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 Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR THE RESPONDENTS

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QUESTIONS PRESENTED

In 2000, the Food and Drug Administration (FDA) approved the high-risk abortion drug mifepristone and imposed critical safety requirements on its use. Yet in 2016, FDA stripped away most of those standards without any study evaluating the changes under the new conditions of use and without a reasonable explanation. Then, in 2021, FDA allowed prescribers to give these drugs to women without an initial in-person visit. It did so based on adverse event data that it elsewhere recognizes as unreliable and studies that it considered inadequate. The questions presented are:

1. Whether doctors and medical associations have Article III standing to challenge FDA's removal of drug-safety standards where (1) the doctors are OB/GYN hospitalists, on-call OB/GYNs, and emergency-room physicians who have suffered repeated injuries, (2) FDA admits 2.9 to 4.6 percent of women who take abortion drugs end up in the emergency room, (3) FDA directed women harmed by abortion drugs to emergency rooms, and (4) FDA's 2021 and 2016 actions have increased the substantial risk of harm to these doctors and their patients.

2. Whether FDA violated the APA by (1) relying on admittedly unreliable information and inadequate studies to remove the initial in-person visit in 2021, (2) failing to evaluate the safety of the 2016 changes as a whole under the conditions of use in the proposed labeling, and (3) failing to reasonably explain its 2021 and 2016 actions.

3. Whether the lower courts properly granted preliminary relief.

CORPORATE DISCLOSURE SATEMENT

Petitioner organizations—Alliance for Hippocratic Medicine, American Association of Pro-Life Obstetricians & Gynecologists, American College of Pediatricians, and Christian Medical & Dental Associations—have no parent corporations, and no publicly held corporation owns 10 percent or more of the stock of any of them.

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INTRODUCTION

No agency is above the law. Congress gave federal courts the authority—and obligation—to review the actions of agencies that regulate nearly "every nook and cranny of daily life." *City of Arlington* v. *FCC*, 569 U.S. 290, 315 (2013) (Roberts, C.J., dissenting). FDA's insistence that this Court cannot check its work runs counter to the Administrative Procedure Act (APA). Judicial review ensures that an agency doesn't "become a monster which rules with no practical limits." *Burlington Truck Lines* v. *United States*, 371 U.S. 156, 167 (1962) (cleaned up). Giving such unfettered power to FDA—an agency whose actions "affect every citizen," 42 Fed. Reg. 4680, 4680 (Jan. 25, 1977)—is particularly problematic. Turning a blind eye to FDA's patently unreasonable actions here, which jeopardize women's health throughout the nation, would be unprecedented.

Petitioners spend the bulk of their briefs erecting procedural roadblocks. None are persuasive. Respondent doctors and medical associations have standing. In removing crucial safeguards for the use of abortion drugs, FDA expressly counted on OB/GYN hospitalists and emergency-room doctors—like Respondents—to manage abortion-drug complications. When faced with these emergencies, Respondents have no choice but to provide immediate treatment, even though this kind of participation in an elective abortion harms their consciences and injures them in other ways. Had FDA retained the safeguards that it called "necessary" and "minimally burdensome" just a few years ago, it could have prevented many of these emergency events. It instead shifted the burden to OB/GYN hospitalists, emergency-room doctors, and on-call OB/GYNs. This is no ordinary agency action.

Petitioners barely defend the merits of FDA's 2021 and 2016 actions. For good reason. In 2021, FDA withdrew the initial in-person office visit—the opportunity to screen for ectopic pregnancies and other dangerous conditions—based on data and studies that the agency acknowledged were insufficient and inadequate. And in 2016, the agency removed numerous interrelated safeguards without studies examining the changes as a whole or explaining why cumulative studies were unnecessary. These arbitrary and unreasonably explained agency actions fall far short of what the APA requires. This Court should affirm.

STATEMENT OF THE CASE

Since the introduction of abortion drugs into the United States, FDA has conscripted OB/GYNs, OB/GYN hospitalists, and emergency-room doctors into addressing serious complications caused by these drugs. FDA's removal of safety standards that the agency once deemed essential increases the likelihood of women needing emergency medical treatment.

A. FDA's approval of mifepristone with safeguards

The Food, Drug, and Cosmetic Act (FDCA) requires FDA to ensure that approved drugs are "safe and effective." 21 U.S.C. 355. Under the FDCA, the agency must reject an application or modification for a drug unless "adequate tests," test "results," and "[ ]sufficient information" demonstrate the drug safe for use "under the conditions … in the proposed labeling." 21 U.S.C. 355(d) (initial approval); 21 C.F.R. 314.71 (modification).

In 2000, FDA approved a two-drug abortion regimen: mifepristone—also known as "RU-486" and "Mifeprex"—and misoprostol. J.A. 18, 39. Mifepristone blocks nutrition to the developing baby. J.A. 18. And misoprostol induces contractions to expel the unborn child from the mother's womb. *Ibid.* Respondents refer to this abortion regimen as chemical abortion.

FDA concluded that mifepristone could not be "safely used" without special measures. J.A. 230. FDA limited the drug's approved use to seven weeks' gestation or less. J.A. 234. Prescribers needed to be licensed doctors able to diagnose ectopic pregnancies and accurately determine gestational age. J.A. 230. And doctors were required to provide ongoing in-person care: (1) the Day 1 in-person administration of mifepristone; (2) the Day 3 in-person administration of misoprostol; and (3) the Day 14 visit to check for complications. J.A. 226–27, 230. FDA emphasized that the Day 3 visit ensured the doctor would "provide ongoing care," J.A. 227; and the Day 14 visit was "very important to confirm by clinical examination or ultrasonographic scan" that the abortion was complete, 2000 Mifeprex Label 15, https://perma.cc/3V7C-SU6Q.

FDA acknowledged that "the percentage of women who considered any particular adverse event as severe ranged from 2 to 35%." *Id.* at 12. FDA also included a Black Box warning to alert women that "surgical intervention may be necessary" and inform them of "what to do in the event of an emergency." J.A. 226.

Given the potential for serious adverse events, FDA recognized that "access to … emergency services

is critical for the safe and effective use of the drug." J.A. 227 (emphasis added). FDA required doctors "to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary." J.A. 230. The drug was "contraindicated" where "access to emergency services" was "[in]adequate." J.A. 229. And FDA required prescribing physicians without the ability to perform emergency services to "direct" women "to a hospital for emergency services." *Ibid.*

B. Challenges and changes to FDA's 2000 approval

In 2002, Respondents American Association of Pro-Life Obstetricians & Gynecologists (AAPLOG) and Christian Medical & Dental Associations (CMDA) submitted a citizen petition asking FDA to rescind the 2000 approval (2002 Citizen Petition). J.A. 44–49.

Before the agency responded, FDA and Danco agreed that Danco would issue a "Dear Emergency Room Director" letter to "assist [ER Directors] in taking care of patients who may present in an emergency room setting" after taking abortion drugs. Danco Letter 1 (Nov. 12, 2004), https://perma.cc/734R-LLSQ. The letter warned that "there may be some women who present to an emergency room with serious and sometimes fatal infections and bleeding" or ruptured ectopic pregnancies. *Ibid.*

In 2007, Congress enacted the Food and Drug Administration Amendments Act (FDAAA). Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, tit. IX § 909(b)(1), 121 Stat. 823, 950. The FDAAA requires a risk evaluation and mitigation

strategy (REMS) whenever FDA determines it "necessary to assure safe use of the drug, because of its … potential harmfulness" and association "with a serious adverse drug experience." 21 U.S.C. 355-1(f)(1). Drugs like mifepristone previously approved with added safeguards were temporarily "deemed to have in effect an approved [REMS]." Pub. L. No. 110-85 at § 909(b)(1).

In 2011, FDA approved a REMS for mifepristone. ROA 671–75. The REMS and accompanying materials "incorporated the restrictions under which the drug was originally approved." J.A. 296. FDA found that three in-person visits remained necessary. J.A. 276. The agency explained that a woman should take mifepristone only after receiving in-person counseling and "getting a physical exam" to diagnose ectopic pregnancies and gestational age at the Day 1 office visit. *Ibid*. FDA also required women to "return to [their] provider on Day 3 and about Day 14." J.A. 277.

The 2011 REMS materials warned that women should not take mifepristone if they "cannot easily get emergency medical help [for] 2 weeks" after taking the drug. J.A. 276. The REMS required prescribers "to assure patient access to appropriate medical facilities," J.A. 272, "equipped to provide blood transfusions and resuscitation, if necessary," J.A. 278. Women were required to acknowledge they understood what to do if they "need emergency care due to the treatment." J.A. 280. And the agency instructed women to take the medication guide with them "[w]hen [they] visit an emergency room." J.A. 275.

In 2016, FDA rejected the 2002 Citizen Petition, 14 years after it was submitted. J.A. 238. In its denial, FDA said it would continue to rely on emergency

rooms as a backstop to "ensure that women have access to medical facilities for emergency care" to manage the expected complications. J.A. 258.

C. FDA's 2016 changes

On the same day FDA denied the 2002 Citizen Petition, the agency approved Danco's request to make "interrelated," "major changes" to mifepristone's conditions of use. J.A. 283–98. Among other things, FDA (1) eliminated the Day 3 visit for misoprostol administration, (2) removed the Day 14 visit to check for complications, and (3) increased the maximum gestational age from seven to ten weeks. J.A. 295. FDA also eliminated the requirements that prescribers be physicians and report serious non-fatal adverse events to the agency. J.A. 318–19. Meanwhile, the agency retained the requirements that providers "assure patient access to medical facilities equipped to provide blood transfusions and resuscitation" and that women have "access to appropriate emergency medical care." J.A. 391.

In making the 2016 changes, FDA did not rely on any study that evaluated the changes as a whole, J.A. 549, or explain why an analysis of the cumulative effects was unnecessary. FDA's piecemeal analysis relied on studies that included safety measures omitted under the labeled conditions of use. J.A. 548. Consider one study FDA cited. J.A. 299, 301, 304 (discussing the Winikoff study). The researchers (1) confirmed gestational age (and presumably screened for ectopic pregnancies) "based on routine ultrasound practices," (2) required the participants to return for a follow-up visit and ultrasound, and (3) "intervened surgically" if necessary or requested. ROA 727–28. But the 2016 changes did not require (1) ultrasounds

to confirm gestational age or screen for ectopic pregnancies, (2) in-person follow-up exams, let alone using ultrasonography, or (3) provider ability to perform surgical intervention. J.A. 292–320. FDA did not explain how it could determine that the new protocol was safe based on studies containing safeguards omitted from the protocol.

D. Challenges and modifications to FDA's 2016 changes

In 2019, Respondents AAPLOG and American College of Pediatricians (ACPeds) filed a citizen petition asking FDA to restore and strengthen the previous safeguards for mifepristone (2019 Citizen Petition). The petition described how the 2016 changes impacted each other and mifepristone's overall safety. J.A. 328. It also asked FDA to retain the in-person dispensing requirement. J.A. 321–47. Respondents explained that remote providers "cannot adequately evaluate patients for contraindications to the drugs," and that "[t]elemedicine abortion further distances women from the practitioners responsible for caring for them." J.A. 339–41. It is "extremely dangerous," the petition added, for women and young girls in rural areas to take mifepristone because "they will have little recourse if they face known and predictable emergency complications." J.A. 340.

One month later, FDA approved GenBioPro, Inc.'s abbreviated new drug application for generic mifepristone. J.A. 348–54. The approval explained that a generic drug "and the listed drug it references must use a single, shared system for elements to assure safe use (ETASU)" under 21 U.S.C. 355-1(i). J.A. 349. FDA thus established a single, shared system REMS

for Mifeprex and GenBioPro's generic version "called the Mifepristone REMS Program." J.A. 357.

In August 2020, FDA asked this Court to stay a lower court order enjoining the in-person dispensing and counseling requirement. Appl. for Stay, *FDA* v. *ACOG*, No. 20A34 (U.S. Aug. 26, 2020) (2020 FDA Stay Appl.). In that filing, the agency affirmed that the initial and only remaining in-person office visit was both "minimally burdensome" and "necessary" to preserve the safety of the women and girls who take abortion drugs. *Id.* at 4, 13. FDA also explained that it had reviewed "thousands of adverse events resulting from the use of Mifeprex," determined that abortion drugs continue to cause "serious risks for up to seven percent of patients," and concluded that an in-office visit was "necessary to mitigate [those] serious risks." *Id.* at 4, 7, 21. This Court granted the requested stay. *FDA* v. *Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).

E. FDA's 2021 actions

In April 2021, FDA said it would "exercise enforcement discretion" and allow "dispensing of mifepristone through the mail" during the COVID-19 pandemic. J.A. 365. Then, in December 2021, FDA denied the 2019 Citizen Petition, J.A. 374, concluded the initial in-person visit was "no longer necessary," and permanently removed it, J.A. 378.

In its petition denial, FDA continued to identify emergency medical care as the backstop for abortion-drug complications. For instance, prescribers were required to "ensure that mifepristone is prescribed [only] to women for whom emergency care is available." J.A. 411. And prescribers were not

themselves required to be able to treat life-threatening complications, just "assure patient access to medical facilities equipped to provide blood transfusions and resuscitation." J.A. 381. Recognizing that this emergency care would frequently come from OB/GYN hospitalists and emergency-room doctors, FDA observed that "[i]t is common practice for healthcare providers to provide emergency care coverage for other healthcare providers' patients, and in many places, hospitals employ 'hospitalists' to provide care to all hospitalized patients." J.A. 384.

FDA based its decision to remove the initial in-person visit on (1) adverse event reports and (2) published literature that the agency conceded was not adequate. J.A. 397.

1. Adverse event reports

FDA relied on its Adverse Event Reporting System (FAERS) database from parts of 2020 and 2021 to "conclud[e] that there d[id] not appear to be a difference" in adverse events when the in-person requirement had not been enforced. J.A. 398–99. But the agency's official position is that "the FAERS data by themselves are *not* an indicator of the safety profile of the drug." J.A. 417 (emphasis added). Indeed, FDA cautions that "[t]he number of suspected reactions in FAERS *should not be used* to determine the likelihood of a side effect occurring." *Ibid.* (emphasis added). And because "FDA does not receive reports for every adverse event … that occurs with a product," FAERS data "cannot be used to estimate the incidence (occurrence rates) of the reactions reported." *Ibid.*

What's more, FDA did not acknowledge its 2016 decision to *eliminate* the requirement that prescribers

report all serious adverse events. J.A. 398–99. The agency, instead, noted that abortion-drug manufacturers "report adverse events, including serious adverse events, to FDA." J.A. 399. But FDA did not explain how these far-removed manufacturers would learn about adverse events from OB/GYNs, hospitalists, and emergency-room doctors who are under no obligation to report. *Ibid.*; accord J.A. 128.

2. Published literature

FDA also claimed support from published literature evaluating mail-order dispensing by pharmacies and clinics. J.A. 399. Yet the agency conceded that it was unable to "generalize" the results to the United States population, and that "the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes." J.A. 400. FDA thus acknowledged that "the studies [it] reviewed are *not adequate* on their own to establish the safety of the model of dispensing mifepristone by mail." J.A. 407 (emphasis added). Instead, the studies were merely "*not inconsistent* with" FDA's conclusion that removing the initial in-person visit would be safe. J.A. 400 (emphasis added).

FDA reviewed three studies for "mail order pharmacy dispensing." J.A. 402. One (Hyland) alarmingly reported that 3 percent of the participants needed to be hospitalized—a 330 percent increase over the rate on the approved label. J.A. 403. FDA disregarded this dramatic increase, saying it could not make any "conclusions on [that study's] safety findings." *Ibid.* Another study (Upadhyay) had certain "deviations" from abortion practices in the United States, "limited follow-up information, and small sample size"—all of which "limit[ed] [its] usefulness." *Ibid.* And the third

study, an "interim analysis" (Grossman), was largely irrelevant because it evaluated outcomes for "dispens[ing] by mail-order pharmacy *after in-person clinical assessment*." J.A. 402 (emphasis added).

FDA also cited five studies that "evaluated clinic dispensing by mail." J.A. 403. In one (Raymond), "7 percent of participants had clinical encounters in [emergency department (ED)]/urgent care centers." J.A. 404. In another (Chong), "6 percent of participants had unplanned clinical encounters in ED/urgent care," and "[s]urgical interventions were required in 4.1 percent to complete abortion." *Ibid.* A third study (Anger) revealed that "12.5 percent had an unplanned clinical encounter." J.A. 404–05. In the fourth study (Kerestes), 5.8 percent in the "telemedicine plus mail group" had "ED visits," which was almost three times higher than "the in-person group." J.A. 405. And the final study (Aiken) had "significant limitations" because "investigators were unable to verify the outcomes" and "the study's design did not capture all serious safety outcomes." J.A. 406.

After reviewing these studies, FDA conceded that "the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic." J.A. 407; accord J.A. 405–06. The agency similarly acknowledged that the Anger study "suggests a preabortion examination *may decrease* the occurrence of procedural intervention *and decrease* the number of unplanned visits for postabortion care." J.A. 405 (emphasis added). Nevertheless, FDA concluded that "these studies overall support that dispensing by mail from the clinic is safe." J.A. 406.

F. Mifepristone's current labeling

FDA's current label for mifepristone continues to require a Black Box warning because the drug can cause "[s]erious and sometimes fatal infections and bleeding." J.A. 526. It also directs women to emergency rooms if one of many adverse complications arise. J.A. 527.

On that label, FDA estimates that 2.9 to 4.6 percent of women will visit the emergency room after taking mifepristone. J.A. 533. And FDA's medication guide acknowledges that as many as 7 percent of women will need surgery after taking mifepristone "to stop bleeding" or to complete the abortion. J.A. 542.

The label also warns that a prescriber must "[e]xclude [ectopic pregnancy] before treatment," J.A. 526, "because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy," J.A. 531.

G. Proceedings below

In November 2022, Respondents filed this lawsuit challenging, among other things, FDA's 2021 and 2016 actions. Pet. App. 202a.[1] Respondents are four medical associations—the Alliance for Hippocratic Medicine (AHM), AAPLOG, CMDA, and ACPeds—their doctor members, and four individual doctors. J.A. 9–10.[2] These medical professionals include OB/GYN hospitalists, OB/GYNs, and emergency-

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[1] All citations to "Pet. App." are to Case No. 23-235.

[2] References to "Respondent doctors" include both the named plaintiff doctors and the associations' physician members.

room physicians. J.A. 120, 152, 161, 172, 178, 184, 195–96. OB/GYN hospitalists "manage both high- and low-risk pregnancies and deliveries, obstetric critical care, gynecological emergencies presenting to [the] Emergency Department, and inpatient obstetric and gynecologic consultations." J.A. 152–54, 161–62. OB/GYNs similarly deliver babies, perform hysterectomies, and provide other women's health treatments, including treating complications from abortion drugs. J.A. 196.

Respondents moved for a preliminary injunction, and Danco intervened. Pet. App. 117a. The district court concluded that FDA's 2021 and 2016 actions were likely unlawful, so it stayed their effective dates under 5 U.S.C. 705, and in the alternative, imposed a preliminary injunction. Pet. App. 111a, 159a, 172a–74a, 193a–95a.

Petitioners appealed and moved to stay. A Fifth Circuit motions panel upheld the district court's ruling on the 2021 and 2016 actions. Pet. App. 196a. The panel found that "the individual plaintiffs and doctors in plaintiff associations have standing." Pet. App. 207a. It also concluded that FDA's 2021 and 2016 changes were likely arbitrary and capricious. Pet. App. 236a. Petitioners then sought, and this Court granted, a stay. Pet. App. 245a.

After full briefing and argument, the Fifth Circuit held that Respondent doctors and associations have standing. The doctors suffer harm because they have no choice but to violate "their conscience" by completing elective abortions in emergency situations and "divert[ing] time and resources away" from their regular obstetrics practice when women present with abortion-drug complications. Pet. App. 31a–32a.

"FDA's [own] data and the Doctors' testimony" establish that Respondents face a "substantial risk" of these injuries, Pet. App. 26a–27a, and FDA's 2021 and 2016 actions increase that risk, Pet. App. 36a–41a.

Exercising well-established principles of judicial review over agency actions, the court of appeals then held that the 2021 and 2016 actions likely violated the APA. Pet. App. 51a–56a, 56a–63a. For 2021, the Fifth Circuit criticized FDA for (1) "g[iving] dispositive weight to adverse event data in FAERS—despite the uncontested limitations of doing so," Pet. App. 59a, and (2) "rel[ying] on various literature relating to remote prescription of mifepristone—despite [its] admission that the literature did not affirmatively support its position," Pet. App. 61a. And for 2016, FDA failed to consider a major aspect of the problem: "the cumulative effect" of the interrelated changes. Pet. App. 53a.

This Court granted certiorari.

SUMMARY OF THE ARGUMENT

That OB/GYNs, OB/GYN hospitalists, and emergency-room physicians will often be called upon to treat abortion-drug complications is not a bug in FDA's abortion-drug plan but part of its very design. When the agency eliminated crucial safeguards in 2021 and 2016—safeguards like the ongoing care of healthcare providers—FDA justified their removal based on the availability of emergency-care coverage.

Respondent doctors have standing to challenge FDA's actions. For starters, they are facing multiple concrete injuries. As to conscience harms, Respondents object not only to taking the life of an unborn

child but also to complicity in the process of an elective abortion. That FDA does not view such participation as morally objectionable is irrelevant. In addition, the emergency situations expressly and repeatedly contemplated by FDA cause Respondents to divert time and resources away from their labor and delivery practices and increase their malpractice risks.

Respondent doctors face a substantial risk of these harms occurring. Petitioners' position that Respondents' harms are too speculative blinks reality. FDA has long recognized that emergency care is essential to handle abortion-drug complications; the agency's own numbers say that roughly one in 25 women who take mifepristone will end up in the emergency room; and Respondent doctors have testified to routinely treating women suffering abortion-drug harm. Factor in that hundreds of thousands of women take abortion drugs each year in the United States, and that FDA's own data indicates that tens of thousands of them go to the emergency room, and Respondents easily establish a "substantial risk" that these harms "will occur" again. *Susan B. Anthony List* v. *Driehaus*, 573 U.S. 149, 158 (2014) ("*SBA List*") (cleaned up).

Traceability also exists. FDA's 2021 removal of the initial in-person visit strips away the best opportunity to diagnose dangerous ectopic pregnancies and accurately assess gestational age. It's no wonder, then, that FDA cited data indicating the need for emergency care will increase without the initial in-person visit. Likewise, the 2016 changes—which increased the gestational-age limit (thereby raising the rates of failed abortions and surgical intervention) and removed the Day 3 and 14 follow-up visits—

heighten the risk that Respondent doctors must participate in elective abortions. 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.

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*, 592 U.S. 414, 423 (2021). FDA did neither here.

FDA's 2021 decision to remove the initial in-person visit was arbitrary and capricious. First, FDA relied on adverse event data from FAERS. But FDA concedes elsewhere that FAERS data cannot be used to estimate the incidence of adverse events or indicate the safety profile of a drug. Equally problematic, FDA did not recognize that it had years before *abandoned* the requirement that mifepristone prescribers report nonfatal adverse events. As the Fifth Circuit stay panel concluded, "[t]his ostrich's-head-in-the-sand approach is deeply troubling" and "unreasonable." Pet. App. 236a. Second, FDA claimed that a small set of studies supported its decision to remove the initial in-person visit. Yet the agency admitted the studies were "not adequate" for that purpose. Indeed, the best FDA could say about them was that they were "not inconsistent" with its (apparently preordained) conclusion. The 2021 action cannot stand because two admittedly insufficient rationales do not a reasoned decision make.

FDA's 2016 action fares no better. Those changes removed two of three office visits, increased the

gestational-age limit, allowed non-doctors to prescribe the drugs, and ended the requirement for prescribers to report all serious adverse events. Yet FDA failed to consider the cumulative impact of removing all these interrelated safeguards at once. And the agency failed to explain why it could extrapolate safety conclusions for its omnibus changes from studies that did not evaluate the changes as a whole. Also troubling is the agency's reliance on studies that included safety measures like ultrasound screenings and follow-up visits, even though those safeguards were not included in the approved regimen. This is not the reasoned decision-making that the APA requires.

FDA unlawfully and without adequate explanation removed safeguards it had once deemed necessary to protect women who use abortion drugs. With so much at stake, "the Government should turn square corners in dealing with the people." *Dep't of Homeland Sec.* v. *Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020) (citation omitted).

ARGUMENT

I. Respondents have standing to challenge the 2021 and 2016 actions.

A. Respondents have individual and associational standing.

Standing requires "(1) an injury in fact, (2) a sufficient causal connection," and "(3) a likelihood that the injury will be redressed." *SBA List*, 573 U.S. at 157–58 (cleaned up). The Fifth Circuit correctly held that Respondent doctors and associations have standing. See *Hunt* v. *Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977) (associational

standing exists where an identified member has standing). After discussing at length the harm suffered by Respondent doctors, the Fifth Circuit "conclude[d] that [they] have made a 'clear showing' that [they] face injury with sufficient likelihood to support entering a preliminary injunction." Pet. App. 16a.

1. Respondents face concrete harms from FDA's actions.

Article III requires an injury in fact that is "concrete." *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). "Central to assessing concreteness is whether the asserted harm has a close relationship to a harm traditionally recognized as providing a basis for a lawsuit in American courts." *TransUnion LLC* v. *Ramirez*, 594 U.S. 413, 417 (2021) (cleaned up). FDA's 2021 and 2016 actions create a substantial risk that Respondent doctors will see more women suffering emergency complications from abortion drugs, which threaten to inflict several concrete harms.

Conscience harms. FDA does not contest that Respondents' conscience harms are concrete. FDA Br. 20–21; accord Pet. App. 32a. Nor could it. "[I]ntangible harms" "traditionally recognized … in American courts" undoubtedly include conscience injuries. *TransUnion*, 594 U.S. at 425 (referencing claims based on religious exercise).

FDA instead denigrates Respondent doctors by suggesting that they object to treating "patients in need of care." FDA Br. 17. That's outrageous. Respondents object *not* to caring for patients but to participating in an elective abortion they find morally and ethically objectionable.

FDA attempts to minimize Respondents' conscience injuries, limiting them to situations where the doctor herself "terminate[s] an ongoing pregnancy." FDA Br. 24. But some Respondent doctors—including many AAPLOG and CMDA members—consider *any* participation in an elective abortion objectionable, including removing fetal parts and placental tissue. Doing so causes them "moral distress" by making them "feel complicit" in a procedure that unnecessarily ends a life. J.A. 142–43; see also J.A. 87. Dr. Francis, for example, has been forced to "finish evacuating [a patient's] uterus of the remaining pregnancy tissue." J.A. 153. She and other AAPLOG and CMDA members consider the "completion of an elective chemical abortion," including the removal of fetal remains and placental materials, to be ethically objectionable. J.A. 155. These sincerely held conscience-based objections are like others this Court has upheld. *E.g.*, *Burwell* v. *Hobby Lobby Stores, Inc.*, 573 U.S. 682, 701 (2014) (ruling for litigants who could not in good conscience provide insurance for abortion-inducing drugs).

To be sure, Respondent doctors also suffer a conscience harm when treating women "suffering complications from chemical abortion while [they are] still carrying a living fetus." J.A. 136. As Dr. Skop explains: "My moral and ethical obligation to my patients is to promote human life and health. But the FDA's actions may force me to end the life of a human being in the womb for no medical reason." J.A. 167.

It's not hard to see why doctors who consider abortion objectionable are harmed when they must complete a chemical abortion—even if the child is no longer alive. J.A. 152–54. During a dilation and curettage surgery, J.A. 136, doctors must scrape out a

patient's uterine lining with a spoon-shaped instrument to remove the unborn baby and pregnancy tissues, *Dilation and Curettage*, Johns Hopkins Medicine, https://perma.cc/M3CR-HUZZ. And for suction aspiration procedures, J.A. 163, doctors use a machine or syringe to suck the baby and pregnancy tissue into a cannister before examining its contents, Lynn Borgatta et al., *Surgical Techniques for First-Trimester Abortion*, The Alliance for Global Women's Medicine (May 2012), https://perma.cc/FLR7-RJG3.

FDA insists that nothing forces Respondent doctors to perform the procedures they deem objectionable. FDA Br. 21–23. But this ignores that FDA expressly relies on doctors like Respondents to treat emergent and life-threatening complications from abortion drugs, J.A. 384, and that Respondents facing these emergency situations must act *immediately*. *E.g.*, J.A. 172–73 ("emergency situations"); J.A. 180 ("life-threatening situations"); J.A. 142 ("life-threatening circumstances"); J.A. 120 ("emergency treatment" for heavy bleeding and sepsis); J.A. 166–67 (emergency surgery).

Respondents have treated an "unconscious" woman with "heavy bleeding" in need of a "blood transfusion," J.A. 179, women presenting with "torrential" or "extremely heavy" bleeding, J.A. 172, 180, and a woman so ill that her Uber driver took her directly from Planned Parenthood to the emergency room, J.A. 173. One doctor has treated "at least a dozen cases of life-threatening complications," J.A. 179; another has treated at least a dozen women "suffering significant bleeding," J.A. 184; and a third described the many "near misses" where women face "potentially deadly situations," J.A. 174. These emergency situations leave Respondent doctors no choice

but to participate in a process that violates their conscience.

Diverted time and resources. "[T]here is no question that [diverting one's] time is a concrete harm." *Losch* v. *Nationstar Mortg. LLC*, 995 F.3d 937, 943 (11th Cir. 2021); cf. *SBA List*, 573 U.S. at 165–66 (noting the hardship when litigants are "forced to divert significant time and resources" without deciding whether that hardship "gives rise to an Article III injury"). Respondent doctors have suffered this harm because FDA's 2021 and 2016 actions have forced them "to divert time and resources away from their regular [labor and delivery] patients"—yet another "quintessential Article III injury." Pet. App. 31a.

Respondents are pro-life OB/GYNs "committed to the care and well-being of … pregnant women and their unborn children" by assisting with their labor and delivery. J.A. 126, 152. FDA's challenged actions have redirected these doctors away from that critical labor and delivery work, compelling them to devote time and resources to facilitating elective abortions. While Respondent doctors entered their professions to bring unborn babies into the world, FDA's recklessness has caused them to reallocate their resources to facilitating processes that bring about those babies' demise.

The record is replete with examples of Respondent doctors experiencing this harm. Dr. Francis testified to being pulled away from her "primary patient responsibilities in the labor and delivery unit" and required to spend "several hours" addressing abortion-drug complications. J.A. 153–54. Dr. Skop said that when she "must perform surgery

to deal with complications from chemical abortions, this takes attention away from … multiple laboring patients" preparing to give birth. J.A. 166–67. And Dr. Wozniak testified that when she "spent a significant amount of time" with a woman "working to save her life from … [abortion] complications," her "time and attention was taken away from [her labor and delivery] patients, who also need[ed] [her] care." J.A. 174. All this constitutes concrete harm.

FDA minimizes the significance of these injuries by contending that they are part of "[e]mergency medicine." FDA Br. 27. Yet FDA misunderstands who Respondent doctors are. Most of them practice as OB/GYNs or OB/GYN hospitalists who are at times pulled into emergency situations. J.A. 152–54, 161–62, 170–74, 184, 196, 198. They normally deliver babies and perform "other women's health treatments." J.A. 152, 161, 166–67, 196. They do *not* spend most of their time in the emergency room "triaging." Contra FDA Br. 27. Only one named Respondent—Dr. Johnson—works full-time in the emergency room. J.A. 178.

Mental, emotional, and spiritual distress. Litigants have "a cognizable interest" in avoiding harm to their "well-being" and "quality of life." *Sierra Club* v. *Morton*, 405 U.S. 727, 734–35 (1972). The common law has historically protected these interests by recognizing "infliction of emotional distress" as a concrete injury. *TransUnion*, 594 U.S. at 436 n.7; accord *Rydholm* v. *Equifax Info. Servs. LLC*, 44 F.4th 1105, 1108 (8th Cir. 2022); *Perez* v. *McCreary, Veselka, Bragg & Allen, P.C.*, 45 F.4th 816, 824 (5th Cir. 2022); *Losch*, 995 F.3d at 943.

FDA's actions have forced Respondent doctors to witness and participate in the grisly process of treating abortion-drug complications—retained fetal parts, heavy bleeding, severe infections—causing the doctors mental, emotional, and spiritual distress. J.A. 87. Dr. Skop called it "heartbreaking" to watch the "suffer[ing]" caused by "[u]nsupervised chemical abortion." J.A. 167. Dr. Jester testified that these are "high-pressure … situation[s]." J.A. 198–99. And Dr. Wozniak affirmed that treating abortion-drug complications "places enormous stress and pressure on physicians and OB/Gyns who work in hospitals." J.A. 172.

If plaintiffs have an "undeniably … cognizable interest" in avoiding the distress of losing "an animal species," *Lujan* v. *Defs. of Wildlife*, 504 U.S. 555, 562–63 (1992), or even the chance to "view[ ] the flora and fauna," *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 494 (2009), then Respondent doctors have a concrete interest in avoiding heartbreaking emergency situations that require them to be complicit in a process that ends an unborn life. Pet. App. 80a–83a (Ho, J., concurring and dissenting in part) (Respondents' "aesthetic injury from the destruction of unborn life" is "cognizable"). The emotional harm Respondents suffer "suffice[s] for Article III standing." *TransUnion*, 594 U.S. at 440.

Increased liability and insurance costs. FDA's illegal actions also expose Respondent doctors to greater liability risks and increased insurance costs. Forcing the doctors to shift more time to "emergency situations ... increases [their] exposure to claims of malpractice and liability." J.A. 180. These emergent and life-threatening circumstances put Respondents

"in increasingly higher risk situations," J.A. 180, and "at increased risk of liability," J.A. 121, 142, 186.

Ongoing lawsuits demonstrate that this liability risk is not mere speculation. *E.g.*, Compl., *Dixon* v. *Dignity Health d/b/a Dignity Health Emerus – Blue Diamond*, No: A-23-877731-C (Clark County, Nev., Sept. 13, 2023) (malpractice suit against hospital and healthcare professionals over abortion drug death). And the increased risk of liability, in turn, drives up Respondents' "insurance costs." J.A. 92, 142. The Fifth Circuit correctly held that these increased risks and costs qualify as concrete harms. Pet. App. 31a–32a.

2. Respondents face a substantial risk of harm anticipated by FDA, supported by data, and confirmed by testimony.

Plaintiffs who allege future injuries satisfy Article III if there is a "'substantial risk that the harm will occur.'" *SBA List*, 573 U.S. at 158 (quoting *Clapper*, 568 U.S. at 414 n.5). As discussed above, Respondents endure various concrete injuries when women experiencing abortion-drug complications seek emergency services from them. Petitioners' primary response is that this harm is too speculative. FDA Br. 22; Danco Br. 24. That argument conflicts with (1) FDA's repeated acknowledgement that OB/GYN hospitalists and emergency-room doctors are the backstop for abortion-drug complications, (2) FDA's data confirming the frequency of those emergency-room visits, and (3) Respondent doctors' testimony that they have treated many women suffering from abortion-drug complications.

FDA's statements. From the initial drug approval in 2000 to the removal of the initial in-person visit in 2021, FDA has repeatedly confirmed that emergency-room visits are part of its solution to abortion-drug complications. FDA's 2000 approval memorandum acknowledged that "access to … emergency services *is critical for the safe* and effective *use of the drug*." J.A. 227 (emphasis added). This was so important that the labeling had "a contraindication if there [was] no access to medical facilities for emergency services." *Ibid.* And in determining that prescribing physicians need not have surgical skills, FDA depended on the "medical practice" of "referr[ing] patients who need surgery … to a physician possessing the skills," including "[r]eferral to a hospital for emergency services." J.A. 229. In fact, FDA required abortion providers unable to perform surgeries to "direct patients to hospitals" for "emergency services." *Ibid.*

To aid those emergency services, Danco issued a 2004 "Dear Emergency Room Director" warning that women may "present to an emergency room with serious and sometimes fatal infections and bleeding" or ruptured ectopic pregnancies. Danco Letter 1 (Nov. 12, 2004), https://perma.cc/734R-LLSQ. And in 2016, the agency reiterated the importance of "access to medical facilities for emergency care" to manage the expected abortion-drug complications. J.A. 258.

In 2021, when FDA permanently removed the initial in-person visit, the agency again relied on the "common practice for healthcare providers to provide emergency care coverage for other healthcare providers' patients." J.A. 384. FDA justified eliminating that initial visit because hospitals "employ 'hospitalists' to provide care" for other physicians' patients. *Ibid.* The agency even admitted "there may be more

frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail." J.A. 407.

In sum, FDA counted on OB/GYN hospitalists and emergency-room doctors like Respondents to treat women harmed by abortion drugs. The harm caused Respondents by abortion-drug complications is not just predictable; it is embedded in FDA's plan.

The data. Of the approximately one million women who obtained an abortion in the United States in 2023, over half used abortion drugs. News Release, Guttmacher Institute, *Number of Abortions in the United States Likely to Be Higher in 2023 than in 2020* (Jan. 17, 2024), https://perma.cc/2UMR-MJAR; Rachel K. Jones et al., *Abortion incidence and service availability in the United States 2020*, Guttmacher Institute (Nov. 2022), https://perma.cc/RK5L-ENUX (Guttmacher 2022 Report). According to mifepristone's current medication guide, between 2.9 and 4.6 percent of women who use the drug go to the emergency room. J.A. 533. Some experience especially severe conditions, such as sepsis, hospitalization, or a blood transfusion because of heavy bleeding. *Ibid.* Additionally, the current mifepristone medication guide discloses that "[a]bout 2 to 7 out of 100 women" taking abortion drugs "will need a surgical procedure" to "stop bleeding" or complete the abortion. J.A. 542. All this data led the Fifth Circuit to conclude that the need for emergency-room treatment is both "predictable and consistent." Pet. App. 27a (cleaned up).

Doctor testimony. Many Respondent doctors "have already been required to treat patients experiencing complications due to mifepristone." Pet. App. 27a. (citing *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 102 (1983)). Drs. Johnson, Frost-Clark, and Skop each

testified to treating emergency medical conditions caused by mifepristone a dozen times or more. J.A. 161–66, 179, 184. Dr. Skop has been required to perform surgery to remove embryos, fetuses, or pregnancy tissue in at least a dozen different cases. J.A. 163.

"[P]ast wrongs" like these "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 correctly held that the record "amply supports" standing because Respondent doctors "are reasonably likely to be injured again." Pet. App. 28a. In short, FDA's statements, its "data[,] and the [d]octors' testimony show that women will continue to present to the emergency room after taking mifepristone, requiring urgent treatment." Pet. App. 27a.

One of this Court's seminal APA decisions involved a challenge to the National Highway Traffic Safety Administration's (NHTSA) removal of car-safety standards. *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983). Because automobile manufacturers benefited from the safeguard's removal, they brought no challenge. But this Court allowed suit by the insurers who had to backstop the injuries caused by the change. *Id.* at 39. Article III standing is even stronger here where FDA *planned* that OB/GYN hospitalists and emergency-room doctors would treat abortion-drug complications. J.A. 229, 384.

Petitioners' flawed arguments. FDA says Respondent doctors' harms are "speculat[ive]" because Respondents do not prescribe abortion drugs. FDA Br. 27–28. But prescribing the drugs isn't what increases

Respondents' exposure. That harm results from FDA's removal of the safeguards. FDA's unlawful actions have left Respondent doctors "to deal with preventable emergent and life-threatening situations." J.A. 180.

Petitioners also suggest that affirming Respondent doctors' standing would open the floodgates. FDA Br. 26–27; Danco Br. 34–35. But Petitioners' parade of horribles does not march. Petitioners fail to identify any other situation where an agency acknowledged that a specific group of doctors are "critical" to managing complications caused by the removal of safety measures. J.A. 327. And none of Petitioners' hypothetical situations involve an agency action so directly traceable to a conscience injury like the forced facilitation of an abortion. Pet. App. 35a.

Danco argues that fewer than one-tenth of one percent of women who take abortion drugs experienced *any* adverse events. Danco Br. 10. But Danco arrives at this number using FAERS data that FDA warns "cannot be used to estimate the incidence (occurrence rates) of the reactions reported." J.A. 417. That argument echoes FDA's reckless suggestion that abortion drugs are as safe as ibuprofen. FDA CA5 Mot. for Stay 1. These rose-colored views of mifepristone's safety cannot be squared with FDA's own documents. As FDA told this Court a few years ago, mifepristone exposes as many as 7 percent of women to serious risks. 2020 FDA Stay Appl. 7. And the current label and medication guide say that 2.9 to 4.6 percent of women will need emergency care, and 2 to 7 percent will need surgical intervention. J.A. 533, 542. That doesn't happen with ibuprofen.

Petitioners next compare Respondents' injuries to the speculative allegations in *Clapper*. FDA Br. 21–22. That case is nothing like this one. Respondents' harms are based not on "a highly attenuated chain of possibilities," 568 U.S. at 410, but on a medical reality FDA repeatedly and expressly anticipated—that OB/GYN hospitalists and emergency-room doctors would manage abortion-drug complications. J.A. 384.

And unlike *Clapper*, the government directly imposes the injury here. As Danco notes, the surveillance statute in *Clapper* "at most authorize[d]—but [did] not mandate or direct—the surveillance that [plaintiffs] fear[ed]." Danco Br. 31 (quoting 568 U.S. at 411–12). Here, however, FDA has repeatedly *directed* women suffering complications from abortion drugs to emergency rooms. J.A. 227, 229, 258, 275–76, 278, 280, 411.

Petitioners fixate on the phrase "certainly impending" and, in so doing, distort the standard for establishing standing through future injuries. FDA Br. 21. As the Court has emphasized, litigants may establish standing through a "future injury" if "the threatened injury is 'certainly impending,' or there is a 'substantial risk that the harm will occur.'" *SBA List*, 573 U.S. at 158 (quoting *Clapper*, 568 U.S. at 414 & n.5). This standard does not require that the threatened injury be "literally certain." Pet. App. 15a (citing *Clapper*, 568 U.S. at 414 n.5). Otherwise, forward-looking relief would seldom be possible. But this Court regularly allows plaintiffs to seek such relief. *E.g.*, *Massachusetts* v. *EPA*, 549 U.S. 497, 525 n.23 (2007) ("Even a small probability of injury is sufficient … provided of course that the relief sought would, if granted, reduce the probability."); *Kolender* v. *Lawson*, 461 U.S. 352, 355 n.3 (1983) (requiring a

"credible threat"); *Babbitt* v. *United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (requiring "a realistic danger of sustaining a direct injury").

Petitioners' reliance on *Summers* is even further afield. Unlike the *Summers* plaintiffs, Respondents here assert "specific allegations establishing that at least one identified [associational] member" will suffer harm. *Summers*, 555 U.S. at 498. In *Summers*, the government conceded that standing would exist where an associational 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*, 600 U.S. 551, 566 n.3 (2023). While it might be doubtful whether a plaintiff will "stumble across" a small forest tract among the 19 million acres of United States forestland, *Summers*, 555 U.S. at 496, it is not speculative that women suffering abortion-drug complications will follow FDA's decades-long directive to seek emergency care. Nor is there any question that Respondent doctors—many of whom have treated such complications more than a dozen times—will be again placed in positions where they must address abortion-drug complications. J.A. 161–66, 178, 184.

Petitioners' flawed conscience arguments. Petitioners take special aim at the likelihood of Respondent doctors' conscience harms. FDA Br. 20–25. Those shots all miss the mark.

FDA argues that Respondents' conscience harms are unlikely because they can "refer the patient to another[ ] non-objecting doctor." FDA Br. 24. Not so.

First, as discussed above, abortion-drug complications often present as emergency situations. See *supra* at 20–21. Respondents don't have the luxury of seeking out a non-objecting colleague. Second, a non-objecting doctor will not always be onsite and available, particularly in "healthcare deserts where there are no OB/Gyn's." J.A. 155. Third, referral itself is a conscience harm for Respondent doctors who object to *any* participation in an elective abortion. See *Little Sisters of the Poor* v. *Pennsylvania*, 140 S. Ct. 2367, 2376 (2020) (alleging that self-certification accommodation burdened plaintiffs' religious exercise). FDA may not force Respondents "to assume special burdens to avoid" what harms their conscience. *Valley Forge Christian Coll.* v. *Ams. United for Separation of Church & State*, 454 U.S. 464, 486 n.22 (1982) (characterizing *Abington Sch. Dist.* v. *Schempp*, 374 U.S. 203 (1963)).

FDA alternatively contends that Respondent doctors' conscience harm is unlikely because they can "invoke federal conscience protections." FDA Br. 21. But when a woman enters the emergency room with severe complications from abortion drugs, the doctor hardly has time to invoke her federal rights. In addition, the nature and scope of federal conscience protections are far from clear. Even the government can't get its story straight. Discussing the Emergency Medical Treatment and Labor Act (EMTALA), FDA here says that the statute "imposes obligations on covered hospitals, not individual doctors." FDA Br. 23 n.3 (cleaned up). But the government told this Court a few months ago that "treating *physicians* who violate EMTALA face civil penalties and exclusion from Medicare." Resp. to Appls. for Stay 5, *Idaho* v. *United States*, No. 23A470 (U.S. Nov. 30, 2023)

(emphasis added). And the government previously argued that EMTALA trumps federal conscience protections. Defs.' Br. in Supp. Mot. to Dismiss at 27, *Texas* v. *Becerra*, No. 5:22-cv-185-H (N.D. Tex. Aug. 15, 2022), ECF No. 40. Given all this, FDA's present attempt to hide behind federal conscience protections rings hollow.

FDA not only ignores that some Respondent doctors object to any participation in an elective abortion, but also overlooks that even doctors who object only to taking the unborn baby's life are at an increased risk of harm because of FDA's actions. That's because abortion drugs taken at ten weeks' gestation—the high end of the currently approved range—fail in roughly 7 percent of cases. J.A. 538; *Medication Abortion up to 70 days of Gestation*, Am. Coll. of Obstetrics & Gynecology Clinical Practice Bulletin (Oct. 2020), https://perma.cc/52KQ-HYF9 (ACOG Gestation Bulletin); Melissa J. Chen & Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review*, U.C. Davis (July 2015), https://perma.cc/ZB7C-UNGE. And many of those women—nearly half—will need a surgical procedure to end the pregnancy. J.A. 538. Dr. Francis testified that one of her colleagues "had no choice but to perform an emergency [surgery]" to end the life of a "preborn baby [who] still had a heartbeat." J.A. 154. Other Respondent doctors are at substantial risk of that happening to them.

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In sum, FDA has spent decades directing women harmed by abortion drugs to emergency rooms. J.A. 229. Many of them have sought treatment from

Respondent doctors. Now that FDA is called to account for the harm caused, the agency cannot insist that the very treatment option it directed is somehow speculative. See *Monsanto Co.* v. *Geertson Seed Farms*, 561 U.S. 139, 153–54 (2010) (finding standing based on a "reasonable probability" and "substantial risk" that an agency's deregulatory action would impact non-regulated parties). To hold otherwise would create a hole in standing jurisprudence allowing agencies to conscript third parties into fixing problems caused by their regulatory actions without affording those parties judicial recourse.

3. Respondents' injuries are traceable to FDA's 2021 and 2016 removal of safety standards.

The Fifth Circuit correctly determined that FDA's 2021 and 2016 actions—which include increasing approved gestational age and removing all three of the in-person office visits—have directly contributed to the substantial risk of harm Respondent doctors face. Pet. App. 36a–41a.

"Article III requires no more than de facto causality." *Dep't of Com.* v. *New York*, 139 S. Ct. 2551, 2566 (2019) (cleaned up). "[T]raceability is satisfied" when third-party action contributing to the plaintiffs' harm is "likely attributable at least in part" to the challenged action. *Ibid.* See also *Khodara Env't, Inc.* v. *Blakey*, 376 F.3d 187, 195 (3d Cir. 2004) (traceability does not demand but-for causation) (Alito, J.).

Petitioners suggest Respondents' harms are not traceable to FDA's removal of abortion-drug safeguards because women make independent decisions to take the drugs. FDA Br. 22; Danco Br. 27. 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 high-risk drug because women reasonably rely on those actions. That's like denying standing to the insurers in *State Farm* because passengers ultimately made the decision to ride in a car without airbags.

Further, the independent actions of third parties do not defeat standing where they are "the predictable effect of Government action." *Dep't of Com.*, 139 S. Ct. at 2566. In *Department of Commerce*, the evidence "established a sufficient likelihood that the reinstatement of a citizenship question would result in noncitizen households responding to the census at lower rates than other groups, which in turn would … lead to many of [plaintiff states'] asserted injuries." *Id.* at 2565. Traceability was satisfied—despite independent third-party actions—because plaintiff states showed that "third parties will likely react in predictable ways" that harm plaintiffs. *Id.* at 2566. Accord *Davis* v. *FEC*, 554 U.S. 724, 734–35 (2008) (standing to challenge asymmetrical funding mechanism despite harm depending on decision of third party).

So too here. FDA's data shows the predictable effect of its actions on third parties. Roughly 500,000 women per year take abortion drugs in the United States. See Guttmacher 2022 Report, *supra*. FDA's recognition that 2.9 to 4.6 percent of mifepristone users go to the emergency room, J.A. 533, means that tens of thousands of women will end up there each year, and many of them will receive treatment from Respondent doctors. As the stay panel concluded, it is

reasonably certain "that women will continue needing [Respondents'] 'emergency care.'" Pet. App. 216a.

Danco next claims that traceability analysis may only consider the number of "additional women" who would not have been prescribed abortion drugs but for the 2021 and 2016 removal of safeguards. Danco Br. 24–25. That is wrong. As FDA recognizes, the question is whether the removal of safeguards increased the *risk* of harm from abortion drugs writ large. FDA Br. 29–30. Danco's cramped traceability analysis ignores that FDA's 2021 and 2016 actions make *every* chemical abortion more likely to result in complications necessitating emergency care. As the Fifth Circuit stay panel explained, FDA's "virtual elimination of controls" has led to "an increasing number of women coming to the emergency room with complications from chemical abortions." Pet. App. 215a; accord J.A. 171.

a. The 2021 action increased the risk of harm to Respondents.

Respondents face a substantial threat of future injury due to the increased risk caused by FDA's 2021 action. That action removed the initial in-office visit, thereby "enabl[ing] women to (1) get the drug without *ever* talking to a physician, (2) take the drug without *ever* having a physical exam to [confirm] gestational age [and rule out] an ectopic pregnancy, and (3) attempt to complete the chemical abortion regimen at home." Pet. App. 215a.

Traceability is satisfied for the 2021 action because studies *on which FDA relied* showed "more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail." J.A. 407.

According to the agency, the continued safe use of abortion drugs after removing that visit depended on the "common practice" of OB/GYN hospitalists and emergency-room doctors like Respondents "provid-[ing] emergency care coverage for other healthcare providers' patients." J.A. 384. FDA knew that eliminating the initial in-office visit—the only opportunity to physically screen for ectopic pregnancy and other contraindications—would result in more women going to emergency rooms when the inevitable complications arose.

The studies in FDA's 2021 decisional document make Respondents' case for increased harm. Almost every study FDA considered on the safety of mailing abortion drugs from a clinic raised significant concerns. The Raymond study reported that 7 percent of women will need emergency or urgent care; Chong found 6 percent will; and Kerestes said the rate of women needing emergency care was 5.8 percent. J.A. 403–06. In addition, Anger found that 12.5 percent of the women (1 out of every 8) who used these drugs without an initial in-person visit sought unplanned medical intervention. J.A. 405. According to FDA, Anger's data suggested that an in-person examination might "decrease the occurrence of procedural intervention." *Ibid.* If that weren't enough, the Kerestes study compared outcomes of women mailed abortion drugs with and without an in-person examination and found that the rate of emergency-room visits increased almost *threefold* when the in-person examination was omitted. *Ibid.*

It's not surprising that eliminating the initial in-person visit increases emergency-room visits. The removal of this safeguard heightens the risk for

women—and the harm to Respondent doctors—in two ways.

First, FDA requires that an ectopic pregnancy be ruled out before taking abortion drugs. J.A. 526. It is undisputed that an ultrasound is the best way to do that. J.A. 212–13; ACOG Practice Bulletin 193 at 2 (Mar. 2018), https://perma.cc/3AA3-CNQX ("The minimum diagnostic evaluation of a suspected ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy."). Ectopic pregnancies occur in about one of every 50 pregnancies and are "a significant cause of pregnancy-related mortality." ACOG Practice Bulletin 193 at 1. Because the "symptoms" of a chemical abortion and a "ruptured ectopic pregnancy" are similar, taking abortion drugs—which are "not effective for terminating ectopic pregnancies"—may cause women to miss "an undiagnosed ectopic pregnancy" and delay critical life-saving care. J.A. 531. Delivering mifepristone through the mail to women who have never been physically examined for contraindications "will cause some women to remain undiagnosed [for ectopic pregnancies] and at high risk for these adverse outcomes." Pet. App. 23a.

FDA tries to minimize this risk, arguing that ectopic pregnancy occurs rarely in women who use mifepristone. FDA Br. 32 n.6. But that's because ectopic pregnancies are contraindicated for abortion drugs; women with ectopic pregnancies aren't supposed to take them. J.A. 542. By eliminating the initial in-person visit, FDA denies women the best opportunity to have ectopic pregnancies diagnosed, increasing the likelihood that more women with ectopic pregnancies will take mifepristone.

Second, because FDA eliminated the requirement for an initial in-person visit, "many women are now being prescribed mifepristone … without a sonogram to verify the gestational age of the unborn child." J.A. 172. FDA acknowledges that abortion "failure rate" and thus the need for surgical intervention steadily "increase[ ] with … gestational age." J.A. 381, 538. Without an initial in-person visit, women may underestimate gestational age and take the drugs past the approved ten-week limit. J.A. 165, 196–97. Women beyond ten weeks' gestation 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." J.A. 165. In addition, as FDA told this Court just a few years ago, "in-person dispensing avoids the possibility of delay" in taking mifepristone and the increased "risks of serious complications" caused by such delay. 2020 FDA Stay Appl. 6.

Respondent doctors' unrebutted testimony corroborates that the 2021 action will contribute to their harm. One doctor testified that "[t]he increasing number of chemical abortions through mail-order or telemedicine methods means that more women will suffer complications from unsupervised use of mifepristone and misoprostol." J.A. 171. And another affirmed that "FDA's suspension of the in-person dispensing requirement … harms women and doctors because it has resulted in an increase in complications." J.A. 185.

For all these reasons, Respondents' harms are traceable to FDA's elimination of what it once viewed as necessary: the initial in-person visit.

b. The 2016 changes increased the risk of harm to Respondents.

FDA's 2016 changes also eliminated critical safeguards and increased the risk that more women taking abortion drugs will need emergency care. It did so in three ways.

First, those changes increased the gestational-age limit from seven to ten weeks. As noted, FDA concedes that "the failure rate" of abortion drugs and thus the need for surgical intervention consistently "increase[ ] with … gestational age." J.A. 381, 538. When moving from seven to ten weeks' gestation, the "failure rate" climbs from roughly 2 to 7 percent, as confirmed by FDA's label, see J.A. 538, ACOG documents, see ACOG Gestation Bulletin, *supra*, and a systematic review that FDA relied on in 2016, see J.A. 447–49 (citing Chen & Creinin, *supra*). This higher failure rate, as FDA's label indicates, increases *tenfold* the rate of "[s]urgical intervention." J.A. 538. FDA thus recognizes that up to 7 percent of "women taking Mifeprex will need a surgical procedure" to end the pregnancy, remove retained fetal parts or tissue, or "stop bleeding." J.A. 542; see also ROA 469 (study finding gestational age increases need for surgical intervention).

FDA cites its 2016 summary review to say that increased gestational age does not increase serious adverse events. FDA Br. 31. But the review omitted incomplete or failed abortions from the definition of adverse events. J.A. 468. Yet it is undisputed, as just discussed, that failure rates increase with gestational age and that failed or incomplete abortions often require surgical intervention. J.A. 381, 538, 542.

Second, FDA's removal of the Day 14 in-person follow-up visit puts Respondent doctors at an "increased risk" of treating women experiencing abortion-drug complications. Pet. App. 37a. A routine follow-up examination can uncover complications—such as retained pregnancy tissue—before they become more serious. J.A. 199–200. Removing the requirement for those visits naturally results in more women "report[ing] to the emergency room." Pet. App. 37a.

Respondent doctors have experienced this avoidable harm dozens of times, performing emergency surgeries to remove embryos, fetuses, or pregnancy tissue. J.A. 163, 179, 184. As Dr. Jester testified when discussing one woman he treated for abortion-drug complications, the "situation could have been avoided before requiring overnight hospitalization and [his patient] being at risk for developing sepsis" if "she had a routine follow-up visit, as required by past REMS." J.A. 200.

Third, the 2016 changes ended the requirement that licensed doctors prescribe and provide ongoing care to women using abortion drugs. As FDA has acknowledged, many abortion providers cannot provide life-saving surgeries and interventions. Pet. App. 217a; see also ROA 2476, 2482–83. When such emergencies occur—and FDA concedes they will—it is OB/GYNs, OB/GYN hospitalists, and emergency-room doctors like Respondents "who must manage the aftermath." Pet. App. 217a.

Given the myriad ways FDA's 2016 removal of safeguards increases the risk of and need for emergency care, Respondents' injuries are traceable to those changes.

4. Respondents' harms are redressable.

Respondents' claims are also redressable. To satisfy this requirement, plaintiffs "need not show that a favorable decision will relieve [their] *every* injury." *Larson* v. *Valente*, 456 U.S. 228, 243 n.15 (1982). A "substantial likelihood," *Duke Power Co.* v. *Carolina Env't Study Grp., Inc.*, 438 U.S. 59, 74–75 (1978), that a favorable ruling will "effectuate a partial remedy" is enough, *Uzuegbunam* v. *Preczewski*, 141 S. Ct. 792, 801 (2021). Restoring the crucial safety standards that once protected women who use abortion drugs will relieve Respondent doctors of at least some of the injuries caused by FDA's 2021 and 2016 actions.

For the 2021 action, FDA discussed studies indicating that removing the initial in-person office visit would send more women to the emergency room. See *supra* at 10–11, 35–36. The agency also conceded that keeping this visit might "decrease the occurrence of procedural intervention." J.A. 405. That is the definition of redressability. And with respect to the 2016 changes, raising the gestational age increases failure and intervention rates, J.A. 381, 538, while removing the follow-up visits leads to increased complications, J.A. 200. This, too, establishes redressability.

Danco (but not FDA) makes the counterintuitive argument that Respondents' injuries are not redressable because FDA's elimination of safeguards somehow made the drugs *safer*. Danco Br. 33 (claiming "reduced adverse events"). This argument ignores that, as FDA acknowledges, Respondents do not challenge the dosing, timing, or route of administration changes made by FDA in 2016. FDA Br. 5 n.2,

41 n.8. The regimen that includes those changes will remain available. *Id.* at 41 n.8. And in fact, providers have been using that regimen since 2001, long before the 2016 changes. J.A. 443, 446, 465.

Petitioners may suggest that Respondents' harms are not redressable because the 2019 approval of GenBioPro's generic mifepristone is not before this Court. But because the generic is "bioequivalent" to Danco's Mifeprex, the drugs "use a single, shared system for [the ETASU]." J.A. 349. So any REMS change necessarily applies to both drugs, as GenBioPro concedes. GenBioPro Am. Br. 24.

B. Respondents have organizational standing.

Respondent medical associations also have organizational standing. Under *Havens Realty Corp.* v. *Coleman*, 455 U.S. 363, 379 (1982), organizational standing exists where, as here, an organization has diverted resources in response to unlawful action. Accord *Bank of Am. Corp.* v. *City of Miami*, 581 U.S. 189, 198 (2017) (recognizing that *Havens* confers standing to "a nonprofit organization that spent money to combat [unlawful action]"). To hold otherwise would require overruling *Havens*—something Petitioners have not requested.

In *Havens*, this Court found standing where the plaintiff organization "had to devote significant resources to identify and counteract the defendant's racially discriminatory steering practices." 455 U.S. at 379 (quoting complaint, cleaned up). The unlawful practices "impaired" the organization's "ability to provide counseling and referral services." *Ibid.* "[T]here can be no question," this Court held, "that the organi-

zation ha[d] suffered injury in fact" because "[s]uch concrete and demonstrable injury to the organization's activities—with the consequent drain on the organization's resources—constitute[d] far more than simply a setback to the organization's abstract social interests." *Ibid.* (citing *Sierra Club,* 405 U.S. at 739). "That the alleged injury result[ed] from the organization's noneconomic interest in encouraging open housing d[id] not [a]ffect the nature of the injury suffered, and accordingly d[id] not deprive the organization of standing." *Id.* at 379 n.20 (citation omitted).

So too here. FDA's 2021 and 2016 actions have impaired Respondent organizations' ability to provide services and achieve their organizational missions. Removing the crucial safety standards and prescriber adverse event reporting requirements—while insisting that abortion drugs are no riskier than ibuprofen, FDA CA5 Mot. for Stay 1—downplays the potential dangers of those drugs. This "frustrates and complicates" the organizations' missions to support women's health and educate the public, their members, and their members' patients about the potential risks of abortion drugs. J.A. 119, 122–23, 133–34, 141–42, 148–49, 156–58.

FDA's actions have caused Respondent organizations to "divert limited time, energy, and resources" to "conduct[ ] their own studies and analyses of the available data" about abortion drugs. J.A. 134, 157. FDA's removal of crucial safeguards has created a false "public impression" of drug safety. *Spann* v. *Colonial Village, Inc.*, 899 F.2d 24, 30 (D.C. Cir. 1990). The same is true for the removal of the prescriber reporting requirements. Without a better reporting obligation, Respondent doctors cannot "accurately

advise their patients and the public about these risks." J.A. 89, 133–34, 141, 166, 172, 181.

FDA's actions have also forced Respondent organizations to expend "considerable time, energy, and resources to draft the 26-page [2019 Citizen Petition], in addition to compiling and analyzing supporting sources and studies." J.A. 149, 157. And the groups continue to spend considerable resources on their public advocacy and educational activities exposing the risks of FDA's 2021 and 2016 actions to women and girls. J.A. 135, 149, 158. This reallocation of resources comes at the expense of other organizational efforts, including exposing "the dangers of surgical abortion" and affirming "the sanctity of life at all stages." J.A. 135, 157.

As in *Havens*, there is "no question" Respondent organizations have suffered injuries in fact. The diversion of their resources in response to FDA's actions has undermined their ability to advance their mission. 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"). This harm fits squarely within lower court caselaw. *E.g.*, *OCA-Greater Houston* v. *Texas*, 867 F.3d 604, 610–12 (5th Cir. 2017) (organization had standing because it "went out of its way" and "spen[t] extra time and money educating its members" about the challenged law and its alleged "negative effects"); *Nnebe* v. *Daus*, 644 F.3d 147, 156–57 (2d Cir. 2011) (taxi drivers' alliance could sue agency for expenditure of 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); *Pac. Legal Found.* v. *Goyan,* 664 F.2d 1221, 1224 (4th Cir. 1981) (organization had standing to sue FDA when the agency caused it to "expend more time and funds" to monitor and comment on agency actions).

FDA takes issue with organizational standing writ large, complaining that any party filing a citizen petition "could bootstrap its way into standing" using that doctrine. FDA Br. 33. But it is FDA that requires citizen petitions to challenge its actions, 21 C.F.R. 10.45(b), with the promise that it will consider parties who file petitions to have "standing to obtain judicial review," 21 C.F.R. 10.45(d)(1)(ii); accord 40 Fed. Reg. 40682, 40689 (Sept. 3, 1975) (adopting this position on standing and acknowledging that FDA's actions "vitally and directly affect the interests of every citizen"). FDA cannot now reasonably object to Respondent organizations following the prescribed process. FDA's real beef is with *Havens*.

C. Respondents have third-party standing.

Respondent doctors also have standing to sue on behalf of their patients. Those patients include the women harmed by FDA's removal of the abortion-drug safeguards and the labor and delivery patients who lose access to their doctors when those doctors are pulled away to manage emergency complications caused by abortion drugs. J.A. 75–79, 120–21.

Standing to assert a third party's interest requires (1) the plaintiff to have a "close relation[ship]" with the third party and (2) the third party to face "some hindrance" to protecting her own interests.

Powers v. *Ohio*, 499 U.S. 400, 410–11 (1991). Both prongs are satisfied here.

First, the doctor-patient relationship is an inherently close one. *Singleton* v. *Wulff*, 428 U.S. 106, 115 (1976). Many Respondent doctors have a close and often years-long relationship with their labor and delivery patients. And they routinely spend hours treating patients harmed by FDA's removal of safeguards. J.A. 153–54.

Second, Respondents' patients are hindered from bringing their own lawsuit. Many of them "desire to protect the very privacy of [their] decision from the publicity of a court suit." *Singleton*, 428 U.S. at 117. And not knowing the finer points of FDA's regulatory actions—much less the safety precautions FDA has stripped away—women often lack awareness of what caused their injuries. *Nasir* v. *Morgan*, 350 F.3d 366, 376 (3d Cir. 2003).

Allowing third-party standing here is consistent with precedent "permitt[ing] abortion providers to invoke the rights of their actual or potential patients in challenges to abortion-related regulations." *June Med. Servs. LLC* v. *Russo*, 140 S. Ct. 2103, 2118 (2020), abrogated on other grounds by *Dobbs* v. *Jackson Women's Health Org.*, 597 U.S. 215 (2022); see also Wright & Miller, *supra*, at § 3531.9.3 ("Doctors regularly achieve standing to protect the rights of patients."). Given that doctors "can invoke the right of a third party for the purpose of attacking legislation enacted to protect the third party," *June Med. Servs.*, 140 S. Ct. at 2153 (Alito, J., dissenting), Respondents must be able to sue on behalf of their injured patients to challenge government action that harms them.

II. FDA's removal of safeguards for abortion drugs was arbitrary, capricious, an abuse of discretion, and otherwise unlawful.

FDA's merits defense boils down to one word: deference. In its haste to consign the federal courts to obeisance, the agency ignores its statutory obligations and overlooks basic APA requirements. But FDA has no discretion to disregard congressional mandates. The lower courts did not second-guess FDA's scientific determinations; they held the agency to well-settled statutory requirements that govern FDA decisions to remove safety measures from high-risk drugs.

The FDCA authorizes drug approvals and modifications only where the drug sponsor proves the drug sufficiently safe. 21 U.S.C. 355(d); 21 C.F.R. 314.3 (defining application to include amendments and supplements). The statute requires adequate tests, test results, and sufficient information to establish the safety of a drug "for use under the conditions prescribed … in the proposed labeling." 21 U.S.C. 355(d). FDA must refuse to modify a REMS where the information submitted by a drug sponsor (1) does "not include adequate tests … to show whether or not [the] drug is safe for use under the conditions prescribed," 21 U.S.C. 355(d)(1); (2) "the results of such tests … do not show that such drug is safe for use under such conditions," 21 U.S.C. 355(d)(2); or (3) FDA "has insufficient information to determine whether such drug is safe for use under such conditions," 21 U.S.C. 355(d)(4). FDA's "discretion … is bounded by [Section 355(d)]; and it is to the courts that the task of policing the boundary falls." *Nat'l Treasury Emps. Union* v. *Campbell*, 589 F.2d 669, 678 (D.C. Cir. 1978).

For its part, the APA requires an agency to "cogently explain why it has exercised its discretion in a given manner." *New York* v. *FERC*, 535 U.S. 1, 36 (2002) (quotation omitted). The 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." *State Farm*, 463 U.S. at 43 (cleaned up). A court must assess "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Ibid.* (cleaned up).

Where an agency changes its longstanding position, it must adequately explain itself and "show that there are good reasons for the new policy." *Encino Motorcars, LLC* v. *Navarro*, 579 U.S. 211, 221 (2016). A "reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Id.* at 222 (quoting *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009)).

FDA's removal of long-existing and commonsense safety standards like the ongoing care of a doctor was arbitrary and capricious.

A. FDA's 2021 removal of the initial in-person office visit was arbitrary, capricious, and unlawful.

In August 2020, FDA told this Court that the initial and only remaining in-person office visit was "minimally burdensome" and "necessary" to preserve safety. 2020 FDA Stay Appl. 4, 13. FDA reaffirmed the need for this visit in three separate agency actions over two decades. *Id.* at 6 (citing 2011, 2013, and 2016

regulatory decisions). After reviewing "thousands of adverse events resulting from the use of Mifeprex," FDA explained that it "has made, and continuously adhered to, the judgment that [the initial office visit] mitigate[s] serious health risks associated with the drug, which can increase if the patient delays taking the drug or fails to receive proper counseling about possible complications." *Id.* at 2, 21.

What a difference a few months make. FDA's 2021 decision to remove the initial in-person visit paved the way for mail-order and unsupervised abortions. FDA's precipitous decision to remove its "longstanding, minimally burdensome" in-office visit, *id.* at 13, was a textbook violation of the APA.

1. FDA's 2021 removal of the initial in-person office visit was arbitrary and capricious.

Section 355(d) of the FDCA is not one of those open-ended statutes that grants unfettered discretion to the agency. It requires substantial evidence, adequate testing, supportive test results, and sufficient information to find a drug safe. FDA must refuse to modify a REMS where the information submitted by a drug sponsor does "not include adequate tests," test "results," or "[ ]sufficient information to determine" whether the drug "is safe for use under the conditions prescribed." 21 U.S.C. 355(d)(1)–(4).

But FDA failed to give a "satisfactory explanation" for its decision to remove the initial in-person visit. *State Farm*, 463 U.S. at 43. That decision rested on (1) adverse event reports from FAERS and the drug sponsors and (2) a review of the scientific

literature. J.A. 397. FDA conceded that neither of these sources independently supported its decision, but nevertheless said that zero plus zero equals one. Cobbling together two insufficient rationales to support a conclusion is not "reasoned decision-making." This is especially true where, as here, the agency changes its longstanding position. *Encino Motorcars*, 579 U.S. at 221–22.

a. It was arbitrary for FDA to conclude that adverse event reports supported its 2021 action.

FDA first erred by giving dispositive weight to adverse event data in FAERS. J.A. 397. Petitioners accuse the lower court of second-guessing FDA. But FDA's own public statements repeatedly acknowledge that FAERS data cannot be used to indicate drug safety. FDA cautions that "[r]ates of occurrence [for an adverse event] cannot be established with [FAERS] reports." J.A. 417. Because reporting is voluntary, "FDA does not receive reports for every adverse event … that occurs." *Ibid.* Indeed, FDA's website warns: (1) "[t]he number of suspected reactions in FAERS *should not be used* to determine the likelihood of a side effect occurring," *ibid.* (emphasis added); and (2) "FAERS data *cannot be used* to calculate the incidence of an adverse event or medication error in the U.S. population," J.A. 415 (emphasis added). Summarizing the utility of the data, FDA says that "the FAERS data by themselves *are not an indicator* of the safety profile of the drug." J.A. 417 (emphasis added).

Yet FDA used mifepristone FAERS data for those prohibited purposes. The agency said that it "analyzed the FAERS data" from parts of 2020 and 2021 "to

determine if there was a difference in adverse events when in-person dispensing was and was not enforced." J.A. 399. It was arbitrary for FDA to use data that admittedly "cannot be used to calculate the incidence of an adverse event," J.A. 415, to determine the incidence of mifepristone's adverse events.

And of course, FDA is responsible for the paucity of FAERS data during 2020 and 2021. In 2016, the agency *removed* the requirement that abortion drug providers report serious adverse events other than death to FDA. "It'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." Pet. App. 236a. "This ostrich's-head-in-the-sand approach is deeply troubling—especially" for a high-risk drug that "necessitates a REMS program … and a 'Black Box' warning." *Ibid*.

FDA additionally considered adverse event data submitted by Danco and GenBioPro. But that data contained the identical adverse events found in FAERS, suffered from the same flaws, and provided no independent justification for removing the initial in-person visit. J.A. 397–99, 402. FDA even admitted that the sponsor information "included the same cases identified in FAERS." J.A. 399. This was not surprising given that abortion providers need not submit non-fatal adverse event reports to the drug sponsors. J.A. 392 (acknowledging some events may not be reported because reporting is voluntary). All FDA could say for the drug-sponsor data was that it did not cause the agency to "change [its] conclusion." J.A. 399. That is hardly a ringing endorsement of safety.

b. It was arbitrary for FDA to conclude that scientific literature supported its 2021 action.

FDA's conclusion that the scientific literature "supported" its decision to remove the initial office visit was also arbitrary and capricious. J.A. 397. FDA conceded the studies were "*not adequate* on their own to establish the safety of … dispensing mifepristone by mail." J.A. 407 (emphasis added). Cf. 21 U.S.C. 355(d)(1) (directing FDA to reject drug applications that "do not include adequate tests"). The best FDA could say was that the studies were "*not inconsistent* with [its] conclusion" that removing the last remaining in-person visit was safe. J.A. 400 (emphasis added). In other words, the literature did not *dis*prove FDA's apparently predetermined view that eliminating the initial office visit was safe. That's cold comfort to women taking high-risk drugs without the safeguards FDA once declared crucial.

It's not hard to see why FDA carefully qualified its statements regarding the literature. The studies it relied on were deeply problematic. FDA conceded that the study results could not be "generalize[d]" to the United States population because small sample sizes, lack of information about safety outcomes, and the inclusion of pre-abortion safeguards like in-person examinations and ultrasounds limited the studies' usefulness. J.A. 400.

FDA's reliance on the literature was also arbitrary because—to the extent the studies showed anything—it was *increased* risk. FDA admitted that "the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic."

J.A. 407. In fact, the studies assessing the safety of mailing abortion drugs from a clinic showed troubling rates of emergency-room visits, urgent-care trips, and unplanned medical encounters. Raymond reported that 7 percent of women sought ER/urgent care attention, Chong said 6 percent did, Kerestes noted that 5.8 percent went to the emergency room, and Anger told of 12.5 percent requiring unplanned medical encounters. J.A. 403–05. These studies showed that as many as 1 in 8 women would need unplanned medical care if the in-person dispensing requirement was eliminated. *Ibid.*

FDA's only explanation for ignoring these alarming figures was its nonanswer that "there are no apparent increases in *other* significant adverse events related to mifepristone use." J.A. 407 (emphasis added). The agency never explained why the high rates of emergency-room visits wasn't *itself* a red flag. Nor did it identify what other serious adverse events it had in mind. That is well "outside the zone of reasonableness." *Prometheus*, 592 U.S. at 428.

It was also unreasonable for FDA to say there were no "apparent" increases in "other serious adverse" outcomes, J.A. 406, when one of the three pharmacy studies found that hospitalization rates increased by 330 percent, J.A. 403. The Hyland study saw hospitalization rates soar beyond the less than 1 percent figure on the label to reach 3 percent of women mailed abortion drugs (not including seven patients hospitalized without follow-up information). *Ibid.* That the reasons for the hospitalizations were unknown is hardly a reason to disregard them—but that's the only rationale FDA gave. FDA's "conclusion[ ]" that "safety findings cannot be made in the absence of information about the reasons for hospital-

ization," *ibid.*, gets the agency's burden backwards. A sponsor must prove a drug safe, a standard that has been clear since the 1962 amendments to the FDCA. Drug Amendments Act of 1962, Pub. L. No. 87-781, 76 Stat. 780. It was unreasonable for FDA to brush away these safety concerns.

Further, FDA conceded that the Anger study "suggests a pre-abortion examination may *decrease* the occurrence of procedural intervention and *decrease* the number of unplanned visits for post-abortion care." J.A. 405 (emphasis added). That's because the study "found that those without an examination or ultrasound prior to medical abortion were more likely to require procedural interventions and had more unplanned clinical encounters." *Ibid.* FDA also noted Kerestes's finding that 5.8 percent in the "telemedicine plus mail group" had "ED visits"—a rate exceeding the range on the label (2.9 to 4.6 percent) and almost three times higher than its 2.1 percent comparator figure for women who had an "in-person" visit. J.A. 405, 533. It was capricious for FDA to blow past these warning signs.

FDA argues that the APA does not obligate it to commission or conduct scientific studies. FDA Br. 37. Of course not. But it does require agencies adequately to explain their decisions and comply with their authorizing legislation. The FDCA demands that an application include adequate testing, test results, and sufficient information to show a drug safe under the proposed labeling. 21 U.S.C. 355(d). But FDA pointed to no testing or information satisfying that burden.

Petitioners also claim this Court's decision in *Prometheus* entitles FDA to rely on its "reasonable predictive judgment" based on the evidence before it.

Danco Br. 51 (quoting *Prometheus*, 592 U.S. at 427). But that case involved the Federal Telecommunications Act's grant of vast discretion to the agency to regulate "as public convenience, interest, or necessity requires." 47 U.S.C. 303; see also 47 U.S.C. 309(a). It is one of those statutes that "employ[s] broad and open-ended terms" that "afford agencies broad policy discretion." *Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2448–49 (2019) (Kavanaugh, J., concurring).

Not so the FDCA. It requires FDA to reject a REMS modification if the evidence before it fails to show that the "drug is safe for use under the conditions" in the proposed labeling. 21 U.S.C. 355(d). Likewise, where tests are not "adequate" or information is "insufficient" to establish safety, FDA must decline to modify a drug's safeguards. *Ibid.* While the FCC might be authorized to make educated guesses about which ownership rules best serve the public interest, FDA is not allowed to engage in conjecture about the safety profile of high-risk drugs. At a minimum, it must reasonably explain its decision to remove long-standing safeguards.

In sum, FDA relied on FAERS data it conceded may not be used to calculate the incidence of an adverse event and scientific literature that it admitted was inadequate. The 2021 elimination of the initial in-person visit does not reflect the careful deliberation that must precede a change of this magnitude.

The arbitrariness of FDA's decision is heightened because it conflicts with decades of agency findings. While an agency may change its mind, it must adequately explain its reasons for doing so. *State Farm*, 463 U.S. at 56. FDA failed to do so here. It did

not address the agency's prior repeated concern—expressed as recently as 2020—that removing the initial office visit creates the potential for a woman to delay taking the drugs. 2020 FDA Stay Appl. 6. FDA's utter silence on these risks of delay (not to mention the benefits of in-person counseling) does not constitute the "reasoned explanation … needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Fox Television Stations*, 556 U.S. at 515–16.

2. FDA's 2021 removal of the initial in-person office visit also violates the Comstock Act.

FDA's 2021 action also violates the Comstock Act, as Respondents argued below. That statute prohibits using "the mails" to send any "drug … advertised or described in a manner calculated to lead another to use or apply it for producing abortion." 18 U.S.C. 1461. It also forbids using a "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 action authorizes the widespread mailing and shipping of abortion drugs. Yet as Judge Ho explained below, mailing drugs that cause abortion is "precisely what the Comstock Act prohibits." Pet. App. 100a.

Petitioners made an assortment of contrary-to-text arguments below. Each fails. FDA's primary argument was that Comstock applies only to "unlawful abortions." FDA CA5 Br. 57–60. But the text contains no such limitation, and Congress in 1978 considered—and rejected—an amendment

limiting the law to "illegal abortions." H.R. 13959, 95th Cong. §§ 6701(a)(2), 6702(1)(C)(i) (1978); accord 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 the amendment would "change[ ] current law by requiring proof … to produce an illegal abortion").

Nor does the prior-construction canon help Petitioners. That rule applies only when "judicial interpretations have *settled* the meaning," *Armstrong* v. *Exceptional Child Ctr., Inc.*, 575 U.S. 320, 330 (2015) (emphasis added, citation omitted), through "a *uniform* interpretation by inferior courts," *Tex. Dep't of Hous. & Cmty. Affs.* v. *Inclusive Cmtys. Project, Inc.*, 576 U.S. 519, 536 (2015) (emphasis added, citation omitted). No such uniformity exists here. Petitioners support their theory with old dicta from a smattering of circuits, most of which construed since-repealed language covering contraception. See ROA 4174–78 (Ethics and Public Policy Center Am. Br.). And at least one circuit rejected Petitioners' reading, explaining that Comstock "indicates a national policy of discountenancing abortion" regardless of "what the local statutory definition of abortion is, what acts of abortion are included, or what excluded." *Bours* v. *United States*, 229 F. 960, 964 (7th Cir. 1915).

Danco (but not FDA) argues that Respondents' challenge to FDA's December 2021 action is moot because FDA's 2023 REMS supposedly "superseded its [2021] *non-enforcement decisions*." Danco Br. 48 (emphasis added). This argument fails factually because FDA's December 2021 action was not a nonenforcement decision but rather permanently removed the in-person dispensing requirement. J.A.

378 (finding in-person dispensing "no longer necessary").

Danco's argument also fails legally because when new government action is "sufficiently similar" to prior action, "the challenged conduct continues," and the controversy remains. *Ne. Fla. Chapter of Associated Gen. Contractors of Am.* v. *City of Jacksonville*, 508 U.S. 656, 662 & n.3 (1993). The 2023 REMS merely effectuated FDA's 2021 decision. See FDA 2023 Summary Review 6, https://perma.cc/W4U3-L38P (noting that FDA "determined" on "12/16/2021" that "the REMS must be modified to remove the in-person dispensing requirement"). So "FDA's formalization of the policy it announced in 2021 does not render this claim moot." Pet. App. 58a. Otherwise, agencies could always escape review by promulgating subsequent action after suit is filed.

B. FDA's 2016 elimination of two of three in-person visits while increasing gestational age and eliminating the reporting requirement was arbitrary and capricious.

FDA announced sweeping changes to abortion-drug safeguards in 2016. It increased the maximum gestational age from seven to ten weeks, eliminated the Day 3 and Day 14 in-person doctors' visits, allowed healthcare providers other than doctors to prescribe and administer chemical abortions, and eliminated the requirement that abortion providers report all serious adverse events. These changes violate the APA for three reasons.

1. FDA failed to consider an important aspect of the problem.

FDA violated the APA when it "failed to consider an important aspect of the problem" by not assessing the 2016 changes as a whole. *State Farm*, 463 U.S. at 43. "The cumulative effect of [those changes] is unquestionably an important aspect of the problem." Pet. App. 53a. FDA admitted as much when it acknowledged that the 2016 changes were not just "major" but "interrelated." J.A. 298. And as explained, the FDCA requires adequate tests, test results, and sufficient information to show mifepristone safe "under the conditions of use … in the proposed labeling." 21 U.S.C. 355(d); accord *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000) (FDA must determine safety "as used by consumers").

Yet FDA concedes that every study it relied on to make the 2016 changes included safeguards missing from the new labeling. J.A. 548–62. And FDA treated studies on the safety of removing one or two of the safeguards in isolation as "sufficient to rescind [all interrelated conditions at once] without explanation." *Regents,* 140 S. Ct. at 1912. FDA's changes are akin to an agency no longer requiring seatbelts and airbags based on studies that evaluated the risk of removing just one of those protections. "That was obviously arbitrary and capricious in *State Farm*." Pet. App. 235a. And it is arbitrary here.

In *State Farm*, NHTSA required that motor vehicles be equipped with a passive restraint—either airbags or automatic seatbelts. 463 U.S. at 37–38, 46. Based on its conclusion that automatic seatbelts would not provide effective protection, the agency rescinded the passive restraint requirement in full.

Id. at 38. The total recission of the requirement was arbitrary and capricious because NHTSA's justification supported only "disallow[ing] compliance by means of" automatic seatbelts. *Id.* at 47. The agency erred by treating a rationale that applied to only part of a policy as sufficient to rescind the entire policy. *Regents*, 140 S. Ct. at 1912 (citing *State Farm*, 463 U.S. at 51). FDA's 2016 changes suffer the same flaw.

Further, the interrelated nature of the changes matters. To take one example: FDA increased the maximum gestational age by three full weeks, which indisputably increases rates of abortion failures, surgical interventions, and complications. See J.A. 538, 542; ACOG Gestation Bulletin, *supra*; Chen & Creinin, *supra*. Simultaneously, the agency removed in-person follow-up visits that afford the opportunity to diagnose and treat complications before they result in an emergency. One mistake compounds the other, which is why it's essential for the agency to assess these changes as a whole.

FDA says that three studies "closely mirrored" the 2016 changes. FDA Br. 38–39. But all of them *included* in-person, post-abortion follow-up visits—one of the safeguards the agency removed despite previously calling it "very important." 2000 Mifeprex Label 15, https://perma.cc/3V7C-SU6Q. It was arbitrary and capricious for the agency to eliminate multiple interrelated safeguards based on studies that addressed the safety of removing only some of them. See *State Farm*, 463 U.S. at 43. Likewise, Danco's reference to "dozens of studies" that addressed various combinations of the 2016 changes, Danco Br. 6, fails because none of those studies evaluated the 2016 changes as a whole or under the labeled conditions of use.

FDA next contends that it relied on evidence about the use of mifepristone since 2000. FDA Br. 37. Yet that past information cannot carry FDA's burden to show that the 2016 changes met the strict safety requirements of the FDCA and complied with the APA. Put differently, the past performance of a drug with safety standards A, B, C, and D is insufficient to establish that the drug will be safe with only safety standard A.

FDA is wrong to suggest this challenge to the 2016 changes was unexhausted. FDA Br. 38. First, Respondents' 2019 Citizen Petition raised objections to the interrelated changes. J.A. 328. Second, the APA requires exhaustion of administrative remedies only when required by statute or when an agency rule "provides that the [agency] action … is inoperative" during appeal. 5 U.S.C. 704; accord *Darby* v. *Cisneros*, 509 U.S. 137, 154 (1993) (exhaustion required "when an agency rule requires appeal before review and the administrative action is made inoperative pending that review"). No such statute or FDA rule exists here. See Michael Krupka, *Exasperated But Not Exhausted: Unlocking the Trap Set by the Exhaustion Doctrine on the FDA's REMS Petitioners*, Vand. L. Rev. (Forthcoming), https://perma.cc/4A3M-7C4H. Third, the equitable doctrine of exhaustion does not apply when, as here, it would have been clearly useless for the plaintiff to raise the argument to an entrenched agency. *Wash. Ass'n for Television & Child.* v. *FCC*, 712 F.2d 677, 682 (D.C. Cir. 1983) (cleaned up).

2. FDA failed to provide a satisfactory explanation.

FDA's 2016 action also violated the APA because it gave no "satisfactory explanation for" its decision to ignore the cumulative effect of the changes. Pet. App. 52a; *State Farm*, 463 U.S. at 43. The FDCA directs the agency to evaluate a drug's safety "under the conditions of use in the proposed labeling." 21 U.S.C. 355(d). At a minimum, the APA requires the agency to explain why it could rely on piecemeal studies to find safe the interrelated changes in the proposed labeling. Yet FDA nowhere provided that explanation.

FDA insists it was not required to consider the changes together. FDA Br. 37–38. But "that there may be a valid reason" not to consider the changes as a whole "does not establish that [FDA] considered that option or that such consideration was unnecessary." *Regents*, 140 S. Ct. at 1913. Under the APA, FDA "must cogently explain why it has exercised its discretion in a given manner, and that explanation must be sufficient to enable [the Court] to conclude that the [agency's action] was the product of reasoned decisionmaking." *A.L. Pharma, Inc.* v. *Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995) (quotations omitted). FDA's failure to explain why it could rely on studies examining some of the 2016 changes as sufficient to justify all of them "prevents [this Court] from evaluating whether or not the agency engaged in reasoned decisionmaking." *New York*, 535 U.S. at 36 (Thomas, J., concurring in part). This is particularly true here, where FDA's changes represent a major deviation from its prior requirements. *Encino Motorcars*, 579 U.S. at 221–22.

3. FDA's elimination of the reporting requirement for all serious adverse events was arbitrary and capricious.

FDA's decision to eliminate the requirement that abortion providers report all serious adverse events was also arbitrary and capricious. J.A. 319. FDA justified this decision by asserting that "after 15 years of reporting serious adverse events, the safety profile of Mifeprex is essentially unchanged." *Ibid.* That backward-looking rationale says nothing about mifepristone's safety profile going forward *without* the removed safeguards.

Petitioners respond that the two drug sponsors remain obligated to report adverse events, FDA Br. 43, Danco Br. 46. But the sponsors lack any meaningful ability to track the problems on the ground. Nowhere near America's emergency rooms, these companies rely entirely on the voluntary reporting of busy doctors. It is unreasonable for the agency to rely on voluntary reporting to assess the ongoing safety of these high-risk drugs.

C. A full administrative record is not necessary at this stage.

Danco (but not FDA) argues that this Court should adopt a new rule prohibiting a lower court from providing preliminary relief without a full administrative record. Danco Br. 36. But the APA expressly allows a court to grant relief based on "the whole record or *those parts of it cited* by a party." 5 U.S.C. 706 (emphasis added); see *Univ. of Tex.* v. *Camenisch*, 451 U.S. 390, 395–96 (1981) (noting that a party seeking a preliminary injunction need neither "present" nor "prove his case in full"). Were Danco

correct, federal agencies would have a potent weapon to marshal against preliminary relief. Case in point: FDA told the Fifth Circuit that the administrative record in this case *still* remains in "cold storage." Oral Arg. at 24:30 (5th Cir. May 17, 2023).

None of Danco's cases are remotely like this one. In *Citizens to Pres. Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 406 (1971), which was decided on summary judgment, the district court had no "part[ ] of" the administrative record before it but only affidavits created during litigation. *Id.* at 409. Similarly, the D.C. Circuit in *American Bioscience, Inc.* v. *Thompson*, 243 F.3d 579, 582 (D.C. Cir. 2001), found that it was "not sufficient" for the district court "to have relied on the parties' written or oral representations to discern the basis on which the FDA acted." Here, in contrast, the agency's decisional documents are "part[ ] of [the record] cited by" the parties. 5 U.S.C. 706. And Petitioners were free to submit to the district court any agency document that they believe would have advanced their case.

In any event, Danco waived this argument. Before the district court, Danco didn't argue that the lack of a full administrative record deprived the court of authority to grant preliminary relief. ROA 2002–35; ROA 2086–137. Rather, Danco acknowledged that only a "ruling beyond the preliminary injunction motion would be premature," and that a "preliminary injunction record is necessarily incomplete" in APA cases. ROA 3589–90; see also ROA 3802 (FDA recognizing that "preliminary proceedings typically are 'granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits'") (citation omitted).

III. The remedy issued is appropriate.

FDA concedes that "the traditional four-factor test for a preliminary injunction" applied by the lower courts is the "correct[ ]" standard. FDA Br. 46 (quoting Pet. App. 44a). As those courts held, the factors favor Respondents. Pet. App. 63a–69a, 150a–193a.

First, Respondents are likely to succeed on the merits. Second, Respondents' harms are irreparable because "[n]o legal remedy can adequately redress" their "conscience," "mental-distress," "economic," and other injuries. Pet. App. 64a. Notably, Petitioners nowhere deny that Respondents' injuries, if established, are irreparable. And Petitioners overlook that Respondents represent the interests of the women they treat who are harmed by FDA actions. Exposing women to frantic emergency-room visits because of FDA's recklessness qualifies as irreparable harm.

The equities and public interest—the remaining two factors, which "merge when the Government is the [defendant]," *Nken* v. *Holder*, 556 U.S. 418, 435 (2009)—also favor Respondents. Pet. App. 63a–69a. Only modest relief is at stake—the restoration of safety standards that FDA required for 16 years and under which millions of women took mifepristone. FDA faces no harm because it lacks any interest in enforcing unlawful agency action. See *Ala. Ass'n of Realtors* v. *Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2490 (2021) (per curiam) ("our system does not permit agencies to act unlawfully"). Any effect on Danco is negligible because it will still be able to sell and profit from mifepristone. And the public—including women using mifepristone—will benefit from

FDA restoring key safeguards that once protected women's health. Indeed, "the public interest is disserved by a drug that does not afford adequate protections to its users." Pet. App. 69a. Respondents satisfy the standard for preliminary relief.

FDA's Section 705 argument. FDA (but not Danco) argues the district court cannot use 5 U.S.C. 705 to stay "agency actions that ha[ve] been in effect for years." FDA Br. 15. Yet the broad statutory text contains no such limitation. It allows courts to "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 (emphasis added).

FDA's myopic focus on the word "postpone," FDA Br. 45, ignores the statutory disjunctive. The authority to enter "*all* necessary and appropriate" relief to "preserve … rights" pending judicial review includes the authority to stay unlawful agency action that has already gone into effect. 5 U.S.C. 705 (emphasis added). Indeed, "[t]he authority granted [by Section 705] is equitable and should be used by … courts to prevent irreparable injury or afford parties an adequate judicial remedy." H.R. Rep. No. 1980, at 277 (1946). And of course, stays are less drastic remedies than injunctions because they don't order defendants to act. *Nken*, 556 U.S. at 428–29.

FDA acknowledges courts may enter stays that are "contemporaneous with *or* predate" an action's "effective date," conceding the power to postpone recently passed effective dates. FDA Br. 45 (emphasis added). But no statutory text supports FDA's distinction between recently past effective dates and older effective dates.

The implications of FDA's cramped construction of Section 705 are untenable. It would prevent courts from *ever* staying FDA drug approvals or modifications given the agency's demand that challengers first file citizen petitions, 21 C.F.R. 10.45(b), and its practice of delaying responses for many years, Pet. App. 112a, sometimes for more than a decade.

At day's end, whether Section 705 authorizes a stay of the effective dates here is an academic question. The district court said that "it alternatively would have ordered" FDA to pause its 2021 and 2016 actions pending final judgment. Pet. App. 195a. That alternative injunction fits squarely within Section 705's equitable authority to issue "all necessary and appropriate" interim relief to "prevent irreparable injury" and "preserve … rights." 5 U.S.C. 705. As discussed, every one of the preliminary-injunction factors favor pausing FDA's actions. And such relief is "necessary to provide complete relief" to Respondents. *Califano* v. *Yamasaki*, 442 U.S. 682, 702 (1979). Members of Respondent associations are located throughout the country, as are the women they serve and whose interests they represent. *E.g.*, J.A. 119, 126, 146–47. And even Respondent doctors located in jurisdictions that limit abortion are affected by women who receive the drugs from other states and seek treatment from Respondents. J.A. 126, 179, 198; Mississippi Multi-State Am. Br. Part II. Anything less than a pause on the challenged actions is insufficient to protect Respondents.

Petitioners' equity arguments. Petitioners' equity arguments also fall flat. Petitioners claim hardship from updating mifepristone's "labeling." FDA Br. 46; Danco Br. 53. But the Fifth Circuit's ruling merely requires FDA and Danco to restore standards

previously in effect—not craft new ones. And Petitioners have had more than six months since the Fifth Circuit's ruling to prepare—and will have several more before this Court rules.

Danco (but not FDA) complains that it might have to submit a supplemental drug application and that FDA might not approve it. Danco Br. 53–54. Talk about speculative. FDA has never expressed any safety or efficacy concerns with the prior protocols. J.A. 302, 502. There's no reason to think they'd do so now.

Petitioners' concerns about "access" to abortion are groundless. FDA Br. 46–47; Danco Br. 52–53. Millions of women had abortions under the prior safety standards—they just did so with the oversight and ongoing care of a healthcare provider. Moreover, Petitioners' "access" arguments disregard women's safety by overlooking the studies that FDA discussed in 2021 indicating that the absence of an in-person visit causes more trips to emergency rooms and urgent care. J.A. 403–07. And Petitioners' focus on women in rural settings, Danco Br. 52, ignores FDA's recognition that women living "significant distances from their providers … have been associated with higher use of [emergency departments]" following chemical abortion. FDA 2023 Approval Letter (Jan. 3, 2023), https://bit.ly/49mvzeL (page 121 of full PDF).

Despite Danco's claim, relief for Respondents does not require FDA to revert to the prior "dosing regimen." Danco Br. 53. As FDA recognizes, Respondents have not challenged the 2016 dosing change. FDA Br. 41 n.8. And FDA's own records show that abortion providers were using the dosing regimen Danco prefers since 2001, long before FDA's 2016

action. J.A. 443, 446, 465. A ruling for Respondents won't change that.

Petitioners also minimize Respondents' injuries, claiming they are unlikely to occur. FDA Br. 47. This adds nothing new but simply rehashes Petitioners' flawed standing arguments. It also ignores that Respondents represent the interests of women they treat who are harmed by FDA's actions. Those women—who rely on FDA to protect them—have strong interests in FDA restoring the unreasonably removed safeguards. Respondents' labor and delivery patients likewise have their own interests in preserving access to Respondents' care.

Staying FDA's 2021 and 2016 actions will not "destabilize" the "pharmaceutical industry." Contra Danco Br. 54. To the contrary, restoring safety standards for abortion drugs removed through FDA's unlawful actions fortifies the public's trust in the pharmaceutical-approval process. Nowhere in their hyperbole do Petitioners cite a single specific drug approval that will be jeopardized. And given that FDA's actions here are especially egregious, pausing them leaves other drug approvals untouched.

No remand for agency reconsideration. Petitioners' final plea is that FDA's actions should not be paused but only remanded for "further [agency] consider[ation]." FDA Br. 48. Yet this Court has not hesitated to vacate other arbitrary and unreasonably explained agency action. *E.g.*, *Regents*, 140 S. Ct. at 1901, 1916 ("vacat[ing]" agency action when the agency failed to "provide a reasoned explanation").

FDA thinks it can better explain itself if given another chance and allowed to invoke its "years of experience" with abortion drugs since 2016. FDA Br.

48–49. But the APA prohibits "*post hoc* rationalization," so any further elaboration would be confined to the original administrative record and "the determinative reason[s] for [each] action." *Regents*, 140 S. Ct. at 1908. In 2021, for example, the record and rationale consisted of only concededly unreliable FAERS data and inadequate studies. No amount of elaboration on that record will "justify [FDA's] decision on remand." *United Steel* v. *Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019). It is revealing that despite over a year of litigation, FDA has never provided a reasonable explanation. Nothing suggests it could do so now.

CONCLUSION

The Court should affirm the Fifth Circuit's order and remand for further proceedings.

Respectfully submitted,

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