NOS. 22A901, 22A902

IN THE
Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
and
DANCO LABORATORIES, LLC,

Applicants,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

Respondents.

To the Honorable Samuel A. Alito, Justice of the Supreme Court of the United States and Circuit Justice for the Fifth Circuit

OPPOSITION TO APPLICATION TO STAY OR VACATE INJUNCTION PENDING APPEAL

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Applicants U.S. Food and Drug Administration (FDA); U.S. Department of Health and Human Services; Robert M. Califf, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; Janet Woodcock, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; Patrizia Cavazzoni, M.D., in her official capacity as Director, Center for Drug Evaluation and Research; U.S. Food and Drug Administration, Xavier Becerra, in his official capacity as Secretary, U.S. Department of Health and Human Services, were Defendants-Appellants below. Applicant Danco Laboratories LLC (Danco) was Intervenor-Defendant-Appellant below.

Respondents are Alliance for Hippocratic Medicine (AHM); American Association of Pro-Life Obstetricians & Gynecologists (AAPLOG); American College of Pediatricians (ACPeds); Christian Medical & Dental Associations (CMDA); Shaun Jester, D.O.; Regina Frost-Clark, M.D.; Tyler Johnson, D.O.; and George Delgado, M.D., who were Plaintiffs-Appellees below.

INTRODUCTION

For nearly a quarter-century, Applicants FDA and Danco have brazenly flouted the law and applicable regulations, disregarded holes and red flags in their own safety data, intentionally evaded judicial review, and continually placed politics above women's health. Both the Fifth Circuit and district court orders paint an alarming picture of this lawlessness—all to the detriment of the women and girls FDA is supposed to protect. Across decades, the agency has stripped away every meaningful and necessary safeguard on chemical abortion, demonstrating callous disregard for women's well-being, unborn life, and statutory limits.

Ignoring these harms and their own stonewalling of judicial review (for *6,000* days), Applicants now ask this Court to award them extraordinary emergency relief. Their main claim is a sky-is-falling-argument that compares chemical abortion to drugs like ibuprofen. But mifepristone's "Black Box" warnings and Danco's own Patient Agreement Form describe serious possible adverse effects—including death—that place it on a vastly different level than ibuprofen. The lower courts' meticulous decisions do not second-guess the agency's scientific determinations; they merely require the agency to follow the law.

Under the Fifth Circuit's reasonable order, women will still have access to chemical abortion drugs under the same restrictions that existed for the first 16 years of mifepristone's use. The only effect of the lower court's order is to restore a modicum of safety for the women and girls who use the drug, including supervision and oversight by a physician. If this litigation involved any other drug, there would not even be a debate as to whether this Court should intervene mid-litigation stream with extraordinary relief.

Accordingly, this Court should deny both Applications so that the Fifth Circuit's expedited merits proceeding may continue. In the unlikely event the Court finds that the present Applications warrant merits briefing and oral argument, the Court

should expand the questions presented to include: (1) whether the Comstock Act's prohibition against mailing articles "intended for producing abortion," 18 U.S.C. 1461, includes mifepristone, (2) whether pregnancy is an "illness" for purposes of FDA's Subpart H regulations for accelerated approval of new drugs, and (3) whether mifepristone provides a "meaningful therapeutic benefit," 21 C.F.R. 314.500, over other abortion alternatives.

SUMMARY OF THE ARGUMENT

Applicants seek to reinstate FDA's unlawful mail-order abortion regimen and strip away necessary and longstanding requirements to protect women's health. But Applicants fail to meet the requirements for emergency relief: "(1) a reasonable probability that four Justices will consider the issue sufficiently meritorious to grant certiorari; (2) a fair prospect that a majority of the Court will vote to reverse the judgment below; and (3) a likelihood that irreparable harm will result from the denial of a stay." *Hollingsworth* v. *Perry*, 558 U.S. 183, 190 (2010) (per curiam).

At the outset, the government takes a radical view of standing that would place insuperable obstacles to forward-looking relief. According to the government, even if the record conclusively demonstrated that "hundreds of thousands of women *will* … need emergency care" after using mifepristone, and even if "plaintiff doctors and their associations *will necessarily* be injured by the consequences," Article III standing does not exist. FDA.Application.23 (citing FDA.App.19a) (emphasis added). That badly misstates the law. Plaintiffs have suffered numerous concrete and specific injuries because of FDA's continual deregulation of chemical abortion, including the forced performance of elective abortions contrary to deeply held beliefs; the interference with Plaintiffs' medical practice and consumption of crucial and limited resources; and the enormous pressure and stress caused by emergency treatment from chemical abortion gone wrong.

These harms are hardly speculative given that FDA has removed every meaningful safeguard, including eliminating in-person visits, the only opportunity to accurately diagnose an ectopic pregnancy and confirm gestational age; raising the gestational age for chemical abortion by over 42%; and authorizing non-physicians to prescribe abortion drugs through the mails. Plaintiff physicians are left to deal with the aftermath, and FDA cannot "deny that serious complications from mifepristone are certainly impending." FDA.App.12a.

At this preliminary stage, there is not a reasonable probability that four justices will vote to grant certiorari. There is no current circuit split, and there may never be one. In particular, the government has not even appealed the decision from the Washington District Court which, to date, is only potentially conflicting.

Moreover, Applicants cannot meet their high burden of showing a likelihood that this Court will reverse on the merits. No amount of agency deference nor repeated incantation of "science" can cure FDA's failure to engage in the reasoned decision-making required by the Administrative Procedure Act (APA). Not a single study that FDA relied on for the 2016 Major Changes, for instance, examined what would happen if FDA removed *every* safeguard. This is akin to an agency finding a car safe based on studies with seatbelts without airbags, then concluding the car was safe without either seatbelts or airbags.

FDA's 2021 Non-Enforcement Decision is just as arbitrary and capricious. In removing the in-person dispensing requirement and allowing for mail-order abortions, that decision relied heavily on FDA's Adverse Event Reporting System (FAERS). But FDA *abandoned reporting* requirements for nonfatal adverse events years before. As the Fifth Circuit concluded, "[t]his ostrich's-head-in-the-sand approach is deeply troubling" and "unreasonable." FDA.App.35a. Not only did FDA violate the APA, but its actions flagrantly violate longstanding federal criminal laws

that prohibit the mailing or delivery of "[e]very article or thing designed, adapted, or intended for producing abortion." 18 U.S.C. 1461–62.

Applicants also fail to show irreparable injury. FDA suggests that the court order blocks it from "fulfilling its statutory responsibilities in accordance with its scientific judgment," but it must exercise that judgment in compliance with the APA. FDA.Application.40. Any "necessary adjustments" FDA must make is hardly irreparable harm; it occurs every time a court sends an agency back to the drawing board. *Id.* And the agency need only go back to its preapproved 2011 regimen and label. The "threat" of conflicting orders here is also illusory, as the Fifth Circuit's order does not require FDA to do anything.

As for women's harms, that consideration favors Plaintiffs; chemical abortion remains available with the restored basic safety requirements in place for the drug's first 16 years. Finally, Danco's financial interests are not harmed—and in fact, the pharmaceutical company is in a *better* financial position because the Fifth Circuit's order maintained the district court's stay of the 2019 approval of its generic competitor.

The Fifth Circuit's order has the effect of restoring crucial safeguards FDA once deemed necessary to protect women from the inherent risks of chemical abortion. Yet FDA and Danco make the strange claim that returning to these basic safeguards causes irreparable harm to the public. Mifepristone was administered to millions of women under these safeguards, and it was only at Danco's urging that FDA put the safety measures to one side.

Plaintiffs and their patients will be harmed without the reinstatement of these safety guardrails—guardrails that allow abortion providers to rule out ectopic pregnancies, verify gestational age, and identify any contraindications prior to prescribing mifepristone. These guardrails also allow providers to identify potential complications like a failed chemical abortion, sepsis, and hemorrhage. Without a stay,

mifepristone will result in more physical complications, emotional trauma, and even death for women. It will also harm Plaintiffs by forcing them to perform elective abortions violating their conscience rights and interfering with their medical practice. The Court should deny FDA and Danco's Applications for emergency relief.

BACKGROUND

The Food and Drug Act requires drug manufacturers to prove, and FDA to ensure, that any new drug is "safe and effective" for its intended use. 21 U.S.C. 321(p), 355(d). FDA's chemical abortion regimen requires two drugs: mifepristone (also known as "RU-486" and "Mifeprex") and misoprostol. FDA.CA5.Add.84. Mifepristone is a synthetic steroid that blocks nutrition to the unborn baby. *Ibid.* Misoprostol induces contractions to expel the dead baby from the mother's womb. FDA.CA5.Add.84–85.

During the early 1990s, the Population Council—a nonprofit founded to address world "overpopulation"—obtained the U.S. patent rights to mifepristone FDA.CA5.Add.100–01. The Population Council later granted Danco Laboratories, LLC—a Cayman Islands-based company with no other pharmaceutical products—an exclusive license to manufacture, market, and distribute mifepristone in the U.S. FDA.CA5.Add.109.

On September 28, 2000, FDA approved mifepristone under Subpart H, a regulation that authorizes accelerated approval of new drugs that safely and effectively treat "serious or life-threatening illnesses" and "provide [a] meaningful therapeutic benefit to patients over existing treatments." 21 C.F.R. 314.500. Before mifepristone, FDA had approved fewer than 40 drugs under Subpart H—including 20 "for the treatment of HIV and HIV-related diseases," nine "for the treatment of various cancers and their symptoms," four "for severe bacterial infections," one for hypertension, and one for leprosy. FDA.App.84a. To add mifepristone to this list, FDA characterized

pregnancy as an "illness," even though it is actually a "natural process" most women will experience. FDA.App.82a–86a. And it concluded that mifepristone provided a "meaningful therapeutic benefit" over surgical abortions, despite the fact that chemical abortion drugs have a "fourfold higher" incident of adverse events than surgical abortions. FDA.App.87a.

Given the known and documented dangers of mifepristone, Subpart H was the only possible regulatory pathway available to FDA to approve the drug. To mitigate the acknowledged, serious, and adverse complications from mifepristone, FDA's 2000 Approval imposed numerous safety requirements, including a seven-week gestational limit, limited prescribing authority to physicians, and three in-person office visits: (1) the Day 1 in-person dispensing and administration of mifepristone; (2) the Day 3 in-person dispensing and administration of misoprostol; and (3) the Day 14 office visit to confirm no fetal parts or tissue remain. FDA.CA5.Add.182–88. Abortion providers were required to report all adverse events. FDA.CA5.Add.186.

The U.S. trials on which FDA relied to approve mifepristone required numerous safeguards, including: (1) an ultrasound to confirm gestational age and exclude a life-threatening ectopic pregnancy; (2) prescribing physicians with experience in performing surgical abortions and admitting privileges at medical facilities that provided emergency care; (3) all women were within one hour of emergency facilities; and (4) monitoring for four hours to check for adverse events after taking misoprostol. FDA.App.91a. FDA had proposed to the Population Council that these safeguards be included in the approved regimen. Alliance.CA5.App.204–05. But then, without any explanation, "FDA included *none* of these requirements—which were explicitly stated in the clinical trial FDA relied on most—in the 2000 Approval." FDA.App.91a.

Years later, in the Food and Drug Administration Amendments Act (FDAAA), Congress amended the FDCA to codify FDA's post-approval safety measures for dangerous drugs authorized under Subpart H. These changes required FDA to obtain a

risk evaluation and mitigation strategy (REMS) when FDA determines that a REMS is "necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness" and its association "with a serious adverse drug experience." 21 U.S.C. 355-1(f)(1). Section 909(b)(1) of the FDAAA specified that a "drug that was approved before the effective date of this Act is … deemed to have in effect an approved [REMS] … if there are in effect on the effective date of this Act elements to assure safe use [pursuant to Subpart H, 21 C.F.R. 514.520]." H.R. 3580, 110th Cong. (2007). Yet this general structure said nothing about any specific drug or post-marketing restriction. FDA approved Danco's supplemental new drug application (sNDA) implementing the REMS in 2011. Pls.PI.App.598–614.

In response to FDA's 2000 Approval, Plaintiffs AAPLOG and CMDA timely filed a citizen petition with FDA challenging that approval (2002 Citizen Petition). Alliance.CA5.App.151–246. *Fourteen years later*, FDA rejected the 2002 Citizen Petition (2016 Petition Denial). FDA.CA5.Add.804–36.

The *same day*, FDA approved "major changes" to the chemical abortion drug regimen, eviscerating crucial safeguards (2016 Major Changes). FDA.CA5.Add.768–75. Among other things, the agency (1) increased the maximum gestational age from seven weeks to ten; (2) eliminated the requirement for an in-person follow-up examination after a chemical abortion; (3) allowed non-doctors to prescribe and administer chemical abortions; (4) removed the in-person administration requirement of misoprostol; and (5) eliminated non-fatal adverse event reporting. Alliance.CA5.App.125, 133. FDA made these changes based on studies that examined "the safety consequences of eliminating *one* or *two* of the" safeguards, but with "zero" studies on the safety consequences of removing all the safeguards at once. FDA.App.35a (emphasis added). Accordingly, in March 2019, Plaintiffs AAPLOG and ACPeds timely filed another citizen petition challenging the 2016 Major Changes (2019 Citizen Petition). FDA.CA5.Add.192–217.

One month later, FDA approved GenBioPro, Inc.'s abbreviated new drug application for a generic version of mifepristone, relying on the safety data for Mifeprex, Danco's name-brand drug (2019 ANDA Approval). Alliance.CA5.App.457–462.

In April 2021, FDA stated that it would "exercise enforcement discretion" and allow "dispensing of mifepristone through the mail … or through a mail-order pharmacy" during the COVID pandemic (2021 Non-Enforcement Decision). Alliance.CA5.App.249. FDA took this action even though the Comstock Act expressly prohibits distribution of chemical abortion drugs by mail, express company, or common carrier. 18 U.S.C. 1461–62. Then, in December 2021, FDA denied almost all the 2019 Citizen Petition (2021 Petition Response). FDA.CA5.Add.837–76. FDA expressly rejected the 2019 Citizen Petition's request to keep the in-person dispensing requirements and simultaneously announced that the agency had decided it would *permanently* allow chemical abortion by mail—requiring only that the sponsors of mifepristone submit updated REMS. FDA.CA5.Add.842. This effectively federalized abortion by allowing pro-abortion states to mail abortion drugs into states where such drugs are prohibited.

The chart below summarizes FDA's changes to the mifepristone regimen:

Regulation	2000 Approval	2016 Major Changes	2021 Non-Enforcement Decision and Petition Denial
Maximum Gestational Age	49 days	70 days	70 days
Dosage	• 600 mg of mifepristone • 400 mcg of misoprostol	• 200 mg of mifepristone • 800 mcg of misoprostol	• 200 mg of mifepristone • 800 mcg of misoprostol
Route of misoprostol administration	Vaginal	Buccal	Buccal
Timing of misoprostol administration	48 hours after mifepristone	24-48 hours after mifepristone	24-48 hours after mifepristone
Repeat dose of 800 mcg misoprostol	No	Yes	Yes
Dispensed only by or under the supervision of a physician	Yes	No	No
In-person *administration* of drug regimen	Yes	No	No
In-person *dispensing* of drug regimen	Yes	Yes	No
Follow-up in-person evaluation post-abortion	Yes	No	No
Requiring prescribers to report all non-fatal serious adverse events	Yes	No	No

PROCEEDINGS BELOW

In November 2022, Plaintiffs filed suit challenging: (1) FDA's 2000 Approval and 2019 Generic Approval; (2) FDA's 2016 Major Changes; and (3) FDA's 2021 Mail-Order Decision and its 2021 Petition Denial of the 2019 Citizen Petition. On April 7, 2023, the district court stayed the effective date of the 2000 Approval and subsequent challenged agency actions. The court then stayed its own order seven days to allow defendants time to appeal. FDA.App.109a.

FDA and Danco filed their notice of appeal and moved the Fifth Circuit for a stay pending appeal. The Fifth Circuit granted and denied those motions in part and expedited the appeal on the merits. FDA.App.42a.

The Fifth Circuit took a measured approach, staying the district court's ruling on the 2000 Approval based on its expedited review. FDA.App.42a. But the court concluded that FDA failed to satisfy the criteria for a stay pending appeal as to all post-2016 agency actions, including: the 2016 major REMS changes, the 2019 generic approval, the 2021 mail-order decision, the 2021 petition denial, and the 2023 mail-order decision. *Ibid.* The court found Plaintiffs satisfied multiple grounds for standing and were likely to succeed on the merits. FDA.App.10a–42a.

As to Plaintiffs' standing, the court found Plaintiff doctors and members of Plaintiff medical associations have concrete, particularized injury since they have provided—and with certainty will continue to provide—emergency care to women who have incomplete chemical abortions or otherwise require follow-up medical care. FDA.App.11–22a. The court highlighted that the Patient Agreement Form, part of the mifepristone REMS, explains that the treatment will not work in 2 to 7 out of 100 women who use it and will require a surgical procedure to end the pregnancy. FDA.App.12a–13a. And "because the 2016 Major REMS Changes, the 2021 Petition Denial, and the 2023 Mail-Order Decision all allow non-doctors to prescribe mifepristone," women are directed to the emergency rooms of Plaintiff doctors and medical association members rather than their physician providers. FDA.App.13a. FDA's relaxed standard beginning with the 2016 Major REMS Changes also increases: the risk of complications for the 2% of cases involving an ectopic pregnancy, FDA.App.15a–16a, the risk of a Plaintiff doctor having to "surgically complete an abortion or remove an unborn child," FDA.App.16a, and the risk of numerous other emergencies (*e.g.*, hemorrhaging) shifted to Plaintiffs by FDA empowering non-doctors to prescribe mifepristone, FDA.App.18a. The Fifth Circuit also held that Plaintiff

associations have associational standing to sue on behalf of their members. FDA.App.22a.

Regarding timing, the Fifth Circuit remained uncertain—based on its truncated review—whether plaintiffs challenge to FDA's 2000 Approval was timely. FDA.App.24a–30a. But the court easily determined that Plaintiffs' claims as to all post-2016 action were timely. FDA.App.23a.

As for exhaustion, there was no dispute that Plaintiffs fully exhausted all arguments challenging 2016 Major REMS changes. FDA.App.31a–32a. As to Plaintiffs' remaining post-2016 claims, the Fifth Circuit concluded that they were either (a) exhausted or (b) did not need to be exhausted due to futility or FDA's repeated failure to follow its own regulations when reviewing Plaintiffs' petitions. FDA.App.32a–33a.

Turning to the merits, the Fifth Circuit found FDA's actions well outside the zone of reasonableness. FDA.App.33a–35a. Having defined the issue as whether to—all in one swoop—(1) increase maximum gestational age to 70 days, (2) reduce in-person office visits from three to one, (3) allow non-doctors to prescribe mifepristone, and (4) eliminate reporting of non-fatal adverse events, FDA failed to "examine the relevant data" when it made the 2016 Major REMS changes. FDA.App.34a. In fact, there were *zero* studies that looked at all the changed conditions, FDA.App.35a, and even the studies FDA considered were woefully insufficient. The court also found it unreasonable for FDA to eliminate the requirement to report non-fatal adverse events and then use the resulting absence of data to support continued deregulation of mifepristone. FDA.App.35a.

The Fifth Circuit next considered equitable factors for an appellate stay. Taking the district court's stay of the 2000 Approval out of the equation, neither FDA nor Danco articulated an irreparable harm they would suffer absent an appellate stay. FDA.App.36a–37a. Conversely, Plaintiffs established the non-speculative likelihood of harm and risks "that stem from the 2016 Major REMS Changes and other post-

2016 FDA decisions." FDA.App.38a. As for the public interest, the court highlighted that FDA and Danco made "no arguments as to why the 2016 Major REMS Changes, the 2019 Generic Approval, or the 2021 and 2023 Mail Order Decisions are … critical to the public." FDA.App.40a. And the court explained that it would be "difficult" for FDA and Danco even to make that argument "given that the Nation operated—and mifepristone was administered to millions of women—" for 16 years with the pre-2016 safety measures in place. FDA.App.40a.

Finally, the Fifth Circuit disagreed with FDA and Danco that the Comstock Act does not mean what it says. FDA.App.40a–42a. Finding that the court's expedited review did not allow conclusive exploration of the statute, the Fifth Circuit determined any uncertainty at this juncture favored Plaintiffs because FDA and Danco "bear the burden of winning a stay." FDA.App.42a.

Two days later, FDA and Danco filed their emergency requests with this Court.

STANDARD OF REVIEW

Applicants invite this Court to plunge prematurely into ongoing lower court proceedings that, at present, merely reinstate a status quo that governed without issue for 16 years. Their request comes with a heavy burden. *Holtzman* v. *Schlesinger*, 414 U.S. 1304, 1308 (1973) (Marshall, J., in chambers). "A stay is an intrusion into the ordinary processes of administration and judicial review" that "disrupts the usual manner of hearing and considering an appeal before rendering a decision and granting relief." *Louisiana* v. *Am. Rivers*, 142 S. Ct. 1347, 1348 (2022) (Kagan, J., dissenting) (quoting *Nken* v. *Holder*, 556 U.S. 418, 427 (2009)). Only "rarely" is such extraordinary relief warranted. *Heckler* v. *Lopez*, 463 U.S. 1328, 1330 (1983) (Rehnquist, J., in chambers). This Court usually "resist[s] the shortcut the Government now invites." *Barr* v. *E. Bay Sanctuary Covenant*, 140 S. Ct. 3, 6 (2019) (Sotomayor, J., dissenting from the grant of a stay).

To obtain an emergency stay, Applicants must show "(1) a reasonable probability that four Justices will consider the issue sufficiently meritorious to grant certiorari; (2) a fair prospect that a majority of the Court will vote to reverse the judgment below; and (3) a likelihood that irreparable harm will result from the denial of a stay." *Hollingsworth*, 558 U.S. at 190.

Though "necessary" to merit this Court's premature intervention, these conditions are "not necessarily sufficient." *Barnes* v. *E-Systems, Inc. Grp. Hosp. Med. & Surgical Ins. Plan*, 501 U.S. 1301, 1304 (1991) (Scalia, J., in chambers). Applicants additionally "bear an augmented burden" to show a necessity to "invade[ ] the normal responsibility" of the Fifth Circuit "to provide for the orderly disposition of cases on its docket." *Certain Named & Unnamed Non-Citizen Child. & Their Parents* v. *Texas*, 448 U.S. 1327, 1331 (1980) (Powell, J., in chambers). This Court's reluctance and "[r]espect for the assessment of the Court of Appeals is especially warranted when," as here, "that court is proceeding to adjudication on the merits with due expedition." *Doe* v. *Gonzales*, 546 U.S. 1301, 1308 (2005) (Ginsburg, J., in chambers); *Yeshiva Univ.* v. *Yu Pride All.*, 143 S. Ct. 1, 1 (2022) (declining to grant a stay pending appeal when applicants could seek "expedite[d] consideration of the merits of their appeal"). Cf. *Ala. Ass'n of Realtors* v. *Dep't of Health & Hum. Servs.*, 141 S. Ct. 2320, 2321 (2021) (Kavanaugh, J., concurring) (denying an application where a "more orderly" resolution was but a "few weeks" away).

ARGUMENT

I. This Court is unlikely to grant review.

Applicants have not demonstrated that this case is a likely candidate for this Court's review. Without any circuit decision to review at present, there is no circuit split. And even when the Fifth Circuit completes its expedited merits review, Applicants have pointed to no cases that will conflict—regardless of how the Fifth Circuit

rules. This Court's "ordinary practice" is to "deny[ ] petitions insofar as they raise legal issues that have not been considered by additional Courts of Appeals." *Box* v. *Planned Parenthood of Ind. & Ky., Inc.*, 139 S. Ct. 1780, 1782 (2019) (per curiam); *Does 1–3* v. *Mills*, 142 S. Ct. 17, 18 (2021) (Barrett, J., concurring in denial of application) (explaining that whenever an applicant seeks "extraordinary relief" from this Court, an applicant's likelihood of success "encompass[es] not only an assessment of the underlying merits but also a discretionary judgment about whether the Court should grant review in the case"). And this Court frequently denies requests for emergency relief when they come as "the first to address the questions presented." *Does 1–3*, 142 S. Ct. at 18 (Barrett, J., concurring in denial of application). The Court should follow the ordinary course here.

II. A majority of this Court likely will not vote to reverse the judgment below because Plaintiffs' claims satisfy Article III, are properly presented, and are likely to succeed on the merits.

A. Plaintiffs satisfy Article III standing.

"To establish Article III standing, a plaintiff must show (1) an 'injury in fact,' (2) a sufficient 'causal connection between the injury and the conduct complained of,' and (3) a 'likelihood' that the injury 'will be redressed by a favorable decision.'" *Susan B. Anthony List* v. *Driehaus*, 573 U.S. 149, 157–58 (2014) (quoting *Lujan* v. *Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (cleaned up)). The "injury-in-fact requirement … helps to ensure that the plaintiff has a 'personal stake in the outcome of the controversy.'" *Id*. at 158 (quoting *Warth* v. *Seldin*, 422 U.S. 490, 498 (1975)). An Article III injury must be both "concrete and particularized" and "actual or imminent." *Lujan*, 504 U.S. at 560 (cleaned up). Allegations of "future injury may suffice [where] 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* v. *Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013) (emphasis added) (cleaned up)).

The Fifth Circuit and the district court correctly concluded that Plaintiffs meet every Article III standing requirement in two ways. FDA.App.10a–23a, 48a–60a. First, the individual plaintiffs and doctors in plaintiff associations have individual and associational standing to challenge FDA's actions. Second, the medical associations have organizational standing because they suffer harms to their organizations qua organizations. In addition, the district court correctly recognized that plaintiff doctors and medical associations satisfy every requirement for third-party standing.

1. Individual Physician and Associational Standing

The lower courts correctly concluded that individual plaintiff doctors have standing to challenge FDA's actions. Associational standing for the plaintiff medical associations also exists because the named plaintiff members have individual standing. *Hunt* v. *Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977) (associational standing exists where one member has standing, interests are germane to the organization's purpose, and neither the claim nor the relief requires individual member participation).

Specifically, Plaintiffs have standing to sue because they allege that FDA's removal of crucial safeguards for chemical abortion: (1) forces doctors into situations in which they must *perform and participate in an elective abortion* contrary to their most deeply held beliefs to save a woman's life, FDA.App.49a–50a; (2) has placed "enormous stress and pressure" on plaintiff doctors during these emergencies, FDA.App.14a; (3) "consume[s] crucial limited resources, including blood for transfusions, physician time and attention, space in hospital and medical centers, and other equipment and medicines," FDA.App.49a; and (4) causes "Plaintiffs to face increased exposure to allegations of malpractice and potential liability, along with higher insurance costs," FDA.App.50a.

1. *Conscience rights*. Plaintiff doctors are harmed because FDA's unlawful deregulation of mifepristone forces them to violate their conscience rights. As one plaintiff doctor explained, while her "moral and ethical obligation" is to "promote human life and health," FDA's actions "force me to end the life of a human being in the womb." FDA.App.16a. Another doctor representing AAPLOG testified:

> AAPLOG members are opposed to being forced to end the life of a human being in the womb for no medical reason, including by having to complete an incomplete elective chemical abortion. The objections are both ethical and medical as they stem from the purpose of medicine itself, which is to heal and not to electively kill human beings regardless of their location. Accordingly, AAPLOG and our members are harmed by the FDA's repeated removal of necessary safeguards, which may force them to treat women and girls seeking the completion of an elective chemical abortion. [Alliance.CA5.App.006–07.]

This constitutional conscience harm is not speculative. Several doctors testified that they have had to surgically perform an abortion either through suction aspiration or dilation and curtilage. See Alliance.CA5.App.111 (needed to "perform[ ] a dilation and curettage procedure" for a woman who took mifepristone at ten weeks' gestation, a late abortion now authorized by the 2016 Major Changes); Alliance.CA5.App.016 (required "to perform a suction aspiration" to remove "a significant amount of pregnancy tissue" after woman received an additional dose of misoprostol from Planned Parenthood, a part of the approved regimen after the 2016 Major Changes); Alliance.CA5.App.005–06 (colleague left with "no choice but to perform an emergency D&C" despite detecting a fetal heartbeat at about ten weeks' gestation—again, now FDA-authorized by the 2016 Major Changes). One doctor testified: "In my practice, I have cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion. Sometimes this includes the embryo or fetus, and sometimes it is placental tissue that has not been completely expelled." Alliance.CA5.App.015. And plaintiff doctors have seen firsthand increasing numbers of complications related to chemical abortions, including cases where

doctors were forced to perform elective abortions to save a mother's life, even though they were "able to detect a fetal heartbeat." Alliance.CA5.App.005. This feeling of complicity causes great emotional suffering, mental anguish, and spiritual distress for plaintiff doctors. FDA.CA5.Add.152–53.

The government callously dismissed these harms as "one-off incidents," FDA.PI.Br.11, but plaintiff doctors are deeply injured by being forced to perform and participate in elective abortions contrary to their most deeply held beliefs. Alliance.CA5.App.006–07. A dilation and curettage abortion, for example, involves a surgical procedure in which the cervix is dilated so the uterine lining can be scraped out with a spoon-shaped instrument called a curette to remove the unborn baby and pregnancy tissues. *Dilation and Curettage (D and C)*, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/dilation-and-curettage-d-and-c (cleaned up). Meanwhile, suction aspiration abortions are a surgical procedure where plaintiff doctors must insert a cannula into the uterus and attach it to either an electric machine or handheld syringe. Lynn Borgatta, *Surgical Techniques for First-Trimester Abortion*, Global Women's Medicine, https://www.glowm.com/section-view/heading/Surgical%20Techniques%20for%20First-Trimester%20Abortion/item/439. The doctor then uses the machine or syringe to create a vacuum and suck the unborn baby and pregnancy tissue into a cannister. *Ibid.* Plaintiff doctors must then examine the cannister's contents to make sure that the complete embryo or fetus, as well as the decidua, chorionic villi, amniotic fluid, and amniotic membrane have all been extracted. *Ibid.*

The Fifth Circuit correctly concluded that Plaintiffs are concretely and specifically harmed by being forced to perform and participate in elective abortions and by "the irreconcilable choice between performing their jobs and abiding by their consciences." FDA.App.14a, 16a.

2. *Mental and emotional harm*. Plaintiff doctors offered specific facts to explain the stress placed on them by FDA's failure to protect women. Women who take these drugs are susceptible to "torrential bleeding." Alliance.CA5.App.025, 264. And as the Fifth Circuit explained, "these situations can quickly go from bad to worse." FDA.App.14a. As one doctor testified about one of her patients who was about nine weeks pregnant—and thus ineligible to use mifepristone under the 2000 Approval but eligible under the 2016 Major REMS Changes:

> [The patient] had previously been treated by hospital staff for a pulmonary embolism with anti-coagulants. She was advised that she could not seek a chemical abortion because it was contraindicated due to the medications; yet the woman left the hospital and sought an abortion at Planned Parenthood of Indiana. The woman was given mifepristone by the doctor at Planned Parenthood and took the drug. The woman called an Uber for a ride home from Planned Parenthood. The woman began to experience bleeding and other adverse effects from the mifepristone. The woman's Uber driver did not take her home because she was so ill and instead brought her to the hospital's emergency department. At the hospital, the woman came under my care. The woman had not yet taken the second abortion drug, misoprostol. I treated the patient for the adverse effects she suffered and told her not to take the misoprostol given to her by Planned Parenthood because of the grave risk that she could bleed out and die. [*Id.* at 14a–15a (citing Alliance.CA5.App.026–27).]

FDA's continual deregulation of mifepristone to remove necessary safeguards from chemical abortion has placed "enormous stress and pressure" on plaintiff doctors during the resultant emergency situations. FDA.App.14a (quoting Alliance.CA5.App.025). One doctor said the strain "is some of the most emotionally taxing work I have done in my career." Alliance.CA5.App.105. This independent injury "significantly affect[s]" the doctors' "quality of life." *Sierra Club* v. *Morton*, 405 U.S. 727, 734–35 (1972). Indeed, this Court has recognized that this sort of mental distress, along with Plaintiffs' other actual emotional and psychological harms, FDA.CA5.Add.152–54, "could suffice for Article III purposes." *TransUnion LLC* v. *Ramirez*, 141 S. Ct. 2190, 2211 & n.7 (2021).

It also grieves Plaintiffs to treat women and girls harmed by chemical abortion drugs, including those who had unsupervised chemical abortions and suffered because they lacked a follow-up visit, Alliance.CA5.App.019, 114, a result of the 2016 Major REMS Changes. FDA's repeated claims that chemical abortion is as safe as Advil and its "ostrich-in-the-sand" approach to reporting adverse events, FDA.App.19a, 35a, have created an inaccurate safety profile for chemical abortion. Many of Plaintiffs' patients do not fully understand the nature and risks of these drugs and suffer distress and regret after undergoing chemical abortion. FDA.CA5.Add.145. One doctor testified to treating "an 18-year-old woman in the emergency department who was experiencing severe pain" and "did not understand what she had been given." Alliance.CA5.App.091. Another doctor testified that "[a]t least a dozen patients have expressed significant emotional distress to me when they viewed the body of their unborn child in the toilet after the chemical abortion." Alliance.CA5.App.015. This happens with increasing frequency because FDA's 2016 Major REMS Changes moved the maximum gestational age from seven weeks to ten weeks.

3. *Interference with medical practice.* "As a result of FDA's failure to regulate this potent drug," Plaintiffs have devoted significant time and resources to caring for women experiencing mifepristone's harmful effects. FDA.App.14a. This interference with their medical practice is a sufficiently concrete harm. *Ibid.* These often-complicated cases "consume crucial limited resources, including blood for transfusions, physician time and attention, space in hospital and medical centers, and other equipment and medicines." FDA.App.49a. Patients have required "overnight hospitalization, intensive care, and even surgical abortions." *Id.* at 13a (citing Alliance.CA5.App.015-16). One doctor describes such a case:

> As an example of how chemical abortion harms my patients and my medical practice, one of my patients had obtained mifepristone and

> misoprostol from a website, without an in-person visit [authorized by FDA today after the 2016 Major REMS Changes and 2021 Mail-Order Decision]. She was told that the drugs would come from India. After taking the chemical abortion drugs, she began having very heavy bleeding followed by significant abdominal pain and a fever. When I saw her in the emergency room, she had evidence of retained pregnancy tissue along with endometritis, an infection of the uterine lining. She also had acute kidney injury, with elevated creatinine. She required a dilation and curettage (D&C) surgery to finish evacuating her uterus of the remaining pregnancy tissue and hospitalization for intravenous (IV) antibiotics, IV hydration, and a blood transfusion. I spent several hours with her the day of her surgery/hospital admission, keeping me from my primary patient responsibilities in the labor and delivery unit and requiring me to call in an additional physician to help cover those responsibilities. [Alliance.CA5.App.004–05.]

Another doctor testified that, in one month while covering the emergency room, her practice group admitted three women to the hospital because of chemical abortion complications: "one required admission to the intensive care unit for sepsis and intravenous antibiotics, one required a blood transfusion for hemorrhage, and one required surgical completion for the retained products of conception (i.e., the doctors had to surgically finish the abortion with a suction aspiration procedure)." FDA.App.13a (citing Alliance.CA5.App.016). "The increased occurrence of complications related to chemical abortions also multiplies the workload of healthcare providers, including AHM and AAPLOG members, in some cases by astronomical amounts. This is especially true in maternity care 'deserts' (i.e., geographic areas where there are not a large number of OB/Gyn providers for patients)." Alliance.CA5.App.265.

The Fifth Circuit thus found Plaintiff "doctors have had to devote significant time and resources to caring for women experiencing mifepristone's harmful effects." FDA.App.14a. It correctly concluded that "[P]laintiff emergency room doctors have a concrete, particularized injury since they have provided—and with certainty will continue to provide—th[at] 'emergency care.'" FDA.App.13a.

4. *Increased liability*. Plaintiff physicians and medical associations are also harmed because FDA's elimination of the requirement for abortion providers to report all adverse events undermines the doctor-patient relationship; Plaintiffs cannot effectively practice evidence-based medicine and accurately advise their patients about the risks of mifepristone without knowing what those risks are. FDA.CA5.Add.154.

Due to FDA's recent actions to deregulate mifepristone, Plaintiff physicians and medical associations are harmed because they face increased exposure "to allegations of malpractice and potential liability, along with higher insurance costs." FDA.App.50a. As one doctor testified, "FDA's deregulation of these dangerous drugs increases our exposure to liability." Alliance.CA5.App.112. In the words of another doctor, this is because: "FDA's actions have created a culture of chaos for emergency room physicians. In my experience, patients who are given abortifacient drugs at clinics do not understand what they have taken and are often reluctant to tell emergency doctors what they have taken. This puts me and my colleagues in a position where we have to treat women in emergency situations without crucial information … which increases our exposure to claims of malpractice and liability." Alliance.CA5.App.092.

In short, FDA's *de*regulatory actions have "[put] more doctors into riskier, emergent medical situations," and these "actions expose physicians to increased claims of liability." Alliance.CA5.App.276 ("The increased risks of exposure to liability and malpractice claims also impacts physicians because it drives up their insurance costs, especially those who practice in the hospital."); Alliance.CA5.App.098 ("I expect to see more and more women with chemical abortion complications as the use of the drugs increases. Because of the increased complications and the limited information available to me due to the FDA's actions, I fear that I will have greater exposure to liability in my practice.").

Plaintiff doctors and medical associations claims are redressable. Restoring crucial safeguards necessary to protect women and girls will relieve Plaintiffs of at

least some of the injuries caused by FDA's unlawful deregulation of mifepristone and FDA's mail-order abortion regimen. *Larson* v. *Valente*, 456 U.S. 228, 243 n.15 (1982) ("[Plaintiffs] need not show that a favorable decision will relieve [their] every injury."); *Duke Power Co.* v. *Carolina Env't Study Grp., Inc.*, 438 U.S. 59, 74–75 (1978) (a "substantial likelihood" of the requested relief redressing the alleged injury is enough).

2. Defendants' grab-bag of standing arguments is meritless.

The government suggests that the lower court proceeded on a "novel" theory of standing. FDA.Application.23. But it is defendants who rewrite standing law. The government makes the outrageous claim that, even if the record conclusively demonstrated that "hundreds of thousands of women *will* … need emergency care" after using mifepristone, and even if "plaintiff doctors and their associations *will necessarily* be injured by the consequences," Article III standing does not exist. *Ibid.* (emphasis added). That badly misstates the law and implies that the very parties who profit from a dangerous drug—the companies that manufacture the drug and those who prescribe it—comprise the narrow, unlikely pool of potential plaintiffs who can sue FDA over an unlawful approval of that drug.

1. The government complains that Plaintiffs have not satisfied standing as to the 2016 Major Changes, the 2019 ANDA approval, or the 2021 Petition Denial because the lower courts failed to address any *additional* harm from FDA's deregulation of chemical abortion. FDA.Application.26-27. That is a selective reading of the Fifth Circuit's opinion and Plaintiffs' evidence. That court expressly found an *increased* risk of harm to Plaintiff doctors and medical associations "*because FDA has removed almost all of mifepristone's REMS*." FDA.App.17a. For example, FDA's removal of the in-person dispensing requirement puts "women at an increased risk" of harm because a life-threatening ectopic pregnancy (occurring in 2% of all pregnancies) cannot be ruled out without an in-person examination. Alliance.CA5.App.111.

As the Fifth Circuit explained, several doctors "testified that they have seen an *increasing number* of women coming to the emergency room with complications from chemical abortions *due to FDA's virtual elimination of controls* on the dispensing and administration of the drugs." FDA.App.17a (emphasis added) (citing Pls.PI.App.194, 205, 215, 866). One doctor testified, "Deregulated chemical abortion harms my practice because it increases the number of women who come to the emergency department with complications." Alliance.CA5.App.019. Specifically, this doctor attributed this increase in harm to FDA's authorization of mail-order abortions, removal of any in-person doctor evaluation, and elimination of the requirement for abortion providers to provide in-person follow-up care. Alliance.CA5.App.017–18. Another testified that he has encountered "at least a dozen cases of life-threatening complications" from these drugs, and the frequency of "[t]hese emergency situations are becoming more common as more women are turning to chemical abortion as the FDA has relaxed its regulations." Alliance.CA5.App.090.

As noted, FDA removed nearly every meaningful safeguard on chemical abortion in the 2016 Major Changes. Specifically, FDA "(1) increas[ed] the maximum gestational age at which a woman can use the drug from 49 to 70 days; (2) reduc[ed] the number of required in-person office visits from three to one; (3) allow[ed] non-doctors to prescribe and administer the chemical abortions drugs; and (4) eliminat[ed] the requirement for prescribers to report non-fatal adverse events from chemical abortion." FDA.App.5a (citing FDA.CA5.Add.777–802).

FDA only made things worse in 2021 when it eliminated the requirement that women see *any* healthcare provider before a chemical abortion, allowing for mail-order chemical abortions. As the Fifth Circuit explained, FDA's *unlawful deregulation* (as opposed to its unlawful approval) has "enabled women to (1) get the drug without *ever* talking to a physician, (2) take the drug without *ever* having a physical

exam to ensure gestational age and/or an ectopic pregnancy, and (3) attempt to complete the chemical abortion regimen at home." FDA.App.17a.

Further, the 2016 Major Changes and the 2021 Actions discontinued the requirement that doctors prescribe chemical abortion. As a result, "women who use this drug cannot possibly go back to their non-doctor-prescribers for surgical abortions [and] must instead seek 'emergency care' from a qualified physician." FDA.App.13a. This means that when emergencies occur—as the government is forced to concede they will—it is Plaintiff emergency room doctors and their colleagues "who must manage the aftermath." FDA.App.18a. In fact, FDA's own studies showed "there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail." FDA.CA5.Add.870. It thus should come as no surprise to anyone—least of all FDA—that its continual stripping away of safety requirements has "created a culture of chaos for emergency room physicians." Alliance.CA5.App.092.

FDA's deregulation and mail-order abortion regimen exacerbates the risks of chemical abortion for women in several specific situations. Alliance.CA5.App.017. First, with respect to ectopic pregnancies, "[t]he risks are greater under FDA's relaxed standards." FDA.App.16a. Ectopic pregnancies occur in about one out of every 50 pregnancies. FDA.App.15a. As one doctor explained: "Chemical abortion drugs will not effectually end an ectopic pregnancy because they exert their effects on the uterus, which leaves women at risk of severe harm from hemorrhage due to tubal rupture, in need of emergent surgery or potentially at risk of death." FDA.App.15a–16a. The "failure to perform an ultrasound prior to prescribing abortion drugs will cause some women to remain undiagnosed and at high risk for these adverse outcomes." FDA.App.16a. As the Fifth Circuit concluded, this is because "without an in-person examination, it is impossible to rule out an ectopic pregnancy,' placing a woman 'at an increased risk of rupture or even death.'" *Ibid.* (quoting Pls.PI.App.886).

Second, the risks increase with gestational age. Standing thus exists for the additional reason that, as ACOG acknowledges, the risk of needing a follow-up D&C or suction aspiration surgery "increases with advancing gestational age through 70 days of gestation." *Medication Abortion up to 70 days of Gestation*, ACOG Clinical Practice Bulletin (Oct. 2020), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation#:~:text=Medication%20abortion%20failure%20(defined%20as,low%20even%20at%20this%20point. Accordingly, ACOG tells doctors to "counsel patients that medication abortion failure rates, especially continuing pregnancy rates, increase as gestational age approaches 10 weeks." *Ibid.* In fact, the U.S. clinical trial on which FDA relied to approve mifepristone in 2000 found that surgical intervention was needed for 17% of women at 50–56 days' gestation and 23% of women at 57–63 days' gestation—leading to the conclusion that "the regimen is less effective and the incidence of adverse events is higher" for gestational ages over 49 days. AHM.App.0002, 0006. And even the systematic review that Danco touts, Danco.Application.5, showed a significant increase in the failure rate as the baby's gestational age increases: 1.9% failed at <7 weeks, 3.3% failed between 7–8 weeks, 4.5% failed between 8–9 weeks, and 6.9% failed between 9–10 weeks. Melissa Chen and Mitchell Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review*, U.C. Davis (July 2015), https://escholarship.org/uc/item/2pw521h5.

Chemical abortion drugs have also heightened risks for women and girls with certain blood types. FDA.CA5.Add.87. In fact, if a woman or girl with a Rh-negative blood type is not administered certain medication (Rhogam) at the time of her chemical abortion, she could experience isoimmunization, which threatens her ability to have future successful pregnancies. *Ibid.* If a Rh-negative woman or girl is left untreated, her future baby will have a 14% chance of being stillborn and a 50% chance

of being born alive but suffering neonatal death or brain injury. *Ibid*. Around 15% of the U.S. population is at risk of this blood condition. *Ibid*.

In the words of the court below, FDA's "virtual elimination of controls" has led to "an *increasing number* of women coming to the emergency room with complications from chemical abortions." FDA.App.17a (emphasis added); see also FDA.CA5.Add.143 ("Since the 2016 Major Changes, the rate of women and girls who have suffered complications from chemical abortion and required medical treatment has increased and will continue to increase."); FDA.CA5.Add.147 ("Since the 2016 Major Changes … medical professionals, including [Plaintiffs], have seen and will continue to see an additional increase in the rate of women and girls who have suffered complications from chemical abortion—complications requiring critical treatment from these doctors."). Indeed, according to Stanford researchers, with the availability of mail-order abortions, "more people will opt to manage their pregnancies outside of the formal medical system," yet "the healthcare system has not yet adjusted to [the] paradigm shift" of self-managed and so-called "no touch" abortions. Isabel Besnar, et al., *Discovery of an Ectopic Pregnancy after Attempted Self-Managed Abortion*, 388 NEW ENG. J. MED. 278–79 (2023), https://www.nejm.org/doi/full/10.1056/NEJMc2214213. They describe, for example, a 22-year-old patient who self-managed a chemical abortion at five weeks gestation and presented to the emergency room with a ruptured tubal ligation that was misdiagnosed as symptoms of chemical abortion. *Ibid*.

The government points to the adverse events reported through June 2021 as evidence that mifepristone—even without crucial safeguards—is safe. FDA.Application.27. But FDA itself has admitted that "FAERS data cannot be used to calculate the incidence of an adverse event … in the U.S. population." Alliance.CA5.App.382. In any event, those numbers are indeterminate because there is *no* requirement that abortion providers or emergency room doctors report adverse events to anyone. Danco

argues that it is still required to report adverse events. But how is Danco to know about an adverse event if no one is required to tell them? And there were already "significant discrepancies" in the data when abortion providers *had* a duty to report adverse events to Danco. Pls.PI.App.801-06. After eliminating the adverse-event reporting requirement, FDA cannot turn around "and declare[ ] the absence of non-fatal adverse-event reports means mifepristone is 'safe.'" FDA.App.35a (citing FDA.CA5.Add.861–76). "This ostrich's-head-in-the-sand approach is deeply troubling—especially on a record that, according to applicants' own documents, necessitates a REMS program, a 'Patient Agreement Form,' and a 'Black Box' warning."[1] *Ibid.*

2. Defendants maintain that all Plaintiffs' harms are speculative. FDA.Application.21–23. That is wrong. Each and every one of Plaintiffs' concrete and particularized harms are sufficiently imminent. As the Fifth Circuit found, FDA's own Patient Agreement Form makes it impossible for FDA to "deny that serious complications from mifepristone are certainly impending." FDA.App.12a. That form indicates that complications from chemical abortions have caused between 100,000 and 350,000 women to be forced to speak with their provider "about a surgical procedure to end [their] pregnanc[ies]." *Id.* at 13a (cleaned up). And because *non*-doctors may prescribe chemical abortion, these women must seek requisite "emergency care" from a qualified physician. *Ibid.* The plaintiff emergency room doctors have a concrete, "particularized injury since they have provided—and with certainty will continue to provide—the 'emergency care' that applicants specified in the 'Patient Agreement Form.'" *Ibid.* (quoting Pls.PI.App. 167, 169, 194, 206). And that problem has substantially increased—along with the skyrocketing number of chemical abortions—following FDA's deregulation in the 2016 Major Changes. See Guttmacher Institute, *As of*

[1] The generic drug comes with all the same harms as does the name brand—so the lower court's harm analysis applies full-fledge to the 2019 ANDA approval.

2020, medication abortions account for the majority of all US abortions, https://www.guttmacher.org/sites/default/files/2022-11/APCnewimaeg.png (charting number of U.S. chemical abortions).

Indeed, Plaintiffs testified that they "often" treat patients suffering adverse complications from chemical abortions—several doctors treating emergency medical conditions caused by FDA's deregulation of chemical abortion a dozen times or more. Alliance.CA5.App.006–07, 014–19, 026–27, 033–34. One doctor has been required to perform emergency surgery to remove embryos, fetuses, and pregnancy tissue in a dozen different cases—much of which could have been avoided if FDA had not removed the Day 14 follow-up office exam. Alliance.CA5.App.012–20. Several doctors detail interference with their medical practice and the need to call in an additional doctor to cover other patients while they treated emergency complications from mifepristone under FDA's deregulated regimen. Alliance.CA5.App.006, 019, 025–28, 091–92, 106. And three doctors state that they were faced with emergency situations and forced to perform and participate in elective abortions because women were suffering life-threatening conditions from mifepristone, even though this violated the doctors' most deeply held beliefs. Alliance.CA5.App.005–007, 016–019, 111.

Plaintiffs' alleged harms are hardly "chimerical." *Steffel* v. *Thompson*, 415 U. S. 452, 459 (1974). To the contrary, they have *happened*—repeatedly. And while allegations of past harm alone are insufficient to obtain forward-looking relief, those past harms can be evidence that similar circumstances forbode a "substantial risk that the harm will occur." *SBA List*, 573 U.S. at 158 (quotation omitted).

Here, past is prologue. As the Fifth Circuit found, given the multitude of women already seen by Plaintiff doctors in emergency rooms, and because Danco's own Patient Agreement Form indicates that thousands more women will need emergency care—a problem that continues to grow worse, not better, under FDA's continual deregulation—it is reasonably certain "that women will continue needing

plaintiffs' 'emergency care.'" See Alliance.CA5.App.015, 025, 093. Accordingly, plaintiffs face a "substantial risk" of recurrence. *SBA List*, 573 U.S. at 158 (quotation omitted).

3. Next, despite citing *Summers* v. *Earth Island Institute*, 555 U.S. 488 (2009), only in passing below, FDA and Danco now frame *Summers* as the key to rejecting the district court's stay. But *Summers* does *not* stand for the proposition that future relief is never available—especially where Plaintiffs "will necessarily be injured." Cf. FDA.App.19a. Indeed, under the government's theory, standing would exist only for the pharmaceutical corporations with vested financial interests. But Article III does not impose an insuperable bar for equitable relief from future harm.

In any event, neither *Summers* v. *Earth Island Institute*, nor *Clapper* v. *Amnesty Int'l USA*, pose a hurdle here. The government mischaracterizes the Fifth Circuit's decision as relying on a statistical-probability-of-injury-to-a-member theory. FDA.Application.23–24. But that court found—and Plaintiffs plainly allege—"specific allegations establishing that at least one identified member had suffered or would suffer harm." *Summers*, 555 U.S. at 498. Plaintiffs' complaint "identif[ied] members who have suffered the requisite harm—surely not a difficult task here, when so many thousands are alleged to have been harmed." *Id.* at 499. Here, both lower courts concluded that *named* organizational as well as individual plaintiffs alleged sufficiently concrete and certainly impending harms from the 2016 Major Changes and subsequent removal of safety standards. Indeed, in *Summers* the government conceded that associational standing would exist where a member alleged injury to "interests in viewing the flora and fauna" and that he "had repeatedly visited [a certain park]" and "had imminent plans to do so again." *Id.* at 494.

Defendants overread *Clapper* to suggest that the Fifth Circuit erred in finding harm to be "certainly impending." FDA.Application.20-23. As the lower courts held, *Clapper* is distinguishable because no plaintiff there had *ever* suffered an injury.

FDA.App.17a, 56a–57a. Further, recent cases reaffirm what *Clapper* stated in footnote five: that a material risk of future harm satisfies Article III "so long as the risk of harm is sufficiently imminent and substantial." *TransUnion*, 141 S. Ct. at 2210; *SBA List*, 573 U.S. at 158 ("An allegation of future injury may suffice if the threatened injury is 'certainly impending,' or there is a 'substantial risk' that the harm will occur.") (cleaned up); *Massachusetts* v. *EPA*, 549 U.S. 497, 525 n.23 (2007).

Here, under FDA's "no-touch" mail-order abortion regimen, "there is a 'substantial risk' that the harm will occur." *SBA List*, 573 U.S. at 158. In short, FDA "cannot deny that serious complications from mifepristone are certainly impending. Those complications are right there on the 'Patient Agreement Form' that FDA itself approved." FDA.App.12a. Plaintiffs "have a concrete, particularized injury since they have provided—and with certainty will continue to provide—the 'emergency care' that applicants specified in the 'Patient Agreement Form.'" *Id.* at 13a.

4. Finally, defendants' parade of horribles doesn't march. This case is unlike one where a doctor refuses to treat an asthmatic child or gunshot victim because of objections to environmental and gun regulations (or lack thereof). FDA.Application.23, Danco.Application.21–22 Such a doctor's harms are not likely to be either concrete or imminent. Redressability would be a non-starter, too. And even if a doctor could clear those hurdles, they would still be required to prove unlawful agency action. Finally, unlike our hypothetical pulmonologist, Plaintiff doctors' medical practices are not harmed just by the chaos caused by unregulated chemical abortions but also suffer concrete and specific harm from "being forced to end the life of a human being in the womb for no medical reason." FDA.CA5.Add.153.

3. Organizational Standing

The lower courts correctly held that plaintiff medical associations have organizational standing. In response to FDA's approval and deregulation of mifepristone,

they "diverted valuable resources away from [their] advocacy and educational efforts" to inform their members, patients, and the public about the dangers of chemical abortion drugs "to the detriment of other priorities and functions." FDA.App.55a, 22a.; accord *Havens Realty Corp.* v. *Coleman*, 455 U.S. 363, 379 (1982) (holding non-profit organization had standing to sue when defendant "frustrated" its activities and non-profit "devote[d] significant resources to identify and counteract the defendant's [behavior]"); *OCA-Greater Houston* v. *Texas*, 867 F.3d 604, 610–12 (5th Cir. 2017) (same). Additionally, Plaintiffs spent significant amounts of time on their citizen petitions. FDA.CA5.Add.70–74, 109–15, 127–30, 157–60.

Here, "there can be no question" that plaintiff medical associations suffered an Article III injury, where their ability to pursue their mission was "perceptibly impaired" because they "had to devote significant resources to … counteract the defendant's [conduct]." *Havens*, 455 U.S. at 379. "Such concrete and demonstrable injury to the organization's activities—with the consequent drain on the organization's resources—constitutes far more than simply a setback to the organization's abstract social interests." *Ibid*. (citing *Sierra Club*, 405 U.S. at 739 (no standing because "mere 'interest in a problem[]' … is not sufficient by itself")); 13A Charles Alan Wright & Arthur R. Miller, Fed. Prac. & Proc. § 3531.9.5 (3d ed. 2022) (standing where "organization has devoted specific effort and expense to combat the challenged activity").

Danco complains Plaintiffs cannot claim organizational standing because they oppose abortion. Danco.Application.23. But by this logic, none of the organizations devoted to promoting voting rights would have been allowed to challenge alleged voting restrictions—that too would have been on mission. See*, e.g.*, *Tex. State LULAC* v. *Elfant*, 52 F.4th 248 (5th Cir. 2022). Here, because of FDA's lawless actions, the plaintiff organizations diverted resources from their routine functions to educate the public about the particular dangers of "no-touch" *chemical* abortions. FDA.CA5.Add.158.

4. Third-Party Standing

The district court also correctly held that Plaintiffs can assert third-party standing because their physician–members' patients: (1) have "endure[d] many intense side effects," "suffer[ed] significant complications requiring medical attention," and "suffer[ed] distress and regret"; (2) have a "close relation" to the physician-members; and (3) are hindered from "protect[ing] their [own] interests." FDA.App.51a. "Doctors regularly achieve standing to protect the rights of patients and their own related professional rights." 13A Charles Alan Wright & Arthur R. Miller, Fed. Prac. & Proc. § 3531.9.3 (3d ed. 2022). And this is particularly true in the abortion context. *Dobbs* v. *Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022). (The Fifth Circuit mistakenly declined to rule on third-party standing *because* of *Dobbs*. FDA.App.10a n.4.).

During proceedings below, the government did not dispute that Plaintiffs have third-party standing to raise the claims of their patients if Plaintiffs themselves have standing. See Pls.PI.Br.9-13. It did not dispute that third-party standing exists when, as here, a plaintiff shares a close relationship with third-parties who are inhibited from bringing suit on their own behalf. See *Kowalski* v. *Tesmer*, 543 U.S. 125, 129–30 (2004). And for good reason. Courts have recognized "the inherent closeness of the doctor-patient relationship" and "a woman's desire to protect her privacy could discourage her from bringing suit." *Pa. Psychiatric Soc'y* v. *Green Spring Health Servs., Inc.*, 280 F.3d 278, 289–90 (3d Cir. 2002). Indeed, this Court has observed that courts "have long permitted abortion providers to invoke the rights of their actual or potential patients in challenges to abortion-related regulations." *June Med. Servs. L.L.C.* v. *Russo*, 140 S. Ct. 2103, 2118 (2020), *abrogated on other grounds by Dobbs*, 142 S. Ct. 2228. If "a regulated party 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), then surely Plaintiffs can sue on behalf of their injured patients—as both seek protection from the harms of chemical abortion drugs.

B. Applicants have not demonstrated a fair probability that they will succeed on the merits.

Applicants have also failed to make the "strong showing" that this Court will reverse the judgment below. *Nken* v. *Holder*, 556 U.S. 418, 426 (2009). As the Fifth Circuit correctly held, FDA acted arbitrarily and capriciously in its 2016 Major Changes and subsequent actions. See 5 U.S.C. 706(2)(A). The APA required FDA to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choices made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (cleaned up). That means FDA could not "entirely fail[ ] to consider an important aspect of the problem, [or] offer[ ] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Ibid.*

Without sufficient explanation, FDA's 2016 Major Changes removed critical safeguards on mifepristone's use. Compounding this failure, FDA justified its decision based on studies that "*included those very safeguards*." FDA.App.34a. That's like an agency that removes seatbelt and airbag requirements based on safety studies that all included seatbelts. Cf. *State Farm*, 463 U.S. at 34–36, 47–49. As this Court has held, that cannot constitute "reasonable" decision-making. *Ibid.* "The fact that mifepristone might be safe when used with" critical safeguards "says nothing about whether FDA can eliminate [those safeguards] (a question *not* studied by the FDA)." FDA.App.35a (emphasis added). By failing to "reasonably consider[ ] the relevant issues and reasonably explain[ ]" its actions, FDA violated the APA. *FCC* v. *Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021).

FDA contends that it studied the safety consequences of eliminating some of these safeguards. But as the Fifth Circuit noted, the agency did so "in isolation." FDA.App.35a (emphasis omitted). FDA conceded that its "major changes [were] interrelated," FDA.CA5.Add.781, yet it "relied on *zero* studies that evaluated the safety-and-effectiveness consequences of the 2016 Major … Changes *as a whole*," FDA.App.35a (emphasis added). By basing its decision to remove "interrelated" safeguards on data that largely studied what would happen if only *one* safeguard was removed, FDA failed to consider "an important aspect of the problem," and that failure violated the APA. *Michigan* v. *EPA*, 576 U.S. 743, 752 (2015) (cleaned up).

Consider FDA's decision to extend gestational age to 70 days. FDA did so based on a study where abortion providers confirmed gestational age "based on routine ultrasound practices" and required study participants—all of whom were required to be at least 18 years old, even though there is no minimum age for mifepristone—to return in-person after taking mifepristone "for clinical assessment, which included ultrasonography." Pls.PI.App.655. Yet the 2016 Major Changes completely *removed* the requirement for an in-person follow-up examination after a chemically induced abortion, while FDA has *never required* an ultrasound to confirm gestational age or identify life-threatening ectopic pregnancies. FDA failed to explain how it was safe to extend the permissible gestational age to 70 days, based on a study involving initial ultrasound exams and follow-up exams, while *never requiring* initial ultrasound exams and *simultaneously removing* a follow-up exam requirement. That was arbitrary and capricious.

Though plugging its "scientific" bona fides to claim that it relied on trusted data to "support multiple changes," FDA has continually failed to grapple with the problems that Plaintiffs highlight about its data. Every study that FDA relied on in its 2016 Major Changes suffered from fatal flaws. As already reviewed, none of the studies examined what would happen if FDA removed *all* the safeguards—even

though FDA defined the scope of the problem to be examined as whether it was safe to remove multiple safeguards collectively.

There's more. For instance, the Winikoff study that FDA touts, FDA.Application.33, "was not powered to detect a difference in safety outcomes"; it focused not on safety but efficacy. Pls.PI.App.658. And the cited Smith study, FDA.Application.33, was similarly designed to measure "method efficacy." Both studies admitted that researchers lost a significant amount of their respective sample populations to follow-up (13–14% for Winikoff, and 4.1% for Smith)—meaning that the health outcomes of these women cannot be determined. Rather than explain why these flaws do not matter, FDA throws up the words "scientific judgment" as if that should end the matter. But FDA is not the unchallengeable king of the "science" domain. The entire point of the APA (and the scientific process itself) is to test, challenge, explain, and improve. FDA's failure to provide a "reasoned explanation" for its decision to rely on flawed data is fatal. *FCC* v. *Fox Television Studios, Inc.*, 556 U.S. 502, 516 (2009); *In re NTE Conn., LLC*, 26 F.4th 980, 989 (D.C. Cir. 2022) ("An agency's failure to respond meaningfully to objections raised by a party renders its decision arbitrary and capricious. We have stressed that unless the agency answers objections that on their face seem legitimate, its decision can hardly be classified as reasoned.").

Worse, FDA "shirked any responsibility for the consequences of its actions by eliminating any requirement that non-fatal adverse events be reported." FDA.CA5.Add.59. This action effectively gave FDA cover to peddle its chemical abortion drug regimen as "safe." FDA.App.35a. FDA contends that "after 15 years of reporting serious adverse events, the safety profile" for mifepristone was "unchanged," so further reporting of adverse events was "not warranted." FDA.Application.35. But simply asserting that "known risks" do not often occur does not make it so. *Ibid.* Even before the 2016 Major Changes, abortion providers' data for adverse events did not match the FAERS database. Pls.PI.App.804. And FDA makes no serious attempt to

reconcile its assertion with Plaintiffs' data showing that adverse events were grossly underincluded, and indeed, the most common adverse events were routinely excluded from consideration. FDA.Application.35.

FDA's "trust-without-verification" approach makes for a poor foundation to support its subsequent actions—and yet FDA builds upon it anyway. FDA's 2021 Non-Enforcement Decision and 2021 Petition Response relied heavily on FDA's database to determine that it was safe to remove in-person dispensing requirements. Given that FDA *abandoned* reporting requirements for nonfatal adverse events, this was stacking the deck. As the Fifth Circuit concluded, "[t]his ostrich's-head-in-the-sand approach is deeply troubling" and "unreasonable." FDA.App.35a. An agency cannot "eliminate a reporting requirement for a thing and then use the resulting absence of data to support its decision." *Ibid.* Such sleight-of-hand is "well 'outside the zone of reasonableness.'" *Ibid.* (quoting *Prometheus Radio Project*, 141 S. Ct. at 1160). What's more, FDA itself has disclaimed the utility of this database because "FAERS data cannot be used to calculate the incidence of an adverse event … in the U.S. population." Alliance.CA5.App.382.

FDA's "offered … explanation for its decision"—that Danco remained obligated to report adverse events, so FDA had a full profile of mifepristone's effects—"runs counter to the evidence." *State Farm*, 463 U.S. at 43. There was already a significant disparity between reported adverse events and FDA's database *before* the 2016 Major Changes, leading one study to conclude that "either Danco did not report a significant number of adverse events to the FDA," or FDA, without explanation, "did not include them in FAERS." Pls.PI.App.804. And after the 2016 Major Changes neither abortion providers nor busy emergency room doctors are required to report adverse events to FDA or Danco.

FDA concedes that abortion providers, like Planned Parenthood, have no obligation to report adverse events to Danco or FDA. And not only are emergency room

doctors not required to report adverse events to Danco or FDA, but many also do not even know about their *ability* to report adverse events or have the time to do so. Alliance.CA5.App.406–07. Even assuming it is in Danco's "best interest" to "report adverse events to those regulating" it, Alliance.CA5.App.406, Danco could not have provided a full picture of mifepristone's adverse events. See *State Farm*, 463 U.S. at 43. Danco is a Cayman Islands-based company with no boots-on-the-ground in emergency rooms to witness adverse events as they happen; it is entirely reliant on others to report them, and those "others" are not reporting.

FDA's argument about so-called "undisturbed … reporting requirements governing mifepristone's sponsors" is all smoke and mirrors. When the 2016 Major Changes removed reporting requirements, FDA lost any ability to gauge mifepristone's adverse impacts. Alliance.CA5.App.407 ("With the relaxation of reporting requirements, the ability to perform any relevant post-marketing evaluation of mifepristone was lost."). It was therefore arbitrary and capricious to point to the lack of adverse events when removing the in-person dispensing requirements.

FDA also claims that it "relied on an extensive review of the published literature" to remove in-person dispensing requirements. Yet FDA acknowledged that this "extensive literature" all had severe flaws. FDA conceded "the ability to generalize the results of these studies to the United States population is hampered," "the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes with regard to both safety and efficacy," and FDA "did not find any large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States." FDA.CA5.Add.864. Recognizing these limitations, FDA further conceded that "the studies [it] reviewed are not adequate on their own to establish safety of the model of dispensing mifepristone by mail." *Id.* at 871. And 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." *Id.* at 870. Even more troubling, FDA's reliance on these studies had its obligations upside-down: "Despite the limitations of the studies … the outcomes of these studies *are not inconsistent with our conclusion* that … mifepristone will remain safe." *Id.* at 864 (emphasis added). To rely on such flawed data and reasoning for its decision is the epitome of arbitrary and capricious.

Applicants argue that all these decisions were within the agency's discretion and this Court should therefore defer to its "scientific judgment." *E.g.*, FDA.Application.6. But there's nothing scientific about identifying safeguards as interrelated but then failing to examine the effect these safeguards would have if removed completely. FDA may have examined "data gained in the last 20 years" when considering removing *one* of those safeguards. FDA.Application.29. And it may have looked at "14 major studies and review articles" when examining *another* safeguard. *Ibid.* But it looked at "*zero*" studies that considered what would happen when *all* safeguards were removed at the same time. This, even after FDA identified these safeguards as "interrelated." FDA.CA5.Add.781. That is a failure to "reasonably consider[ ] the relevant issues," not scientific judgment. *Prometheus Radio Project*, 141 S. Ct. at 1158.

Similarly, no amount of agency discretion allows FDA to "entirely fail[ ] to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. Applicants spill much ink arguing that the Fifth Circuit's holding would require an exact "study match," but it would do no such thing. Nowhere in its opinion did the Fifth Circuit say that FDA needed to approve mifepristone under the exact conditions studied in trials. In fact, the court went out of its way to say the *opposite*. FDA.App.19a. What the court did hold was that when FDA identifies various safeguards as "interrelated," it is arbitrary and capricious for the agency to remove all of those safeguards based on "*zero* studies that evaluated the safety-and-effectiveness of" removing those safeguards "*as a whole*." FDA.App.35a. In other words: a problem identified needs to be,

at the very least, a problem "reasonably explained." *Prometheus Radio Project*, 141 S. Ct. at 1158. That's not novel—it's basic administrative law.

This is precisely why the district court stayed the approval of GenBioPro, Inc.'s abbreviated new drug application (ANDA) for a generic version of mifepristone. FDA.App.102a. That court "agree[d] that Plaintiffs have a substantial likelihood of success in their challenges to the 2000 and 2016 Actions." *Ibid.* As the court observed, "[i]f FDA withdraws the listed drug on which the ANDA-approved generic drug is based, the agency is generally required to withdraw the generic drug as well." *Ibid.* (citing 21 U.S.C. 355(j)(6); 21 C.F.R. 314.151). The Fifth Circuit concluded that Plaintiffs' challenge to FDA's 2019 ANDA Approval falls "squarely within the six-year window" of the relevant statute of limitations—even if the challenge to the 2000 Approval did not—and is "not barred by exhaustion." FDA.App.23a, 32a. Defendants offer no reason why the stay of the 2019 ANDA Approval should be paused.

Not only did FDA violate the APA, but its actions also run afoul of longstanding federal criminal laws. The Comstock Act prohibits the mailing or delivery of "[e]very article or thing designed, adapted, or intended for producing abortion" and "[e]very article … which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion." 18 U.S.C. 1461–62. Yet FDA's 2021 Non-Enforcement Decision and 2021 Petition Response *authorized* the mailing of chemical abortion drugs. These actions flouted unambiguous federal law—and, in doing so, further violated the APA, which requires federal agencies to follow all laws. *FCC* v. *NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003).

Thus far FDA's primary defense has been to argue that federal regulations require it only to evaluate a drug's safety and effectiveness, not its compliance with federal criminal law. But as this Court has held, the APA requires agencies to follow "*any* law, and not merely those laws that the agency itself is charged with administering." *Ibid.*

FDA's second defense, a weak statutory argument, fares no better. FDA contends that historically the Comstock Act never prohibited the distribution of abortion drugs for *lawful* uses. But the Comstock Act's text controls over any such history.[2] *N.Y. State Rifle & Pistol Ass'n* v. *Bruen*, 142 S. Ct. 2111, 2137 (2022). When FDA acted, the Comstock Act plainly prohibited the mailing of chemical abortion drugs.

FDA suggests that Congress, in the FDAAA, silently repealed the Comstock Act's plain meaning. As the Fifth Circuit noted, "repeals by implication are not favored," and exist only when "Congress' intention to repeal is clear and manifest." *Me. Cmty. Health Options* v. *United States*, 140 S. Ct. 1308, 1323 (2020) (cleaned up). And the FDAAA did not expressly legalize mifepristone. Its brief text only created "a statutory framework governing REMS and drugs [like mifepristone] with then-existing distribution restrictions." FDA.App.41a. The Fifth Circuit was thus appropriately hesitant to "find clear and manifest intention to repeal a 150-year-old statute that Congress has otherwise repeatedly declined to alter in the far reaches of a single section of the cavernous FDAAA." FDA.App42a.

III. The applicants fail to make a strong showing on any of the equitable factors.

A. FDA cannot demonstrate irreparable injury.

In the Fifth Circuit, the government failed to "articulate any irreparable harm that *FDA* will suffer absent a stay." FDA.App.36a. So FDA now changes course and comes up with three new harms: (1) "it is blocked from fulling its statutory responsibilities in accordance with its scientific judgment," (2) it will have to spend time "to make the necessary adjustments to the regulatory scheme," and (3) it has to deal with the "threat" of "conflicting court orders." FDA.Application.40–41.

[2] And as the district court rightly noted, this Court should be skeptical of Applicants' newfound history. Until *Roe*, most jurisdictions overwhelmingly made abortions illegal. FDA.CA5.Add.37–38.

The first alleged harm is entirely derivative of the merits. "[A] party may not satisfy the irreparable harm requirement if the harm complained of is self-inflicted." 11A Charles Alan Wright, et al., Fed. Prac. & Proc. § 2948.1 (2021). *Accord, e.g.*, *Texas* v. *Biden*, 10 F.4th 538, 558 (5th Cir. 2021) (per curiam) (citation omitted), *rev'd and remanded on other grounds*, 142 S. Ct. 2528 (2022); *Al Otro Lado* v. *Wolf*, 952 F.3d 999, 1008 (9th Cir. 2020). And the Fifth Circuit correctly held that FDA did *not* fulfill its statutory responsibilities and instead acted in arbitrary and capricious ways. FDA.App.33a–35a. No irreparable harm here.

A government agency's expenditure of bureaucratic time and money is also not an irreparable injury. *Al Otro Lado*, 952 F.3d at 1008. At best, a diversion of an agency's "time, resources, and personnel from other pressing" projects is a "minimal" governmental harm. *Hernandez* v. *Sessions*, 872 F.3d 976, 995 (9th Cir. 2017). And candidly, there's no work ahead. The Fifth Circuit's Solomonic decision leaves FDA's 2000 approval of mifepristone in place while staying later FDA actions that unlawfully removed protections to keep women safe. That means the operable standards are the agency's 2011 REMS for mifepristone.

As the Washington district court recognized, and FDA has not contested, "[t]he effect of invalidating an agency rule is to reinstate the rule previously in force." Order at 26, *Washington* v. *FDA*, No. 23-cv-3026 (E.D. Wash. Apr. 7, 2023), ECF No. 80 (quoting *Paulsen* v. *Daniels*, 413 F.3d 999, 1008) (9th Cir. 2005) (citation omitted)). FDA thus need not take any action to effectuate the Fifth Circuit's decision. See Defs.' Mot. For Clarification at 2, *Washington* v. *FDA*, No. 23-cv-3026 (E.D. Wash. Apr. 10, 2023), ECF No. 81 (acknowledging that the Texas district court's "order would—of its own force and without any further action by FDA—stay the effectiveness of FDA's prior approvals"). There is nothing preventing FDA from complying with the Washington district court's injunction prohibiting the agency from "altering … the

availability of Mifepristone." Order at 6, *Washington* v. *FDA*, No. 23-cv-3026 (E.D. Wash. Apr. 13, 2023), ECF No. 91.

Indeed, the agency already has approved mifepristone under Danco's supplemental new drug application (sNDA) for the 2011 REMS, which includes the relevant labeling, Medication Guide, Patient Agreement, and Prescriber's Agreement. Pls.PI.App.598–614. All FDA needs to do is sit tight—hardly an onerous, untenable requirement.

FDA's claim of conflicting orders is not only factually incorrect, but it is also premature. While FDA has gone to extraordinary lengths to appeal the district court and Fifth Circuit decisions below on an emergency basis, it has not lifted a finger to relieve itself of the purported "conflict" by appealing the injunction issued by the district court in the Washington litigation. (Curiously, FDA and Danco also oppose the intervention of states in the Washington litigation who would create true adversity and advance the same position adopted here by the district court and Fifth Circuit.) The agency no doubt has political preferences that motivate that decision, but it is hardly this Court's job to fix a conflict that has not yet manifested itself and before FDA has even tried to exhaust its lower-court remedies.

Alternatively, FDA asserts harm to women who will seek to take mifepristone. FDA.Application.38–39. To begin, they "are not stay applicants in this case." FDA.App.36a. More important, as noted above and below, the harm runs the opposite way—removing safety protections like in-person doctor visits (including the possibility of an ultrasound) and mandatory reporting of adverse events causes greater harm to women than alternatives. And when approving the 2016 Major Changes, FDA stressed that it had "no safety or efficacy concerns about the originally approved dosing regimen that led to re-moving it from the labeling." FDA.CA5Add.785.

B. Danco cannot demonstrate irreparable injury.

In the Fifth Circuit, Danco claimed financial losses only from the district court staying FDA's 2000 Approval, FDA.App.36a–37a, a harm that motivated the Fifth Circuit in part to stay that portion of the district court's order. *Ibid.*; FDA.App.42a. Notably, Danco made "no argument as to why the district court's treatment of the 2016 Major REMS Changes and later FDA activity irreparably harms anyone." FDA.App.37a. But like FDA, Danco also makes up new harms for this Court's consideration. Both its new alleged harms are specious.

First, Danco complains that it will have to revise product labels and collateral documents all "currently based on the 2023 REMS." Danco.Application.32. Danco says it cannot make any changes until FDA approves new REMS. But that grossly overstates the burden. As just explained, the Fifth Circuit left FDA's 2000 Approval in place, enjoining only later FDA actions that unlawfully removed protections designed to keep women safe. So the operable standards are the agency's 2011 REMS for mifepristone. In a world where drug manufacturers can take a new vaccine from laboratory to market in a matter of months, it is disingenuous to say labels and documents *that already exist* cannot be speedily deployed.

Second, Danco doubles down on the purportedly conflicting Washington court order. Danco.Application.33–34. But Danco has even less reason to protest about this possible problem than FDA. To be sure, both that proceeding and this one have the potential to jeopardize Danco's interests. Yet Danco chose to participate only here. Even today, Danco could intervene in the Washington federal-court matter and seek emergency relief on appeal. Its failure to pursue that readily available lower-court remedy undercuts the company's request for extraordinary relief from this Court. Like FDA, Danco should exhaust its lower-court remedies before asking this Court for extraordinary relief. *Yeshiva Univ.*, 143 S. Ct. at 1.

In addition, the Court cannot ignore that Danco has been complicit in FDA's unlawful actions since the beginning. Danco and its allies pressured FDA not to require ultrasounds as part of the 2000 Approval. Alliance.CA5.App.115–21. It was Danco that lobbied FDA to remove several crucial safeguards and completely revise the regimen in the 2016 Major Changes. *Id.* at 122–50. And Danco continues to distribute chemical abortion drugs in violation of the Comstock Act; as the Fifth Circuit found, "Danco has no interest in continuing to violate the law, which (under a plain view of the Act) it does every time it ships mifepristone." FDA.App.41a. And even if Danco were harmed economically by the Fifth Circuit's order (it is placed in a better position as the generic is off the market), any economic harm to a company that has financially benefitted from its own unlawful behavior is far outweighed by the harms to women and their doctors.

C. Conversely, a stay would irreparably harm plaintiff doctors and organizations.

As explained in Section I, Plaintiffs face imminent, non-speculative harm. For those reasons, FDA's and Danco's contrary arguments are not well-founded in law or fact, contra FDA.Application.43–44; Danco.Application.40, and Plaintiffs will not repeat all their responses here.

Alternatively, FDA and Danco criticize Plaintiffs for delay, such as Plaintiffs' suggestion below that the district court take a few extra weeks (or months, if necessary) to conduct an evidentiary hearing and decide this case on the merits rather than rule on preliminary injunction motion paperwork, or Plaintiffs taking the time to gather evidence after FDA denied their petitions but before filing this lawsuit. FDA.App.43–44; Danco.Application.40. These criticisms miss the mark.

First and foremost, Plaintiffs have already persuaded the district court and the Fifth Circuit to grant relief. So the burden for proving irreparable harm has shifted to FDA and Danco. FDA.Application.17 (an applicant for a stay pending appeal in

this Court must establish "that *the applicant* would likely suffer irreparable harm absent the stay") (quoting *Merrill* v. *Milligan*, 142 S. Ct. 879, 880 (2022) (Kavanaugh, J., concurring) (emphasis added)). And as just explained, neither FDA nor Danco can satisfy that burden.

Next, it was eminently sensible for Plaintiffs to request the modest additional time that would have allowed the district court to rule on the merits. Such a course would have resulted in a final judgment that could then be litigated on the merits in the Fifth Circuit and presented to this Court in a petition for certiorari rather than in an emergency application. Plaintiffs took pains to ensure orderly appellate review; FDA and Danco did not.

Finally, it's a bit much for FDA to chastise Plaintiffs for delay in filing suit when FDA "stonewalled judicial review" by "postpone[ing] and proscrastinat[ing]" to adjudicate Plaintiffs' petitions "for nearly *6,000 days*." FDA.App.43a. "Had FDA responded to Plaintiffs' petitions within the 360 total days allotted [by regulation], this case would have been in federal court *decades* earlier." *Ibid.* As the Fifth Circuit found, FDA and Danco's delay argument against Plaintiffs "is untenable given FDA's *fourteen-year delay* in adjudicating the 2002 Citizen Petition." FDA.App.38a. And, that court continued, "even setting aside FDA's own delays, the applicants do not explain why the plaintiffs' alleged procrastination warrants a stay of the entirety of the district court's order, rather than just the portion of the order impacted by long litigation delay (the 2000 Approval)." *Ibid.*

D. A stay would also irreparably harm the public interest.

Below, FDA and Danco "ma[d]e no arguments as to why the 2016 Major REMS Changes, the 2019 Generic Approval, or the 2021 and 2023 Mail Order Decisions are … critical to the public even though [FDA and Danco] were on notice of plaintiffs' alternative requests for relief." FDA.App.40a. "And it would be difficult for [FDA and

Danco] to argue that the 2016 Major REMS Changes and subsequent FDA activity were so critical to the public given that the Nation operated—and mifepristone was administered to millions of women—without them for sixteen years following the 2000 Approval." *Ibid.* Nonetheless, Danco now claims harm to the public, to women, and to the pharmaceutical industry from those Changes.

1. The public

Start with the public. "[O]ur system [of government] does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors* v. *Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2490 (2021) (per curiam). Accordingly, "there is generally no public interest in the perpetuation of unlawful agency action." *Louisiana* v. *Biden*, 55 F.4th 1017, 1035 (5th Cir. 2022) (quoting *Texas* v. *Biden*, 10 F. 4th at 560, itself quoting *League of Women Voters of U.S.* v. *Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016)). To the contrary, allowing illegal actions by government agencies to stand "*undermine[s]*" the public interest. *Valley* v. *Rapides Par. Sch. Bd.*, 118 F.3d 1047, 1056 (5th Cir. 1997) (emphasis added). And "there is a substantial public interest 'in having governmental agencies abide by the federal laws that govern their existence and operations.'" *Texas* v. *United States*, 40 F.4th 205, 229 (5th Cir. 2022) (quoting *League of Women Voters*, 838 F.3d at 12, itself quoting *Washington* v. *Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994)). Similarly, abortion advocates have been forthright about the utility of the mails to evade legitimate state laws protecting unborn life, but there is no public interest in providing a mail-order pathway to evade state law. See States CA5 amicus brief. If Plaintiffs are right on the merits—and they are—then the public interest tilts decisively against this Court's grant of a stay pending appeal.

2. Women

Now consider the women that FDA and Danco say they want to protect. Danco includes two charts, one compiling U.S. studies, the other non-U.S. studies, that

purportedly show the "success" rate of mifepristone after the 2016 Major Changes as 97.4% and 96.1%, respectively. Danco.Application.5–6. Taking those charts at face value, a 3-4% "failure" rate multiplied by millions of future women and girls who will be taking mifepristone is problematic. But there is also much information Danco did *not* disclose in its Emergency Application for Stay:

- The charts are from a single systematic review where 76 percent of the data was from two retrospective studies with significant limitations. "One of these (n = 13,373) did not evaluate ER visits … and the other study (n = 11,155) did not evaluate ER visits or hospitalizations …. The loss to follow-up in these two studies was 15.5 percent and 16 percent, respectively." Christina A. Cirucci, MD, *Self-Managed Medication Abortion: Implications for Clinical Practice*, The Linacre Quarterly (2022). AHM.App.12.

- The studies' "success" rate is a fiction. That number can and often does include women who had serious complications from a chemical abortion but were "successfully" treated at the researchers' facilities or excludes women who had serious complications from the results because they sought subsequent emergency care elsewhere. Alliance.CA5.App.298, Pls.PI.App.803. The average woman who takes an Advil would *not* consider recovery following surgery or an ER visit a "successful" use of the drug.

- In the 2015 Gatter study, by far the largest U.S. study that Danco cites by a factor of 11: (1) all women had an ultrasound to determine gestational age, (2) all women returned to a medical clinic for an in-person follow-up visit, and (3) all women received prophylactic antibiotics. Alliance.CA5.App.419. Again, FDA required *none* of these safeguards when it approved the 2016 Major Changes. There are similar deficiencies in all the rest of the studies that undergird FDA's approval. Alliance.CA5.App.416–428.

- The 2012 Goldstone study, by far the largest non-U.S. study Danco cites by a factor of nine, involved women: (1) whose babies' gestational age and pregnancy location (e.g., ruling out an ectopic pregnancy) were all confirmed by ultrasound, (2) who had an in-person follow-up exam in 85% of cases, (3) whose babies had gestated 63 days or less, (4) who were prescribed Rhogam if they tested Rh negative, and (5) who received prophylactic antibiotics if they were a high infection risk. Alliance.CA5.App.417. But FDA's 2016 Major Changes *did not include* safety measures (1), (2), (4), or (5) and set the gestational limit at 70 days, not 63, when every extra day increases the risk to the mother of taking mifepristone.

- In fact, "*none* of the studies on which the FDA relied were designed to evaluate the safety and effectiveness of chemical abortion drugs for use under the conditions prescribed, recommended or suggested in the proposed labeling." Alliance.CA5.App.414. And all this was evidence the district court had before it and considered when it rendered its decision.

The reality is that *since the 2016 Major Changes*, the rate of women and girls who have suffered complications from chemical abortion and required critical medical treatment has and will continue to increase. Alliance.CA5.App.004, 025, 032, 090 105, 106, 113, 253, 265. That is because FDA's decision to expand the gestational age for approved mifepristone use while eliminating in-person dispensing and follow-up visit requirements is dangerous and harmful. Alliance.CA5.App.024, 110, 111.

In sum, FDA has eliminated all safeguards that gave abortion providers the opportunity to rule out ectopic pregnancies, verify gestational age, identify any contraindications to prescribing mifepristone, or identify potential complications like sepsis and hemorrhage, remaining baby body parts and pregnancy tissue. The result is women and girls suffering unexpected episodes of heavy bleeding or severe pain and being rushed to the ER of the near hospital. Alliance.CA5.App.014–16, 018, 032, 097–98, 110–11, 113, 275. When considering women's health, the public interest weighs conclusively against a stay.

3. Industry

Next, consider "the biopharmaceutical industry writ large." Danco.Application.34. Danco claims regulatory uncertainty because "under the Fifth Circuit's logic, FDA cannot approve a drug unless it relies on a *single study* that evaluated the drug under the *exact* conditions approved." Danco.Application.34–35. But that's not what the Fifth Circuit held. As explained in the merits section above, the issue here is that FDA identified the "problem" that needed solving as the entirety of the 2016 Major Changes but then failed to rely on any studies that addressed that problem. That holding in no way imperils other drug approvals.

E. The lower courts issued an appropriate remedy.

Finally, Danco—though not FDA—argues that the appropriate remedy if Plaintiffs ultimately prevail on the merits is "*remand without vacatur*," allowing a dangerous drug without adequate safety precautions to remain on the market while FDA decides how it wants to proceed. Danco.Application.39–40 (citing *Cent. & S. W. Servs., Inc.* v. *EPA*, 220 F.3d 683, 692 (5th Cir. 2000)). Not so. "[U]nsupported agency action normally warrants vacatur." *Advocs. for Highway & Auto Safety* v. *Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1151 (D.C. Cir. 2005); see also Defs.' Resp. in Opp'n to Mot. Prelim. Inj. at 32, *Washington* v. *FDA*, No. 23-cv-3026 (E.D. Wash. Mar. 17, 2023), ECF No. 51 (FDA arguing that "when a party prevails on its APA challenge, the proper remedy—even in the context of a preliminary injunction—is limited only to vacating the unlawful action") (cleaned up).

A remand without vacatur is appropriate only "when 'there is at least a serious possibility that the [agency] will be able to substantiate its decision' given an opportunity to so." *Cent. & S. W. Servs.*, 220 F.3d at 692 (quoting *Radio-Television News Dirs. Ass'n* v. *FCC*, 184 F.3d 872, 888 (D.C. Cir. 1999), itself quoting *Allied-Signal, Inc.* v. *U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993)). A remand without vacatur "invites agency indifference." *In re Core Commc'ns, Inc.*, 531 F.3d 849, 862 (D.C. Cir. 2008) (Griffith, J., concurring). Accord *Nat. Res. Def. Council* v. *EPA*, 489 F.3d 1250, 1262–64 (D.C. Cir. 2007) (Randolph, J., concurring) ("A remand-only disposition is, in effect, an indefinite stay of the effectiveness of the court's decision and agencies naturally treat it as such.").

Here, FDA put all its cards on the table below, accepting Plaintiffs' massive record with the district court and filing a four-volume addendum with the Fifth Circuit. If FDA had data to substantiate its decision, it would have proffered it. Failing that, it is simply not true to say that the district court awarded "more relief than would be available on the merits." Danco.Application.21. *E.g.*, *Dep't of Homeland Sec.*

v. *Regents of the Univ. of Cal.*, 140 S. Ct. 1891 (2020) (affirming district court judgment which awarded plaintiffs vacatur of arbitrary and capricious agency decision).

CONCLUSION

The Court should deny Defendants' motion for stay pending appeal. If the Court grants FDA's alternative request for expedited merits review, then the Court should expand the questions presented to include (1) whether the Comstock Act's prohibition against mailing articles "intended for producing abortion," 18 U.S.C. 1461, includes mifepristone, (2) whether pregnancy is an "illness" for purposes of FDA's Subpart H regulations for accelerated approval of new drugs, and (3) whether mifepristone provides a "meaningful therapeutic benefit," 21 C.F.R. 314.500, over alternatives.

Respectfully submitted,

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