencing complications as a result of taking mifepristone." FDA.Pet.App.32a. As noted, Dr. Skop has provided "care in these circumstances" at least a dozen times. *Ibid.* And Dr. Francis, the CEO of Respondent AAPLOG, discussed how her colleague was required to perform an emergency surgical abortion following an unsuccessful chemical abortion despite detecting the unborn child's heartbeat. *Ibid.* This caused her pro-life

partner to feel "as though she was forced to participate in something that she did not want to be a part of—completing the abortion." *Ibid.* "And other doctors testified of fear that they or fellow physicians will be forced into similar situations." *Ibid.* This is especially true in rural areas that are more likely to be "maternity-care 'deserts'—geographical areas with limited physician availability." *Id.* at 119a. As Judge Ho explained in his concurrence below, "the harm to conscience" that Respondents face is "a paradigmatically cognizable injury" that "American law has recognized … from the start." *Id.* at 78a.

Petitioners "do not dispute that the Medical Organizations and Doctors' conscience injury is cognizable." FDA.Pet.App.32a. They instead attempt to erase those conscience harms by pointing to various federal conscience protections. FDA.Pet.17 n.2. Yet the decision below correctly concluded that the Government's position in other litigation "tend[s] to rebut the notion that Doctors are free to refuse" to complete an abortion for a "mifepristone patient[ ]." FDA.Pet.App.34a. In that other litigation, the government has argued that "when pregnant women come to a Medicare-funded hospital with an emergency medical condition, [federal law] obligates the treating physician to provide stabilizing treatment, including abortion care." Br. for Appellants at 27, *Texas* v. *Becerra*, No. 23-10246 (5th Cir. May 1, 2023) (quoting *United States* v. *Idaho*, 623 F. Supp. 3d 1096, 1109 (D. Idaho 2022)).

Closely related to these conscience harms, FDA's actions have imposed "enormous" mental and emotional distress on Respondent doctors and association members. FDA.Pet.App.34a. It grieves them to treat women and girls suffering trauma from a chemical

abortion. ROA.1157. One doctor testified that "[u]n-supervised chemical abortion is heartbreaking to me because it causes women to suffer unnecessarily, and my patients deserve quality medical care." ROA.282. This emotional injury "significantly affect[s]" the doctors' "quality of life," *Sierra Club* v. *Morton*, 405 U.S. 727, 734–35 (1972), and independently "suffice[s] for Article III purposes," *TransUnion LLC* v. *Ramirez*, 141 S. Ct. 2190, 2211 n.7 (2021); see also FDA.Pet.App.80a–83a (Ho, J., concurring and dissenting in part) (explaining that Respondents' "aesthetic injury from the destruction of unborn life" is "cognizable").

Interference with medical practice. The Fifth Circuit also correctly held that Respondent doctors and medical association members sustain "economic harm" to their "business interest[s]"—"a quintessential Article III injury"—"when they are forced to divert time and resources away from their regular patients." FDA.Pet.App.31a. (citations omitted). Because of FDA's failure to regulate chemical abortion drugs properly, Respondents have devoted significant time and resources to caring for women experiencing mifepristone's harmful effects. *Id.* at 211a. These often-complicated cases "consume crucial limited resources, including blood for transfusions, physician time and attention, space in hospital and medical centers, and other equipment and medicines." *Id.* at 119a. Forcing emergency room physicians to divert their resources to help women experiencing chemical abortion complications is not happenstance but part and parcel of FDA's plan for how to address the removal of mifepristone's critical safeguards. ROA.814.

Increased liability. The Fifth Circuit similarly concluded that Respondent doctors and medical association members "sustain a concrete injury when mifepristone patients expose them to greater liability and increased insurance costs." FDA.Pet.App.31a. This is because FDA's deregulatory actions raise the likelihood of doctors finding themselves in "riskier, emergent medical situations," exposing them to "increased claims of liability." ROA.255; see also ROA.960 ("FDA's deregulation of these dangerous drugs increases our exposure to liability."); ROA.4314 (increasing the exposure "to allegations of malpractice and potential liability, along with higher insurance costs").

Trying to avoid these harms, Petitioners suggest that to find standing here would open the floodgates to litigation. FDA.Pet.31 n.4. But their parade of horribles does not march. They do not reference other agency decisions identifying emergency room doctors as "critical" to managing complications. ROA.593. Nor do Petitioners cite other instances where agency action is so directly traceable to an injury like the forced facilitation of an elective abortion that ends the life of an unborn child. See FDA.Pet.App.35a (dismissing these parade-of-horribles concerns because of "the rigorous evidence needed to prove traceability and redressability" and "the requirement that a plaintiff be threatened with injury akin to being forced to violate his or her sincerely held conscience beliefs"). Petitioners' line-drawing concerns simply don't hold up to scrutiny.

4. Respondents have established organizational standing.

Respondent medical associations also have organizational standing, thus providing an alternative basis upon which to affirm the Fifth Circuit's ruling and an additional reason to deny review. Organizational standing exists where, as here, an entity alleges that it has diverted resources in response to unlawful action. See *Havens Realty Corp.* v. *Coleman*, 455 U.S. 363, 379 (1982) (holding that the impairment of counseling services and devotion of resources to counteract defendant's actions was an Article III injury); *Bank of Am. Corp.* v. *City of Miami*, 581 U.S. 189, 198 (2017) (recognizing that *Havens Realty* confers standing on "a nonprofit organization that spent money to combat [unlawful action]"). In *Havens Realty*, this Court held that an organization "suffered injury in fact" when racial steering practices "frustrated" its "counseling and referral services, with a consequent drain on resources." 455 U.S. at 369, 379.

Similarly here, in response to FDA's removal of the safeguards in 2016 and 2021, Respondent organizations have "recalibrated their outreach efforts to spend extra time and money educating their members" about the new dangers of mifepristone. FDA.Pet.App.126a. The organizations have been forced to divert "time, energy, and resources" away from their ordinary mission—educating the public "about the dangers of surgical abortion, the conscience rights of doctors, and the sanctity of life at all stages," ROA.164–66—and instead "conduct[ ] their own studies and analyses of the available data" to share accurate and up-to-date information on the

risks of chemical abortions with member physicians, their patients, and the public. ROA.164.

More specifically, Respondent organizations expended "considerable time, energy, and resources" on their 26-page petition challenging the 2016 Major Changes. ROA.165. See 13A Charles Alan Wright & Arthur R. Miller, Fed. Prac. & Proc. § 3531.9.5 (3d ed. 2023) (standing exists where "organization has devoted specific effort and expense to combat the challenged activity"). And FDA's 2021 actions completely removed doctors from the administration of mifepristone and "impaired [Respondents'] ability to provide [chemical abortion] counseling" to pregnant women. *Havens Realty*, 455 U.S. at 379. These various diversions of resources have "perceptibly impaired" Respondent organizations' pro-life missions. *Ibid*. "Such concrete and demonstrable injury" to the organizations' activities—"with the consequent drain on the organization's resources—constitutes far more than simply a setback to [their] abstract social interests." *Ibid*. It establishes an "injury in fact." *Ibid*.

The organizational harm here fits squarely within both this Court's precedent under *Havens Realty* and lower court caselaw. For example, the Fifth Circuit found standing for an organization that "calibrated its outreach efforts to spend extra time and money educating its members … how to avoid the[ ] negative effects" of challenged government action. *OCA-Greater Houston* v. *Texas*, 867 F.3d 604, 610 (5th Cir. 2017). Other circuits have found organizational standing in similar circumstances. See, e.g., *Fort Lauderdale Food Not Bombs* v. *City of Fort Lauderdale*, 11 F.4th 1266, 1287 (11th Cir. 2021) (organization had standing to challenge ordinance

restricting its "food-sharing demonstrations to criticize society's allocation of resources between food and war" because "volunteers who would have normally worked on preparing for food-sharing demonstrations had to divert their energies to advocacy activities"); *Nnebe* v. *Daus*, 644 F.3d 147, 156–57 (2d Cir. 2011) (taxi drivers' alliance had standing because it was forced to divert resources in counseling and assisting drivers threatened with summary suspension); *Crawford* v. *Marion Cnty. Election Bd.*, 472 F.3d 949, 951 (7th Cir. 2007) (political party had standing to challenge voting law because it caused party "to devote resources" to getting supporters to the polls).

Petitioners suggested below that circuit precedent on organizational standing excludes harm related to litigation preparation. But the resource expenditures here—including the petition challenging the 2016 Major Changes—were not made in anticipation of litigation. Rather, because REMS are never subject to notice and comment, the petition was the only means available for Respondents to inform the agency of their concerns.

Organizational standing provides another basis upon which Respondents may press their claims.

B. FDA's 2016 Major Changes and 2021 actions violated the APA and the FDCA.

FDA cannot avoid judicial accountability for its failure to comply with the APA and other federal laws. No agency is above the law. All six judges that have opined on the merits of this case below have agreed that FDA's 2016 Major Changes and 2021 actions were unlawful. FDA.Pet.App.4a, 151a, 185a, 236a. These rulings faithfully follow the well-traveled path of this Court's previous APA decisions.

1. The APA and the FDCA provide the relevant legal framework.

The APA "sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts." *Dep't of Homeland Sec.* v. *Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020) (cleaned up). Under the APA, "arbitrary" and "capricious" agency actions are unlawful. 5 U.S.C. 706(2)(A). At its most basic, the "arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *Prometheus*, 141 S. Ct. at 1158. Under this Court's seminal decision in *State Farm*—a case FDA never cites—an agency must "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." 463 U.S. at 43 (cleaned up). And an action is arbitrary and capricious when an agency "relie[s] on factors which Congress has not intended it to consider, entirely fail[s] to consider an important aspect of the problem, [or] offer[s] an explanation for its decision that runs counter to the evidence before the agency." *Ibid.*

The APA also requires courts "to determine whether the agency [action] conformed with controlling statutes." *Balt. Gas & Elec. Co.* v. *Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 97 (1983). And the APA "requires federal courts to set aside federal agency action that is 'not in accordance with law,' 5 U.S.C. § 706(2)(A)—which means, of course, any law, and not merely those laws that the agency itself is charged with administering." *FCC* v. *NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003).

The FDCA requires that any supplemental drug application (sNDA) include "adequate tests," "[ ]sufficient information," and "substantial evidence" that show the drug is safe and effective. 21 U.S.C. 355(d). If the sNDA fails to meet *any* of these requirements, FDA cannot approve it. *Pharm. Mfg. Rsch. Servs., Inc.* v. *FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020). Moreover, those tests, information, and evidence must demonstrate the safety and effectiveness of the drug "for use under the conditions prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. 355(d). In other words, the FDCA "require[s] the FDA to determine that the product itself is safe *as used by consumers*." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000) (emphasis added and removed).

2. FDA's 2016 Major Changes violated federal law.

At Danco's request, FDA announced sweeping changes to the chemical abortion drug regimen in 2016, including (1) increasing the maximum gestational age from seven weeks to ten, (2) allowing non-doctors to prescribe and administer chemical abortions, (3) decreasing the mifepristone dose from 600 mg to 200 mg, (4) increasing the misoprostol dose from 400 mcg to 800 mcg, (5) amending the misoprostol administration period from 48 hours to 24–48 hours, (6) allowing a repeat 800 mcg dose of misoprostol, (7) switching to buccal administration of misoprostol, (8) removing the Day 3 in-person administration requirement for misoprostol, (9) eliminating the Day 14 in-person follow-up examination to identify complications, and (10) removing the require-

ment that prescribers report non-fatal adverse events. FDA.Pet.App.10a.

FDA appropriately categorized these modifications as both "major" and "interrelated." FDA.Pet.App.10a. Yet FDA acknowledges that *none* of the studies on which it relied evaluated the safety and effectiveness of the 2016 Major Changes as a whole or evaluated the safety of the drugs under the labeled conditions of use. *Id.* at 53a; ROA.128. The 2016 Major Changes violate the APA in at least five ways.

First, FDA "fail[ed] to consider an important aspect of the problem." FDA.Pet.App.52a; see *State Farm*, 463 U.S. at 43 (requiring agencies to consider "important aspects of the problem"). "The cumulative effect of the 2016 Amendments is unquestionably an important aspect of the problem." FDA.Pet.App.53a. Indeed, FDA admitted this problem when it acknowledged that the 2016 Major Changes were "interrelated." *Id.* at 10a. Yet "FDA failed to address the cumulative effect at all." *Id.* at 54a. That failure, as both Fifth Circuit panels recognized, was arbitrary and capricious. *Id.* at 52a–54a (merits panel); *id.* at 236a (stay panel).[3]

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[3] FDA is wrong to suggest this challenge was unexhausted. FDA.Pet.23. The 2019 Citizen Petition explained how these interrelated changes impacted each other and the overall safety of the drug regimen. ROA.747. For example, changing the route and timing of misoprostol administration while removing the two follow-up office visits further exacerbated the risks to women's safety. *Ibid.*

Second, FDA gave no "satisfactory explanation for" its decision to ignore the cumulative effect of the 2016 Major Changes. See FDA.Pet.App.52a; *State Farm*, 463 U.S. at 43. Nowhere does FDA explain why it could reasonably presume overall safety of the sweeping, interrelated changes by examining each change separately. Logical leaps require satisfactory explanations. Left unspoken, they render agency actions arbitrary and capricious.

Third, FDA neglected to provide a satisfactory explanation for its reliance on studies that included additional safeguards like ultrasounds and follow-up visits. The APA demands more—indeed, an agency must "acknowledge the question, determine if the evidence before it adequately satisfied the concern, and explain its reasoning." FDA.Pet.App.54a. FDA did none of that here, but rather "eliminated … safeguards based on studies that *included those very safeguards*." *Id.* at 235a. That is arbitrary and capricious.

Fourth, FDA failed to consider "relevant factors" embodied in the governing statutes. *State Farm*, 463 U.S. at 43. The FDCA requires adequate tests, sufficient information, and substantial evidence showing the safety and effectiveness of the 2016 Major Changes *under the conditions of use in the proposed labeling*. 21 U.S.C. 355(d). But FDA ignored this statutory requirement because none of the studies evaluated the safety of the regimen under the labeled conditions of use. These studies all included safeguards and conditions not found under the approved label. *Ibid.* The APA required FDA to consider the relevant factors and explain how the studies in its possession could meet the FDCA's safety requirements. *State Farm*, 463 U.S. at 43. But the

2016 Major Changes did not consider or discuss these relevant statutory factors.

For example, FDA relied on a study to support extending the maximum gestational age to ten weeks. ROA.128–29; see also FDA.Pet.23 (citing Winikoff et al. 2012 study). Yet the abortion providers in the study (1) confirmed gestational age "based on routine ultrasound practices," (2) required follow-up visits "for clinical assessment, which included ultrasonography," and (3) "intervened surgically if they deemed it medically necessary or at the patient's request." ROA.1126. The 2016 Major Changes did not require any of these safeguards. In fact, all the studies FDA cited in its Summary Review document, which FDA said "serve[d] as the Division's decisional memorandum," ROA.701, included safeguards *not* included in the new labeling, ROA.4232–46.

Fifth, FDA's decision to eliminate the requirement for prescribers to report nonfatal adverse events was another "important aspect that FDA failed to consider" or adequately explain. FDA.Pet.App.54a. FDA's only rationale for removing this requirement was that "after 15 years of reporting serious adverse events, the safety profile for [mifepristone] is essentially unchanged." *Ibid.* "But FDA failed to account for the fact that it was about to significantly loosen mifepristone's conditions for use." *Id.* at 55a. Indeed, "[a]t no point during the decision did the agency acknowledge that the 2016 Amendments might alter the risk profile." *Ibid.* Petitioners respond by noting that the drugs' sponsors must still report adverse events FDA.Pet.24; Danco.Pet.28. But that does not save FDA. Nowhere near America's emergency rooms, the sponsor companies rely entirely

on others to report, and those others have no obligation to report nonfatal adverse events.

Continuing its theme, FDA argues that courts should paper over its failures because they owe "significant deference" to the agency's "expertise" and must not "unduly second-guess" its decisions. FDA.Pet.21, 27. But "unless [the Court] make[s] the requirements for administrative action strict and demanding, *expertise* … can become a monster which rules with no practical limits on its discretion." *State Farm*, 463 U.S. at 48 (cleaned up). No matter an agency's expertise, this Court has "frequently reiterated that an agency must cogently explain why it has exercised its discretion in a given manner." *Ibid*. And "[i]f judicial review is to be more than an empty ritual, it must demand something better" than what FDA gave in this case. *Dep't of Com.*, 139 S. Ct. at 2576.

FDA next contends that it had "a voluminous body of medical evidence on the widespread use of mifepristone over decades." FDA.Pet.22. Yet none of that evidence is germane to whether the 2016 Major Changes complied with the APA. Danco also references "dozens of studies that addressed various combinations of the changes." Danco.Pet.28. But none evaluated the 2016 Major Changes as a whole or under the labeled conditions of use. At a minimum, FDA was required to explain how it could justify the safety of the new regimen based on the cited studies. But it didn't even bother to do that.

In the end, Petitioners resort to general language from unrelated cases, like *Garland* v. *Ming Dai*, 141 S. Ct. 1669 (2021), and *Prometheus*. FDA.Pet.21–24; Danco.Pet.27, 29. Neither case rescues Petitioners. Citing to *Ming Dai*—a non-APA case on adverse

credibility determinations under the Immigration and Nationality Act—FDA argues it need not "incant 'magic words'" to justify its 2016 Major Changes. FDA.Pet.23–24 (quoting *Ming Dai*, 141 S. Ct. at 1679). True enough, but FDA *did* need to adequately explain why it was appropriate to extrapolate from the cited studies—something it wholly failed to do.

Prometheus likewise provides no lifeline. There, the Court held that the FCC did not act arbitrarily when repealing three media ownership rules "based on the sparse record evidence." *Prometheus*, 141 S. Ct. at 1160. Crucial to that holding was the Court's conclusion that "nothing in the Telecommunications Act (or any other statute) requires the FCC to conduct its own empirical or statistical studies before exercising its discretion." *Ibid*. The FDCA is quite different. It demands that an application include adequate testing, sufficient information, and substantial evidence of safety and effectiveness under the proposed labeling. 21 U.S.C. 355(d). When a drug manufacturer fails to meet any of these requirements, FDA must reject the application. *Ibid*. Petitioners may look with envy at FCC's reliance on sparse record evidence, but that case cannot save FDA from its separate statutory obligations.

3. FDA's 2021 actions violated federal law.

FDA's 2021 actions authorizing mail-order chemical abortions also violated the APA and the FDCA. The agency relied on three sources for those actions: (1) FDA's FAERS database; (2) sponsors' reports of adverse events; and (3) published literature. ROA.827. None supports the agency's decision here.

FAERS database. The Fifth Circuit correctly concluded that FDA erred by "g[iving] dispositive weight to adverse-event data in FAERS—despite the uncontested limitations of doing so." FDA.Pet.App.59a. In support of its claim that in-person dispensing of mifepristone is unnecessary, FDA relied on the "small" number of adverse events voluntarily reported in the FAERS database. ROA.827–28. But "[i]t's unreasonable for an agency to eliminate a reporting requirement for a thing and then use the resulting absence of data to support its decision." FDA.Pet.App.236a. "This ostrich's-head-in-the-sand approach is deeply troubling." *Ibid.*

What's more, any reliance on the frequency of adverse events reported to FAERS ignores FDA's own warnings about the database's substantial "limitations." ROA.845. FDA concedes that "FAERS data cannot be used to calculate the incidence of an adverse event … in the U.S. population." FDA.Pet.App.59a. This is because FDA "does not receive reports for every adverse event … that occurs with a product." ROA.847. And Respondents offered testimony explaining why many physicians do not report to FAERS the adverse events that they treat. FDA.Pet.App.60a–61a. Yet FDA failed to adhere to its own warning when authorizing mail-order chemical abortions. ROA.827–28.

Sponsors' data. In approving mail-order chemical abortion, FDA also relied on adverse event data from the drug sponsors. FDA.Pet.App.61a. But no one is required to report nonfatal adverse events to the sponsors. Not surprisingly, then, the sponsors' report mirrors what's found in FAERS. *Ibid*. That the sponsors "submitted identical data" to FAERS "tends to confirm the assertion that FDA lacked sufficient

information; it shows that neither FDA nor Danco had the means to collect data directly from prescribers." *Ibid.*

Published literature. Nor was it reasonable, the Fifth Circuit correctly concluded, "for FDA to depend on the published literature to support its decision" to allow mail-order abortion. FDA.Pet.App.63a. Indeed, FDA conceded that (1) "the ability to generalize the results of the[ ] studies to the United States population is hampered," (2) "the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes with regard to both safety and efficacy," and (3) the agency "did not find any large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States." *Id.* at 62a.

Given these limitations, FDA admitted that the studies it reviewed are "*not adequate on their own* to establish safety of the model of dispensing mifepristone by mail." FDA.Pet.App.63a (emphasis added). In fact, "the literature suggests there may be *more frequent ED/urgent care visits* related to the use of mifepristone when dispensed by mail." ROA.837. (emphasis added). Most troubling, FDA's reliance on these studies had its obligations under the FDCA backwards. The agency relied on the studies despite acknowledging that they were only "*not inconsistent with [the] conclusion* … mifepristone will remain safe." FDA.Pet.App.57a (emphasis added).

FDA's reliance on such flawed datasets to justify permanently removing the in-person dispensing requirement was arbitrary and capricious under the APA. This decision ignored the relevant facts and "the relevant factors." *State Farm*, 463 U.S. at 43. FDA's

explanations were not just unsatisfactory; they ran "counter to the evidence" that the agency cited. See *ibid.* Nor did FDA come close to meeting the FDCA's strict requirements that adequate tests, sufficient information, and substantial evidence show the safety and effectiveness of the new drug regimen. See 21 U.S.C. 355(d).

Given the lack of evidence that abortion by mail is safe, FDA again retreats to the "significant deference" supposedly owed it by the courts. FDA.Pet.21. FDA says that—like the FCC—it should be allowed to make "a reasonable predictive judgment" based on "sparse record evidence." *Prometheus*, 141 S. Ct. at 1160. FDA.Pet.27; see also Danco.Pet.29. Yet an agency may not defend its decision based on studies failing to confirm that "mifepristone would be safe if the in-person dispensing requirement were removed." FDA.Pet.App.62a. Make no mistake that FDA's plea for "significant deference" on this record effectively asks the judiciary to shirk its statutory duty to hold agencies accountable to the APA.

C. FDA's actions also violate the Comstock Act.

The Comstock Act prohibits the mailing or delivery of "[e]very ... drug … which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion." 18 U.S.C. 1461. This longstanding statute also forbids a person from "knowingly us[ing] any express company … other common carrier or interactive computer service" to ship "any drug ... designed, adapted, or intended for producing abortion." 18 U.S.C. 1462.

FDA's 2021 actions authorize the dispensing of mifepristone through the mail. But "the mailing of a

drug" to bring about an abortion is "precisely what the Comstock Act prohibits." FDA.Pet.App.100a (Ho, J., concurring and dissenting in part) (cleaned up); see also ROA.2849–2864 (amicus brief on Comstock Act).

Petitioners made a grab-bag of contrary-to-text arguments below. But each of them fails. Concerning FDA's claim that the Comstock Act applies only to "unlawful abortions," Congress in 1978 considered—and rejected—an amendment limiting the law to "illegal abortions." See H.R. 13959, 95th Cong. §§ 6701(a)(2), 6702(1)(C)(i) (1978); see also Rep. of the Subcomm. On Crim. Just. On Recodification of Fed. Crim. L., H.R. Rep. No. 95-29, pt. 3, at 42 (1978) (explaining that the amendment would "change[ ] current law by requiring proof that the relevant material or object to be used to produce an illegal abortion" under state law). Nor does the prior-construction canon help Petitioners because a smattering of conflicting court of appeals decisions do not establish an authoritative judicial interpretation. See, e.g., *Bours* v. *United States*, 229 F. 960, 964 (7th Cir. 1915) ("[T]he word 'abortion' … indicat[es] a national policy of discountenancing abortion as inimical to the national life").

By permitting mail-order chemical abortion in violation of the Comstock Act, FDA did not act "in accordance with law." 5 U.S.C. 706(2)(A). This violation provides another basis for the Fifth Circuit's ruling on FDA's 2021 actions and is therefore an additional reason to deny review.

D. The lower courts issued an appropriate remedy.

Ruling for Respondents, the district court invoked its authority under 5 U.S.C. 705 to "postpone the

effective date" of FDA's unlawful 2016 and 2021 actions pending full judicial review. FDA.Pet.App.194a–95a. The district court also clarified that "it alternatively would have ordered [FDA] to suspend" the 2016 and 2021 actions "until [it could] render a decision on the merits." *Id.* at 195a. The Fifth Circuit correctly affirmed that relief. *Id.* at 70a, 74a.

"[U]nsupported agency action normally warrants vacatur." *Advocs. for Highway & Auto Safety* v. *Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1151 (D.C. Cir. 2005). Vacatur is a "less drastic remedy" than an injunction, *Monsanto Co.*, 561 U.S. at 165–66, "because vacatur does not order the defendant to do anything; it only removes the source of the defendant's authority, FDA.Pet.App.70a (citing *Nken* v. *Holder*, 556 U.S. 418, 428–29 (2009)). Just as a district court has authority to enter "a preliminary injunction [as] the temporary form of a permanent injunction," it may also enter "a stay [as] the temporary form of vacatur." *Ibid.* The district court did not err here by choosing this more limited form of relief.

Petitioners argue that the lower court should have remanded the actions to the agency *without vacatur or stay*. FDA.Pet.29–30; Danco.Pet.32. But in recent mifepristone-related litigation, FDA took the opposite position—that "when a party prevails on its APA challenge, the proper remedy—*even in the context of a preliminary injunction*—is limited only to vacating the unlawful action." Defs.' Resp. in Opp'n to Pl. States' Mot. Prelim. Inj. at 32, *Washington* v. *FDA*, No. 1:23-cv-03026 (E.D. Wash. Mar. 17, 2023), ECF No. 51 (cleaned up) (emphasis added).

A remand without vacatur is appropriate only "when there is at least a serious possibility that the agency will be able to substantiate its decision given an opportunity to do so." *Cent. & S.W. Servs., Inc.* v. *EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (cleaned up). Otherwise, such a remedy would "invite[ ] agency indifference." *In re Core Commc'ns, Inc.*, 531 F.3d 849, 862 (D.C. Cir. 2008) (Griffith, J., concurring). A remand without vacatur is not fitting here because "'it is far from certain' that FDA could cure its mistakes with further consideration." FDA.Pet.App.72a. Indeed, FDA has been given plenty of opportunities and time to bring forth explanations and data to address its unlawful actions. Yet to date, the agency has failed to produce sufficient evidence or satisfactory explanations.

In addition, Respondents have satisfied the traditional factors supporting the district court's alternative preliminary injunction. FDA.Pet.App.69a ("The Medical Organizations and Doctors therefore satisfy the remaining preliminary-injunction factors."). Respondents' harms are "irreparable" because "[n]o legal remedy can adequately redress the Doctors' conscience and mental-distress injuries." *Id.* at 64a. In contrast, the district court's "limited relief" "threatens neither FDA nor Danco with substantial harm." *Id.* at 65a, 69a. Women will retain access to, and Danco can still sell, mifepristone under the modest and common-sense protections—like the oversight of a physician—that governed the drug for over sixteen years. The equities thus favor Respondents. *Id.* at 63a–69a. So do public-interest considerations, which are "disserved by a drug that does not afford adequate protections to its users." *Id.* at 69a.

CONCLUSION

This Court should deny the petitions.

Respectfully submitted,

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